



# Ethics and Public Health: Model Curriculum

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## Preface

There is a growing interest in the ethical, legal, and social aspects of public health policy and practice. This interest no doubt has been fueled by the threat of bioterrorism after 9/11. But it had been growing for some time before that in the wake of various infectious disease outbreaks and with the growing recognition that public health issues are inseparable from issues of human rights and social justice, problems of cultural and behavioral change, and environmental issues on a global scale. With this growing interest in ethics in public health comes a demand for the teaching of ethics and for resource materials to support it. Ethics education is needed both in pre-professional degree and certificate programs, and in settings of continuing professional education. This model curriculum for Ethics in Public Health is intended as a resource to enhance and encourage thoughtful, well informed, and critical discussions of ethical issues in the field.

*Ethics in Public Health: A Model Curriculum* grew out of a series of meetings and discussions by leading researchers and educators in public health beginning with a meeting convened in Washington DC in May 2000. This meeting was sponsored by the Association of Schools of Public Health (ASPH) and the Health Resources and Service Administration (HRSA). It brought together teachers of ethics from nearly every school of public health, other experts in ethics and public health, and representatives of the government and public health practice communities. One of the clearest recommendations to come out of that meeting was that educational materials and resources should be developed to enhance curricular and continuing professional education offerings. HRSA generously agreed to fund the development of a collection of modules, through their Cooperative Agreement with ASPH.

In June 2001 a special advisory group was formed and met in Washington to plan the new curriculum. During this period The Hastings Center was working on a project funded by the Robert Wood Johnson Foundation to promote the discussion of ethical issues within public health. This effort converged so well with the HRSA/ASPH effort that the two groups joined forces and their collaboration began with the advisory meeting. At that meeting it was agreed that the curriculum would take the form of several self-contained units or modules, each written by a leading expert on the topic in question, and each containing the same types of resources for classroom use—an analysis of the ethical question, several case studies with commentary for discussion, resources for further study and research, and the like. Shortly after the June 2001 advisory group meeting experts in ethics and public health were recruited to write the modules, with the understanding that they would work closely with local members of the public health practice community to be sure that concerns and issues from the practice community were well represented. The input of the practice community was critical to the quality and credibility of the modules, and we thank these consultants for their generous participation.

During the period in which the modules were being developed, meetings and workshops continued the discussion begun in Washington. These included a working group on ethics and public health at The Hastings Center, a summer workshop on ethics and public health co-sponsored by the University of Minnesota Center for Bioethics and The Hastings Center, and conference workshops on teaching ethics in public health at annual meetings of both the American Public Health Association and the American Society for Bioethics and Humanities.

We trust that this collection will serve as the springboard for many discussions of public health ethics in classrooms and workshops, and we hope that the curriculum development discussion continues as well.

Since the modules exist in electronic form, we see them as continuing works in progress. To that end, we hope that those who use these materials will provide us with feedback about what works, what needs improvement, and what additional information and topics might be added to future editions of this curriculum. You can e-mail your comments to either Jeff Kahn at [kahnx009@umn.edu](mailto:kahnx009@umn.edu), or Bruce Jennings at [publichealthcurriculum@thehastingscenter.org](mailto:publichealthcurriculum@thehastingscenter.org) and please type “public health ethics modules” in the subject line.

The development of this curriculum was made possible by the support of HRSA and the Robert Wood Johnson Foundation, and through the cooperation of ASPH, the University of Minnesota Center for Bioethics, and The Hastings Center.

Finally, the entire project could not have been completed without the staff at ASPH, who included Wendy Katz, Sandra Maldague, and Monica Stadtler. We thank them, along with all those who participated in the many workshops and conferences for their input and insights. Lastly, we offer our sincere thanks to the modules’ authors who enthusiastically undertook the task of creating this valuable resource for the public health community.

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# **INTRODUCTION:**

## **A Strategy for Discussing Ethical Issues in Public Health**

***Bruce Jennings, M.A.***  
***The Hastings Center***  
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This is a general introduction and orientation to the ethics and public health curriculum. It explains the goals and strategy for ethics education and training and provides guidance about the skills of facilitating an ethics discussion with adult learners.

### **Why This Curriculum Was Created**

Public health policy and interventions are always the product of controversy, and often remain surrounded by controversy as they are implemented. Routinely in public health, scientific considerations blend with political and ethical conflicts, and questions of autonomy, individual rights, coercion, justice, community, the common good, the norms of research, and multi-cultural values are central. In public health today several different types of political and moral theory overlap, converge, and contend with one another, including libertarian liberalism, egalitarian liberalism, utilitarianism, human rights frameworks, and communitarianism. This curriculum will explore the “application” of ethics to a broad range of contemporary public health issues. It is intended for use both in pre-service educational programs at the undergraduate and graduate level, and for in-service continuing professional education settings in public health agencies and related organizations.

This curriculum and facilitator’s guide offers a planned approach to the discussion of ethical and values issues in public health. It is designed to help you identify appropriate topics and issues for discussion—issues that are pertinent to the public health practitioner and policymaker, and issues that lend themselves to an in-depth discussion of the often-conflicting values and ethical dilemmas raised by current public health knowledge and its applications.

Ethical issues are rarely neat, tidy, or cut-and dried. The questions of genetics, international and community based research, the control of infectious disease, and others that have been selected for this program are particularly difficult. They pose ethical “dilemmas” rather than black and white moral questions. They involve quandaries about which well-informed persons of good will can reasonably disagree.

For this reason, these materials will not offer clear-cut answers to many of the ethical issues raised. The best and most responsible thing an educational program can do in the face of these moral and social dilemmas is to provide public health practitioners with many perspectives on the issues, and to guide their own reasoning processes toward conclusions with which not everyone will necessarily agree, but which can stand up under close scrutiny and open dialogue with others.



## What is Ethics?

Terms like “ethics,” “morals,” “morality,” and “values” will occur frequently in this curriculum. It would be helpful to define them clearly and succinctly at the outset. Unfortunately, however, this is not easy or even possible to do.

Ethics and morals are most often used interchangeably, so that the sentence “He acted ethically,” and the sentence “He acted morally,” mean the same thing. Sometimes, though, morality (or morals) is defined as the beliefs and standards of good and bad, right and wrong, that people actually do and should follow in a society, while ethics is defined as the systematic study of morality. Ethics, in other words, is the theory and morality is the practice; morality is what people do and believe, ethics gives a philosophical account of justified behavior and belief.

Moral values are those things that people should prize and promote. Values are names for states of affairs that conform to what is ethically right and that further the human good (or the good of all beings).

Understood as the systematic study of morality, ethics is often divided into two subfields, **metaethics** and **normative ethics**. The relationship between them may be compared to the relationship between the philosophy of science, on the one hand, and science itself, on the other. Metaethics tries to clarify the rational standards and methods for the study of ethics, much as philosophy of science tries to clarify the nature and method of scientific inquiry. Normative ethics is where the substance of ethics resides. It develops ethical principles, rules, and ideals that spell out standards of good and bad, right and wrong. Normative ethics tries to offer a substantive, albeit general answer to the questions, What should I do? And How ought I to live? And it tries to spell out reasons why a rational person ought to accept the answer it gives.

Bioethics is normative ethics applied to decisionmaking and public policy in the domains of biology, medicine, and health care. It is concerned with matters of basic scientific research and with the social applications of biological knowledge and biomedical technology. Medical ethics, the ethics of the physician’s role, is as old as medicine itself. But bioethics is a newer, broader field of study that has arisen largely during the past twenty to thirty years as new powers, new choices, and new dilemmas have been opened up by the biological revolution.

Public health ethics, in turn, has arisen along side bioethics and the two fields of applied ethics have many strong affinities and connections. Just as the perspective and focus of public health often differs from that of clinical medicine, however, so too are there important differences between bioethics and medical ethics, on the one hand, and public health ethics on the other. In a nutshell, the difference can be characterized by the individualistic orientation of clinical medicine and the social or population based perspective of public health. Public health deals with patterns of disease, the social determinants of disease, and collective and institutional solutions to alleviate the risk or burden of disease in a population and to affect the distribution of health benefit and disease burden in a society, or globally. Nonetheless, public health should not overlook the rights, interests, and freedom of the individual. Whenever possible, public health goals should be reconciled with the promotion of human rights and the protection of civil liberties. If there is an inevitable clash between public health and civil liberties, then the situation must be open to public debate, the elements of the conflict should be made explicit,

and rigorous, critical reasoning should be brought to bear on the relative benefits and burdens of a particular policy or intervention.

### **A Strategy for Ethics Education**

Many teachers or facilitators find group discussions of ethics and values frustrating and difficult because such discussions tend to jump all over the place. They may seem to have no rhyme or reason, no logical order or sequence of information to discover and points to consider. Ethics discussions seem to have no starting point, no sense of progress and forward movement, and, worst of all, no satisfying resolution or conclusion.

Ethics discussions need not be like this; they need not be an educator's nightmare. They can—and should—follow an orderly progression of steps. And they can end, if not always with firm, agreed-upon conclusions, then at least with the feeling that something has been clarified—people have been led to think.

As with any education program, regardless of the subject matter, achieving these results when discussing public health ethics requires careful planning and some background preparation by the discussion leader or facilitator. If you have a good grasp of the issues on all sides of a question (which is not the same thing as having strong personal convictions on one side or another), then you will be in a position to guide the class discussion so that the participants are led to discover and express these issues themselves and to think thoroughly about the pros and cons. Much of the material in this instructor's guide is designed to provide the background information and ideas that will assist facilitators in this way.

Moreover, to keep the participant's thinking about ethical questions focused and moving forward, you need to devise a strategy for analyzing ethical questions in concrete cases or situations. A strategy for guiding discussion and learning gives you an overview of what a good ethics discussion should contain and where it should lead.

The strategy we recommend for use with these educational materials and case studies consists of the following six steps or tasks to complete during each module. Completing these tasks is one way to provide a structure for discussion and to keep it focused. Completing these tasks is also one way to ensure that the participants are given a thorough exposure to the ethical issues in each unit.

***Identify the ethical problem(s) germane to the decision.*** What has to be decided, by whom, and what ethical problem(s) does this decision seem to raise? In complex cases this problem identification step will actually be only a "first cut"; the identification of the problem will be refined and revised as the situation is understood more deeply and as the ethical values and concepts that explain why the problem is a problem are articulated.

***Assess the factual information available to the decisionmaker(s).*** Of all the facts that are known now, which are relevant to the ethical problem, and which are not relevant? For example, the fact that a pregnant woman has brown hair is not relevant to the ethical question of genetic screening, while the fact that she has a history of cystic fibrosis in her family is. Equally important, what is not known that should be known before a decision is made, and how can that information be obtained? Finally, how

reliable is the information we have, and what type of information is it? How can we separate fact from hearsay or opinion? How can we assess probabilistic information in making ethical decisions?

***Identify the “stakeholders” in the decision.*** Who will be affected by the decision, and in what ways? How directly will they be affected—if they will be harmed is the harm justified by greater benefit to others? Is the harm intended by the decision-maker or is it merely foreseeable? Have they placed themselves in a position to be harmed voluntarily and with appropriate information and understanding of the risks involved? Or are they “innocent bystanders”? How do all these factors affect the weighing of benefits and harms involved in the decision?

***Identify the values at stake in the decision.*** Values are those things that have significance or worth relative to some state of affairs, such as human well-being, respect for persons, or fairness that is taken to be good or desirable in itself. In this step the values that seem relevant to the situation should be identified and discussed. Here the instructor can provide a kind of common vocabulary of concepts to assist with the discussion, for participants will often grasp the concept without having the commonly used word or label to express it. Freedom, truth telling, protecting another from harm, fairness, respect for other people, empathy, altruism, the growth of scientific knowledge—these are a few of the values that are typically presented by cases in public health ethics.

***Identify the options available to the decisionmaker.*** At first glance, many ethical cases seem to pose very stark moral choices, even tragic choices where no outcome is without significant human cost. There are tragic choices in life, it is true, and it is important for participants to be able to face that fact and consider how they will learn to live with the decision they had to make. But it is equally important not to give the impression that all moral choices are tragic choices. Part of the skill of thinking analytically about moral decisionmaking is to see beyond artificially narrow options and forced choices. Insightful moral reasoning is often a process of resisting forced choice, and wiggling out of a moral dead end in order to find some more acceptable alternative. Would more information enable us to see more options here? Can we wait until that information is available? Is some compromise or middle way possible that will respect a broader range of values and more stakeholders’ interests than any other option? Ethical decisionmaking is akin to creative problem solving, and seeking the Yes-Yes or Win-Win solution.

***Consider the process for making the decision and the values that pertain to the process.*** A few such values would be authority, legitimacy, participation, and due process rights to be heard and to appeal. These topics may appear legalistic, but they apply in virtually any decisionmaking situation to some extent, in families no less than in bureaucratic or legal settings. Should I be the one making this decision? To what extent and in what ways should I involve others in the decision? Will the outcome of my decision be shaped by the cooperation of others with the decision I have made, and will their willingness to cooperate be shaped by whether or not they view my decision as fair and legitimate? If the ethical justification of my decision hinges on a good outcome I expect, but if that good outcome assumes the cooperation of others, then ethically I also have to take steps to assure that cooperation beforehand. So what I decide is only half of the ethical equation. How I decide is also important.

## **What Should You Try To Accomplish?: Learning Objectives**

The goals of ethics education at various developmental levels remains a subject of considerable controversy. Our program does not assume that the teaching of ethics will automatically produce professionals who are more ethical in their personal choices and behavior than they would be without

the instruction proposed by the program. That goal demands too much—clearly there are many more important sources of moral belief and motivation in their lives than a few hours of discussion in a classroom or a conference room. But, in another way, that goal also demands too little—for the teaching of ethics is concerned not only with how people behave but also with the reasons they have for behaving as they do.

There are five general goals of ethics education that have guided the development of these materials and that facilitators should bear in mind when using them.

**1. *Stimulating the Moral Imagination.*** Ethics education should produce a blend of cognitive and affective components. Ethical thinking, judgment, and sensibility are neither matters of pure, abstract intellect nor of unreflective “gut feelings” and prejudices. Regardless of the specific subject matter under discussion, guiding your participants or colleagues through the components of ethical reasoning can help them gain a better appreciation of the fact that human beings live their lives in a web of moral relationships. It will also show them that moral conflicts, which are frequently inevitable and difficult, involve high stakes in the lives of real people. Stimulating the moral imagination involves the ability to gain a feel for the lives of others, some sense of the motions and the feelings that are provoked by difficult ethical choices, and some insight into how moral viewpoints influence the way individuals live their lives. And the goal is not simply to stimulate but also to broaden the moral imagination—to begin with what people at first feel to be right or good, but then to deepen and sometimes to challenge and change those feelings by transforming them into more reflective judgments and more sophisticated and well-informed convictions.

**2. *Recognizing Ethical Issues.*** Ethics education is not unlike scientific education in one respect: it involves a certain structuring of perception, a certain kind of “seeing as.” To see a certain state of affairs or decision as a moral issue is to see that it raises considerations of human value, and that it has significant implications for harms or benefits human beings experience. To see something as a moral issue is also to see that it involves questions of human freedom and choice, that it could be different from what it is, and that the way the choice it permits is made significantly affects the rights and well-being of individuals involved in or affected by the choice.

**3. *Developing Analytical Skills.*** Ethical analysis involves the use of a certain set of prescriptive and evaluative categories, such as rights, duties, virtue, justice, responsibility, freedom, respect, dignity, and well being. These categories comprise the basic moral vocabulary of our society. However, they are difficult to define and their meaning is never determined once and for all, but is worked out instead in a process of dialogue, moral disagreement and debate. Participants need to acquire the ability to use these concepts in constructing arguments that are logical, consistent, and defensible in the face of reasoned disagreement and challenge. Analytical skills also involve the ability to make conceptual distinctions so that ethical claims are not unduly broad and indiscriminating. Finally, the ability to detach oneself from personal interests and parochial perspectives is an analytical ability that must be practiced and learned. During the course of discussion it is a good idea to check for the presence of this detachment from time to time. If a participant states or agrees with a moral rule that would limit the freedom of others, ask if he or she would be willing to have the rule applied to his or her behavior too.

**4. *Eliciting a Sense of Moral Obligation and Responsibility.*** Ethics discussions usually start with simple assumptions and beliefs, challenge them, and replace them with more nuanced thinking. In this way, ethical analysis sometimes makes moral choice more, not less, difficult and complex. And properly

so. On the other hand, in ethics teaching you should be careful not to paralyze or intimidate the participant with such hard cases or dilemmas that ethics seems hopeless. The point is to enable them to make better, more thoughtful choices, not to make choices seem impossible or simply arbitrary, like a coin toss. The goal is to enable participants to see when and how their own actions and choices do make a difference in the lives of others as well as in their own life. It is to motivate them to take action in accordance with ethical commitments and to assume a sense of responsibility for their own conduct, as well as for the effects of their conduct on others.

**5. *Coping with Moral Ambiguity.*** It is simply a fact of life that we must learn to tolerate disagreements and to accept the inevitable ambiguities that arise when examining ethical problems. Many ethical issues admit of no final, clear resolution. Reasonable persons of good will may disagree on the course of action that ethical considerations require. Yet while we must tolerate disagreement and ambiguity, we must also attempt to locate and clarify the sources of disagreement, to resolve ambiguities as far as possible, and to see if ways can be found to overcome differences of moral viewpoint and belief. Group discussion built around the ethics modules in this curriculum can model these goals. Through directed group discussion you can demonstrate that progress can be made in reducing disagreement, and in gaining a narrower, and perhaps more manageable, area of disagreement. It is important not to simply assert this but to show how it can happen. Participants should be led to understand that there are general standards by which to judge the quality of ethical arguments, that disagreements are inevitable but can be reduced, and that ethical perspectives can be detached from pure subjectivity or self-interest. Questions of right and wrong, good and bad may finally admit of no single or final answer, but this does not mean that the answers we do and must give are simply matters of taste.

### **Leading Ethics Discussions**

It is perfectly natural to feel uncomfortable with the subject matter of public health ethics and with the special challenges of “teaching ethics.” Most public health professionals who will be using these materials will not have any formal training in philosophy or ethics.

Make no mistake: the key to any successful group discussion of ethical questions lies in the skill of the facilitator who guides the discussion and in the curiosity and engagement of the participants. They must open their minds to unfamiliar ideas and learn to see connections between decision, actions, and their consequences for the person, for others, and for society as whole. Curriculum materials can’t do the work of good teaching. Drawing on the strengths that public health professionals can bring to the task—maturity of judgment, logical reasoning and analytic skills, and mastery of the scientific subject matter—we believe that these materials will provide you with the tools you need to handle ethical and value questions in a constructive, thoughtful fashion with your participants.

You won’t be preaching to them. You won’t be giving them the definitive answers or imposing your own personal moral beliefs on them. Nor will you be presiding over a session in which everyone simply makes personal statements of their “values” without engaging in genuine dialogue or without being called on to give reasons in support of their beliefs.

You will be helping participants and colleagues think more consistently and completely through problems that they will have to face soon—or are facing now—in their own careers in public health.

Each of the ethical topics in the program raises questions of choice—understanding the options one has—and questions of responsibility—what values are at stake in one’s choices and what moral principles, rights, and obligations should guide those choices. Eliciting a sense of responsibility on the part of the participant is one important objective of all ethics teaching, and especially in health care, where so many of the issues do in fact involve decisions that individuals will probably have to make sometime in their lives, be it reproduction, medical care for a child or a loved one, or choices as consumers and as citizens that affect the environment.

Before a discussion of ethics can get off the ground, two pervasive feelings, which are probably widespread even among advanced students and public health professionals, must be overcome. The first is a sense of powerlessness and alienation--the feeling that nothing one does as an individual really makes any difference. When you feel helpless you are not prone to accept the idea that you have responsibility for what happens to you or for what goes on in society. Of course, this perception is not simply to be dismissed; there is a large kernel of truth in it. But it should not be allowed to lead to apathy and the denial of the participant’s own moral agency and responsibility. The trick is to make connections between the “big issues” and more tangible, controllable aspects of personal life, and to lead the discussion beyond the classroom by considering ways participants can get involved in community activities that address some of the problems discussed in class. These materials have been organized in a way that will help make those connections and provide some type of follow up.

The second obstacle to overcome is the feeling of invulnerability—the belief that these issues affect the interests and lives of others, but won’t touch my family or me. Here too eliciting a sense of responsibility is coupled with good factual information and with the connection-making capacity that is inherent in what we have called the moral imagination. However comforting it may be, the notion of personal invulnerability is an illusion in contemporary society. The bad choices others make with the knowledge and technologies made available by the life sciences do affect us all.

A large part of ethical analysis involves tracing the chain of consequences that follow from a given action as they ripple through the lives of other people. It involves estimating the probability or likelihood of various possible outcomes that are foreseeable at the time of the action, and evaluating those possible consequences as beneficial or harmful, good or bad, right or wrong, in terms of some background ideas of ethical principles, duties, and ideals of human freedom and well-being. Examining these consequences of action is one part of the process of giving reasons for or against the action, and it also has the side effect of enabling participants to perceive—perhaps for the first time—the interconnections between what they do and the lives of other people, as well as what other people do and their own lives. Blindness, not maliciousness, is often the source of harmful, irresponsible conduct. Ethics education may or may not be able to overcome bad character, but it can mitigate ethical and social misperception.

To elicit a sense of responsibility and to chip away at feelings of powerlessness and invulnerability, the materials in this program have been set up to focus oftentimes on an analysis of ethical decisionmaking. This is only one approach to ethics, to be sure, since it is also important to look at large patterns of conduct, the shape and functioning of institutions, and broad social and historical forces that serve to limit the actions of individuals. To handle those issues that are in fact matters of collective choice and public policy rather than private, individual choices, the discussion can be framed as the decisionmaking of government policymakers (or corporate officials), or indeed as a question for society as a whole. The question: “How should I decide what to do morally in this situation?” is parallel to the

question “How should society (or decisionmakers acting on behalf of society) decide what to do morally in this situation?” The considerations that factor into each of these questions may be different and the answers may not be the same: at times it may be ethically appropriate for an individual to decide one thing and for society to decide another. But in this case you still have good food for thought in an ethics discussion because after the class has come to the conclusion that society’s answer should be different from the individual’s, you can go on to ask: What then should be done about this conflict or tension? How should the rights, freedom, and privacy of the individual be protected, and how should the interests of the individual be balanced against the interests of others and of society as a whole?

One of the biggest single hurdles to overcome in leading an ethics discussion is to become willing to tolerate disagreement and ambiguity yourself. So much education today assumes that participants are containers into which the teacher pours facts, information, and authoritative opinion. And in science especially perhaps, the participants come to expect that there are right answers that they must learn to come to, and which the teacher possesses to give them if necessary. In public health ethics the right answers are not in the back of the book; and you won’t have them all either, because there are sometimes no definitive right answers, only answers that are more or less reasonable, more or less defensible and justifiable in the light of reflection, analysis, and dialogue. So an ethics session will take some adjustment of expectations on your part and on the part of your participants. Perhaps it is best to raise this very point with the participants right at the outset.

In ethics things become clearer as you talk about them in group discussion. Initial ideas and feelings (philosophers call them moral intuitions) are not supposed to be flawless or complete at the beginning. Make the point that an ethics discussion is not a competition. (That is another habit of our schooling that ethics pedagogy must resist.) There is nothing wrong with expressing an idea that others will disagree with, and that the participant will modify as he or she goes along. Initial ideas and opinions must be put out on the table so the whole thing can get started. If you can create a non-threatening environment, most participants will present ideas on these ethical questions because they do have ideas and because it is gratifying for all of us to be in a situation where others want to hear our ideas and take them seriously, even if they disagree with them.

Note, however, that a non-threatening environment does not mean a value-neutral or non-judgmental environment. This is one mistake that has been made by the so-called values clarification approach to ethics education. The ethics discussion should be open to many different ethical or value perspectives—indeed one key part of the exercise is to inventory the various and often conflicting values at stake. But openness is not value-neutrality or indifference. The teaching approach we recommend in these materials is very definitely and strongly affirming of several substantive educational values (which are also ethical values): namely, the values of clear and logical reasoning, empathetic imagination, tolerance and respect for others, decisionmaking on the basis of solid information, and a careful assessment of the consequences of the action on others.

Gently, but firmly, the ideas, reasons, and arguments offered by the participants should be guided and redirected in accordance with those standards. False factual or scientific assumptions should be corrected, inconsistent beliefs and ideas should be exposed, faulty reasoning and logic should be pointed out and avoided, and the hidden assumptions and implications of ideas should be clarified and made explicit so that participants will more fully and deeply understand the nature and implications of the moral arguments they are making. A greater degree of self-consciousness about one’s moral beliefs is usually a more effective means of getting participants to rethink and refashion those beliefs than is

the authoritative imposition of the facilitator's moral beliefs on the participant. This is the kind of moral learning that will last.

As much as possible try to allow the give and take of class discussion to discover these standards of argument and analysis spontaneously. Be patient if things don't move forward quickly; the discussion should be exploratory as well as task oriented. Try not to lecture or to do the analysis for the participants; instead, you can accomplish more when you play traffic cop and let participants express themselves for awhile and then intervene to summarize and clarify from time to time, fitting what has just been said into a framework: "Now, let's pause for a minute to think about what John just said and how it relates to Nancy's position. John is basically saying that Nancy can't have it both ways," and so on.

This will have the added benefit of helping to deal with another common obstacle to a productive ethics discussion: the widespread ethical subjectivism and relativism of American culture. In a nutshell, ethical subjectivism is the idea that moral beliefs have no rational or interpersonal basis, they are only outward projections of subjective preference that may (and probably will) differ from one person to the next. Relativism, a closely related notion, is the view that there are no universal standards of right and wrong; what is right for one person, or society, is not necessarily right for another person or society. For both subjectivism and relativism the entire enterprise of having a reasoned discussion about ethics is suspect inasmuch as rational dialogue, persuasion, and agreement about ethics and values are impossible.

Few people will articulate these positions in any elaborate way, but many will feel an uneasiness about having an ethics discussion. This uneasiness comes from relativism and subjectivism. Many may also associate ethics with the imposition of rules and restrictions by authority figures whom they consider arbitrary and illegitimate. Relativism and subjectivism tend to see all of ethics in this way and feed off of rebellion against such authority.

In keeping with the goal of developing a sense of personal responsibility and empowerment, it is important to stress that "ethics" as it will be discussed in these sessions does not have primarily to do with the imposition of rules from above; it has to do instead with the creation of rules and standards from within each of us; it has to do with being a responsibly self-directing adult in a free society where individuals are allowed a fairly wide range of moral discretion and choice. But that freedom is possible only because reason and clear thinking do make a difference in ethics. We may often not know exactly what is right, but we can attempt to justify and give reasons for what we do, and we can be guided in our choices by what seem to be the best justifications and reasons we can come up with from our own thinking and with the help of others.

The best response to ethical subjectivism and relativism as they are vaguely felt by participants is simply to plunge in and "do ethics." To say, "It's all right to be skeptical, but just put your doubts on hold for a while and let's try this and see what happens." Much of their wariness and skepticism will fade as they experience a sustained ethics discussion and discover what it is like to think hard and carefully about ethical and value questions in the company of a facilitator and fellow participants who are also trying to be serious and thoughtful.

At the other extreme, some participants or colleagues may be ethical absolutists, who also do not see the point of an ethics discussion because they already know the right answer and do not wish to defend their beliefs by giving reasons or to make themselves open to other views. Obviously, it is important to



respect participant beliefs that are strongly held or are based in a religious perspective. In this case it is probably best to depersonalize the meaning of the exercise somewhat by pointing out that however secure a person may be in his or her own religious faith and belief, we still must live with others in a secular and pluralistic society where it is important to at least understand other people's point of view, even if we don't share it. And we must all learn to find some common ground and some shared ideas so that we can communicate with one another about matters of ethics and values. Just as an educated person must understand something about science and biology to cope with information and decisions in today's society, so too must one comprehend a way of talking about ethics that is not directly tied to any particular faith tradition. You can reassure such participants or colleagues that the ethics sessions will not attack their faith or put it down, but will simply explore whether reason and dialogue will lead to the same conclusions or not.

### **How To Use the Curriculum**

Nine modules are included in this program: (1) Tradition, Profession and Values in Public Health; (2) The Legacy of the Tuskegee Syphilis Study; (3) Public Health Research and Practice in International Settings; (4) Community Based Practice and Research; (5) Ethics and Infectious Disease Control; (6) Ethical Issues in Health Promotion and Disease Prevention; (7) Ethical Issues in Environmental and Occupational Health; (8) Public Health Genetics; (9) Public Health and Health System Reform.

Each module addresses a particular area of public health where practices and policy are in a state of flux, where new knowledge is changing the way we understand what these practices can and should be, and where there are active ethical, social, and political debates taking place in society. Hence most participants will have some background exposure to these topics from the media and elsewhere. Thus you may find some pre-existing interest in these topics in your class, or else that interest can readily be stimulated by presenting a basic amount of factual information—for example, that it may soon be possible to test people for a genetic predisposition to alcoholism—and posing some questions for discussion.

Clearly these units are interrelated in various ways, and the themes of choice, responsibility, taking risks, individual rights, and social welfare serve as connecting threads woven throughout the program. Nonetheless each unit has been designed so that it may stand alone and the material within it is self-contained. The order in which the units are presented in this guide is arbitrary; the units are not sequential, and later units do not presuppose familiarity with earlier units. Therefore you have the flexibility to use any or all of these materials in many different ways and at many different times.

We would make only one recommendation in this respect: do not attempt to cover the material in a module in less than one hour. Ideally, 90 minutes to two hours per unit would be better. If time is very limited, it would be advisable to cover one or two units in more depth than to skim over all of them.

Most units have a common format and features:

#### ***1. Issue essay***

This is designed to provide background information on the history, social and cultural context, and factual elements of the issue(s) addressed by the module. It also provides a "state of the debate" discussion, summarizing the leading arguments surrounding the topic and proposed actions or policy initiatives germane to it.

## ***2. Fact Sheets***

A quick reference to significant study findings, health statistics or epidemiological data pertinent to the module issue, as well as key concepts. Suitable for use as a handout. Provides a common factual and terminological frame for the session. It notes areas of significant factual controversy. It may also note methodological problems in studying this topic.

## ***3. Cases***

Each case is designed to be realistic and relevant, and to serve as a discussion vehicle for raising and discussing salient ethical or value issues. The events, actions, and decisions narrated by the case place ethics in a suitably complex context (in terms of either internal organizational structures, or external socio-political context). Suitable for use as handouts, these cases often reflect “real time” decision making in the presence of limited information. Some case studies reflect actual historical and current cases.

## ***4. Analytic discussion of the cases***

Following each case there is an analysis that provides a framework or approach designed to assist the facilitator in leading a session on the case. While the participants themselves should bring up most of the important questions and issues on their own, if they do not, the facilitator may utilize discussion questions to initiate discussion. The case analyses are frequently organized around the key steps in a model ethical decision-making process and emphasize key questions, concepts, or issues introduced in the issue essay.

In the case discussions, participants are encouraged to:

- (a) identify the ethical problem(s);
- (c) identify the information needed before a responsible decision can be made—what is this information and from whom should it come?
- (d) identify the stakeholders involved in the decision;
- (b) articulate the values relevant to this problem;
- (e) identify the available options and assess them in light of values served and in light of feasibility (e.g., financial, political, organizational constraints); and
- (f) discuss the process by which the decision should be made and who should be involved in making it.

## ***5. Tools for best practice and policy assessment***

Having discussed cases, the next activity of the training module may be to apply the ideas generated by this discussion to actual agency policy and practice. The participants are asked to identify real issues that would lend themselves to such analysis, effectively creating a case study of their own. The product of the exercise would be to agree on action steps that could be taken by the agency, and to identify who should be part of the process.

## **For Further Reading:**

M. Aroskar, Exploring Ethical Terrain in Public Health. 1999. *Journal of Public Health Administration Management and Practice*. 1(3):16-22.

- M. Aroskar, Teaching ethics in health care administration: a course profile. 1993. *Journal of Health Administration Education*. Fall; 11(4): 601-608.
- M. Aroskar, Stuart D. Yoak, Ethics teaching in health administration programs: A report. 1996. *Journal of Health Administration Education*. Summer; 14(3): 355-363.
- D. Beauchamp and B. Steinbock, Eds. *New Ethics for the Public's Health*  
New York: Oxford Press, 1999.
- P. Bradley and A. Burls, *Ethics in Public and Community Health*. New York: Routledge, 2000.
- Daniel Callahan and Sissela Bok, eds., *Ethics Teaching in Higher Education*. New York: Plenum Press, 1980.
- Daniel Callahan and Bruce Jennings, "Ethics and Public Health: Forging a Strong Relationship," *American Journal of Public Health* 92: 2 (February 2002), 169-176
- S. S. Coughlin, T. L. Beauchamp, eds., *Ethics and Epidemiology*, NY: Oxford University Press, 1996.
- C. Roland Christensen, *Teaching and the Case Method*. Boston: Harvard Business School Publishing Division, 1987.
- Howard B. Radest, *Can We Teach Ethics?* New York: Praeger Publishers, 1989.
- N. Stevens and T. McCormick, What are students thinking when we present ethics cases?: An example focusing on confidentiality and substance abuse. 1994. *Journal of Medical Ethics*. 20:112-117.
- The Teaching of Ethics in Higher Education: A Report by The Hastings Center*. Hastings-on-Hudson, N.Y.: The Hastings Center, 1980.

# **MODULE 1**

## **Tradition, Profession, and Values in Public Health**

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### **Issue Essay**

This module asks the difficult questions—what is public health? and what is public health ethics? The module also recognizes that even though public health and biomedical ethics overlap, they have distinct aspects. The module examines the unique population-based perspective of public health and how it can be distinguished from patient-centered biomedical ethics. Additionally, scholars and practitioners often use ethical analyses with other forms of reasoning, particularly law and human rights. The module, therefore, explores the relationship among public health ethics, public health law (notably the exercise of the state's police power), and human rights. The various meanings of each form of reasoning are discussed, as well as the similarities and differences among them.

### **What Is Public Health?**

In thinking about the application of ethical thought to problems in public health, it is important first to understand what we mean by public health. How is the field defined and what is its content—mission, functions, and services? Who engages in the practice of public health—government, the private sector, charities, community-based organizations? What are the principal methods or techniques of public health practitioners? In truth, finding answers to these fundamental questions is not easy because the field of public health is highly eclectic and conflicted.

Definitions of public health vary widely, ranging from the utopian conception of the World Health Organization of an ideal state of physical and mental health to a more concrete listing of public health practices. The Institute of Medicine, in its seminal report on the *Future of Public Health* in 1988, proposed one of the most influential contemporary definitions: “Public health is what we, as a society, do collectively to assure the conditions for people to be healthy.” The IOM’s definition emphasizes the cooperative and mutually shared obligation (“we, as a society”). It reinforces the fact that collective entities such as governments and communities take responsibility for health. The goal of public health is the health of populations—rather than the health of individuals—and this goal is reached by a generally high level of health throughout society, rather than the best possible health for a few. The field of public health is concerned with health promotion and disease prevention throughout society. Consequently, public health is less interested in clinical interactions between health care professionals and patients, and more interested in devising broad strategies to prevent, or ameliorate, injury and disease.

***The State of Debate.*** Scholars and practitioners are conflicted about the “reach” or domain of public health. Some prefer a narrow focus on the proximal risk factors for injury and disease. The role of public health agencies, according to this perspective, is to identify risks or harms and intervene to prevent or ameliorate them. Others prefer a broad focus on the socio-cultural-economic foundations of health. Those

favoring this position see public health as interested in a more equitable distribution of social and economic resources because social status, race, and wealth are important influences on the health of populations.

### **What are Public Health Ethics?**

If public health is what society does collectively to assure the conditions for healthy people, then what are public health ethics? Public health ethics may be defined as the principles and values that help guide actions designed to promote health and prevent injury and disease in the population. In thinking about this problem it will be helpful to distinguish public health ethics from biomedical ethics.

The field of biomedical ethics has richly informed practice and policy in medicine and health care. Biomedical ethics has often stressed the importance of individual interests of patients, notably the right to autonomy, privacy, and liberty. Ethicists, however, at least until recently, have given insufficient attention to the equally strong values of partnership, citizenship, and community. As members of a society in which we all share a common bond, we also have an obligation to protect and defend the community against threats to health, safety, and security. There remains much work to do in public health ethics. Is the population-based perspective of public health different from the patient-centered perspective of medicine? Is a public health ethic merely the aggregation of individual interests in a population? What is the moral standing that should be attached to the common good? Under what circumstances should individual interests yield to achieve a collective benefit for the population?

Some scholars have thought about public health ethics in three overlapping ways: professional ethics (the values that help public health professionals to act in virtuous ways); applied ethics (the values that help to illuminate hard problems in public health policy and practice); and advocacy ethics (the overarching value of population health and social justice).

Professional ethics are concerned with the ethical dimensions of professionalism and the moral trust that society bestows on public health professionals to act for the common welfare. This form of ethical discourse stresses the distinct history and traditions of the profession, seeking to create a culture of professionalism among public health students and practitioners. It instills in professionals a sense of public duty and trust. Professional ethics are role oriented, helping practitioners to act in virtuous ways as they undertake their functions. Currently, the Public Health Leadership Society is developing a Code of Public Health Ethics (available at [www.publichealthlaw.net/reader](http://www.publichealthlaw.net/reader)).

Applied public health ethics are concerned not so much with the character of professionals as with the ethical dimensions of the public health enterprise itself. Here, scholars study the philosophical knowledge and analytic reasoning necessary for careful thinking and decision making in creating and implementing public health policy. This kind of applied ethics is situation or case-oriented, seeking to understand morally appropriate decisions in concrete cases. Scholars can helpfully apply general ethical theory and detached analytical reasoning to the societal debates common in public health.

In addition to “professional” and “applied” ethics, it is possible to think of an “advocacy” ethic informed by the single overriding value of a healthy community. Under this rationale, public health authorities think they know what is ethically appropriate, and their function is to advocate for that social goal. This populist ethic serves the interests of populations, particularly the powerless and oppressed, and its methods are principally pragmatic and political. Public health professionals strive to convince the public and its

representative political bodies that healthy populations, reduced inequalities, and social justice are the preferred societal responses.

***The State of Debate.*** Scholars and practitioners disagree on each of the three forms of public health ethics. First, many believe that a code of ethics, or at least a well-articulated values statement, could increase the status of the field and help clarify the distinctive ethical dilemmas faced by public health professionals. Others, however, point to the fact that no single public health profession exists, but rather a variety of different disciplines—e.g., epidemiologists, nurses, sanitary engineers, and public health educators. It would be difficult to find a single set of values that is relevant to each of these distinct groups. Second, many believe that the value of population health and safety should be salient. However, others criticize the public health model because it assumes that the appropriate mode of evaluating options is some form of cost-benefit calculation that appears to permit, or even require, that the most fundamental interests of individuals be sacrificed in order to produce the best overall outcome. Applied public health ethics draws from the traditions of utilitarianism, which is not always favored in modern philosophical scholarship. Third, many believe that the central role of public health is to advocate for community health and social justice. Public health advocates are supported by a body of literature demonstrating a relationship between socio-economic status and healthy populations. However, others believe that it is not self-evident that health and justice should always be the prevailing value. They also point to the fact that the redistributive agenda of public health is best reserved to the political branches of government.

### **What is Public Health Law?**

Public health law differs from ethics in that it is concerned with a body of rules of action prescribed by controlling authority and having binding legal force. Law is found in constitutions, which empower governments to act and set limits on their power; statutes, which are enacted by legislative bodies and control the actions of individuals and businesses; regulations, which have similar effects as statutes but are usually promulgated by the executive branch; and court cases, which interpret the constitution, statutes and regulations, often setting binding precedent.

Law is a primary means with which government creates the conditions for people to lead healthier and safer lives. Law creates a mission for public health authorities, assigns their functions, and specifies the manner in which they may exercise their authority. Law is a tool in public health work which is used to influence norms for healthy behavior, identify and respond to health threats, and set and enforce health and safety standards. The most important social debates about public health take place in legal fora—legislatures, courts, and administrative agencies—and in the law's language of rights, duties, and justice.

The police power is the most famous expression of the natural authority of sovereign governments to regulate private interests for the public good. The police power is the inherent authority of a state to protect, preserve and promote the health, safety, morals, and general welfare of the people. To achieve these communal benefits, the state retains the power to restrict, within constitutional limits, private interests—personal interests in autonomy, privacy, association, and liberty as well as economic interests in freedom to contract and use property.

Law can be an effective tool to achieve the goal of improved health for the population. Statutes, regulations, and litigation, like other public health prevention strategies, intervene at a variety of levels, each designed to secure safer and healthier populations. First, government interventions are aimed at *individual* behavior

through education (e.g., health communication campaigns), incentives (e.g., taxing and spending powers), or deterrence (e.g., civil and criminal penalties for risky behaviors). Second, law regulates the *agents of behavioral change* by requiring safer product design (e.g., safety standards and indirect regulation through the tort system). Finally, law alters the informational (e.g., advertising restraints), physical (e.g., city planning and housing codes), or business (e.g., inspections and licenses) *environment*.

***The State of Debate.*** Not everyone believes that law is an appropriate way to protect and promote the community's health, and when law is used in any of its manifestations it is bound to create controversy. Coercive interventions aimed at changing individual behavior are perhaps most contentious, such as infectious disease powers. Many people believe that government should rarely exercise coercive powers either because they are ineffective (e.g., it will "drive the epidemic underground") or overly intrusive (e.g., it will undermine autonomy, privacy, or liberty). Regulation of products through the tort system is also controversial. Here, people argue that tort law often offers the wrong kind of incentives (e.g., deterring innovation for vaccines or pharmaceuticals) and is inefficient (e.g., devoting too many resources to lawyers). Finally, regulation of the informational or economic environment is controversial. Think about the disputes that arise from regulation of advertising of cigarettes (public health versus free speech) or the regulation of businesses through licenses and inspections (public health versus property rights).

### **What is the Role of Human Rights in Public Health?**

The language of human rights is used in different, but overlapping, ways. Some use human rights language to mean a set of entitlements under international law, while others use human rights for its aspirational, or rhetorical, qualities. Depending on the way in which human rights is used, the field can have features that are quite similar to law or ethics.

Legal scholars use human rights to refer to a body of international law that originated in response to the egregious affronts to peace and human dignity committed during World War II. The main source of human rights law within the United Nations system is the International Bill of Human Rights comprising the United Nations Charter, the Universal Declaration of Human Rights, and two International Covenants of Human Rights. Human rights are also protected under regional systems, including those in American, European, and African countries.

Human rights are often divided between those that protect civil and political rights on the one hand and economic, social, and cultural rights on the other. Civil and political entitlements include the right to life, liberty, and security of person; the prohibition of slavery, torture, and cruel, inhuman, or degrading treatment; freedom from arbitrary interference with privacy, family, or home; and freedom of conscience, religion, expression, and association. Economic, social and cultural rights include the right to social security, education, and work, as well as the right to share in scientific advancement and its benefits. Notably, human rights instruments recognize the right of everyone to the highest attainable standard of physical and mental health, "including the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services." (Universal Declaration of Human Rights, Art. 25).

The language of human rights is often used for its aspirational, or rhetorical, qualities. When "rights" language is invoked, it is intended to convey the fundamental importance of the claim. It expresses the idea that government should adhere to certain standards, or provide certain services, because it is right and just

to do so. Human rights as a symbol commands reverence and respect. Used in this aspirational sense, human rights need not be supported by text, precedent, or reasoning; they are self-evident and government's responsibility simply is to conform.

***The State of Debate.*** Although human rights are supported by a body of international law and express an inspiring idea about personal dignity, they are often criticized for imprecision and lack of enforceability. Civil and political rights are perhaps the most precisely defined and carefully studied, but international agencies often fail to rigorously defend these rights in the real world. Economic, social and cultural rights are thought to be vague and unenforceable. For example, the conceptualization of health as a human right, and not simply a moral claim, suggests that states possess binding obligations to respect, defend, and promote that entitlement. Considerable disagreement, however, exists as to whether "health" is a meaningful, identifiable, operational, and enforceable right, or whether it is merely aspirational or rhetorical. To achieve the goal of greater clarity and enforceability, the United Nations Committee on Economic, Social, and Cultural Rights issued *General Comment No. 14: The Right to the Highest Attainable Standard of Health* (2000). This General Comment seeks to define the right to health and suggest ways in which it can be enforced.

### **Tradeoffs Between the Collective Good and Individual Rights**

Public health law and ethics often require careful balancing between individual interests in personal (e.g., autonomy, privacy, and liberty) and economic (e.g., contracts and property) freedoms on the one hand and collective interests in health safety and security on the other. Certainly, freedom and security can be mutually reinforcing. Affording individuals their rights can result in greater overall wellbeing by empowering people to safeguard their own health and safety. For example, if people do not fear loss of privacy or liberty, they are more likely to seek medical and public health services. Coercive powers can literally "drive epidemics underground."

Sometimes policy makers must make hard tradeoffs between individual and collective interests and, in these circumstances, they need to be guided by ethical values and attentive to legal procedures and norms. Public health laws and our courts have traditionally balanced the common good with individual civil liberties. As Justice John Marshall Harlan wrote in the seminal United States Supreme Court case of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), "the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for the 'common good.'" *Jacobson* was a case that concerned compulsory vaccination, but the difficult tradeoffs between public and private interests can extend to many areas of public health concern ranging from infectious disease control powers (e.g., testing and screening, partner notification, and quarantine) to control of businesses (e.g., inspections and nuisance abatements) and the professions (e.g., licensing).

How should society determine whether to intervene to protect the public's health and safety when doing so will diminish a personal or economic interest? There is no sure way to know when interventions are necessary and appropriate, but here are some of the factors that need to be taken into consideration:

***Step One: Demonstrate Risk.*** Risk is a complex idea that involves several dimensions. First, what is the nature of the risk? Risks arise from numerous sources including physical, chemical, organic, environmental, and behavioral. Second, what is the duration of the risk? Risks may be imminent, distant, acute or chronic. Third, what is the probability that the risk will actually occur? Risks may be either highly likely or remote.



Finally, what is the severity of harm should the risk materialize? Harms can be catastrophic or relatively trivial if they do occur. They may affect individuals or populations, current or future generations, or people or the things that people value (e.g., plants, animals, or the environment).

**Step Two: Demonstrate the Intervention's Effectiveness.** The intervention should be reasonable likely to reduce the risk. Public health is primarily about prevention so one important measure is whether the intervention is reasonably like to work. This is a "means-ends" inquiry, which seeks to understand if the public health intervention will lead to effective risk reduction.

**Step Three: Assess the Economic Cost.** The intervention should not only be capable of reducing the risk, but it should do so at a reasonable cost. Policy makers, therefore, should discover the costs to the regulatory agency and the subject of the regulation. Wherever possible, policy makers should prefer strategies that are least expensive and most effective. The reason is that government only has limited resources. If it spends money wastefully on an intervention, it will not have those resources available for another, potentially more effective, intervention. Thus, cost-ineffective measures have "lost opportunity" costs.

The criterion to prefer cost-effective measures does not mean that society must wait until there is unassailable scientific evidence before it can intervene. Some advocates have argued for the adoption of a "precautionary principle." The precautionary principle is not consistently defined but it means that public health authorities may act to prevent future harms to people and the environment even in the absence of conclusive proof that the harm is real or that the intervention will be effective.

**Step Four: Assess the Burdens on Human Rights.** Sometimes even cost-effective policies should not be undertaken if they disproportionately burden human rights. Policy makers, therefore, should think about the invasiveness of the intervention, the frequency and scope of the infringement, and the duration of the infringement. Human rights do not always trump public health, but they certainly need to be weighed carefully.

**Step Five: Assess the Fairness of the Intervention.** Policies should be formed and implemented in just ways. Thus, there should be a fair distribution of benefits and burdens. Ethicists examine fairness in a variety of different ways, but they often focus on need and risk. Benefits or public health services should often be distributed based on need. That is, those who have the greatest need should have some claim to the benefit or service. On the other hand, regulatory burdens should often be distributed on the basis of risks posed. That is, those who pose the greatest risks to the public or the environment should bear the costs and burdens of regulation. There are certainly other ways to evaluate the just allocation of benefits and burdens (e.g., principles of the most efficient distribution), but need and risk are two likely criteria.

In summary, a public health intervention can be evaluated using several criteria: (i) the nature, probability, and severity of the risk; (ii) the likelihood that it will be effective in meeting its objectives; (iii) the economic costs entailed, including opportunity costs; (iv) the burdens on human rights, and (v) the fairness, including a just allocation of benefits and burdens.

## Conclusion

The field of public health is highly complex. What is the meaning of pivotally important abstract concepts that are common in public health: population, community, risk, harm, and benefit? How should society decide when it is necessary and appropriate to intervene to protect the public's health? Are factors such as risk, effectiveness, cost, burdens, and fairness the best ways to evaluate public health interventions? How does the population perspective differ from the individual perspective? To what extent should social justice be an animating value in public health? Scholars and practitioners use various forms of reasoning in analyzing these problems, notably ethics, law, and human rights. Each form of reasoning has its own benefits and disadvantages. While each form of reasoning is distinct, all the forms overlap in important ways. One thing is certainly clear, there are no "correct" answers in public health. However, careful examination of principles and values taken from each of these fields can clarify thinking and, ultimately, lead to more effective and just policies and practices in public health.

## Further Readings in Public Health Law and Ethics

### **Books**

Beauchamp DE, Steinbock B (eds.), *New Ethics for the Public's Health*, New York: Oxford University Press, 1999.

Gostin LO (ed.), *Public Health Law and Ethics: A Reader*, Berkeley and New York: University of California Press and Milbank Memorial Fund, 2002.

Gostin LO, *Public Health Law: Power, Duty, Restraint*, Berkeley and New York: University of California Press and Milbank Memorial Fund, 2000.

### **Articles**

Callahan D, Jennings B, Ethics and Public Health: Forging a Strong Relationship, *Am J Pub Health* (2002): 92:169-176.

Childress JF, Faden, RR, Gaare RD, *et al.*, Public Health Ethics: Mapping the Terrain, *J Law, Med & Ethics* (2002) 30:170-178.

Gostin LO, Sapsin JW, Teret SP, *et al.*, The Model State Emergency Health Powers Act: Planning and Response to Bioterrorism and Naturally Occurring Infectious Diseases, *JAMA* (2002) 288:622-628.

Gostin LO, Public Health, Ethics, and Human Rights: A Tribute to the Late Jonathan Mann, *J Law, Med & Ethics* (2001) 29: 121-130.

Kass NE, An Ethics Framework for Public Health, *Am J Pub Health* (2001): 91:1776-1782.

Roberts MJ, Reich MR, Ethical Analysis in Public Health, *Lancet* (2002) 359:1055-1059.

Thomas JC, Sage M, Dillenberg J, Guillory VJ, A Code of Ethics for Public Health, *Am J Pub Health* (2002): 92:1057-59.

### **Internet Resources**

Web site of the Center for Law and the Public's Health at Georgetown and Johns Hopkins University (CDC Collaborating Center Promoting Health Through Law): <http://www.publichealthlaw.net>

Web site accompanying the book, Gostin LO (ed.), *Public Health Law and Ethics: A Reader*, Berkeley and New York: University of California Press and Milbank Memorial Fund, 2002:  
<http://www.publichealthlaw.net/reader>

## Fact Sheet: Tradition, Profession, and Values in Public Health

This module explores the relationship between public health ethics, public health law (notably the exercise of the state's police power), and human rights. The various meanings of each form of reasoning are discussed, as well as the similarities and differences among them.

### I. What Is Public Health?

- Definitions of public health vary widely; however, a unifying theme is that public health is a mutually-shared, societal obligation. Collective entities such as governments and communities must take responsibility for promoting the health of the public.
- The Institute of Medicine defines public health as “what we, as a society, do collectively to assure the conditions for people to be healthy.” (*Future of Public Health*, 1988)
- The focus of public health is the health of populations, rather than the health of individuals.
- Public health is more concerned with broad strategies to prevent or ameliorate injury and disease than with clinical interactions between professionals and patients.
- Scholars and practitioners are conflicted about the “reach” or domain of public health between 2 major foci:
  - Narrow focus on the proximal risk factors for injury and disease; or
  - Broad focus on the socio-cultural-economic foundations of health.

### II. What are Public Health Ethics?

- Public health ethics are principles and values that guide actions to promote health and prevent injury and disease among the population.
- Public health ethics should be distinguished from biomedical ethics.
  - Biomedical ethics often stress the importance of individual interests of patients.
  - Public health ethics emphasize partnership, citizenship, and community.
- Some scholars have structured public health ethics in three overlapping ways:
  - Professional ethics are concerned with ethical dimensions of professionalism.
  - Applied ethics relate to dynamics of the public health enterprise itself.
  - Advocacy ethics are informed by the single overriding value of a healthy community.
- Scholars and practitioners disagree on each of the three forms of public health ethics.
  - A code of ethics could clarify the field and provide guidance regarding ethical dilemmas.
  - Some suggest that no single public health profession exists. It is difficult to find a single set of values that relates to all public health professionals.

### **III. What is Public Health Law?**

- Public health law refers to rules of action prescribed by controlling authority and having binding legal force. Law is found in constitutions, statutes, regulations, and court cases.
- Law creates a mission for public health authorities, assigns their functions, and specifies the manner in which they may exercise their authority.
- The most important public health debates occur in legal fora—legislatures, courts, and administrative agencies—and in the law's language of rights, duties, and justice.
- Police power is the inherent authority of a state to protect, preserve and promote the health, safety, morals, and general welfare of the people. The state may restrict individual interests within limits to achieve these communal benefits.
- Law regulates behavior and alters the informational, physical, and business environment. However, the appropriate role of law in public health is controversial (e.g., coercive interventions aimed at changing individual behavior may unduly restrict liberty and foster resentment).

### **IV. What is the Role of Human Rights in Public Health?**

- The language of human rights is used in different, but overlapping, ways in public health.
- Human rights may refer to a set of entitlements under international law, or may be invoked for aspirational, or rhetorical, purposes.
- Considerable disagreement exists as to whether “health” is a meaningful, identifiable, operational, and enforceable right, or whether it is merely aspirational or rhetorical.
- Although human rights are supported by international law and express an inspiring idea about personal dignity, they are often criticized for imprecision and lack of enforceability.

### **V. How to Evaluate Public Health Interventions**

- Policy makers should subject public health interventions to systematic evaluation.
  - Demonstrate risk.
  - Demonstrate effectiveness.
  - Assess economic cost.
  - Assess human rights burdens.
  - Assess fairness.

## **Case Study 1: Legal and Ethical Implications of a Public Health Approach to Disability<sup>1</sup>**

Malik Johnson has been the Human Resources Manager of MedCentre, a hospital in West Virginia, for two years. Monday morning, Juanita Carlson, the Benefits Coordinator at MedCentre, informed Malik of the hospital's plan to implement screening procedures to detect hepatitis B among prospective and incumbent employees.

Viral hepatitis B can be transmitted when blood or bodily fluids from an infected individual enter the body of an individual who is not immune to the virus; e.g., from mother to unborn child or from partner to partner via unprotected sexual intercourse, blood transfusion, or sharing needles. Symptoms of hepatitis B include jaundice, fatigue, abdominal and/or joint pain, loss of appetite, and nausea. These symptoms are more common in adults than in children, yet approximately 30% of infected individuals will not experience any symptoms. In the absence of vaccination or treatment, death from chronic liver disease occurs among 15-25% of hepatitis B infected individuals. The hepatitis B vaccine, available since 1982, is the best protection against contracting the virus; however, other precautions are also advisable, such as condom use and/or refraining from injection drug use.

Juanita stated that screening MedCentre employees for hepatitis B was necessary to (1) alert MedCentre's HMO to potential elevated costs in its medical coverage, (2) notify the hospital's administration that special accommodations may be needed (e.g., infection control and/or leaves of absence for seropositive individuals), and (3) protect the hospital's patients and employees from the transmission of this contagious disease. Malik suspected that the screening plan was also influenced by the recent hepatitis B diagnosis of MedCentre's chief cardiac surgeon, Michele Kim.

MedCentre provided notification of the screening plan in a brief memorandum to current employees and to individuals who received an offer of employment from the hospital as of Monday afternoon. The plan was to become effective the following Friday, at which point all prospective and current employees were instructed to report to the hospital's laboratory for screening.

Malik is responsible for responding to employees' questions about MedCentre's screening plan. Juanita also assigned Malik the task of evaluating the plan in light of employees' concerns in a confidential memorandum to MedCentre's Board of Directors.

### **Prospective Employees**

Paula Smith, a prospective employee in MedCentre's maintenance department, called Malik on the telephone immediately after she read MedCentre's notification memo on Tuesday morning. Ms. Smith was concerned that MedCentre would rescind its recent offer of employment once her seropositive status was discovered.

Ms. Smith questioned why MedCentre needs to screen maintenance staff members at all. Ms. Smith does not understand how screening for hepatitis B status relates to the responsibilities or performance of her job.

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<sup>1</sup> I thank James G. Hodge, Jr., and research students at the Georgetown University Law Center, for help in researching and drafting these case studies.

Because maintenance staff members have limited contact with patients and/or other MedCentre employees, Ms. Smith argued that the threat posed by infected maintenance staff members at the hospital is minimal. Although Ms. Smith agrees that the effects of hepatitis B may be debilitating and the costs of treatment may be considerable, she does not see why hepatitis B should be singled out from other diseases that impose a similar burden, such as syphilis.

Malik thanked Ms. Smith for expressing her concerns, promised to research the answers to her questions, and told her he would return her telephone call in a couple of days.

### **Current Employees**

After Malik ended his conversation with Ms. Smith, he received a second urgent telephone call. This time, the voice on the other side of the line belonged to Robert Jones, a loyal employee and respected orthopedic surgeon at MedCentre for fifteen years. Dr. Jones suspected that he contracted hepatitis B from a recent, unprotected homosexual encounter. Dr. Jones told Malik that he was keenly aware of the case of Dr. Kim, whose hepatitis B diagnosis last month prompted her leave of absence, contributed to the temporary rescission of her surgical privileges, and generated relentless gossip around the hospital.

The prospect of sharing Dr. Kim's fate terrified Dr. Jones. He is troubled that his homosexual orientation and his seropositive status could both be exposed to the detriment of his career at the conservative hospital. Dr. Jones is afraid that a hepatitis B diagnosis will quickly become a stigma, and that people will perceive him as incapable of performing his responsibilities as a surgeon. Dr. Jones needs assurance that he will not be discriminated against by MedCentre staff or patients on the basis of his serological status.

Malik sympathized with Dr. Jones' predicament and promised to address his concerns in a confidential meeting with him on Thursday morning.

### **Disability Discrimination**

Tonya Perez, MedCentre's general legal counsel, outlined the relevant disability law pertaining to the hospital's screening plan. Ms. Perez told Malik that the Americans with Disabilities Act of 1990 (ADA) places certain limitations on employer-mandated medical examinations, including the screening of employees. Under the ADA, an employer can require the screening of prospective employees *after* an offer of employment has been made but before a prospective employee commences work. All prospective employees must be subjected to the same examination and the information collected must be maintained in a separate, confidential medical record. Furthermore, an employer can require the screening of current employees if such medical examinations are shown to be "job-related" or "consistent with business necessity." Again, the results must be kept in a separate, confidential medical record. Prospective or current employees may not be discriminated against on the basis of their disabilities. Thus, qualified persons with a disability may not be terminated or adversely treated because of their disabilities. A "qualified" person with a disability must meet all the essential criteria for performing the job and must not pose a significant risk to himself or others.

Ms. Perez noted that even if MedCentre's screening plan is otherwise legally permissible, MedCentre must also avoid unlawful discrimination in violation of the ADA. Modern jurisprudence indicates that hepatitis B meets the criteria for a "disability" under the ADA since its taxing physiological manifestations may "substantially limit" the "major life activity" of working. For example, symptoms such as extreme nausea or

fatigue may constrain Paula Smith's ability to perform the physical tasks associated with her position as a hospital maintenance staff member. Furthermore, the ADA protects individuals such as Robert Jones who are "regarded as" disabled, or who have a record of disability. However, the courts have been divided as to whether a person infected, but not yet symptomatic, is covered under the ADA as a person with a disability. Therefore, the question arises, from a perspective of law and ethics, can MedCentre use the information acquired from the screening to discriminate against seropositive individuals on the basis of their serological status? If we assume that seropositive individuals do have a disability, then MedCentre must neither manifest nor tolerate adverse treatment of an individual diagnosed with hepatitis B who is "otherwise qualified" for a hospital position, if "reasonable accommodations" or "modifications" can be made on his or her behalf (e.g., leaves of absence).

### **A Public Health Approach**

You are Malik's first choice for consultation regarding his assignment from MedCentre's Board of Directors. Malik wants to adopt a public health perspective that addresses the human rights and ethical issues implicated in MedCentre's screening plan. Malik's memorandum must offer recommendations that are legally and ethically sound. Due to Malik's time constraints, he has asked that you e-mail him responses to the following questions by tomorrow evening:

- Should MedCentre screen all employees, or should it "target" or limit screening to employees whose jobs involve regular contact with hospital patients and employees, as Paula Smith suggested? Assuming that certain jobs are less likely to transmit infection via interpersonal contact, will general screening be perceived as paternalistic?
- Should MedCentre obtain employees' consent to the screening? If so, how can MedCentre ensure that the employees are sufficiently informed?
- How should MedCentre document and store the records of screening results?
- How should MedCentre notify employees of their serological status? Should or must MedCentre provide counseling?
- What "reasonable accommodations" can or should MedCentre make for seropositive individuals? Is vaccination legally, ethically, or economically feasible?
- What preventative procedures and/or programs can MedCentre implement to ensure that seropositive individuals are not discriminated against on the basis of their serological status?



## **Case Study 1: Discussion**

### **Ethical Problems**

This case study presents two sets of ethical dilemmas.

Paula Smith, a prospective employee at MedCentre, raises concerns regarding the ethical implications of general versus targeted screening procedures. Assuming that certain jobs at MedCentre are less conducive to transmission of hepatitis B than others, is general screening of all employees unnecessary, inefficient, and/or paternalistic? Conversely, would targeted screening exclude seropositive individuals and/or alienate already marginalized individuals or groups? Also, how should MedCentre decide which employees to “target” for screening; e.g., by the level of risk associated with their employment positions (e.g., extent of interpersonal contact) or by the level of risk associated with their personal habits (e.g., intravenous drug use or promiscuous sexual behavior)? As Human Resources Manager of MedCentre, Malik Johnson must evaluate the costs and benefits, both economic and philosophical, of these two screening alternatives before writing his memorandum of recommendations to the Board of Directors.

Second, Malik must address the concerns of Robert Jones, a current employee at MedCentre, regarding discrimination. What safeguards (e.g., educational or training programs) should MedCentre implement to ensure that seropositive individuals will not be discriminated against on the basis of their serological status? Malik must be attentive to the privacy and bodily integrity concerns of individuals who will be screened, yet he must also ensure effective screening procedures that will protect MedCentre’s patients and staff from transmission of hepatitis B.

### **Relevant Values**

As the liaison between MedCentre’s staff and administration, Malik is aware that different values are motivating the perspectives of each “side.” For example, MedCentre employees subject to screening, such as Paula Smith and Robert Jones, have prioritized the values of bodily integrity, autonomy, liberty, and privacy; whereas MedCentre’s Board of Directors will likely prioritize the values of efficacy and efficiency, and MedCentre’s investors/patrons may prioritize the value of conservatism. Malik’s recommendations must be informed by each of these values, yet Malik must also acknowledge the value of compromise.

### **Necessary Information**

An integral step in resolving these ethical dilemmas is for Malik to gather all information pertaining to MedCentre’s screening plan and to the individuals whom it will involve. For example, Malik should consult with other MedCentre officials to determine the source and extent of funding allocated for the screening procedure. This information may determine which type of screening is more feasible and/or appropriate (e.g., are sufficient funds available for general screening of all employees?) as well as which preventative measures or safeguards can be implemented to prevent discrimination subsequent to the screening (e.g., are sufficient funds available for educational/training programs and/or for counseling?).

Malik should also have several informal discussions with MedCentre’s administrators and employees about the screening plan. These talks will help Malik identify where sensitivities may lie and where compromises

may be made. They will also reinforce the values mentioned above and ensure that Malik's recommendations to the Board of Directors are ethically sound.

Finally, Malik should schedule another meeting with Tonya Perez, MedCentre's general legal counsel, to ensure that his recommendations are legally valid. Malik will want to discover and avoid legal issues that surfaced in comparable screening programs in other medical centers. He will also want to ensure that Tonya is prepared to defend MedCentre's screening plan against potential lawsuits.

### **Stakeholders to the Decision**

Throughout the decision-making process, Malik must be respectful of and attentive to the many stakeholders to this decision. Malik's recommendations to the Board of Directors must be informed by the interests, concerns, and values of MedCentre's prospective employees, current employees, patients, administrators, and investors/patrons. As was noted in the above sections, each of these parties and entities has values and needs that may conflict with those of the others.

### **Available Options**

Malik must carefully assess the values that each recommendation serves, as well as its financial, political, and organizational feasibility. A sample of the many potential recommendations that Malik can offer in his memorandum to MedCentre's Board of Directors includes the following:

- General screening of all employees to minimize stigma and/or alienation associated with targeted screening and to convey the message that everyone should be cognizant of the risks associated with hepatitis B
- Confidential and professional screening procedures conducted by authorized medical personnel who are respectful and discreet
- Notification of serological status via contact information provided directly by the employee who was subject to the screening, with provision of referrals and a free counseling session for seropositive individuals
- Access to and disclosure of medical records limited to those with a legitimate need to know; e.g., to medically treat the employee
- Implementation of educational and training initiatives to prevent discrimination

### **Decision Process**

Although the foregoing analysis is essential for Malik's own decision process regarding recommendations to MedCentre's Board of Directors, the "official" decision process that determines the fate of the screening plan will begin (or will recommence) when the Board receives Malik's memorandum. It is hoped that the Board's final decision on the plan will be influenced by the input of each of the stakeholders discussed above. However, to ensure that the plan continues to be responsive to the interests, needs, and values of these diverse stakeholders, perhaps Malik can suggest the formation of an Oversight Committee that contains a representative from each "side."

## Case Study 2: Protecting Health Information Privacy

Dr. Sharon Smart is a senior genetics researcher for Genomatic, Inc., an emerging pharmaceutical company that researches and develops pharmacogenomic products. Dr. Smart was the lead researcher in a recent large-scale clinical study designed to test the efficacy of *Alive*, a new pharmaceutical. *Alive* is designed to successfully treat a terminal form of ovarian cancer that has common genetic links in a sizable portion of the general public. The study amassed considerable, longitudinal health data on thousands of research subjects. Genomatic's shares recently soared on the NASDAQ stock exchange in expectation of potential approval of *Alive* through the Food and Drug Administration (FDA). Genomatic had sought final FDA approval after completing its clinical drug trials.

### Seeking FDA Approval

As part of the approval process, the FDA requested copies of relevant medical records of individuals involved in the clinical drug trials for *Alive*. In its correspondence, the FDA said that it needed the data for review and examination pursuant to the approval process for *Alive*. In her laboratory in Rockville, Maryland, Dr. Smart assembled the personally identifiable data, including research subjects' informed consent forms. Each of the research subjects had previously executed a general waiver for the release of his or her medical records to "federal authorities, including the FDA, for the purposes of conveying study results."

In the same letter, the FDA also asked for additional medical data about whether the research subjects involved in the *Alive* clinical trials had participated in other clinical trials at Genomatic. The FDA suggested that it wanted this data to confirm that Genomatic had not improperly recruited its research subjects for multiple trials, or provided incentives for their long-term participation in the company's clinical trials programs. Another pharmaceutical company had recently engaged in a practice of soliciting clinical trial research subjects from community homeless shelters. These individuals became "career" research subjects, participating in dozens of trials and reaping sizeable financial incentives.

Dr. Smart contacted an FDA official about the second request for information. She inquired as to whether the approval process for *Alive* was contingent upon forwarding the research subjects' additional medical data. The official suggested that "while the approval process is independent of the request for the additional data, companies that fail to comply with all FDA information requests may see their products' approval delayed."

### Responding to Public Health Authorities

That same afternoon, Dr. Smart received a telephone call from Dr. Needy at the state cancer registry. Operated as part of the state department of health, the cancer registry tracks a variety of cancer cases pursuant to state statutory authorization. Dr. Needy had recently learned about Genomatic's drug trials for ovarian cancer. He asked Dr. Smart to provide the names of all of Genomatic's clinical research subjects who had been diagnosed with ovarian cancer. Dr. Smart suggested that the names of these individuals would have already been provided by the subjects' treating physicians or private laboratories that had tested tissue samples for cancer cells. Dr. Needy agreed, but responded that his office had recently uncovered a new type of ovarian cancer that did not typify existing forms of the disease. Specifically, he wanted Dr. Smart to provide the requested information so that the state cancer registry might confirm this potential new form of ovarian cancer tied to the genetic link.

## Sharing with Academic Researchers

Before Dr. Smart could respond to the state cancer registry's request for her research subjects' data, she opened an e-mail from her colleague at Genomatic, Dr. Duit, who worked in the company's headquarters in Seattle. Dr. Duit was the chief information officer for Genomatic. He had recently received a request from the dean of the medical school at a major university that sought access to some of the company's clinical trials databases. Researchers at the medical school thought that some of Genomatic's information might further research on a joint pharmaceutical project between the university and Genomatic.

Dr. Smart called Dr. Duit to question whether she could share the data without the specific informed consent of the subjects. Dr. Duit assured her, "I've spoken with our legal counsel, and he told me that there is no state law against sharing this data (at least in Washington state). We need this data, Sharon. Our CEO recently pledged monetary support to the university to broaden our information-sharing network. The university has some data we can use, and we have some data they can use." Dr. Smart further questioned the use of the data, to which Dr. Duit responded, "Sharon, this is a mutually beneficial practice. Genomatic and the university may both benefit, but the public will benefit as well through improvements in medical science. There's a strong need to collaborate to bring these medical advancements to the public. I'm as sensitive to the privacy issues as you are, but no one debates the value of using this data. Now, send me the data tomorrow."

## Toward A Resolution of these Information Requests

Dr. Smart is uncertain what to do regarding each of these requests for data. Each entity requesting the data seems to have a legitimate claim to the identifiable information. Yet, to share the data with each of these entities may compromise the research subjects' interests in maintaining the privacy of their health information. Dr. Smart seeks your help in answering the following questions:

- Should Dr. Smart provide the identifiable health data about her clinical research subjects to the FDA as part of the drug approval process for *Alive*?
- Must Dr. Smart provide additional identifiable health data to the FDA for its review of Genomatic's recruitment of clinical research subjects?
- Must Genomatic meet the state cancer registry's request for data on those research subjects enrolled in the *Alive* trials?
- Should Dr. Smart forward the requested data to the chief information officer at Genomatic if she knows the officer will share the data with outside researchers at the university medical school?

## Case Study 2: Discussion

### Ethical Problems

The four contexts in which Dr. Smart is asked to share identifiable health data about Genomatic research subjects enrolled in clinical trials for the cancer drug, *Alive*, implicate significant ethical issues.

First, Dr. Smart must decide whether she can provide the information to the FDA for drug approval purposes. Federal health information privacy law clearly permits disclosure of health information where the FDA needs the data for approving or rejecting new or existing drugs. Although individuals may prefer to keep their health information private, there is strong public health support for the FDA's role in approving pharmaceuticals to serve the public's interests in safe and efficacious drugs.

Second, Dr. Smart must consider whether she can share the information with the FDA for purposes of broadly monitoring enrollees in clinical drug trials. This issue raises the implied question of whether the research subjects have any claim to prevent Dr. Smart from disclosing their data to the FDA. If the FDA's second request is not justified by existing informed consent, and assuming that obtaining further consent is impractical, Dr. Smart must determine whether a communal need to protect potential or actual human research subjects from exploitation or abuse may warrant the otherwise prohibited disclosure of information.

Third, Dr. Smart must determine if the state cancer registry is entitled to the subjects' health information for the purposes of identifying new cancer cases, or at least for verifying existing cases. State laws generally authorize state cancer registries to collect information on cancer prevalence through mandatory reporting requirements. These reporting requirements allow public health authorities to more accurately gauge the prevalence of cancer in the population, identify cancer trends, and take preventative measures to address avoidable incidences of cancer. Therefore, Dr. Smart's response to this data request is contingent upon whether or not individual privacy rights to highly-sensitive cancer data outweigh communal goals of cancer reporting.

Finally, Dr. Smart must decide if she can offer the information to Genomatic's chief information officer, who plans to share the data with medical researchers at a university supported by the company. Federal privacy law and human subject research provisions may permit the sharing of identifiable health data for research purposes in some contexts. However, Dr. Smart must acknowledge that the monetary incentive underlying Genomatic's corporate interests in sharing the data may complicate her ethical decision-making.

### Relevant Values

The information requests above invoke a series of legal, ethical, and human rights values that center on the balance between respecting an individual's right to health information privacy and promoting the use of identifiable data where needed to protect the public health or accomplish other communal goods.

Individuals, such as the subjects in Genomatic's clinical research trials, may put a premium on the value of privacy regarding their health information. Normative values of autonomy and justice strongly support the rights of persons to control the circumstances in which their identifiable health data are acquired, used, disclosed, or stored. Legal, ethical, and human rights principles also support some levels of individual control over identifiable health data, including limiting the access, use, or disclosure of this information.

Storage access prohibitions, use restrictions, and informed consent requirements are protections that derive from these privacy concerns.

However, the value of individual privacy regarding health information is not absolute. Sharing identifiable health data may be justified where needed to promote various communal goods and values (e.g., public health, human research), or where necessary to prevent harms to others (e.g., duty to warn requirements). Particularly in the public health setting, the access, use, and disclosure of individual health data is needed to survey the population's health and protect against actual or potential threats to community health. The ability to share data to accomplish the communal values or goals of public health is justified under the ethical theory of utilitarianism and the moral principle of paternalism.

### **Necessary Information**

Dr. Smart must obtain more information before she can respond appropriately to each of the data requests.

First, Dr. Smart must determine the scope of Genomatic subjects' informed consent. The original informed consent language suggests that the release of a subject's research record shall be made to "federal authorities, including the FDA, for the purposes of conveying study results." This language seems to authorize the FDA's initial request for such data pursuant to the approval process for *Alive*. However, even if each subject did provide informed consent, Dr. Smart must assess whether his or her consent is sufficiently broad to release data to the FDA for purposes of confirming that Genomatic did not improperly recruit the research subjects for multiple trials, or provide incentives for their long-term participation.

It may also be necessary to determine whether the subjects' informed consent was obtained under duress. For example, many of the Genomatic subjects enrolled in the study may suffer from a terminal form of ovarian cancer. If *Alive* represents the only available treatment option, the agreement of the subjects to enroll in the study and release their data to the FDA may not be truly informed consent. It will therefore be important for Dr. Smart to examine exactly what the subjects understood from the language and context of the consent. Alternatively, Dr. Smart may want to determine if it is feasible to obtain further consent from the subjects.

Second, Dr. Smart will want to carefully review the state reporting requirements and privacy laws, perhaps with the guidance of an attorney. These laws may set the parameters of Dr. Smart's responses to the data requests.

Finally, Dr. Smart should ensure that Genomatic officials support her decisions before she offers them to the individuals who requested the data. Perhaps company policy and the input of company officials will facilitate Dr. Smart's decision-making.

### **Stakeholders to the Decision**

In this scenario, there are several stakeholders to Dr. Smart's decisions regarding the release of Genomatic subjects' health information. For example, individuals and/or entities with a vested interest in the outcome of Dr. Smart's deliberations include: Genomatic, Genomatic's research subjects, the FDA, the state cancer registry, the university, and perhaps all past, present, and future subjects in clinical research trials (assuming that Dr. Smart's decisions may set a standard or precedent for Genomatic, if not for other pharmaceutical companies).

### **Available Options**

Dr. Smart may choose to explore the following options, assuming they are compatible with the further investigations that were recommended above:

- Obtain further informed consent from Genomatic subjects
- Release all health information requested by each individual/entity
- Limit disclosure to that which is clearly authorized by state privacy and reporting laws
- Defer to Genomatic company policy and/or input from company officials

### **Decision Process**

Dr. Smart's decision process will be influenced by each of the steps, individuals, and entities outlined above. To ensure that Dr. Smart's responses to the data requests are responsible as well as legally and ethically sound, she will want to involve as many knowledgeable people as possible in her decision-making process. Perhaps Dr. Smart should summarize her planned responses to the data requests in a memorandum to Genomatic officials. Dr. Smart can then schedule a meeting with the Genomatic officials to discuss the legal, ethical, and human rights issues implicated in this scenario, and reach a consensus regarding the extent of permissible disclosure.

### **Case Study 3: Legal and Ethical Implications of a Public Health Approach to Funding Cancer Research and Treatment**

Barry Fine is the Chief Financial Officer of BioTech, a Fortune 500 company that makes generous annual contributions to promote biomedical research in national laboratories and medical centers. Barry is responsible for ensuring that BioTech's resources and reputation are well-served by its charitable contribution. He has carefully evaluated the funding requests of dozens of worthwhile organizations. After weeks of indecision, Barry has determined two potential recipients for this year's gift.

#### **Center for Lung Cancer Research**

The appeal from the director of the Center for Lung Cancer Research (CLCR), a governmental public health agency in Washington, D.C., resonated with Barry. The letter explained that CLCR desperately needed BioTech's funds to develop new methods of screening for lung cancer. For nearly two decades, CLCR had advocated chest X-Rays for screening purposes. CLCR now sought alternative screening methodologies after findings from the Mayo Lung Project indicated that chest X-Rays were not necessarily efficient means of tracking the cancer. (National Institute of Health, Press Release, Aug. 15, 2000). To date, no alternative screening method for lung cancer has been shown to significantly improve survival rates.

CLCR hoped to reduce the "false positive" problems associated with chest X-Ray screenings (e.g., exposure of non-malignant tumors) by refining its spiral computed tomography (CT) technology. CLCR scientists were on the brink of developing a modified CT scan that was better able to locate abnormal, malignant growths on the lungs, but additional financial support was needed to continue their work.

The CLCR letter characterized lung cancer as the most common and fatal, yet least well-funded, form of cancer, with approximately 170,000 new cases diagnosed each year. The American Cancer Society reported in 2001 that lung cancer kills more Americans than breast, prostate, and colorectal cancers combined, with dramatic increases in the number of new diagnoses of lung cancer among women. Although most causes of lung cancer are related to the use of tobacco, lung cancer can also be caused by radon or asbestos exposure and lung diseases, including tuberculosis. Early detection of lung cancer when it is localized (e.g., before the cancer spreads to other organs in the body) greatly increases the five-year survival rate. By helping to improve measures of early detection of lung cancer, CLCR's proposal concluded that BioTech can prolong, if not save, countless lives.

#### **BioLogics**

Next to CLCR's letter on Barry's desk was a fax from the chief executive officer of BioLogics, a small medical research center in Florida. BioLogics' plea for BioTech's funds was also compelling. The CEO confided that based on blood and urine tests and a bone marrow biopsy, he had recently been diagnosed with Waldenström's Macroglobulinemia (WM), a rare, chronic form of cancer classified as a low-grade lymphoma. This disease causes abnormal plasma cells to multiply out of control, invading bone marrow, lymph nodes, and the spleen and producing excessive amounts of IgM, an antibody that causes thickening of the blood. In extreme cases, the increased concentration of IgM in the blood can lead to heart failure, typically within five to seven years.

BioLogics' fax stated that approximately five out of 1,000,000 people are diagnosed with WM each year. The disease usually affects people who are over the age of sixty-five; however, it can also be found in



younger people. Cancer registries in the United States indicate that this cancer is more common among men than women and among Caucasians than African-Americans. Some patients do not report any symptoms prior to diagnosis. Other patients experience enlarged lymph nodes or spleen, as well as fatigue, headaches, weight loss, a tendency to bleed easily, visual problems, confusion, dizziness, and loss of coordination. The CEO of BioLogics was told that these symptoms are due to the thickening of his blood from the IgM. Unfortunately, WM has an unknown cause and no known cure. Many hematologists have never seen a single case of this form of cancer, hence its nickname as an “orphan” disease.

A lack of satisfactory treatment of WM inspired the CEO of BioLogics to send BioTech the request for funds. Because WM is such a rare disease, there is no government-approved course of treatment. Current treatment methodologies are determined by the thickness of the patient's blood, and may include chemotherapy, plasmapheresis, and/or biological therapy. The main goal of treatment is to reduce the amount of abnormal blood cells, bone marrow cells, and protein in the blood.

Consistent with its reputation as an “innovative” or “cutting-edge” research center- and with its compassion for its CEO- BioLogics has prioritized research of new treatment methodologies for WM, and seeks BioTech’s financial backing for this endeavor.

### **A Public Health Approach to Funding Decisions**

After reviewing the proposals extensively, Barry concluded that both projects would be worthwhile investments for BioTech, yet each had distinct benefits and disadvantages. Funding for lung cancer research was clearly needed and could lead to significant improvements in early detection and treatment for this common, fatal disease. Alternatively, funding for WM could directly benefit the CEO of BioLogics and could bring much needed attention and resources to this rare disease.

Barry needs guidance on the legal, ethical, and human rights implications of this important decision. Specifically, Barry requests your professional opinion on the following issues:

- What criteria should Barry use to make the funding decision; e.g., how will legal, ethical, practical, and financial issues contribute to BioTech’s decision-making process?
- Should Barry, and BioTech by extension, adopt a public health perspective or a clinical approach regarding the implications of this decision?
- What influence should the demographics of the two diseases have on the decision?

## **Case Study 3: Discussion**

### **Ethical Problems**

This case study presents Barry Fine, the Chief Financial Officer of BioTech, with the ethical dilemma of choosing between the Center for Lung Cancer Research (CLCR), a governmental public health agency in Washington, D.C., and BioLogics, a private medical research center in Florida, as potential recipients of BioTech's annual contribution to promote biomedical research.

Barry must consider the ethical implications of this important decision. The framework for Barry's ethical analysis will be shaped by his conception of cancer as either a clinical matter or as a public health issue. The demographics of the two diseases may influence BioTech's funding decision. For example, should the tendency of WM to disproportionately affect older, Caucasian men disincite Barry to support its funding, in favor of a more "equal opportunity" disease, such as lung cancer? The answer to that question will depend on whether Barry wants to use the BioTech funds to directly address clinical cases (e.g., helping the CEO of BioLogics treat his WM) or to convey a more general, population-oriented message (e.g., highlighting the public health problem of tobacco use by exposing lung cancer as one of its long-term consequences).

### **Relevant Values**

Barry's decision will be influenced by several important values. First, Barry must consider the values of BioTech, a conservative, prestigious organization that will want to preserve its reputation as such. Second, Barry must consider BioTech's like-minded investors, who want to ensure that BioTech retains its status as a Fortune 500 company. Third, Barry will be influenced by his own values, such as integrity and psychological and/or financial security. Finally, Barry must carefully weigh the values of CLCR and BioLogics, and determine if their values are compatible with those of the other people and entities involved in this decision.

### **Necessary Information**

Before selecting the recipient organization, Barry must gather more information.

First, Barry should consult with other executives at BioTech regarding whether the funds can be split between CLCR and BioLogics. If dividing the funds is not an option, Barry should inquire as to which organization is preferable- and why. Perhaps Barry can schedule a meeting with BioTech's Board of Directors to discuss the benefits and disadvantages associated with each organization.

Second, Barry must obtain more detailed information regarding exactly how CLCR and BioLogics plan to use the BioTech funds. For example, it may be important to discover whether these organizations anticipate short-term or long-term results; e.g., whether they will use the funds to support further academic research, clinical trials, and/or technological development and innovation. Barry may request that CLCR and BioLogics send him proposals that elaborate on their specific intentions. This additional information would also enhance Barry's presentation to BioTech's Board of Directors, enabling a more thoughtful and informed decision.

Finally, Barry should review past funding decisions and reevaluate the criteria that BioTech used to make those decisions. Perhaps certain patterns or organizational profiles will emerge that would simplify Barry's decision process.

### **Stakeholders to the Decision**

There are various stakeholders to BioTech's funding decision, including: BioTech, BioTech's investors, Barry Fine (in his capacity as Chief Financial Officer of BioTech), CLCR, BioLogics, and all current and future patients diagnosed with lung cancer or WM.

### **Available Options**

Depending on the outcome of the above investigations, Barry may have the following options regarding the BioTech funding decision:

- Divide the BioTech funds equally (or as otherwise needed) between CLCR and BioLogics
- Choose CLCR since BioTech's funds will likely reach more people due to the prevalence of lung cancer in the general population
- Choose BioLogics since WM is arguably more in need of attention and resources
- Choose another worthy recipient from among the dozens of funding requests that BioTech received
- Defer to BioTech's Board of Directors to make the final decision

### **Decision Process**

Barry's decision process will be influenced and informed by each of the stakeholders listed above. The final funding decision will also reflect the considerations and values that have been mentioned. Perhaps a formal meeting involving Barry Fine, BioTech's Board of Directors, the director of CLCR, and the CEO of BioLogics is the most appropriate forum for the final decision process. Attention to each of these factors, individuals, and entities is essential to making an ethical decision that will promote the public health and serve the private interests involved.

## **MODULE 2**

# **The Legacy of the Tuskegee Syphilis Study**

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### **Introduction**

Any consideration of ethics in public health research and practice must acknowledge the legacy of what has come to be called the Tuskegee Syphilis Study. Indeed, all public health research is conducted in the shadow of the actual study and the cultural icon that it has become. In some contexts and communities, mere reference to “Tuskegee” conjures images and reflects ideas that public health workers need to confront, as a practical matter, in order to provide services and conduct research. This following issue essay discusses the history of the Tuskegee Study of Untreated Syphilis, its legacy, and the way in which it functions as both a cultural icon and a framework for consideration of ethical concerns in public health.

What does it mean to say that a public health study has become a “cultural icon,” indeed a symbol of what it means to conduct unethical research on human beings? The charge that something is “just like Tuskegee” summons emotionally charged meanings for researchers, the American public in general, and African-Americans in particular. “Just like Tuskegee” has rhetorical force: it immediately suggests a set of ethical concerns that warrant attention. However, the rhetoric surrounding “Tuskegee” can cloud careful and accurate analysis of what is actually at stake. With respect to the three cases following the issue essay, readers are invited to consider the ways in which the cases really are, or are not, just like Tuskegee. Such an initial analysis provides a starting point for deeper consideration of the ethics of research that appears to involve issues of race and racism, vulnerability of particular communities or populations, power, deception, exploitation, and questions about consent, appropriate study design and research hypotheses, distinctions between research and treatment, and standard of care—all issues raised by the original Tuskegee Syphilis Study.

Two initial issues of ethical relevance must be raised before the essay can commence. These are issues of terminology that have more than typical semantic importance. First, what should the Study be called? The official title of the study was “The Tuskegee Study of Untreated Syphilis in the Negro Male,” but those with various interests have argued that other appellations would actually be more historically accurate. One commentator suggests the “US Public Health Service Study of Untreated Syphilis in the Negro Male” (Brawley 1998), while a Public Health Service (PHS) spokesman termed it a cooperative project of the PHS, the Tuskegee Institute, the Tuskegee Medical Society, and the Macon County Health Department in Alabama (Jones 1993, p. 7). Some contend that referring to it as the *Tuskegee*

Syphilis Study unfairly marks the Tuskegee Institute and taints its good name (Brawley 1998), when it could be argued that the Institute was manipulated into its institutional participation almost to the same degree as the individual men who were convinced to participate in the study. Unfortunate as it may be that the Institute is probably most widely known for this study, and unfair as it may be to single out the Institute for its participation, nevertheless it is important to refer to the Study by its common—indeed almost iconographical—name, for it is not just the history of the Study, but its cultural legacy that concerns us. For this reason, we shall refer to it as the Tuskegee Study of Untreated Syphilis or the TSUS. In addition, some refer to the TSUS as “the Tuskegee Syphilis Experiment,” presumably to emphasize that the men enrolled in the study were experimented upon, were treated as guinea pigs, and perhaps to emphasize that people have reason to be wary of such research.<sup>1</sup> On the other hand, the TSUS was not an experiment in the sense that an intervention was tested. Its initial methodology involved collecting data to trace the course of a disease in members of a population and the prevalence of the disease in that population; it resembles an epidemiological study. Since penicillin eventually became widely available but was not given to men enrolled in the TSUS, the TSUS might be viewed as an “experiment in withholding treatment,” an experiment designed to discover what occurred under conditions of non-treatment. Nevertheless, we shall avoid ‘experiment’ as a less appropriate term.

The second question is what the men enrolled in the study should be called. Current parlance suggests that those enrolled in research be called ‘participants’; however, this term suggests a far more collaborative interaction than the men enrolled in the TSUS actually experienced. At the same time, to refer to them as ‘subjects’ seems to perpetuate their status as people to whom things were done—subjects, subjugated and acted upon—rather than as agents in their own right. As the account below reflects, these images are perhaps the most accurate in describing how the men in the TSUS were treated. Nevertheless, to refer to them today as ‘subjects’, in light of both contemporary understanding of that term and historical understanding of the wrongs done to them may seem to perpetuate the lack of respect for their dignity and agency. Finally, although the men were certainly enrolled in the study, referring to them as ‘enrollees’ is misleading if it suggests the contemporary notion of individuals who enroll in research through a process of informed consent. Having raised these considerations, in the following discussion, we tend to refer to those enrolled in the TSUS as ‘the men in the study’ or as the study ‘enrollees’.

## Issue Essay

### *Questions for Consideration*

In addition to its historical and cultural importance, one of the reasons for considering the Tuskegee Study of Untreated Syphilis (TSUS) is that it raises so many ethically rich questions. First, ethical concerns attach to the premise of the study, its research design, its use of deception and social pressures to enroll, and the lack of informed consent. Next, background questions can be raised about the appropriateness of conducting research with members of “vulnerable populations” (and how to define or identify such vulnerability), about research in the context of a lack of access to adequate health care, and about research conducted against the social backdrop of racism or other social injustice and prejudiced cultural attitudes. These background issues raise questions about the practical

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<sup>1</sup> Research has shown that people have a more positive attitude toward a study that is described as being “research,” and are more wary when it is termed “an experiment.” ‘Research’ or a ‘research study’ seems to imply cutting edge and possibly beneficial interventions, while ‘experimentation’ suggests images of scientists using people as guinea pigs. See Sugarman *et al.* 1998.

possibility of ensuring the voluntariness of participation in research, *informed* consent, and public trust in the conduct of research and the use of research results. That the TSUS's inception predated, but its cessation postdated, the Nazi experiments and the Nuremberg Trials only intensifies questions about the adequacy of regulations to ensure ethical conduct of research. Finally, because the TSUS involved a traditionally exploited group—African-American men—who were also poor, rural, and uneducated, consideration of the TSUS raises a variety of questions for current and future research: How should the concept of 'race' be used in research? How will society respond to identification of disease risks (e.g., dietary customs or genetic factors) associated with racially or ethnically defined populations? How should research on such questions be designed? How may research results be used to avoid further disadvantaging racially or ethnically defined groups? Finally, given the past and current structure of American society, how can social and economic factors (e.g., educational and economic background, or rural/urban environment) be meaningfully distinguished from racial categories in both the conduct and the reporting of research? In fact, particular features of the TSUS raise questions about the conceptual foundation and practical implementation of what may be considered the tools for best practice in conducting research with vulnerable populations or in minority communities.

### ***Brief History of Tuskegee Study***

In the 1920s, the medical and public health communities hypothesized that blacks and whites differed in their response to disease (King 1998, pp. 92-7). In Macon County, Alabama, where 35-40% of those tested were positive for syphilis, the PHS felt that it had an ideal opportunity to study the course of syphilis in blacks and to compare the course of the disease against a study on syphilis in whites, done several years earlier in Oslo, Norway. The impetus for the Tuskegee Study of Untreated Syphilis was rooted in earlier work by the US Public Health Service (PHS) in the rural south. In 1928, the PHS completed a study in Mississippi in which 25% of the sample (all black) tested positive for syphilis. With financial backing from the Julius Rosenwald Fund, the PHS planned to continue studies of syphilis in rural blacks and to provide treatment, which at the time was comprised of doses of arsenic, mercury, and bismuth. However, the beginning of the Depression in 1929 wiped out the finances for the project, and the PHS scaled down its plans and tried to salvage a much smaller-scale study (Thomas and Quinn 1991).

Nurse Eunice Rivers, a black woman who graduated from the Tuskegee Institute in 1922 and then worked for the state of Alabama on various public health projects, was hired as coordinator of the TSUS. She set up transportation, organized clinics, and generally served as the primary contact for the men enrolled in the study. With her help, the PHS was able to efficiently reach the men of Macon County, holding clinics in schools and churches and enlisting the enthusiasm of both leaders in the black community and white plantation owners, who had an interest in the health of their employees. The cooperation of the Tuskegee Institute—whose earlier involvement in syphilis treatment programs gave the appearance to the public that these efforts were being renewed—helped to set blacks at ease with the government doctors (Thomas and Quinn 1991). The Institute was persuaded to participate by promises of training and employment for its doctors and nurses, as well as credit for aiding an important scientific study (Jones 1993, p.102).

The men in the study were told that they were being tested for "bad blood," a Southern catchphrase for a variety of illnesses. They were not informed that they had syphilis or given information about what syphilis was, how it was transmitted, or how it could be treated. Originally, the study was to last only 6-12 months, not enough time to deliver a full course of treatment, but at the insistence of the Alabama state health officer involved in the study, enrolled men who tested positive for syphilis received a

minimal course of treatment: eight doses of an arsenic compound and some mercury pills. This would not have been enough to cure the men, though it might have rendered them noninfectious (Jones 1993, p. 99). However, the study was soon extended in an attempt to examine the men periodically until their death, and then to perform an autopsy, to give the doctors a chance to track the complete course of syphilis left untreated (Jones 1993, p. 132). Nurse Rivers and area doctors encouraged dying men to enter the hospital, and after death Rivers would sit with the grieving families and eventually ask permission to perform an autopsy, carefully explaining that no one at the funeral would be able to tell that the body had been opened. After 1935, the Millbank Memorial Fund in New York provided \$500 each year to be given out as \$50 burial stipends to each family in exchange for permission to perform the autopsy (Jones 1993, pp.153-4).

It was not difficult to persuade enrollees to continue in the study past the original few months. The men were given iron and aspirin as placebo treatments, which did in fact improve their general health and make them enthusiastic participants in the study (Jones 1993, pp.147-8). They were aware that they were receiving far more medical care than they could otherwise afford, just as today some uninsured Americans enroll in research studies to gain access to basic medical care. The illusion of treatment was carefully perpetuated by the researchers, who even advertised spinal taps—a painful and potentially debilitating procedure—as “special free treatment” in addition to the “great deal of treatment for bad blood” that the men had already received (Brandt 1978). The spinal taps had no therapeutic value whatsoever and were performed solely to gather information on the presence of neuro-syphilis.

Soon, with awareness of venereal diseases rising, it was deemed important by those running the study that it not be compromised by enrollees’ receiving treatment. In the late 1930s and early 1940s, PHS clinics in the rural south were dispensing an accelerated, week-long course of an arsenic derivative and bismuth to those with syphilis. Nurse Rivers was assigned to coordinate with these clinics to ensure that the men in the study were not given treatment (Jones 1993, p. 162). In 1943, the PHS clinics began using penicillin to treat syphilis, and Alabama passed a law that all citizens between 14 and 50 be tested for venereal diseases and TB and that those testing positive be treated (Jones 1993, p. 178). TSUS enrollees were not tested or treated (Jones 1993, p. 178). During World War II, the PHS arranged with the draft board that draftees from the study population would not need to take the penicillin treatment given to all other drafted men diagnosed with syphilis (Thomas and Quinn 1991). The men, identified to local and state doctors on a list provided by the Tuskegee researchers, did not know enough about their condition to question being turned away. Accustomed to having no access to health care, with their enrollment in the study, the men believed that they were already receiving adequate medical care (Brandt 1978).

In 1951, penicillin became the standard treatment for syphilis, but despite a full-scale review of the study by the PHS, and despite the new attention that was being cast on the ethics of research after the Nazi experiments were revealed, the study continued (Jones 1993, p. 181). Throughout this time, occasional papers on the study were given at conferences and published in medical journals with no ethical objections being raised (White 2000). Continued conduct of the TSUS was clearly unethical according to the guidelines set forth in the Nuremberg Code in response to the Nazi war crimes trials, which emphasized informed consent and the researcher’s duty to avoid causing harm to the subject. The Code was followed in 1964 by the World Health Organization’s Declaration of Helsinki, which also set out guidelines on human experimentation and insisted on a stringent informed consent process. In the late 1960s and early 1970s, the PHS developed guidelines for clinical trials that it funded; these established the first structures for peer review at the investigators’ institutions—the forerunners of today’s

institutional review boards (IRBs)—and eventually required that community members and those without scientific backgrounds sit on these panels. However, these guidelines were not applied to the PHS' own studies like the TSUS (Jones 1993, p. 190).

In 1964, an article was published about the last thirty years of the study. In response, Irwin Schatz, a Michigan doctor, wrote to the authors raising questions about the ethics of denying effective therapy for a potentially fatal disease, but the study continued (White 2000). In the late 1960s, Peter Buxton, a physician who worked for the PHS in San Francisco, began scrutinizing the study and voicing his concerns. Because of this attention, the PHS convened a blue ribbon panel to decide whether the study should continue. The panel was comprised entirely of white physicians, of whom all but one had previous knowledge of the study. The sole previously uninvolved member, Gene Stollerman, was the only panelist in favor of examining the men and providing appropriate treatment. The others, who wanted to continue the study without change in its protocol or provisions, emphasized the risks of penicillin treatment: it could cause adverse and allergic reactions, such as fibrillations and anaphylaxis, and in addition there was some evidence that penicillin cured syphilitic lesions but sometimes failed to kill the spirochetes that were the source of the disease. One panelist made the groundless assertion that the men would not accept treatment even if it were offered (Jones 1993, pp. 193-6).

The panelists also determined that informed consent was impossible to obtain from men with so little education and social status, and decided to approach the Macon County Medical Society (MCMS) to ask for a sort of surrogate consent. The MCMS, which was mainly comprised of black doctors, agreed that the experiment could go forward and promised not to give anyone in the study antibiotics for syphilis or for other diseases. At this time, the PHS also increased its efforts to find men who had been lost to the study in the preceding years, going so far as to enlist the assistance of the assistant postmaster in Tuskegee and to hire a retail credit agency to locate the men (Jones 1993, p. 196-200).<sup>2</sup> Buxton finally told the story of the Tuskegee study to Associated Press reporter Jean Heller in 1972. Her article, entitled "Human guinea pigs: syphilis patients died untreated," appeared in the *Washington Star* and alerted the nation and the world to the existence and details of the TSUS. The article and the reaction to it finally forced the study to end, forty years after its inception and nearly 20 years after penicillin had become standard treatment for syphilis (White 2000).

## The Legacy of the TSUS

There are, in fact, multiple legacies of "Tuskegee." Public and political attention focused on the TSUS led to regulatory changes regarding the conduct of research. African-Americans who became aware of the conduct of the TSUS were outraged, and the TSUS served to reinforce and magnify the mistrust many African-Americans feel toward the government, its services, and those in power in the "establishment," including the medical establishment. Researchers must now confront this widespread and magnified mistrust, as well as fulfill the regulatory requirements spawned by Tuskegee and other research scandals and outrages (e.g., Nazi experimentation, viral hepatitis research at Willowbrook State School, cancer research at the Jewish Hospital for Chronic Diseases). Enrollment of members of minority groups in research studies is more difficult because of prevalent mistrust and lack of

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<sup>2</sup> Thus it is not only since the events of September 11, 2001, that US government officials have proposed the use of public and private employees to track citizens for the sake of some supposed public good. While in the TSUS such employees were asked to locate study enrollees, in the 21<sup>st</sup> century "war on terrorism," it was proposed that postal employees and meter readers be officially encouraged to report suspicious activities observed in their daily work.



community-researcher collaboration, and therefore, members of these groups may fail to benefit maximally from research advances (e.g., drugs and other interventions) as these are developed without participation of people relevantly “like them” (Merton 1996, King 1998). (Moreover, such mistrust affects minority members’ seeking of health care services, especially preventive interventions, and their interactions with health care providers [e.g., Roberts 1996].)

*The regulatory legacy.* In 1973, the Department of Health, Education and Welfare completely revamped regulations on human subjects protection. A class action suit was filed by TSUS enrollees and was settled out-of-court the next year; all of the participants or their families were compensated (Thomas and Quinn 1991). The total settlement amount of \$10 million was distributed in amounts ranging from \$5,000 to \$37,500, according to whether the participants were still alive and whether they had been part of the syphilitic or control group (Jones 1993, p. 217). A task force was created in 1975 to consider whether injured research subjects should be entitled to compensation. In its 1977 report, it argued that just as military personnel who incur risks on behalf of society are compensated for service-related injuries, research subjects should be compensated for research-related harms suffered. No action was taken on the task force’s recommendation.

In 1974, federal legislation created a national commission to oversee human subjects in research, and the National Research Act mandated the establishment of IRBs to review all federally funded grants involving human subjects (Corbie-Smith 1999). In 1991, the US Department of Health and Human Services (HHS) issued revised regulations on human subjects research. They have been accepted by almost all federal departments that fund such research, and have therefore come to be referred to as the Common Rule (Title 45 Code of Federal Regulations Par. 46 [45 CFR 46]). Many institutions not legally obligated to abide by the Common Rule have nevertheless adopted it, and many states have similar regulations. According to the regulations, in order for persons (or their legally authorized representatives) to give “legally effective informed consent,” the researchers seeking participation must disclose eight elements of information about the study:

1. a statement that the study involves research, and description of that research and its purposes;
2. a description of reasonably foreseeable risks;
3. a description of reasonably expected benefits;
4. a disclosure of appropriate alternatives;
5. a statement about maintenance of confidentiality;
6. an explanation of possible compensation in case of injury, if the study involves more than minimal risks;
7. information about how subjects can have questions answered;
8. and a statement that participation is voluntary.

In some cases, participants must also be told about unforeseeable risks, circumstances under which their participation will be terminated, additional costs they might incur, consequences of a decision to withdraw, dissemination of findings during the study related to their willingness to continue, and the approximate number of total subjects. Some studies which involve no more than minimal risk to participants are eligible for expedited review, and some studies (e.g., many surveys, observations, or studies of existing data) are exempt from these informed consent requirements; however, it is the IRB—not the research investigators—who must determine whether a project is exempt or eligible for expedited review.

Prospective review by an IRB offers several ethical advantages: IRB panelists examine the importance of the study question, the reasonableness of the risk-benefit ratio, and the provisions for informed consent. This process, in theory at least, prevents participants' rights from being violated and ensures that participants incur the risks of research only for the sake of producing meaningful research results. In contrast, outside of the research context, when informed consent to treatment is lacking, criticism only emerges after the intervention has taken place. More stringent requirements for informed consent are considered necessary in a research context, as opposed to a purely therapeutic context. In the therapeutic relationship, doctor and patient typically share the same goal of the patient's good health or personal benefit. In research, the researcher and subject have at least some divergent goals, and the risk is that the subject's interests could be sacrificed for what the scientist or society considers the greater good served by the experiment (Berg *et al.* 2001, pp. 279-84).

Despite its important advantages, there are several limitations to prospective IRB review. IRBs are often staffed by volunteers or appointees who are not compensated for their time, yet appropriate review of research protocols is time-consuming and demands substantial commitment and expertise or education on the part of IRB members. Moreover, after an IRB has deemed a study design to be ethically acceptable, moral complacency—on the part of researchers, or IRBs in their overseer capacities—can set in. Finally, IRB review is subject to factual and ethical error, and in practice often focuses more on the completeness of the consent form the researchers plan to use than on the overall design of the study (Berg *et al.* 2001, pp. 259-66).

Members of some communities or study populations—so-called special or vulnerable populations—have additional reasons to worry that compliance with research regulations and award of IRB approval are inadequate to ensure that their participation is non-exploitive and even advantageous. The notion of “vulnerability” in the context of research is employed to describe groups of potential research subjects who may be more than usually susceptible to exploitation in the process of research, either because they may be more likely to be pressured to participate, or may be more likely to fail to understand the full implications of participation and may therefore be misled into participation.

The regulations in the Common Rule identify the following as “vulnerable populations” in the context of human subjects research: children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons” (45 CFR 46 §III[b]). These regulations provide for IRBs to appoint consent auditors and provide special regulatory protections of fetuses and pregnant women, children, and prisoners (45 CFR 46, Subparts B, C, and D).

Of course, in reality, a variety of individuals may be rendered vulnerable in virtue of various situational or persistent social factors. People who are sick or in pain, frightened, or overwhelmed by information or “bad news” may be vulnerable in virtue of these situational factors. Those who lack the education, emotional maturity, or language and communication skills to understand and appreciate what is disclosed to them during an informed consent process may also be vulnerable to inappropriate pressure to participate (or, instead, to reject precipitously the option of research participation that might benefit them). Those who feel disempowered in virtue of the social roles they occupy, or who lack economic resources to investigate the proposed research or alternatives to it, may not feel free to refuse participation. With respect to research risks, protection of competent adults who are economically or educationally disadvantaged has proved complicated and highlights concerns about both respecting autonomy and achieving social justice (Berg, *et al.* 2001, pp. 271-2; Kahn, *et al.* 1998).

After the TSUS, heightened sensitivity to the use of vulnerable populations in research resulted in many studies completely excluding these populations. Minority members and women were simply not recruited for trials, which protected them from the research-associated risks, but also meant that they were less likely to share in any benefits, both during the study and later when results were generalized to populations in which the interventions had not been studied (Corbie-Smith 1999, DeBruin 1994, Dresser 1992, Merton 1996, Kass 1998, King 1998). In addition, conditions more prevalent among, or disproportionately affecting, minority group members or women simply went unstudied (e.g., Faden *et al.* 1996). Finally, in 1993, the National Institutes of Health Revitalization Act mandated proportional representation of minorities and women as subjects in all research projects, unless there was a compelling reason to exclude them (Corbie-Smith 1999), and researchers are recognizing advantages with respect to funding priorities of studying conditions affecting minority members and women.

***The legacy of mistrust among minority community members.*** Despite strict regulations on research, requirements of informed consent, and requirements that they be adequately and appropriately represented in study populations, minority populations often distrust both the government and the medical community. This mistrust is largely due to past injustices, such as the TSUS, which still plays a great role in African-Americans' reluctance to participate in research (Richardson 1997, Freimuth *et al.* 2001, Thomas and Quinn 1991, Corbie-Smith *et al.* 1999, Corbie-Smith 1999, King 1998). This prevalent mistrust is particularly harmful in light of the AIDS crisis, which affects so many blacks and other marginalized populations, such as gay men and intravenous drug users (IDUs). A phone survey on medical research and the TSUS revealed that 9% of 500 black households believed that HIV and AIDS were part of a plot to kill blacks. Only 1% those in a survey of the general population responded similarly (Richardson 1997).<sup>3</sup>

The history of mistrust carries over to the very informed consent process designed to protect research participants, with a substantial number of African-Americans viewing informed consent as primarily a legal protection for physicians and researchers and considering their signing a consent form as a relinquishment of their rights (Corbie-Smith *et al.* 1999).<sup>4</sup> Increasing African-Americans' understanding

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<sup>3</sup> Again terminology carries important ethical and social implications. To contrast African-Americans and "the general population" in reporting the survey results conveys the message that African-Americans are not part of the general population. To take a similar example, talking about different levels of risk of HIV among urban gay men and in "the general population," marks gay men as being outside the general population. The "us vs. them" message implicitly conveyed has been shown to undermine HIV risk reduction education efforts, for example, and perpetuates the disenfranchisement of already marginalized groups (Grover 1988, Treichler 1998). The term 'subpopulation', rather than conveying that, for example, African-Americans or gay men constitute a group *within* a larger group, is often considered to emphasize the "sub" or lower status of the included group and to reinforce its subjugation.

<sup>4</sup> In focus-group interviews with African-Americans, researchers have discovered many misconceptions about the informed consent process (Freimuth *et al.* 2001, Corbie-Smith *et al.* 1999). Many participants believed that signing a consent form meant that they were waiving their rights, including those to sue if something went wrong, and that the primary purpose of a consent form is to protect doctors and hospitals from legal liability. In addition, they stated that the forms were often incomprehensible to them, and it was therefore impossible to fully understand what they were agreeing to. The process of informed consent itself could be improved most radically by providing information, both written and spoken, in terms that can be understood by laypersons. This is particularly important for members of minority groups, who may be disadvantaged educationally (Freimuth *et al.* 2001, Corbie-Smith 1999). Those who sign consent documents should be given copies of those documents to keep (Corbie-Smith 1999). Focus group participants also stated that they wished to have time to make a decision about participation in research, so that they could consult family members and do some research on their own about what they were being asked to do. They suggested it was important to have information from several different points of view (Corbie-Smith 1999).

of and trust in the informed consent process will be necessary to encourage their increased participation in research. Yet investigators who have studied the reluctance of African-Americans to join studies identify reason for African-Americans to be wary of recent policies that permit a waiver of consent for some types of research (specifically, emergency research) (Corbie-Smith *et al.* 1999). They are also concerned that incentives to participate in research could be unintentionally coercive (Freimuth *et al.* 2001). Since community ties are often particularly strong in minority groups, some form of community consent—in addition to individual consent—has been advocated as an important and valuable addition to the consent process (Corbie-Smith *et al.* 1999; Freimuth *et al.* 2001). Studies have also revealed that many African-Americans—indeed many Americans—do not understand the process and purpose of human subjects research (Berg *et al.* 2001, pp. 288-95). Gaining greater understanding of the purpose and process of research could allay many fears about participation. Education, both in schools and in the wider community, should seek to define the vocabulary of research and to explain its procedures and purpose (Freimuth *et al.* 2001, Corbie-Smith 1999). It should also address head-on the realities of and the misconceptions and myths surrounding the TSUS and other research controversies (Freimuth *et al.* 2001).

*Responding to this legacy: steps to restore trust.* In 1997, President Clinton took a major, at least symbolic step, toward addressing the realities of the TSUS and enabling productive confrontation of its cultural legacy. President Clinton apologized for the government's involvement in the Tuskegee study and introduced several initiatives to make amends, including establishment of a memorial and scholarships for minority bioethics students (<http://clinton4.nara.gov/textonly/New/Remarks/Fri/19970516-898.html>).

It may seem unlikely, or trivializing of a serious wrong, to suggest that the offer of a formal apology for wrongs as great as those committed in “Tuskegee” could provide grounds for the restoration of trust. Apologies—even or perhaps especially formal official ones—may seem more a matter of manners than of substantive ethics. Nevertheless, showing courtesy—or in this case specifically, offering an apology—is a means of showing respect, of demonstrating directly that the person to whom the courtesy or apology is paid is a person *worthy of respect* (Buss 1999). Although in most instances *doing* the right thing is more important than, after the fact, saying the correct thing—“I/we am sorry; we apologize for having done wrong”—the apology most directly acknowledges that the wronged parties were worthy of better treatment, were worthy of having their rights and their dignity respected. Such direct acknowledgment, if followed by attempts at both restitution or atonement, and appropriate future action, may constitute an initial step toward restoration of the trust of those previously wronged. In contrast, apology coupled with uncorrected action in the future would seem hollow, false, disrespectful, and manipulative. An apology not coupled with “follow through,” i.e., with appropriate future action and with attempts to restore those wronged in the past or to atone for past wrongs, would further erode conditions of trust.

The establishment of the memorial and scholarship fund, the payment of some monetary compensation to study enrollees or their descendents, as well as the implementation of research regulations to prevent future similar wrongs, suggest that the Presidential Apology is not mere rhetoric, but instead is a formal statement of assumption of responsibility, recognition of wrongdoing, and acknowledgment of the moral standing of those wronged. Coupled with action, the Apology may indeed help to rebuild trust between African-Americans and the government and researchers.

In recent years, the important role of trust in morality has gained the attention of a number of moral philosophers, especially Annette Baier (1986). They observe that whatever ethical system is adopted—e.g., a set of principles and rules, a social agreement or contract about how to live, or a system of duties—that system relies on trust. Trust grounds a person's reliance on another to fulfill his duty or to follow established rules or abide by terms of a social contract. Morality requires trust in order to thrive (Baier 1986, p. 232). Indeed, trust is a necessary condition for many important human activities; because we need the assistance of others to accomplish what we care about, we must trust others with what we value in ways that make us vulnerable. We assume some risks—for example, the baring of our bodies before our physicians and the sharing of intimate details about our lives with friends—in order to seek benefits we cannot achieve without incurring such vulnerability. "We must allow many other people to get into positions where they can, if they choose, injure what we care about [e.g., our bodies, reputations, or confidences], since those are the same positions that they must be in in order to help us take care of what we care about [e.g., by treating our symptoms or sharing our dreams]" (Baier 1986, p. 236).

Health, aspirations, friendship, education, promise-making, secret-sharing—all of these goods flourish within an environment of trust. Of course, much that is negative and immoral may flourish when trust is misplaced and betrayed, including ridicule, exploitation, and conspiracy. "Trust alters power positions, and both the position one is in without a given form of trust and the position one has within a relation of trust need to be considered before one can judge whether that form of trust is sensible and morally decent" (Baier 1986 p. 240). Thus Baier suggests that when the parties to a possible trust-relationship occupy very different positions of power (e.g., teacher-student, researcher-study participant, doctor-patient, employer-employee), the terms of an appropriate trust-relationship must be different than if the parties were in a position of relative equality (e.g., classmates, buddies). Of course, contextual and structural factors can render apparent equals vastly unequal in power. Pain of injury can make one team member quite dependent on her fellow athletes. Persistent sex inequalities can make one parent (Mom) a less powerful wage-earner than her co-parent (Dad). An appropriate trust-relationship must not rely on or exploit these underlying power differences.

What are conditions of appropriate, morally decent trust? Baier proposes an expressibility test to determine whether a situation is one of morally decent (non-exploitive) trust: a trust relationship is morally decent if the maintenance of trust need not rely "on successful threats held over the trusted, or on her successful cover-up of breaches of trust" (1986, p. 255). Trust is appropriate only if the reasons for each party's confident reliance on the other could in principle be expressed openly without deterioration of either party's reliance. "To the extent that mutual reliance can be accompanied by mutual knowledge of the conditions for that reliance, trust is above suspicion" (Baier 1986, p. 259).

Clearly, the men in the TSUS did not have appropriate trust in the PHS researchers and Nurse Rivers. Had they had known that they were not being treated for their "bad blood," if they had known what researchers meant by "bad blood," or if they had known that the researchers' actions were undertaken primarily for the benefit of others, they would probably not have entrusted their bodies for spinal taps and other examinations. The researchers relied on "successful cover-ups of breaches of trust" to maintain the trust of study enrollees. They were successful in their exploitation because of the lack of educational and economic power of the men they enrolled and because those factors and racism combined to render those men more compliant with authority figures than others were likely to be.

It remains to be seen whether the regulatory steps taken to prevent future successful cover-ups of trust, future exploitation, coupled with the government's admission of wrongdoing, its acts of compensation and atonement, and the formal seeking of forgiveness successfully restore public trust, particularly that of African-Americans and other vulnerable groups. Complicating both this restoration of trust and a sense that clear lessons from the TSUS have been learned is ongoing debate about the "facts" of the TSUS and about what ethical lessons should be learned from it.

***Debate about TSUS itself.*** Several authors have sought to show that the study's original design was scientifically appropriate and ethical, and that even after penicillin became available, it was not wrong to deny it to TSUS enrollees. These arguments focus on the decision to examine *untreated* syphilis, and whether this study design can be justified. Benedeck and Erlen (1999) point out six potential justifications that were relevant at the study's inception in 1930.

First, syphilis was recognized as a major public health problem, worthy of study. Second, it was more prevalent in the black population, there was significant evidence that blacks and whites were affected by the condition differently, and because whites had already been studied in Oslo, it made sense to focus a study on a black population. Third, there was plenty of disagreement about how best to treat syphilis, with different doctors recommending different dosages and lengths of treatments with a variety of compounds, including mercury, bismuth, and arsenicals. No standard treatment had been established and proven. Fourth, all treatment courses were lengthy (months to years), painful (involving frequent injections), and potentially toxic. They were completed by a very low percentage of patients who began treatment. Fifth, a large proportion of those with syphilis never obtained treatment, or were treated but not sufficiently to cure the disease. Because of their race and socioeconomic class, the men in the Tuskegee study were not denied treatment that they would otherwise have had access to in the 1930s. And sixth, according to the Oslo study, a majority of syphilis cases were cured spontaneously, with no treatment, leading doctors to believe that denying treatment to the men in the study would not adversely affect most of them. Doctors hoped that the study would yield significant knowledge about syphilis: the effects of the heavy metals and arsenicals were so variable, as was the course of syphilis itself, that observation of a significant number of untreated patients would hopefully give a baseline against which to measure the efficacy of various treatments.

White adds that in 1935 it was standard medical practice not to treat latent syphilis in men over fifty (White 2000, p. 587). Thirty percent of the men in the TSUS fell into this category, and 52% had had syphilis for more than fifteen years, making them ineligible for treatment in almost any medical institution in the 1930s and 1940s (p. 594). There was a study of untreated syphilis conducted at Stanford University, as well, with white subjects who were affluent enough that without the study, they would almost certainly have received the treatment to which rural blacks never would have had access. No one, White asserts, complains about this study (p. 595).

Most of those who accept that the study was ethical at its inception view the introduction of penicillin and the study's continuation—including attempts to prevent participants from being treated with penicillin even for other conditions besides syphilis—as the point at which the TSUS went wrong. However, some still argue that the doctors had no ethical obligation to provide penicillin to the men in the study and that they were looking out for the participants' best interests when they decided not to offer penicillin. Though the "miracle drug" was first used to cure syphilis in 1943, penicillin was not without problems. As with the heavy metals and arsenicals before it, there was no set dosage, route of administration, or duration of treatment known to be effective, and administration varied widely. This

was partly because new preparations were continually being invented, so none was the focus of the intense investigation that would have been necessary to determine the optimal course of treatment. At the beginning, the strength of the drug also varied, until techniques for its manufacture were standardized. And as with previous treatments, some people reacted to the drug or to the resulting buildup of dead spirochetes. As late as 1958, scientists were questioning penicillin's efficacy and safety for those in the late stages of syphilis, the condition from which the men in the TSUS suffered (Benedek and Erlen 1999, p.18). Most doctors believed that a cure at such a late stage, after being infected for so many years, was highly unlikely (Benedek and Erlen 1999, p. 25).

Even if failing to offer penicillin to TSUS participants could be justified on grounds that the men would not likely benefit from it, there is no question that the men in the TSUS never gave informed consent. In 1972, the Tuskegee Syphilis Study Ad Hoc Advisory Panel was formed and charged with determining "whether the study was justified in 1932 and whether it should have continued when penicillin became generally available" (see King 1998). Focusing on the lack of informed consent, the panel concluded that "in retrospect" the study was unjustified in 1932. The panel failed to consider whether the study would have been justified had the enrollees consented, and many commentators suggest that the panel's focus on the absence of consent obscured underlying issues of the justice of conducting the study in the environment of racism and racial segregation, poverty, and lack of education that characterized the TSUS enrollees' situation (King 1998).

Benedek and Erlen admonish against succumbing to "presentism"; the concept of informed consent was not formulated until 1957, and the doctor-patient relationship before that time was extremely paternalistic and often secretive (p. 24). In response, however, it should be argued that the TSUS involved timeless putative ethical wrongs. Deception, telling less than the whole truth, causing pain to some for the benefit of others, taking advantage of other's trust, treating others as one would not want to be treated oneself—all of these actions have raised ethical suspicions for centuries. It is those who would seek to employ them with impunity in a particular context (e.g., research) who must provide a justification for doing so. That no specific regulation, or specific social practice like informed consent, prohibited what the TSUS researchers undertook in 1932 does not provide such justification.

***The legacy of race as a variable in research.*** A final thread of the legacies of the TSUS deserves particular attention: race. Assumptions about race and racial difference provided the scientific justification (such as it was) for the TSUS. In two senses, the men enrolled in the TSUS were enrolled because they were black: first, because syphilis in blacks was the study question; second, because if they had been white, they probably could not have been enrolled and retained in the study. This second claim is contestable. One of the physician-researchers involved in the TSUS, in fact, responded in an interview that he believes non-blacks could have been convinced to enroll (ABC News 1992). He suggests, for example, that "hillbillies" could have been enrolled instead, if only they had possessed the medical and quasi-scientific features of interest to the scientists. The social features that he considered critical to enrollment in the study—relative isolation and lack of education and sophistication—were not race-dependent. However, such socially-disempowering features did attach almost uniformly to blacks in the 1930s in the rural south.

But what of "race" as a non-social, scientific concept? Whether 'race' is a meaningful concept in any scientific sense, with relevance for public health care and medical interventions, or whether it is merely a social construct (and an often pernicious one at that), is the topic of much current scholarship (Bradby 1996, Graves 2002, King 1998). We have made progress since the days when African slaves

were diagnosed with a peculiar disease that manifested itself in the symptom of their absconding from the service of their masters (i.e., *Drapetomania*; Cartwright in Caplan *et al.* 1981), yet experience with sickle cell screening programs and other interventions targeting African-Americans suggests the need to increase conceptual and scientific clarity and to employ these accurate understandings to combat persistent prejudice (Seton Hall Law Rev. 1997).

Yet controversy surrounds the use of racial categories for research, for offering appropriate health care, and for understanding and addressing health disparities across various populations (King 1998, Roberts 1996, Epstein and Ayanian 2002, Laveist 1993, Daniels *et al.* 1999). With growing attention to both social determinants of health and advances in understanding genetic components of disease, the relevance of 'race' as a variable in research will garner greater attention. As one of the lawyers for the men seeking compensation for the TSUS wrote: "the Human Genome Project will bring to the forefront of human consciousness awareness of the range of variability not only among individuals but among groups. To acknowledge those differences, while insisting on their irrelevance to respect for individual dignity and equality of right, is a challenge we shall have to face" (Edgar 1992, p. 25). In this essay, we can only identify, but not fully or resolve what may be called the "dilemma of difference": "If...racial difference is ignored and all groups or persons are treated similarly, unintended harm may result from the failure to recognize racially correlated factors. Conversely, if differences among groups or persons are recognized and attempts are made to respond to past injustices or special burdens, the effort is likely to reinforce existing negative stereotypes that contributed to the racial differences in the first place" (King 1992, p. 35). Awareness of these pitfalls and open discussion of steps to avoid them may help to avoid at least the most flagrant abuses of trust, greatest injustices, and serious harms.

### **Rhetorical Advantages and Analytical Disadvantages to Being "Just Like Tuskegee"**

Since the details of the TSUS became public, several subsequent research studies have been accused of being "just like Tuskegee." (The TSUS legacy extends beyond the borders and context of the United States; one commentator on an ethically suspect oncology study in New Zealand entitled her paper "New Zealand's 'Tuskegee'? Some Comparisons between the Tuskegee Syphilis Study and a Study at National Women's Hospital" (Crosthwaite 1995).)

Assessing whether this claim is strictly accurate may be less important than, asking, initially, whether "Tuskegee" provides a useful framework for considering the ethical issues raised in a particular case, and then more importantly, carefully analyzing the present ethical concerns. The following three cases may be considered in light of the legacy of and considerations raised by Tuskegee. The cases involve study of a needle exchange program in Alaska, a study of different lead abatement efforts and their effects on blood lead levels in children, and various studies to prevent the transmission of HIV/AIDS. In each case somewhat inflammatory emotional rhetoric reflecting the legacy of Tuskegee directs public attention to the cases. The legacy of Tuskegee also, very directly and practically, creates (or perpetuates) some of the attitudes, social conditions, and problems of trust and communication that give rise to ethical concern.



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## Additional Resources

### *Tuskegee Syphilis Study*

The Least of My Brothers. a self-contained, Web-based module on the ethics of research with human subjects that uses a dramatization of the TSUS, <http://poynter.indiana.edu/sas/lb/>

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## Fact Sheet: AIDS Clinical Trials in Developing Countries

- Approximately 1600 HIV-infected infants are born each day, or over one half million annually (Fowler 2000). In the US in the late 1990s, there were approximately 280-370 cases of maternal-fetal HIV transmission annually.
- AIDS Clinical Trial Group Study 076 interim results released in 1994 showed a 25.5% mother-to-child transmission rate in the placebo group and a 8.3% transmission rate in the group receiving zidovudine, which led a US PHS Task Force to recommend that zidovudine be offered to all HIV-infected pregnant women and their newborns (MMWR 1994). The original 076 protocol enrolled women with only early or mild HIV infection. It is not known whether administration of zidovudine during the later stages of pregnancy may reduce the drug's future effectiveness thus limiting the woman's treatment options when her own disease progresses.
- The incidence of HIV infection in babies born to HIV-infected women who *do not breastfeed* is approximately 25%, and the majority of infection seems to occur at the time of delivery not *in utero*. Cesarean delivery (under standard surgical conditions of developed nations) reduces the risk of transmission to approximately 10% *without* zidovudine treatment.
- Parents are generally allowed to refuse, on behalf of their already born children, a burdensome therapy with only a 10% chance of benefit.
- The long-term risks of using zidovudine in newborns is unknown.
- Zidovudine (ZDV) is also known as Azidovudine (AZT).

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## Fact Sheet: Kennedy Krieger Institute Lead Abatement Study

**Lead levels.** Elevated blood lead levels are dangerous for adults, contributing to hypertension and cardiovascular disease, but are particularly harmful to children (Kitman 15). Children are 4-5 times more susceptible to lead than adults because their digestive systems absorb 40-50 percent of lead ingested as opposed to 10-15 percent for adults (Kitman 38). Young children in particular are often exposed to more lead than their elders because they frequently put in their mouths objects on which airborne lead has settled (Kitman 38). Even low exposures of lead can lead to reduced IQ, behavioral problems, reading and learning disabilities, and hyperactivity (Kitman 16, 38). Pregnant women are also very susceptible to miscarriages and their fetuses to poor development if there is excessive lead exposure (Kitman 16). These problems are due to the fact that lead both retards neuro-anatomical development and degrades neurotransmitters (Masters 15).

There is no “safe” level of lead in the blood, but levels of 10 or more mcg/dl (micrograms per deciliter) is generally considered the threshold for concern, since at this point intelligence, behavior, and development can be adversely affected (<http://www.cdc.gov/nceh/lead/lead.htm>). When a child’s blood lead level is between 10 and 20 mcg/dl, parents and communities should begin making changes to reduce lead exposure, such as more careful housecleaning and handwashing, and better nutrition to support the body’s recovery. When the blood lead level is 20 or more mcg/dl, oral medication—chelation therapy—is considered, particularly if the child is showing symptoms. These medications bind to lead so that it will be excreted in the urine. Such therapy is always instituted (as standard care) at levels above 45. A reading of 70 or more mcg/dl is deemed a life-threatening emergency (<http://www.keepkidshealthy.com/welcome/lead/leadtreatment.html>).

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Kitman JL. “The Secret History of Lead,” *The Nation* pp 11-14, 16-22, 24-28, 30-40, 42-22 (March 20, 2000).

Masters RD, Hone BT and Doshi S. Environmental pollution, neurotoxicity and criminal violence. RJ Rose (ed) *Aspects of Environmental Toxicology*. London: Gordon and Breach, 1997, pp. 132-148.

## **Fact Sheet: Research with children, from the “Common Rule,” 45 CFR.**

§46.404 Research not involving greater than minimal risk [see below].

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

- (a) the risk is justified by the anticipated benefit to the subjects;
- (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- (c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

DHHS [Department of Health and Human Services] will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

- (a) the risk represents a minor increase over minimal risk;
- (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- (d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

DHHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

- (a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) finds

- (1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or
- (2) the following:
  - (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
  - (ii) the research will be conducted in accordance with sound ethical principles;
  - (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.



## **Fact Sheet: Anchorage Needle Exchange Program (and Kennedy Krieger Institute Study)**

From the Common Rule, 45 CFR:

§46.102 Definitions.

- (i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

## **Case Study 1: AIDS Clinical Trials in Developing Countries**

In 1994, AIDS Clinical Trial Group Study 076, conducted in the United States and France, showed that a regimen of zidovudine administered to pregnant mothers and newborns decreased the likelihood of HIV transmission from mother to child. At that point, the ACTG 076 regimen became the standard of care in the developed world for the treatment of HIV-positive pregnant women. However, the regimen is expensive and intensive, and as a consequence, is not generally available for use in the developing countries of Asia and Africa. Therefore, several trials in the mid-1990s sought to determine whether reduced regimens of drugs, or other methods of treatment, would decrease transmission. These trials were funded by the US and other governments, or by international AIDS organizations, since the developing countries where they were carried out did not have the financial resources or public health infrastructure to fund and conduct the studies themselves.

According to 1993 World Health Organization (WHO) guidelines on human-subjects research, “the ethical standards applied [to a study in a host country] should be no less exacting than they would be in the case of research carried out in [the sponsoring] country” (CIOMS 1993, see Brody 1998, pp. 36, App. 1.8). Earlier, the WHO, in its Declaration of Helsinki IV, had decreed that “in any medical study, every patient—including those of a control group, if any—should be assured of the best proven diagnostic and therapeutic method” (WHO 1989, see Brody 1998, App. 1.2). According to these guidelines, because of the efficacy of the ACTG 076 regimen and its demonstrated superiority to no care at all, the control group of any study within or funded by the United States would have to receive the 076 regimen rather than a placebo. However, 15 of the 16 trials in developing countries begun after the ACTG study was completed involved a control arm in which participants were not provided with any antiretroviral drugs (Lurie and Wolfe 1997).

## Case Study 1: Discussion

Opponents of these trials—including Peter Lurie, MD, MPH, and Sidney Wolfe, MD, of the Public Citizen's Health Research Group, and Marcia Angell, MD, former editor of the *New England Journal of Medicine*—claim that equivalency studies (which compare investigative interventions to a proven treatment), rather than placebo-controlled trials, are the best and most ethical way to assess less expensive interventions. They argue that researchers should search for a regimen that equals the 076 regimen in efficacy, rather than trying to determine whether various treatments are better than nothing. In addition, these opponents respond to claims that no care is the standard of care in developing countries by insisting that “standard of care” is a medical term that indicates a scientifically-determined effective level of care, which is not dependent on social context. The lack of treatment to prevent maternal-fetal transmission of HIV in the developing world is due to economic and social constraints rather than scientific knowledge, and therefore cannot be termed a “standard of care” (Angell 1997, Lurie and Wolfe 1997). Furthermore, these critics of placebo-controlled trials point out that manufacturers make drugs available for free for use in clinical trials, so money, at least in the experimental stages, should not be a barrier to the use of zidovudine (Lurie and Wolfe 1997). In addition, the number of trial participants and length of time necessary to do an active-controlled trial rather than a placebo-controlled trial are not prohibitively larger (Lurie and Wolfe 1997).

Marcia Angell condemned placebo-controlled trials in Africa, pointing out that “only when there is no known effective treatment is it ethical to compare a potential new treatment with a placebo” (Angell 1997). She claims that justifications for the use of placebos with women in the third world are similar to those used to justify the Tuskegee study: the women, without the study, would not receive treatment anyway, and the placebo-controlled studies are the fastest way to get information that will be useful in developing countries. Lurie and Wolfe outlined these points of comparison:

*We invoked the Tuskegee study analogy in the perinatal AZT trials because (i) both were prospective studies in which participants were denied known effective treatments; (ii) both were conducted or funded by the U.S. Public Health Service; (iii) both involved people of color; (iv) both included violations of informed consent; (v) both were justified by claiming that this was the only appropriate study design; (vi) both were defended by positing differences between previous and present study populations; (vii) both were justified by asserting that study participants would not have been treated anyway; and (viii) both were terminated only after exposure in the lay press. (Lurie and Wolfe 1999)*

Amy Fairchild, PhD, MPH, and Ronald Bayer, PhD, respond, “Of the eight criteria Lurie and Wolfe list, four might apply to any ethical, well-designed, publicly funded study involving people of color” (Fairchild and Bayer 1999a). They argue that “for Tuskegee to serve as a useful analogy for illuminating research abuses, the challenged study must meet some reasonable, general criteria. It must involve deception regarding the nature and very existence of the research study, it must capitalize on social deprivation or vulnerability, and not only must it fail to provide the best available effective therapy but it must also contrive to keep individuals from receiving such therapy” (Fairchild and Bayer 1999b).

Harold Varmus, MD, and David Satcher, MD, PhD, of the National Institutes of Health (NIH) answered critics of placebo-controlled studies by attempting to explain the complexities of AIDS research in the

third world, where economic and social conditions make deviations from first-world standards necessary (Varmus and Satcher 1997). They also pointed out, against Angell's comparison to Tuskegee, that the Tuskegee study did not test *any* intervention, whereas the purpose of all of the NIH-sponsored studies was to find effective treatments for AIDS and to prevent HIV-transmission. The first point made by Varmus and Satcher was that the ACTG 076 regimen is not feasible in most places in Asia and sub-Saharan Africa, since it requires that women are tested and counseled early in pregnancy, take a long course of oral zidovudine, have the drug administered intravenously during labor, refrain from breast-feeding, and administer a six-week course of the drug to their newborns. Mother and infant also must be carefully monitored for side effects. In the third world, women do not usually have early prenatal care, if any, customarily do not deliver in the hospital, and rely on breastfeeding to nourish and protect their children.

The second point emphasized by Varmus and Satcher was that in the developing world, where delivering the 076 regimen is not feasible because of economic and social circumstances, comparing other, more accessible treatments with it may not result in useful information for patients in those areas. "If the affordable intervention is less effective than the 076 regimen—not an unlikely outcome—this information will be of little use in a country where the more effective regimen is unavailable. Equally important, it will still be unclear whether the affordable intervention is better than nothing and worth the investment of scarce health care dollars."

A final relevant point was raised by Edward Mbidde, chairman of the AIDS Research Committee of the Uganda Cancer Institute. He reminds critics that, although funding originated with the NIH, "it is not NIH conducting the studies in Uganda but Ugandans conducting their study on their people for the good of their people" (Varmus and Satcher 1997). All of the studies in question have been developed with the help and approval of doctors and organizations in the countries where they have been conducted.

The placebo-controlled design would be considered unethical in the United States, where it is economically possible to provide the best-known treatment both within and outside of the clinical trial environment. Insistence on using the standards of the funding country is a protection designed to prevent the governments and companies of first-world countries from exploiting the citizens of developing countries, by enrolling them in studies and providing no treatment because no treatment is the norm in the host country. However, the question of whether the study will be relevant and beneficial for the people enrolled is an equally important one: if it is true that a placebo-controlled study has been devised by African scientists as the most useful study for Africans, taking into account the circumstances in those nations, then placebo-controlled studies may be the most ethical way to proceed if the goal is to find workable solutions to the African AIDS epidemic. In the Tuskegee study, the intervention that was denied was a series of doses of penicillin over a fairly short period of time, which could have been easily transported to affected populations in the United States and efficiently administered using existing public health infrastructures. In contrast, to provide the best-known treatment to prevent the transmission of HIV in the trials in question would have involved an intense regimen of very expensive drugs over a long period of time, requiring resources and facilities not currently available in sub-Saharan Africa and requiring the introduction of an entire health care infrastructure. Perhaps developed nations are ethically obligated to assist developing countries in creating this infrastructure, but doing so is generally considered beyond the scope of the individual studies.

Unlike the Tuskegee Study, the protocols for the placebo-controlled HIV/AIDS trials were developed by members of the population targeted for study. However, despite their common racial and ethnic background, those who proposed the study were generally more economically and educationally advantaged than those who enrolled as subjects. Also unlike Tuskegee, deception was not an integral part of the participant recruitment plan, and the studies sought to test interventions rather than to observe the natural progression of disease. Complicating this positive picture of the HIV/AIDS trials, however, are questions about whether the participants and similarly situated residents of the host countries would benefit from the findings of the studies, or whether those societies would lack resources and political commitment to provide treatment following the end of the trials. Might the study results be used instead in developed countries to argue for providing a less expensive, and probably somewhat less effective course of treatment to poor residents in developed nations who could not themselves afford the more expensive standard of care? In addition, investigation of what participants—especially those in the placebo-control arms—actually understood about the HIV/AIDS trials suggested that the informed consent process had not been effective in enabling them to make an informed, voluntary decision about study participation, nor in some cases were social structures conducive to their participation in the very Western or Anglo-American practice of obtaining informed consent. Some participants lived in cultures where deference to authority figures or elders, or where non-individual decision making was the cultural norm.

### Questions for Additional Discussion

- Is it always better to do something than nothing; in other words, is it better to conduct the trials described above with the intention of developing some at least partially effective, potentially affordable intervention now, rather than waiting for broad social changes that would enable delivery of what is standard of care in the developed world? On the other hand, does permitting such studies and the eventual implementation of inferior (but better than nothing) therapy in developing nations reduce pressure to do more, e.g., to develop the public health infrastructure and political will to provide care more closely approximating that of the developed world? Susan Wolf makes this argument about current efforts to address genetic discrimination in the US; she argues that an anti-discrimination approach in health insurance, for example, “blunts any challenge to the rating system itself by suggesting that the problem is adequately handled by prohibiting disadvantage based on ... genetic information” (195, p. 348). In what other areas of health policy and research do you recognize a similar concern that by doing something rather than nothing, people undertaking these “band-aid measures” relieve pressure to address the problem more fully?
- What role should individual researchers play in the development of another country’s public health infrastructure? What are the elements of such an infrastructure? Are there communities in the US—geographically defined or defined in other terms—that could similarly benefit from researchers’ efforts?
- If an investigator undertakes a “non-intervention” epidemiological study—for example, a study of the prevalence of disease  $x$ —in a developing country, what responsibilities might that investigator incur and toward whom? Can an argument be made that *all* studies, even observational studies or assessments of disease prevalence, are in some sense interventions in the community studied? Which responsibilities of researchers are connected to the researchers’

awareness of a problem and which are attached to the researchers' intervention to study the problem?

- Of the criteria offered by Lurie and Wolf, and by Fairchild and Bayer, for being relevantly “like Tuskegee,” which do you think are the most salient criteria? Why does it matter whether the AIDS trials are “just like Tuskegee” or not?

### **Additional Resources**

Ho, D. (1997, September 29). It's AIDS, Not Tuskegee. *Time*,  
[http://www.time.com/time/magazine/1997/dom/970929/viewpoint.its\\_aids\\_not\\_.html](http://www.time.com/time/magazine/1997/dom/970929/viewpoint.its_aids_not_.html)

London, L. (2002). Ethical Oversight of Public Health Research: Can Rules and IRBs Make a Difference in Developing Countries? *American Journal of Public Health* 92 (7), 1079-1084.

## Case Study 2: Kennedy Krieger Institute Lead Abatement Study

In 1993-1995, the Kennedy Krieger Institute (KKI), an affiliate of Johns Hopkins University (JHU), conducted the Lead Poisoning Prevention Study in Baltimore, Maryland, to determine the effectiveness of various levels of lead removal ("abatement") from housing. Identification of the minimal effective level of lead abatement was deemed a socially and scientifically valuable goal because of both the health risks of lead and the need to maintain the availability of low-rent housing in Baltimore.

There were five study arms, involving 108 houses and their residents. The first group of homes received about \$1650 worth of repairs such as lead paint scraping, the second about \$3500 worth, and the third about \$6500 worth. Abatement became increasingly more extensive and more nearly complete with the additional increments of cost. Group four homes received the most extensive abatement possible, and finally group five consisted of houses built after 1978 that presumably were free of lead paint although located in neighborhoods known to have many houses with lead paint. All the houses in the study, even the ones repaired "minimally," were freer of lead than about 95% of housing stock in Baltimore, and the lowest level of repair reduced lead dust by 80%. The repairs were paid for through a loan program from the Maryland Department of Housing and Development, and probably would not have occurred without such a program, because of the high cost of lead abatement measures in relation to the value of the housing stock that needed it. The owners of the properties were given assistance in obtaining the loans by KKI. Landlords were also strongly encouraged to rent to tenants with small children; the study design called for enrolling families with young children in the study and testing the children's blood for lead levels.

All children enrolled in the study received blood lead testing four to five times per year during the two-year duration of the study, and the houses, soil, and drinking water of each property were tested immediately after abatement was completed and then 1, 3, 6, 12, 18, and 24 months later. Participants were paid \$15 for completing a questionnaire "about other potential sources of lead exposure in your home and activities which relate to exposure" every six months, and were given free transportation to the KKI clinic for blood testing. The study's consent form promised that "we would provide you with specific blood lead results. We would contact you to discuss a summary of house test results and steps that you could take to reduce any risks of exposure" (Clinical Investigation Consent Form).

Two mothers residing in houses that received less than full abatement later sued KKI, alleging that they had not been informed in a timely manner that their children's lead levels were elevated, that they had not been adequately warned about the risks of lead exposure and risks of the study, and that the study design placed their children at unnecessary risk. (*Grimes v. Kennedy Krieger Institute* 2001; Mastroianni and Kahn 2002). Their suits received a great deal of media attention, perhaps in part because KKI's insurance lawyers initially responded by claiming that the Institute had "no legal duty" to report lead levels to families.

## Case Study 2: Discussion

KKI's rather hard-hearted and legalistic response, coupled with reports that at least one plaintiff was a minority member on public assistance, fueled concerns that poor minority families may have been exploited or mistreated by the more powerful university-affiliated institute. After a Maryland trial court refused to hear the suits, Judge Dale Cathell of the Maryland Court of Appeals not only declared that the cases should go to trial, but severely condemned the study itself. He likened the lead study to Nazi experimentation and the Tuskegee Syphilis Study, and held that parents and guardians could not consent to nontherapeutic research in which there was *any* risk to the child, a far more stringent standard than the nationally accepted one of minimal risk in research involving children. His ruling, if it had stood, would have resulted in shutting down much research on childhood vaccines and diseases in Maryland, and may have set a crippling, albeit not legally binding precedent,<sup>5</sup> nationally for research involving not only children, but also mentally disabled or demented patients, who are subject to the same research protections as minors (AHRP 2001). Two months after offering its initial decision, the court clarified that it had not intended the "no risk" standard to apply to nontherapeutic pediatric research studies and that it endorsed the federal regulations in this regard (see Fact Sheet).

Several children in the study suffered effects of lead poisoning and had elevated blood lead levels. Three more families have since filed charges against KKI, but none of the cases have yet gone to trial. Because the legal cases are ongoing, it is likely that many relevant facts remain to be discovered. Readers are cautioned about engaging in ethical analysis on the basis of an incomplete set of facts. Nevertheless, ethical criticisms and comparisons to the Tuskegee Syphilis Study focused on several aspects of the design and execution of the study about which enough is known that some preliminary discussion may take place. First, the subjects were children, a vulnerable population due to their inability to understand and consent personally and their particular susceptibility to toxins in the environment. Second, it was alleged that the study encouraged families to live in dwellings where lead, a known toxin, was present. Third, the scientists may have downplayed or failed to mention all of the risks of participation in the study to the children's parents, and failed to disclose in a timely fashion elevated blood lead results that would have indicated that children were at risk of lead poisoning. Similarly, in Tuskegee, the poor, uneducated black enrollees were vulnerable to exploitation, and were not informed of their syphilis, of what could be done to prevent its transmission or to cure it, or of the risks of participating in the study, including undergoing such invasive procedures as spinal taps.

Although we cannot possibly reach any conclusions about the actual legal charges and arguments being made, for the purpose of discussion, we can identify two distinct sets of issues concerning the ethics of the KKI study: questions concerning the basic *design* of the study, and concerns about how the study was *conducted*. In the first category are questions such as, should children have been used for this study? Children are more susceptible to lead poisoning than adults, but that fact also makes it more important that ways are found to lessen their exposure (Kitman 2000). The researchers knew that some of the children in the study were being exposed to more lead than others, but every house in the study had far less lead than most dwellings available for similar rental costs in the city. This meant that the children in the study were generally better off in terms of lead exposure through their living environment by participating in the study, although it is conceivable that a family could have moved

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<sup>5</sup> Although individual state court decisions are not binding on citizens or courts of other states, in the relatively uncharted terrain of human subject protections, researchers and funding agencies could be justifiably reluctant to undertake practices deemed wrong in such strong terms at a state appellate level.



from a more highly abated house to one with more lead present. The only way to have determined whether individual families (children) were better or worse off in virtue of their study participation decision would have been to have traced every family and determine the relative levels of lead in their previous and study dwellings.

The second set of questions focuses on the conduct of the study, including the provisions for informed consent, which could have been inadequate even if the basic design of the study was appropriate. The design met the approval of the JHU IRB, but did the researchers fully explain the study and the risks to the parents? In the consent form, the purpose of the study was explained as follows:

*As you may know, lead poisoning in children is a problem in Baltimore City and other communities across the country. Lead in paint, house dust and outside soil are major sources of lead exposure for children. Children can also be exposed to lead in drinking water and other sources. We understand that your house is going to have special repairs done in order to reduce exposure to lead in paint and dust. On a random basis, homes will receive one of two levels of repair. We are interested in finding out how well the two levels of repair work. The repairs are not intended, or expected, to completely remove exposure to lead.*

*We are now doing a study to learn about how well different practices work for reducing exposure to lead in paint and dust.... This study is intended to monitor the effects of the repairs and is not intended to replace the regular medical care your family obtains.*

The form then explains that the study will sample lead levels in and around the dwellings and in children's blood, only hinting at the fact that the children's blood lead levels were to be used as indicators of the efficacy of the lead abatement procedures. The form also fails to explain the symptoms or effects of lead poisoning (see accompanying Fact sheet). Further, the consent form refers to "two levels of repair work," when there were actually five different levels of lead abatement (or lead-freeness) involved in the study. Although a consent form should be used only to guide and to document the process of informed consent, it is troubling when the information contained in the form is confusing, inaccurate, or incomplete. In addition, it appears that researchers did not follow through on the benefits or protections promised in the consent form. In at least one of the cases now slated for trial, the results of dust collection in a home was not reported to the family for nine months, and then only after the child's blood showed elevated levels of lead (Mastroianni and Kahn 2002).

A further interesting topic for ethical discussion was raised by Judge Cathell's initial decision that children could not take part in any nontherapeutic research that posited *any* risk to the child, rather than the existing "minimal risk" standard (see Fact Sheet). Though this judicial opinion was later reinterpreted, it highlights the conflict between protecting vulnerable populations and undertaking research that could benefit people like them (although not the participants themselves). This echoes similar debates over the inclusion of other vulnerable populations in research. Indeed, after recounting research abuses including the TSUS, Nazi experiments in concentration camps, and Japanese military "disease bomb" experiments in World War II, Judge Cathell claimed that "in the present case, children, especially young children, living in lower economic circumstances, albeit not as vulnerable as the other examples, are nonetheless, vulnerable as well." (<http://www.claimrep.com/laws/cases/Md/caseMDGrimes.htm>)

Because few health care interventions have been tested for use with pediatric patients, it would seem critical to encourage such pediatric studies, particularly drug testing. However, if the individual child's best interest is to be the overriding standard as the initial decision in *Grimes* suggested, then parents and guardians cannot be expected (or allowed) to consent to the participation of their children in research that is not designed to afford their children direct therapeutic benefit. Most important for public health research, no currently healthy child could be placed at potential risk in a study of preventive interventions for the sake of other children. Similar arguments could be made for others who cannot consent for themselves, e.g., the mentally disabled or "never competent," senile demented elderly and other "previously competent" people.

### Questions for Additional Discussion

- In what ways does this study resemble features of the TSUS, and in what ways is it dissimilar?
- Could this study have been done, as a practical matter, if the families enrolled in the study were more affluent, for example, affluent enough to live in lead-free homes or to hire private lead-testing of their properties?
- What is the relevance for the ethical assessment of this study of the "current reality" that landlords would simply abandon their properties if the highest, most effective, and most costly lead abatement measures were required in order for them to rent their properties? How can the reality of this assumed "current reality" be determined? Would it be relevant to the assessment of this study if it could be predicted that landlords would generally be willing to invest, for example, \$1700 per property for lead abatement? How is the "current reality" of housing economics in Baltimore similar or dissimilar to the "current reality" of the lack of public health infrastructure and funding for HIV treatment in developing nations?
- Is it relevant to the ethical evaluation of this study that most, indeed almost all, of the participants probably benefited, i.e., most lived in houses more free from lead than they otherwise would have? Did the KKI researchers rely on the "background level" of risk of lead poisoning to justify offering less than maximally effective interventions in the course of the study? How, if at all, did this justification differ from that made by Tuskegee researchers?
- How, if at all, was the design of the study faulty? Would the study have been unethical even if the researchers had reported testing results to parents in a timely fashion? What other measures, if any, should the researchers be required to undertake to protect the enrolled children from dangerous lead levels? At what blood lead level should such measures be undertaken (refer to Fact Sheet)?
- The appeals court held that in nontherapeutic research studies in which subjects are compensated in any amount or form, a contract is created between the researcher and subject which creates legally binding obligations for the researchers, such as a duty to warn of impending harm (Glantz 2002). Should researchers be held to obligations other than those stated in the consent document and discussed in the informed consent process?
- Is the informed consent document revealing enough? What information should researchers be obligated to disclose in this study? Although regulations govern the elements of disclosure in

the research context is there other information that should be disclosed to prospective research participants? What would a “reasonable person,” or a typical parent in this situation, want to know? How should researchers respond if a prospective participant expresses the desire for more information? In the therapeutic context this would be called a request for disclosure according to a subjective (or individualized) standard. Is this appropriate in research?

- Nontherapeutic research on children can be carried out if the risk presented is “no greater than minimal risk,” where ‘minimal risk’ “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CFR §46.102(i); see Glantz 2002). However, children living in different environments have very different daily exposures to risk. Should the acceptable risk be greater for inner-city Baltimore children than suburban New York children, and if not, which group’s daily life should be chosen as the standard?

### **Additional Resources**

Keiger, D. and De Pasquale, S. (2002). Trials and Tribulation. *Johns Hopkins Magazine* Feb 2002. Accessed at <http://www.jhu.edu/~jhumag/0202web/trials.html> on 13 March 2002.

Kopelman, L.M. (2002). Pediatric Research Regulations under Legal Scrutiny: *Grimes* Narrows their Interpretation. *Journal of Law, medicine & Ethics* 30(1), 38-49.

Putney, S.B. and Gruskin, S. (2002). Time, Place, and Consciousness: Three Dimensions of Meaning for US Institutional Review Boards. *American Journal of Public Health* 92 (7), 1067-1070.

### **Case Study 3: Anchorage Needle Exchange Program**

An NIH sponsored study in Anchorage, Alaska was designed to determine whether over-the-counter sale of sterile drug injection equipment was more effective than needle exchange programs (NEPs). The study randomly assigned 600 intravenous drug users (IDUs) and 500 former IDUs to one of two arms: those in one arm were enrolled in a needle exchange program, and those in the other were given a map of pharmacies in Anchorage that sold syringes. Researchers also sought to determine which method of needle distribution was more effective in preventing infectious diseases such as hepatitis and HIV, which are transmitted by shared needles. To this end, subjects were tested for hepatitis and HIV before and after the study period, with the number of new cases of those diseases indicating which method was preferable. Researchers additionally wanted to determine whether the availability of clean needles would cause a relapse in recovered users. Hepatitis B vaccination vouchers were provided to all participants. The conclusion of the researchers was that NEPs do not increase IV drug use.

### Case Study 3: Discussion

Many ethical objections to this study were raised. Sidney Wolfe, MD, director of Public Citizen's Health Research Group, opposed the study on the grounds that it was unnecessary since the study questions have already been answered by other experiments (Caplan and Annas 1999). Art Caplan, PhD, and George Annas, JD, MPH, add that the study would be unethical regardless of whether or not it was redundant: "the ethical argument invoked in defense of this morally repugnant design was that the knowledge to be gained could not be gained by any other methods and was of such value as to justify the design. This, of course, is precisely the justification some defenders of the Tuskegee trial argued at the time the study was being challenged as unethical" (Caplan and Annas 1999).

The most frequent objection centers on the fact that one group of study participants was deprived of the option of obtaining free needles and was thereby at increased risk of contracting hepatitis or HIV. Drug users assigned to the pharmacy arm might be prevented from buying needles due to poverty, lack of transportation, or denial by pharmacists (Recer 1996). "The clinical trial at issue was constructed so as to leave subjects open to preventable infection by a serious disease by limiting their knowledge and their options" (Caplan and Annas 1999). Further criticisms focused on the use of the incidence of hepatitis B and HIV as endpoints of the study. George Annas believes that the use of Hepatitis B (for which there is a vaccine) as an end point of the study is in violation of the 1947 Nuremberg Code, under which "no human experiment is to be conducted that could induce life-threatening—and preventable—harm" (in Benowitz 1997). However, the question of whether the experiment can be considered to "induce" hepatitis B is also a subject of debate. Nonetheless, in response to such claims, the NIH added the provision that participants be given vouchers for Hepatitis B vaccines. However, some critics argue that the vaccines themselves, and not just vouchers, should have been given (Recer 1996). Caplan and Annas argue that the study allowed researchers to "stand by and observe as their subjects develop devastating diseases that could be prevented." (1997). Others suggested that "treatment of the underlying medical condition and the social context were not addressed by the intervention, leaving the subjects persistently vulnerable to the possibility of disease. The disconnect between the researchers' agenda and the needs of the community under study parallels the Tuskegee study" (Corbie-Smith 1999b). Finally, the study was criticized for encouraging participants to break the law: "drug injectors in the study...are also instructed how to talk and dress in order to convince a pharmacist to sell them a syringe, a violation of local Anchorage law" (Lurie and Wolfe 1999).

Other commentators seek to justify the Anchorage study in its own terms and to distinguish it from the Tuskegee study. "Whereas in Tuskegee the PHS used the social circumstances of poor African-American men to manipulate them into a study that would deprive them of treatment, proposals to provide sterile injection equipment seek to address the vulnerable situation of those exposed to HIV by offering a potentially life-saving intervention....Only insofar as the original study failed to offer hepatitis B vaccination to participants did it arguably involve an ethical lapse—a lapse addressed by the NIH despite the recommendations of its ethical review panel" (Fairchild and Bayer 1999b). Needle exchange programs didn't exist in Anchorage before the study, so drug addicts were not deprived of a service that they had grown used to—their access either improved or stayed the same. Like the men in the Tuskegee Study, some of the participants in the Anchorage trial were actively denied one type of intervention: they were refused access to the NEP. In addition, none of the men were offered counseling or assistance in treating their addiction, just as the Tuskegee men were not told how to prevent the transmission of syphilis. However, the Anchorage participants were not prohibited from entering drug rehabilitation if

they so chose, while at least some TSUS enrollees were actively prevented from seeking treatment for syphilis. Entrance into the Anchorage study was voluntary, and none were deceived.

### Questions for Additional Discussion

- What aspects of the Anchorage study, if any, make it unethical? Would it make a difference if the research question had already been answered satisfactorily elsewhere, or if a NEP had been operating in the area previously and had been open to all, or if the pharmacy arm participants hadn't been instructed in breaking the law? Does the inclusion of former IV drug users in the study, in a situation in which they might be tempted into a relapse by the easy availability of sterile needles, raise any ethical problems?
- As in the TSUS, the AIDS perinatal studies, and the KKI lead study, in the Anchorage study the development of disease was used as one of the study's endpoints. Under what conditions, is the transmission or development of disease an appropriate endpoint?
- What is the level of risk that participants in this study might justifiably be asked to incur? Why? Is the Common Rule's definition of 'minimal risk' relevant in this study (see Fact Sheet)? Does the actual level of risk faced in daily life by the current and former IDUs enrolled in this study differ?
- The Anchorage study was an NIH-sponsored study conducted by non-IDUs. To what extent is it ethically beneficial or ethically problematic that the study was conducted by "outsiders" to the community being studied (i.e., the drug-using community). Would it have been appropriate, for example, for former IDUs to have been recruited to work with researchers to recruit current IDUs as participants in the Anchorage study? In what ways would they have played a role like that of Nurse Rivers in the TSUS?
- Imagine yourself as a researcher hoping to enlist the support of African-American community leaders in a large urban setting for a pilot needle exchange project targeting African-American IDUs. First, who, or what sorts of leaders, would you approach? What would you anticipate their response would be to your proposed project? How would your plans differ if you were approaching another minority community in your area, and how might leaders of that community respond?
- How would you respond if African-American community leaders charged that you were pursuing a NEP as a cheap alternative to providing effective drug treatment and that such NEPs are in reality part of a genocidal conspiracy to eliminate poor African-Americans, just like the Tuskegee project was (see Fairchild and Bayer 1999b)?

### Additional Resources

Fisher, D. (2000). Does Needle Exchange Cause an Increase in Drug Use? Presented at APHA meeting, abstract online at [http://apha.confex.com/apha/128am/techprogram/paper\\_1914.htm](http://apha.confex.com/apha/128am/techprogram/paper_1914.htm).

Fisher, D. (2002). Selection effect of needle exchange in Anchorage, Alaska. *Journal of Urban Health* Mar 2002, 79 (1), 128-35.

## Tools for Best Practice

Community consultation has been proposed as a tool with multiple benefits for public health research and practice. It is suggested that if researchers and public health practitioners were encouraged, or even required, to consult with members of the communities in which they conduct research and offer interventions, their research questions and health services might better fit the actual needs of community members (Strauss *et al.* 2001, Green and Mercer 2001). Such consultation might help to restore trust and promote a collaborative relationship between researchers or service providers and members of the public. And, depending on the degree of influence that community members exerted (or were recognized to have), community consultation could reinforce the goals of the process of obtaining individual informed consent—namely, the protection of well-being and the promotion of self-determination. As module 4 discusses, some commentators suggest that communities have interests, just as individuals do, that these interests are distinct from those of individuals, and that community consultation (or even a process of obtaining community consent) is necessary to protect those community interests. This perspective is the subject of much debate (e.g., see Foster *et al.* 1998, Juengst 1998, Sharp and Foster 2000, Weijer and Emanuel 2000).

In relation to the Tuskegee Syphilis Study, however, one issue is interesting to consider. The PHS officials conducting the TSUS might be thought to have engaged in a form of community consultation at various stages of the study, and it may be argued such consultation did little to promote the enrollees' autonomy, protect their welfare, or protect the interests of the rural and African-American community which they formed. (Others might suggest that the TSUS did bring more health care to Macon County Alabama than it had ever experienced before, or otherwise would have, and therefore that the TSUS did serve some community interests.) Nurse Rivers was in some ways a member of the African-American community of Macon County, although she was more educated and more affluent than the men she enrolled in the study. Was she a representative of the research community (the PHS) or of the African-American men she enrolled and treated? Can one person be a representative of both "communities?"

The Macon County Medical Society (MCMS) was consulted to provide a form of surrogate consent, presumably because its members were geographically and racially of the same community as the study population, and the Tuskegee Institute itself was approached for its initial involvement in part because of its ties to the African-American public in the area. Were these consultations and collaborations duplicitous and co-opting of those consulted, or were they appropriate attempts to consult representatives of, or at least people more similar to, those being studied? One commentator notes that during the history of the study, fourteen articles about it were published in nine medical journals, and the peer-review process and readership failed to discern ethical problems with the methodology of the study; moreover, black physicians were an integral part of the study and never raised ethical concerns, even after the project's focus changed from its initial commitment to treatment into a strictly observational study (White 2000). Given the conditions of racism and segregation that constitute the context of the TSUS, perhaps no appropriate community consultation could have been conducted, or could have resulted in redesign of the TSUS as an ethical study.

What about today? Consult Module 4, "Community-Based Practice and Research: Collaboration and Sharing Power." In light of the methods it suggests and the potential ethical pitfalls discussed above,

design a process of community consultation to implement a (hypothetical) research study or community-based intervention. Here are some ideas that you might study or implement:

- A program to increase the activity level of low-income elderly
- A program to assess whether school lunch programs address nutritional needs
- A study to determine whether, in an effort to improve diet among African-American heads of household, group-based education or individual mentoring is more effective
- A study to assess the effectiveness of various media messages to encourage use of car seats
- A study to increase enrollment of minority group members in cancer screening programs, including prostate and breast cancer
- A study of a program to reduce the presence of firearms in various neighborhoods through a “buy back” system
- A study to compare the effectiveness of programs that “buy back” firearms for cash and those that trade firearms for gift vouchers at local stores
- How do you identify the relevant communities in which to conduct your work? Are these “vulnerable” communities, and if so, in what ways? Does their vulnerability relate to the *voluntariness* of the community members’ participation, their ability to be adequately *informed* about participating in your study or program, or some other factors?
- Who are the community representatives or leaders? What do you anticipate their concerns will be? How will you approach them? How will you approach members of the community, beyond these leaders? What role will community input into your study or program have and at what stages (e.g., study design or data analysis)? What risks are there of community leaders being (or being perceived) as being co-opted by you? What is the likelihood that you would be co-opted by them to serve interests that are not really your own (i.e., the interests of promoting public health)?
- How does the process of community consultation that you design resemble what was done in the TSUS? How does it help to avoid some of the ethical problems raised about the TSUS?

If possible (and appropriate within the framework of your educational program), conduct your hypothetical community consultation (as an individual, small group, or class). You will need to be clear that your objective is to learn about the process of consulting members of the public who come from and perhaps represent different communities. You will need to express your appreciation to those who are willing to talk with you, and you should invite their critique of the process you propose and stress that your goal is to learn from them. At the same time, you should be prepared to discuss the process of conducting research and providing public health services, and you should be prepared to productively confront the multiple legacies of Tuskegee in your discussions of your education, future work, and current hypothetical project.





# **INTRODUCTION TO MODULES 3 and 4:**

## **Research Ethics in Public Health**

***James Thomas, MPH, PhD***

This introduction to research ethics in public health describes types of research, with an emphasis on studies involving humans; the elements of public health that are unique to research; basic ethical considerations in public health research; and standard processes for ensuring the ethical conduct of research.

### **Types of Public Health Research**

Research is an integral component of public health. If there is an obligation to protect the health of the community, then there is also an obligation to learn how best to do that. This entails collecting information to: identify the causes of disease; identify factors affecting the distribution of disease; and evaluate approaches to protect or promote health. Research is defined in the Code of Federal Regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46).

Public health research includes the study of: inanimate substances such as water and air quality; biological processes not involving humans (e.g., the natural history of arthropods that are disease vectors) and questions that involve humans. There are ethical concerns in each of these types of research, but the majority of ethical deliberation is about research involving humans.

In some studies, the research questions pertain to the health, experiences, behaviors, or other aspects of individuals. In these studies, individual people are the unit of analysis. Other units of analysis are: pairs of people (e.g., couples); families; social networks; agencies and institutions; and communities or other populations. Generally, there are two ways to quantify characteristics of a group or population. Measures on individuals in the group (e.g., annual income) can be presented in an aggregate, such as a mean. Other factors more or less affect everyone in a group equally and cannot be measured by obtaining information from each person. Examples include climate, air quality, and whether a town is located on an interstate highway. The ethical concerns in a study will vary according to the population being studied. For example, the process of informed consent will be different in a study with communities than it will be with a study of individuals.

Studies also vary by the degree of participation they offer to those being studied. Some feel the ideal of observational research is to conduct a study as if it weren't really happening; to know what people would be doing in the absence of the study. In many instances, such deception in research is unethical or cannot be achieved. Most typically, the researchers need to interact with participants to pose questions or obtain biological specimens (e.g., a blood sample). In many instances, experiments or intervention studies require that the individual participants agree to follow a regimen, such as a particular diet, dictated by the researchers. In the examples given so far, however, the participants play a small role at best in the collection of data and have little say in how a study is conducted. In some types of participatory action research, the participants are regarded as research collaborators. They can determine what will be studied and how the study will be conducted, collect some or all of the data, and contribute to the data analysis. Advocates of this type of research argue that research that excludes the

participants from active participation can yield irrelevant and inaccurate data, and can disempower those studied (Israel, 1998). The principle of participation is one that is central to public health.<sup>1</sup>

### **The Elements of Public Health that are Unique to Research**

Public health often distinguishes itself from medicine by stating that it is concerned principally with populations rather than individuals and with prevention rather than cures. While many in public health agencies work directly with individuals and offer them treatments, claims that the dominant interests in public health are in populations and prevention remain valid. These two emphases bring a number of ethical concerns to the forefront in public health research.

In many instances, the best interests of a population or community as a whole are at odds with the preferences of some members of the community. Less frequently, the good of the community stands in contrast to the recognized rights of individuals. For example, the right to privacy may be abrogated when some people need to know that a person they've been in contact with is infectious with a sexually transmitted disease. More generally, it is often stated that any risk to participants in a study is to be weighed against the benefits that the study will bring to greater society (see, for example, the Belmont Report, part C, section 2). This would apply to many studies in public health, but there are perhaps additional ethical dilemmas in studies where populations are the unit of analysis.

### **Basic Ethical Considerations in Research on Humans**

Philosophers, policy makers and others first turned their attention to the ethical practice of research after the atrocities of medical experiments during World War II were revealed. Since then, much of the agenda in the field of ethics has been driven by the dilemmas presented by advances in medical technology and by research on human subjects. In response, ethics discussions have focused on a number of key issues: informed consent; research in vulnerable populations; and balancing the risks and benefits of research. Contemporary conventions regarding these issues have been guided by three ethical principles.

These three principles, articulated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in their document known as the Belmont Report, are respect for persons, beneficence, and justice.

#### ***Informed consent***

The main idea of informed consent is ensuring that each person participating in a study has agreed to do so of their own volition and with full knowledge of the risks and possible benefits to them. The principle was first articulated for studies with individuals as the unit of analysis. There is a need, however, to incorporate respect for and attention to communities in the principles that guide protection of research subjects in public health. Some ethicists have gone as far as recommending that the principle of community ought to be added to the other three identified in the Belmont Report (Weijer, 2000). There are instances, particularly in research conducted by westerners in developing countries,

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<sup>1</sup> This and other values that are inherent to a public health perspective are enumerated in a document that accompanies the code of ethics adopted by the American Public Health Association, found on the internet at <http://www.apha.org/codeofethics>.

when it is appropriate to seek the permission of a tribal chief or village elder to conduct a study in their community. But this is generally not understood to be a substitute for also requiring the informed consent of each individual in the study, when individuals are the unit of analysis.

Extravagant benefits offered to a potential study participant are considered to work against voluntary enrollment in a study because the benefits, which may be hard to resist, are seen as tantamount to coercion. This is particularly a concern when conducting research on vulnerable populations, such as children and prisoners. The principle would also apply to those who are extremely poor. For example, a woman living in an undeveloped country, subsisting on an income of a dollar a day, would find it very hard to turn down \$20 paid as reimbursement for a study procedure despite of being informed of the risks.

Extra precautions are taken when the research participants are considered to be vulnerable. Types of vulnerability include: cognitive or communicative (e.g., young children), institutional (e.g., imprisonment); deferential (i.e., cognitively able to consent, but subject to the authority of someone else); medical (e.g., having a serious condition for which there is no satisfactory treatment); economic; and social (i.e., members of undervalued social groups) (National Bioethics Advisory Commission, 2001). Typically, the parents of minors are required to give consent for their child to participate in a study. If the child is old enough to understand the risks and benefits of their participation in the study, it usually required that they give their assent in addition to the consent of their parent(s). Furthermore, there are limits to the level of risk to which a parent can give consent. In the case of prisoners, researchers must take precautions not to give the impression that participation or the refusal to participate in a study will in any way affect the duration of the prisoner's incarceration.

A major concern in every instance of obtaining informed consent is the ability of the potential study participant to truly understand the study and the risks and benefits they may experience; that is, to be truly informed. This concern is heightened when a study is being conducted in a culture where studies are not common or where western scientific thinking is not dominant. In such instances, researchers need to expend an extra effort to understand: the culture of the study participants; what their motivations might be for participating in a study; how best to communicate with them about the study. The researchers also need to enable the potential study participants to understand the culture of the researchers, especially as it pertains to scientific inquiry.

### ***Risks and benefits of research***

The risks to a participant of a study vary according to the type of study. Examples include: physical harm from a procedure performed on the participant; illness from a medication; emotional trauma from interactions with the researchers; loss of a relationship or a job because the researchers failed to keep confidential information given to them; and social stigma or embarrassment from loss of privacy. The confidentiality of information, which is one of the most important ethical considerations of research, means that the researchers know who gave the information but they will not tell anyone else. This is contrasted with anonymous data in which even the researchers are unable to identify to which person the information pertains.

In contrast to the obligation to keep some information confidential, researchers have another obligation to share the findings of their research. Research findings, however, are typically presented as aggregated data that do not reveal the identities of the individual participants. There is an obligation to share the findings with the larger society because the information is potentially useful, even if the

results are negative. An increasing number of investigators are also perceiving an obligation to share the study results with the participants because they helped contribute to the study.

### ***Oversight of research***

The mechanism that ensures that a researcher adheres to these principles of ethical research is the institutional review board (IRB) for research involving human subjects. The roles of an IRB are to: review study proposals; inform investigators when their study protocols fall short of conventional ethical standards; approve ethically sound protocols; and monitor studies over their duration to ensure that ethical standards are adhered to throughout the course of the study. For an institution, such as a university, to receive funding for research from most funding agencies, it must have an IRB registered with the federal Office for Human Research Protections (OHRP). Many professional journals in which study findings are published also require that a manuscript submitted for publication indicate that an IRB approved the study. An IRB is typically composed of other researchers at the same institution and a number of “community” or lay members from outside the institution.

### **Surveillance and Research**

Research was defined at the beginning of this paper as “a systematic investigation . . . . designed to develop or contribute to generalizable knowledge.” In some instances, public health surveillance activities can fit this definition. Yet, most researchers and public health agencies have not regarded surveillance as research; thus it has not been subject to the scrutiny of an IRB. To better understand the distinctions and similarities between surveillance and research, we will describe in this section how surveillance works and the criteria used by the Centers for Disease Control and Prevention (CDC) for distinguishing between surveillance and research.

Perhaps the best known public health surveillance system is the National Notifiable Disease Surveillance System (NNDSS). This system requires physicians to report certain diseases, such as tuberculosis and some sexually transmitted diseases when they are diagnosed. When a physician diagnoses gonorrhea, for example, he or she is to fill out a brief report form with information on the patient, including: name, age, sex, race and ethnicity, residential address, the diagnosed disease, the date of diagnosis, and the reporting physician. The form (often a card) is then usually mailed to the local health department. They may use the information to follow-up with an interview to learn the names and addresses of sexual partners and then visit them to notify them of their potential exposure to infection. In some instances, the sexual contacts will be taken to the health department for treatment of an infection.

The local health department will send a copy of the reported infections to the state health department. They will use them to monitor the rates of infection throughout the state and to allocate resources for disease control. In a similar fashion and for similar purposes, the state health department will send its reports to the CDC. The data forwarded to the CDC often does not include personal identifiers for each case. Instead, the state will report the numbers of cases of a particular disease by age group, sex, race/ethnicity, and county.

The system described is “passive” in that the local health department relies on physicians to report without prompting from the health department. In some instances, the health department will proactively call physicians’ offices to ask if they have identified any cases of a particular condition. Because this “active” surveillance is more expensive than passive surveillance, it is typically reserved for relatively infrequent but important infections or events. The diseases of importance vary regionally. In

California one such disease is Kawasaki syndrome, a rare and fatal disease of unknown cause that most often affects children. Also, the information sought on cases for which there is active surveillance is usually more detailed than the cursory information required for passive surveillance. Active surveillance is used in some instances because the disease is not well understood and the surveillance system provides a means to collect information that may help identify the causes or risk factors for the disease. Sentinel surveillance is a type of active surveillance in which a sample of physicians are contacted regularly to learn about any diagnosed cases.

Other situations in which data are collected systematically in a public health system include disease registries, program evaluations, and emergency responses. As with active surveillance, a disease registry collects thorough information on individuals with a particular condition (for example a cancer registry would include information on the primary site and morphology of the cancer). A registry usually aims to collect information on every case occurring within some geographical area. Diagnosing physicians are not required by law to report diagnoses to registries; instead, registry personnel identify cases through hospital record reviews. The purpose of a registry is to gather information that may advance the scientific understanding of a disease.

When a public health program has been implemented, such as seat belt laws or an anti-smoking campaign, data are often collected to evaluate the efficacy (whether the program can work in a single instance), effectiveness (whether the program works more generally in many settings), efficiency (e.g., whether the program is economical), and other characteristics of the program. Public health programs are typically implemented in non-emergency situations. In an emergency, such as an acute disease outbreak, data may be collected on each case in order to guide the emergency response.

Each of the data collection processes named—surveillance, registries, evaluation, and emergency responses—entails the systematic collection of data and may, in some situations, meet the criteria for research. When those criteria are met, and when the data are collected on human subjects, the data collection needs to be reviewed by an IRB. The key consideration for distinguishing routine data collection inherent to the daily functioning of public health systems from research is the intent of the data collection. The primary intent of research is to generate generalizable knowledge. The CDC does not consider as research data collection in which the primary intent is the prevention or control of a disease, or the improvement of a particular program (Snider, 1999). To generalize means to infer the findings from the analysis of one data set to other settings or populations where the data were not collected. In contrast, non-research is typically concerned with one specific situation.

Standard disease reporting, such as in the NNDSS, is not considered research; it is used to guide the management of public health programs and the allocation of resources for disease control and prevention. Standard data collection in such a system is limited to information on the specific health condition or disease, demographic information, and accepted, known risk factors. When the data collected extend significantly beyond these standard data, it is usually for the purpose of studying the etiology of the disease or injury in which case it is research. Thus, disease registries are often regarded as research and are subject to review by an IRB. Their purposes may be dual in nature, to guide public health responses and to elucidate the etiology. Regardless of other intents, where research on human subjects is involved, the data collection must be approved by an IRB.

On occasion, surveillance data are subsequently used for research purposes. The use of surveillance in this way must be preceded by the review of an IRB. The publication of findings based on surveillance

data, however, is not necessarily an indication that the data have been used for research purposes. For example, with the publication of disease trends by state in the United States, the intent of the article may be to inform public health practitioners of disease trends in the country and how their state figures into the bigger picture. This is an intent that is consistent with the management of public health programs rather than elucidation of the causes of the disease patterns. Similarly, data collected for an emergency response, such as an outbreak investigation, are used to inform that one response, thus the process is not considered research. A disease outbreak may be published and even used as a teaching tool, but it would not be considered research unless extra data were collected in order to further elucidate the etiology of the infection or identify new mechanisms of transmission.

Program evaluation is also typically concerned with management of a particular program. This is especially so when it is a program shown by prior research to be efficacious. Evaluation data are then used to adjust the program components to achieve the maximum benefit for a given cost. If a program is new, however, and has not been tested before, then the purpose of the evaluation is to establish whether the program is efficacious. By the CDC standards, this is considered research (Snider, 1999).

### **Data Confidentiality**

Information about a person can be used for their benefit or can harm them either intentionally or unintentionally. Some information carries a particularly strong possibility of resulting in harm. For example, in a study of sexually transmitted diseases, researchers may ask a study participant the number of people with whom he or she had sex in the last month. If the number is greater than zero, that piece of information could lead to retribution, such as physical abuse or the termination of a relationship, if it were to be made known inadvertently to a parent or a sexual partner. Other types of information can lead to unemployment or loss of health insurance if it falls into the hands of a person who can make such decisions, and social stigmatization or psychological distress.

The first step in avoiding deliberate or inadvertent breeches of confidentiality is to inform the study participant of the potential risk to him or her if information is not properly guarded by the researcher. The complementary step, of course, is to actually guard the information properly. The precautions to be taken depend on the type of study and the potential benefits to study participants from the information they provide. For example, some epidemiologic studies require information on each study participant at two points in time (i.e., longitudinal or follow-up studies). If the information collected initially lacks identifiers, there will be no way to associate it with information collected on the same person at a later date. Without the ability to link initial and follow-up data, there is no means to calculate risk (i.e., the proportion of study participants who experienced a particular outcome by the end of the study). This formal calculation of risk is a basic measure in epidemiology; losing this tool would greatly limit the benefits to be gained by epidemiologic research. One should not assume that the risk of participating in a study can or must be completely eliminated, particularly when the value of otherwise beneficial research may be significantly compromised. It is important not only to assess the likelihood that identifiable, private information obtained or generated in the course of research could be inappropriately disclosed, but also the probability and magnitude of the harms that could realistically result if such disclosure were to occur.

There are several levels of identification or anonymity of samples or data. A data set that includes for each participant a personal identifier, such as the name or patient number, along with other information on the person is called *directly identified* data. The utility of the identifiers for linking information to

other datasets or information collected on the same person at other times can be maintained while decreasing the risk of revealing the identity of study participants by replacing the identifiers with a code. This is done by creating another data set that lists the code and identifiers for each study participant. Access to this *coded* data set is restricted to the minimum number of people (perhaps just the lead investigator) and it is further protected by a password or by keeping it locked in a file cabinet or safe.

The next step towards enhancing confidentiality is removing the link between a code and personal identifiers. These data are then referred to as *unlinked* or "*anonymized*." Data or samples for which identifiable information was either never collected or was not maintained and cannot be retrieved are termed *unidentified* or *anonymous*. By using anonymous data or rendering it anonymous, it is difficult, though not necessarily impossible, to identify the person associated with the information. Genetic data are difficult to anonymize because, at least in theory, they can be linked to another biological sample with genetic information and identifiers. Also, although identifying information such as names and patient numbers can be removed from data or samples, the remaining data needed for the analysis may point to one or a small number of individuals. This is referred to as deductive identification. For example, in the case of a dataset pertaining to people in a particular town or city section, information on the gender, age, race, occupation, and street block of residence of a study participant, could be used to deduce who the person is.

Some studies cannot be done with anonymous data, however, particularly when a researcher needs identifiers to link one record to another. This can be the case when merging datasets from two different sources or in a longitudinal study with measurements taken from the same person at several points in time. The data can often be anonymized once the study is over, but the risks of failed confidentiality persist for the duration of the study.

We have mentioned that the benefits of research often accrue to society as a whole. Likewise, the harms from research can be experienced by a group of people; they need not be only to individuals. Thus, even with anonymous data, and short of deductive identification, the way in which study findings are reported can have the effect of stigmatizing either a particular subset of study participants or the people they are intended to represent in the community. This can occur, for example, when a particular group is singled out and only negative study findings are used to characterize them. Alternatively, when a community is the unit of study, particular communities can be damaged by the study findings when the community is identified. For example, new industries may choose not to locate in a town based on information from a study that paints the town in a negative light.



## Definitions and Concepts

Anonymous data	Data or samples for which identifying information, such as name, social security number, or address was either never collected or was not maintained and cannot be retrieved. Such data are referred to as “unidentified” by the National Bioethics Advisory Commission (NBAC, 2000). When a data set has been made anonymous by the removal of identifiers and any hope of making a connection back to identifying information it is called an “anonymized” data set (or “unlinked” by NBAC).
Coded data	A data set that lacks explicit identifiers of study participants, such as name, social security number, or address, but contains a code that links each observation to another data set with identifiers. Access to the code that links the data sets is limited to the smallest number of people feasible to aid in the protection of confidentiality.
Community advisory board	A group of people from a community under study who advise researchers on the design, conduct, or other aspects of the study, especially as it pertains to interactions with the community.
Confidential data	A data set containing information identifying study participants; information which the researchers are to conceal from others.
Deductive identification	The use of information other than a direct identifier, such as a name or social security number, to deduce the identity of a study participant; for example, the age, gender, race, and street block of residence may point to just one or two people who fit all the criteria.
Evaluation	The systematic application of scientific and statistical procedures for measuring program conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes (Rossi and Freeman, 1993; Fink, 1993).
Informed consent	A potential study participant’s voluntary consent to participate in research after having been adequately informed of the relevant risks and benefits of the research in a way that is understandable to the potential participant.
Institutional review board (IRB)	A group of people, often affiliated with a research institution, who review scientific protocols for research involving humans and who decide whether the proposed study design is ethical. Also known as a human subjects review committee. More detail on IRB purposes and procedures can be found in the Code of Federal Regulations (CFR), Title 45, Part 46.
Program evaluation	An essential organizational practice in public health using a systematic approach, including data collection and analysis, to improve and account for public health actions (Snider, 1999).

Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Code of Federal Regulations, Title 45, Part 46).
Risks and benefits	Risks in a study are the harms that may be experienced by a participant because of their participation. Examples are physical trauma and social embarrassment. Examples of benefits from participating in a study are improved health and contributing to the betterment of society through the accrual of useful information.
Surveillance	The ongoing, systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury (Thacker and Berkelman, 1988).

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# **MODULE 3**

## **Public Health Research and Practice in International Settings: Special Ethical Concerns**

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### **Issue Essay**

Scientific and technological advances in biomedicine mark the beginning of a new era in public health research. Now, more than ever before, public health research offers the promise of a greater understanding of human disease and its expression in populations throughout the world. Public health professionals working in international contexts face unique ethical dilemmas at all stages of research design and implementation. A number of important questions are raised: How should U.S. regulations for scientific research be applied in international settings? When there are disagreements about the application of federal regulations governing research, who should decide—American officials or local authorities? What is the meaning of “respect for cultural differences” in the context of international public health research? How should requirements for informed consent—with their strong emphasis on individual autonomy--be implemented in cultural settings that do not share this autonomy-oriented perspective? How are standards of care applied in international studies? What are the fundamental requirements for conducting ethically sound research with human subjects?

This module considers ethical issues in international public health research. This essay begins with a brief review of ethical guidelines for research with human subjects. A discussion of respect for cultural difference follows, describing notions of cultural relativism and ethical universalism. Ethical and social issues surrounding informed consent in public health research are also explored. Particular attention is given to challenges associated with comprehension, language barriers and beliefs about who should provide consent. The application of culturally specific standards of care and the meaning of “best proven therapeutic method” are discussed, drawing on controversial cases such as the recent AZT trials with pregnant women in developing countries to illustrate the myriad problems that confront public health researchers working in international settings. Particular attention will be given to the use of placebos in clinical trials. Finally, requirements for ethical conduct in research are outlined

### **Ethical Guidelines for International Health Research**

International concerns with ethical issues surrounding human experimentation were heightened by the Nuremberg War Crime Trials following World War II. These proceedings judged medical experiments conducted by Nazis on prisoners of concentration camps. The Nuremberg Code, the first international code of ethics for research involving human subjects, was issued in 1947. The Nuremberg Code outlined a strong commitment to the informed and voluntary consent of research participants. The World Medical Association’s Declaration of Helsinki, adopted in 1964 and revised most recently in 2000, reiterated the importance of voluntary and informed consent to research. In the United States, in 1979, the *Belmont Report* was published by the National Commission for the Protection of Human

Subjects of Biomedical and Behavioral Research.<sup>1</sup> The Belmont Report outlines ethical principles underlying research with human subjects, and emphasizes informed consent, consideration of risks and benefits associated with scientific research, and the protection of vulnerable populations. Final regulations concerning policies governing research on human subjects were issued in 1981 by the U.S. Department of Health and Human Service and reissued a decade later. The federal mandates, generally referred to as *The Common Rule*, were clear: any research involving human subjects that is funded by a Department agency, with certain exemptions, must be evaluated by an Institutional Review Board (ORB). Eight criteria for IRB approval are listed, including documentation of informed consent and the protection of privacy and confidentiality.

In 1982, the Council of International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) published the *Proposed International Guidelines for Biomedical Research Involving Human Subjects*.<sup>2</sup> These guidelines were developed in response to concerns raised about the particular circumstances surrounding the implementation of scientific research in developing countries. In 1991, in collaboration with WHO, CIOMS prepared a separate document addressing public health and epidemiological research (*International Guidelines for Ethical Review of Epidemiological Studies*). The *International Guidelines for Biomedical Research Involving Human Subjects*, revised in 1993, were endorsed by the WHO Global Advisory Committee on Health Research and the Executive Committee of CIOMS. The CIOMS guidelines consist of a description of general ethical principles and fifteen recommendations with commentary. As with the original guidelines, contributors to the revision were particularly concerned with the application of ethical standards and the establishment of mechanisms for ethical review of human subjects research in developing countries where local standards for scientific conduct may differ from those in western industrialized nations.

In recent years, reports of misconduct associated with international biomedical investigations have called into question research practices and the application of study results in medical care and health policy, particularly in resource poor nations. These controversies have influenced debates over the recent revision of the Declaration of Helsinki (2000) and discussions to finalize revisions of the CIOMS Guidelines.

In 2002, the Nuffield Council on Bioethics published the *Ethics of Research Related to Healthcare in Developing Countries*.<sup>3</sup> This document provides specific recommendations for ethical issues related to standards of care, informed consent, obligations of researchers to individuals and communities, and independent ethical review.

Official international policies governing human subjects research such as the CIOMS Guidelines encourage cultural sensitivity in implementing research in non-western settings (see also International Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guidelines for Good Clinical Practice<sup>4</sup>). In his systematic review of the ethics of biomedical research in international settings, Brody<sup>5</sup> argues that policies such as those promulgated by CIOMS (1993) strengthen a commitment to transcending cross-cultural differences by mandating that the same standards be applied to research subjects from both developing and industrialized countries (e.g., research participants in any cultural setting should provide individual voluntary consent; research participants in the developing world should be advised of everything that would be told to research subjects in an industrialized country; research participants in any setting should be aware of their right of refusal).

## Respecting Cultural Difference

The problem of balancing universal and local standards for ethical conduct in public health research is challenging for investigators facing the very real constraints of implementing a study in an area in which traditional customs may be in conflict with international guidelines and policies. Currently, there are ongoing debates over the importance of respecting cultural difference and simultaneously applying universal ethical standards in international scientific research. These issues are particularly complex when public health research is implemented in areas known for human rights violations. The situation is exacerbated by the economic and social disparities that exist between resource rich nations—who generally sponsor public health research—and resource poor nations—where the research may be conducted. Public and professional debates concerning health research in international settings often center around notions of cultural relativism and beliefs about ethical universalism.

Cultural relativism refers to the notion that because human social and psychological characteristics are culturally produced, the diverse representation of these characteristics across human groups is relative to cultural variability. From this perspective, the only normative judgment that is possible is one that recognizes the equal worth of culturally different moral standards. Thus, transcultural standards for the ethical assessment of cultural practices or human conduct are not objective or rationally valid, but always represent the imposition of one set of cultural values on another. Indeed, the term *ethical imperialism* has been used to refer to the application of western ethical standards in scientific research implemented in developing nations with different cultural norms concerning ethical conduct in research.<sup>6</sup> Ethical relativism holds that the moral standards of different cultures cannot be rank ordered in terms of a common criterion of comparison; such standards are “incommensurable” with one another. Moreover, generalizations concerning human behavior may form a basis for ethical judgment within a given culture (although even there such generalizations are often problematic and lacking in empirical demonstration), but are so tenuous when made across different cultures that they cannot form the basis for a rational ethical system.

On the other hand, the problem with ethical relativism, in its broadest conceptualization, is that it seems to condone every permutation of human behavior, if the surrounding cultural context would also condone it. So neither internal critique of a malfunctioning culture nor outside critique on the basis of universal human standards--such as human rights—are possible if the theory of ethical relativism is accepted. Genocide, racism, violence against women and children, war crimes, and the like are highly problematic implications of the theory. There are certain situations in which an appeal of ethical universals, such as notions of human rights, seems both appropriate and essential to the very integrity of the international community.

At the heart of this debate over cultural relativism and ethical universals is the problem of *empirical fact* vs. *moral value*. How can an empirical description of what “is” influence the formulation of statements about what “ought” to be? In her recent book *Against Relativism*, Macklin argues for the existence of overarching principles that could be used to determine the rightness or wrongness of specific cultural beliefs and practices.<sup>7</sup> Macklin’s articulation of a strong version of anti-relativism is based upon her adherence to the universalizing discourse of moral fundamentalism--the idea that certain ethical principles are applicable cross-culturally. However, Macklin acknowledges that, in some cases, it might be appropriate to consider cultural difference in the application of ethical standards, noting that flexibility in the application of ethical rules can be consistent with adherence to more fundamental ethical principles.<sup>7</sup>

What is especially troubling for investigators concerned about human rights is the reliance on cultural or ethical relativism to justify or in some way dignify social and political practices that condone the systematic oppression of individuals and groups based on their gender, ethnicity, religion or political affiliation.

Arguing from an autonomy perspective, Macklin is clearly committed to the notion of basic human rights and their global applicability.<sup>7</sup> In his exploration of international bioethics, Baker offers instead a model for negotiating value differences relevant to science and health in a multicultural world.<sup>8,9</sup> Thomasma takes a slightly different approach in his discussion of bioethics and international human rights.<sup>10</sup> Rather than rely on the language of rights and the importance of autonomy and individual freedom, Thomasma proposes that we consider, alternatively, notions of the “common good” as a foundation for human rights.<sup>10</sup> Thomasma distinguishes between procedural and substantive rules that could form the basis of an international multicultural bioethics.<sup>10</sup>

An important question concerns the way in which conflicts are resolved when there are disagreements about the ethical appropriateness of conducting particular public health studies. In these cases, the fundamental issue might be framed as: Who decides? Should it be local authorities, an international body, or the government represented by the funding agency? International guidelines provide sound advice for investigators, but often the guidelines are difficult to apply to specific contexts. Moreover, they are not legally binding. In some cases, the research sponsor imposes special requirements for ethical conduct. For example, all international research funded by the U.S. federal government is required to undergo review by an independent ethics committee constituted in the host country to insure that certain standards are met in the implementation research in international settings. Of particular concern is that the study design and procedures respect the welfare and rights of individuals participating in the study, and that participation is voluntary.

While public health researchers should be sensitive to local customs, they are never authorized to conduct research without regard to potential risks and without attempts to seek individual consent from potential study participants. In particular, public health researchers working in international settings must avoid the exploitation of non-western populations in research that would not be allowed in the investigator's home country. As the debates over cultural difference and ethical standards for research continue, it is likely that there will be further revisions to the existing guidelines for ethical conduct in international research, and greater efforts made to negotiate the more difficult obstacles to reaching consensus.

## **Informed Consent**

National and international guidelines for ethical conduct in scientific research identify specific requirements for informed consent. These requirements include the following three key elements: provision of information, comprehension of information, and voluntariness. Informed consent describes a process in which an individual voluntarily agrees to participate in a research study after the purpose, procedures, risks, benefits and alternatives have been thoroughly described. Informed consent is based upon the notion that individuals are autonomous agents with the capacity for expressing a self-determined choice.

Offers of excessive financial compensation, bribes, or unrealistic promises to potential research participants in public health research can undermine autonomy and voluntary consent as much as lying or coercive threats do. Consent is truly voluntary only when the option reasonably exists to withhold consent. Additionally, the voluntary nature of participation in research is influenced significantly by the implicit or explicit power of investigators and the institutions they represent.

In international settings, particularly resource poor nations, individuals and communities involved in public health studies may be vulnerable to coercion because of their poverty and high rates of illiteracy. Moreover, challenges associated with implementing informed consent may be heightened because of language barriers that diminish effective communication, particularly regarding the translation of scientific or medical concepts, and because of differences in beliefs about who may provide consent to participate in research.<sup>11,12</sup>

The following discussion of these factors and their influence on the process of informed consent is organized around three issues: 1) comprehension of information; 2) language barriers; and 3) location of decisional authority to provide consent to research.

***Comprehension of information:*** Investigators often must explain sophisticated scientific concepts in international public health research, particularly in complex trials involving the use of placebos or randomization. Yet, studies have shown repeatedly that information included in informed consent documents is difficult for potential research participants or patients to understand. In the United States, most consent forms are written for someone educated at the college or graduate school level, although the average reading ability is significantly lower. Even when consent documents are simplified, higher rates of illiteracy in many resource poor nations contribute to problems associated with comprehension of informed consent documents. For example, in a study of informed consent for an influenza vaccine for children in The Gambia, although 90% of the 189 consenting parents knew the purpose of the vaccine was to prevent disease, only 10% understood the placebo control design.<sup>13</sup>

In addition to the length and complexity of consent forms, difficulties surrounding comprehension may also be associated with requirements for written consent, particularly among people who cannot read or write. The challenges of meeting U.S. requirements for written documentation of informed consent in international public health studies is particularly problematic when study participants are reluctant to formalize a document with their signature or thumbprint because of previous experiences that resulted in their victimization including the loss of personal property or land, when “legal” documents were used against them.

***Language barriers:*** There are two dimensions of language that are relevant for informed consent. One dimension concerns the choice of words--the specific language that will be employed in the consent discussion. The second dimension concerns the language used to express concepts related to the research itself *and* concepts related to informed consent such as “voluntary participation” or “confidentiality.”

Misunderstandings and miscommunication about scientific research are more likely to occur when investigators and participants speak different languages and when informed consent documents must be translated, especially when there are no equivalent expressions for particular biomedical concepts or when the notion of informed consent is unfamiliar. For example, in Marshall’s case study of informed consent in genetic epidemiological research in Nigeria, investigators interviewed discussed problems



associated with back translation (translating a document from one language to another and then having an independent native speaker back translate the document into the original language).<sup>13</sup> Several investigators reported an incident that occurred in which an English consent form was translated into Yoruba, and then back translated by language experts at the local university. Yet, when the final document was used with potential subjects in the field, individuals had difficulty understanding it. The investigators were required to revise the consent once more so that it could be used effectively.

Although the use of an interpreter may reduce linguistic barriers, potential problems remain. Translators are often portrayed as straightforward interpreters of information exchanged between health providers or researchers and patients. However, the translator must negotiate not only language, but also cultural and contextual factors. A broad range of problems are associated with medical interpretation: The inability to translate equivalent expressions across languages; paraphrasing language that results in omissions or erroneous substitutions of terms; different levels of comprehension among participants in the interaction; and the influence of conflicting cultural beliefs and values among participants.

Cultural norms governing the structure and content of discourse in medical encounters are vitally important to effective communication. Beliefs and expectations regarding what is considered to be "appropriate" discourse in medical interactions vary considerably across cultures and are affected by social factors that reinforce differences in the relative power experienced and expressed by the individuals involved in the interaction. For example, in cultural environments where women are subordinate to their husbands, fathers, or male heads of households, women might be expected to remain quiet and allow a male family representative to respond to questions or to ask them. Under these conditions, obtaining voluntary consent may be compromised if a woman does not believe she is able to make inquiries or if she believes she must acquiesce to the authority of the health care investigator and her husband, father or brother. Her voice is silenced in these communications, not necessarily because she cannot understand the "language" of the consent discussion, but because of normative behavior associated with "appropriate" discourse in medical interactions.

Public health investigators working in international settings must ensure that the research community and the individual participants understand clearly the nature of the research and its potential harms. The absence of linguistically equivalent terms is never a justification for minimizing the importance of communicating the essential aspects of a study and its implications for personal well-being; to do so would seriously jeopardize the ability to obtain voluntary *informed* consent.

***Autonomy and Locus of Decisional Authority.*** Notions of personhood, individual autonomy and decisional capacity are embedded within the social and cultural patterns of family ties and community. In the United States and other western industrialized countries where personal autonomy is emphasized, individuals are expected to make decisions about medical treatments or research participation for themselves or through designated surrogates. However, in many non-western settings, religious or tribal leaders, or a patient's extended family may play a significant role in decisions concerning health care and medical research. Cultural differences regarding the nature of personhood and the location of decisional authority for consent have been problematic for investigators conducting international public health research.

In an early report on consent for smallpox vaccination research in five areas of West Africa, investigators found that in certain regions, the strongest factor influencing a community's receptivity to

the program was compliance with the decisions of tribal leaders.<sup>14</sup> In her discussion of AIDS research in Africa, Barry addressed the challenge of translating the concept of autonomy in areas where personhood is defined by one's tribe, village, or social group.<sup>15</sup> Before obtaining consent from individuals in these settings, tribal elders, community leaders, religious authorities or family members of the research participant may need to be approached.

It is important to note the distinction between consulting community authorities before approaching the individual and obtaining "approval" or "consent" only from community leaders. The former strategy is not problematic for researchers, but the latter poses inherent conflicts for investigators. An individual does not have a *right* to take part in research; she only has a right not to be forced to take part and a right not to take part under ignorant or deceiving circumstances. The key moral point is that rights exist even if the individual does not recognize or acknowledge those rights for himself.

More recently, Loue, Okello and Kawuma described the social context surrounding consent in Uganda.<sup>16</sup> They note that according to Ugandan civil law an eighteen-year-old male living at home has the legal right to make his own decisions. However, it is customary for the son to obtain his father's consent prior to entering into any obligation or contract, including participation in research. In addition, Ugandan women often refuse to make a decision regarding their own or their child's participation in research without the consent of their partner. Loue and her associates describe the compromise solution that was reached at a workshop held in Uganda to discuss the issue of family consent for participation in research.<sup>16</sup> Participants at the workshop suggested a waiting period of forty-eight hours between the time individuals were approached about participation and the time they signed the consent form. This would give them an opportunity to consult with family members if they chose before making the final decision about their participation in a research project. The groups recommendation for a delayed consent accommodates the cultural norms regarding family involvement in the decision making process without diminishing the importance of respect for the individual.

The problem of balancing universal and local standards for ethical conduct in scientific research is challenging for investigators facing the very real constraints of implementing a study in an area in which traditional customs regarding decisional authority may be in conflict with international guidelines for individual consent. Current recommendations (e.g., Nuffield Council on Bioethics<sup>3</sup>; National Bioethics Advisory Commission<sup>17</sup>) suggest that a tribal chief, village elder, or community leader may express approval of a research agenda, but sensitivity to cultural customs is secondary to honoring individual choice. When consent is viewed as a process, not a single event, there is greater flexibility in devising mechanisms that honor expressions of individual autonomy *and* cultural norms regarding the involvement of others in decision making, including for example, family members or community elders.

### **Standard of care**

An important concept in biomedical research is the notion of equipoise. Equipoise refers to the general acceptance among scientists and health providers that patients or prospective research participants should not be subjected to greater risk through research than they would be if they were receiving standard therapy. Complex issues, however, surround interpretations of whether or not individuals actually would be exposed to greater harms in research than if they received conventional medical therapies; the pivotal question is: What is the force of the "if"? Does it mean that standard therapy is available? Or does it just mean that it is hypothetically available? The fact that a given area does not have financial resources or the clinical infrastructure to provide what might be considered standard

therapy never justifies subjecting individuals to experimental treatment without serious consideration of the social and ethical challenges involved in the study. Standard of care refers to the level of care provided to participants involved in biomedical clinical trials. There are two broad categories for deciding the level of care: 1) a universal standard refers to the best possible treatments that are available anywhere (any place in the world); and 2) a non-universal standard refers to the treatment that is actually available in a specific region of the world.<sup>3</sup>

A fundamental ethical principle underlying the application of standards of care in health research with human subjects is the avoidance of exploitation, particularly for individuals or communities who may be vulnerable because of their poverty or ethnicity. The issue of what standard to apply is especially complex when researchers conduct studies in international settings where health delivery systems are compromised because of lack of medical resources, including drugs, equipment, and personnel.

Debates over the meaning and application of standard of care in international scientific experiments are ongoing.<sup>18,19</sup> International attention on this issue was heightened in 1997 as a result of the US-sponsored research on the prevention of maternal-fetal HIV transmission.<sup>20,21,22</sup> In this study, researchers in Thailand, Uganda and other developing nations were criticized because control groups received a placebo, which would not have been acceptable if the study had been conducted in the US. Extensive discussion of this particular study, and its implications for other studies, has not resulted in a strong consensus among health professionals, bioethicists, and policy makers throughout the world. Views tend to be polarized—proponents of a universal standard argue strongly that anything less is inherently exploitative, suggesting that it is only the poor of the world, and usually poor people of color, who are placed at risk through their participation in studies. In sharp contrast, opponents argue that it is simply not realistic to apply a universal standard in locations where the existing infrastructures for health care delivery cannot support the “best proven therapy” for the local population. In the AZT study to prevent maternal-fetal transmission of HIV, for example, opponents of the universal standard of care point out that providing control groups with the placebo was, in fact, providing them with the locally available standard of care. Moreover, opponents of a universal approach call attention to the fact that local governments and health professionals were actively involved in reviewing and approving the study design. There was, in fact, broad approval for the study by the World Health Organization; a panel convened by WHO recommended that there was an urgent need to find less costly drug regimens for preventing HIV maternal-fetal transmission, noting that randomized controlled trials would be the most effective way to quickly produce scientifically valid results.

Determination of which approach to use for standard of care in clinical trials—universal or non-universal—remains one of the most contentious ethical issues in international public health research. The Declaration of Helsinki<sup>23</sup> states: “The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods...This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic, or therapeutic method exists” (paragraph 29). Recent recommendations proposed by the Nuffield Council on Bioethics for health research in developing countries generally agree with the revised Declaration of Helsinki.<sup>23</sup> Members of the Working Party for the Nuffield Council suggest that the appropriate standard of care for control groups can only be decided through consultation with representatives of the country where the study will be conducted, that whenever possible, control groups should be offered a universal standard of care, and that when it is not possible, the best intervention currently available as part of the national health system should be provided.

The Nuffield Council on Bioethics offer specific criteria for determining what standard of care should be used in international settings, acknowledging the complexities that exist in local contexts (e.g., available treatment, sustainability of treatment following the trial, health services infrastructure).<sup>3</sup> Factors to consider include: a) the appropriate research design to answer the question; the severity of the disease and the effect of proven treatments; c) the existence of a universal standard of care for the disease being studied and the quality of the supporting evidence; d) the standards of care which can be afforded by the host and the sponsoring country ; and e) the standard of care which can be sustained in the host country.

## **Ethical Requirements for International Public Health Research**

The promulgation of ethical guidelines for research, both nationally and internationally, provides frameworks for consideration of appropriate conduct in the design and implementation of research, including international research on public health issues. Recently, Emmanuel, Wendler, and Grady, outlined seven requirements for determining whether a research trial is ethical.<sup>24</sup> Although the authors focused their attention on biomedical clinical trials, their requirements have relevance for research in general, and international public health investigations specifically. The seven ethical points these authors consider are briefly outlined below:

### ***1. Social or scientific value***

Consideration of the social and scientific value of the study requires that investigators evaluate the treatments or interventions proposed to determine that they will improve the health and well-being of the individuals and communities involved. This requirement is justified by ethical concerns related to the scarcity of resources and the importance of not exploiting the populations who participate in the research.

### ***2. Scientific validity***

The requirement for scientific validity refers to the application of acceptable scientific principles and methodologies, including statistical techniques, in order to produce valid data. This requirement appeals to ethical concerns over the use of scarce resources and the importance of nonexploitation.

### ***3. Fair subject selection***

Fairness in choosing individuals and communities who participate in research requires that stigmatized and vulnerable populations will not be exposed to risky research, and conversely, that rich and powerful individuals will not be selectively chosen for potentially beneficial research. Fairness in subject selection appeals to the ethical principle of justice.

### ***4. Favorable risk-benefit ratio***

Consideration of a favorable risk-benefit ratio requires that investigators minimize risk and enhance benefits, and that risks for those who participate in research are proportionate to the benefits that may be derived for the subjects and for society. This requirement is justified by the ethical principles of nonmaleficence, beneficence, and nonexploitation.

### ***5. Independent review***

The requirement for independent review refers to the importance of an ethical review of the study design, potential research participants, and the risk-benefit ratio by a group unaffiliated with the study.

Independent ethical review is justified by the importance of public accountability and minimizing the influence of potential conflicts of interest.

### ***6. Informed consent***

Informed consent refers to the provision of information to potential research participants (study goals, procedures, risks, benefits, alternatives) using an approach that insures comprehension and understanding so that individuals can make a voluntary decision about their participation and continued enrollment. This requirement is based on the ethical principle of respect for individual autonomy.

### ***7. Respect for potential and enrolled subjects***

This requirement emphasizes respect for research participants by: a) permitting them to withdraw from the study; b) protecting privacy and confidentiality; c) providing information about newly discovered risks or benefits; d) providing feedback about the study results; and e) maintaining the welfare of study participants. This requirement is justified by the ethical principle of respect for persons.

In any public health investigation, establishing a collaborative relationship with local investigators and the host community contributes to the successful implementation of a project and the potential for insuring that the study results may have a long-term impact. Ideally, collaboration might be implemented throughout the duration of the study, beginning with community assistance in deciding on the topic to be examined and its relevance and significance for the local population. This is not always possible, although in most cases, the establishment of a Community Advisory Board before the study begins will assist public health investigators in determining the most effective approaches for implementing the study and providing feedback to the community.

Capacity building is an important aspect of instituting ethically sound international public health research. Capacity building refers to the efforts of investigators to provide assistance to host institutions and communities in establishing mechanisms and resources that promote the health and well-being of individuals. Educational programs designed to develop and enhance professional expertise, and financial support for technological resources, medical equipment, and administrative assistance represent various forms of capacity building that public health investigators might provide to the host community in international public health research.

## **Conclusion**

The globalization of scientific and medical research has increased dramatically in recent years. Public and private sectors alike are engaged in multinational clinical trials, epidemiological community based research, and behavioral studies. The complexity of international politics and the economic disparities that exist between industrialized and “developing” nations create myriad challenges for public health investigators. In the future, institutional and governmental authorities will exercise greater authority over the regulation and management of public health research. While individuals and communities who participate in public health research may benefit from the stronger oversight, investigators may experience tighter regulations as administratively cumbersome and restrictive. Successful resolution of political and scientific challenges in international public health research will only occur when there is a solid foundation for the development of mutual trust. A vital measure of international cooperation will be the extent to which there is a strong commitment to capacity building and resource sharing among the various stakeholders involved in public health investigations, including governmental authorities, institutions, and individual researchers.

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## **Case Study: Clinical Trials of AZT to Prevent Maternal-Infant Transmission of HIV in Resource Poor Nations**

The HIV/AIDS pandemic has been devastating for populations worldwide, particularly those in sub-Saharan Africa and Asia because of the personal and economic burdens for families and communities. Complex social and ethical issues surround the design and implementation of research on HIV/AIDS in any setting. However, transnational research on HIV/AIDS sponsored by resource rich countries and carried out in the developing world raise serious questions about the application of international guidelines for ethical conduct in biomedical studies regarding standards of care, placebo-controlled trials, informed consent, and the obligations of researchers to participants when a study has ended.

In 1994, investigators in France and the U.S. reported conclusive evidence that an AZT drug regimen administered to HIV-positive pregnant women and their babies after birth reduced the transmission of HIV to the infant. The findings were impressive: the difference in transmission rate between those who received AZT and those who received the placebo was significant (8% versus 25%). The new regimen was known by its study name, AIDS Clinical Trials Group (ACTG) 076. Based on the study conclusions, the U.S. Public Health Service recommended the 076 regimen as the standard treatment for all HIV-infected pregnant women in the U.S. This regimen represented a great breakthrough for those women with access to the drug, primarily those in wealthy industrialized nations. HIV-infected women in the developing world, however, were less fortunate, and their numbers were growing. In areas such as Uganda and South Africa, it was estimated that about 40% of pregnant women were HIV-positive and roughly one of every four or five children would be born infected with HIV.

The spread of the HIV/AIDS epidemic was, and continues to be, devastating for the developing world. In 1998, for example, 5.8 million new cases of HIV infection were reported by United Nations AIDS officials (1.2 million from South and Southeast Asia and 4 million from sub-Saharan Africa). Combination drug therapies for the millions of people infected with HIV in resource poor nations are largely unavailable because of their expense and the lack of health care resources. Drug regimens for HIV/AIDS treatment cost roughly \$15,000 per person each year in industrialized nations, a cost that far exceeds the annual income of most individuals in the developing world.

The cost of the 076 treatment protocol—at \$800-\$1000 for the AZT alone—was prohibitive for developing countries. Other barriers to the successful implementation of the 076 regimen included the costs of screening for HIV and complications associated with administering the protocol. The 076 regimen required five oral doses of AZT daily over approximately 12 weeks of pregnancy, intravenous AZT during labor and delivery, and six weeks of postpartum AZT for the infant. It was generally agreed that the 076 regimen was not a practical solution for areas such as sub-Saharan Africa where financial resources and the clinical infrastructure to manage the complicated protocol were not available. Moreover, women often did not seek prenatal care until their third trimester.

Following the publication of the success of the 076 regimen, in 1994, the World Health Organization convened a panel of over fifty experts from around the world to consider global recommendations for the use of this regimen for pregnant women. This panel acknowledged the potential impact of 076 for reducing maternal-infant HIV transmission but noted the practical limitations of the regimen for the developing world. However, The WHO panel called for innovative research to consider less complicated and less expensive regimens that would have the same effect as 076. Moreover, the WHO panel



recommended that the new research be coordinated at a global level to avoid duplication and to ensure that all aspects of the issue could be addressed in a robust and comprehensive manner.

By 1995, the United Nations AIDS program and agencies in the U.S., Belgium, France, Denmark, and South Africa agreed to sponsor sixteen clinical trials in Cote d'Ivoire, Uganda, Tanzania, South Africa, Malawi, Ethiopia, Burkina Faso, Zimbabwe, Kenya, Thailand, and the Dominican Republic. The National Institutes of Health (NIH) and the Centers for Disease Control (CDC) sponsored nine of the studies. The specific goals of the studies varied. The effectiveness of shorter courses of AZT or other antiretroviral drugs were assessed in about half of the investigations. Other studies focused on the impact of much less complex interventions such as Vitamin A supplements or vaginal disinfection during labor. Except for one study, these investigations were placebo-controlled trials. In Thailand, researchers compared three short course regimens with a control group receiving a protocol similar to 076.

All studies had been carefully examined by ethical review committees in the sponsoring and host countries, all studies were determined to meet international ethical standards for biomedical research and, in every case, individuals from the host-countries were involved in the design and implementation of the projects.

In February of 1998, the CDC reported the findings from a placebo controlled study in Thailand showing that the oral administration of AZT during the last four weeks of pregnancy as well as during labor, reduced maternal-infant transmission of HIV by fifty percent. A year later, the results of a placebo controlled trial conducted in three African nations (known as the PETRA trials) indicated that transmission rate was reduced by 37% at six weeks after birth when antiviral treatment drugs were administered at the time of delivery and continued for one week for both mother and infant. These results were heralded as a strong indication that alternative therapies—more practical and less expensive for women in developing countries—could be used to reduce maternal-infant transmission of HIV. Following the initial report of findings from the study in Thailand, the CDC suspended the placebo arm of the Thai investigation which was conducting equivalency trials to test the effect of reduced AZT therapy to prevent maternal-infant HIV transmission. Other clinical trials stopped recruiting women to placebo control groups.

While these studies were on-going, a debate ensued over the ethical appropriateness of the investigations, specifically in relation to the use of placebo control groups. The primary charge from critics was that researchers gave priority to their own research goals over the lives of the women participating in the studies.

### **Key Questions for Public Health Professionals**

- What ethical review processes should be deemed acceptable for the implementation of multi-national clinical trials with vulnerable populations? Should the study move forward if host country researchers, along with other designated national and international review committees, approve the research for implementation, regardless of concerns raised by other individuals or groups (locally and internationally)? Whose views should be considered as the “final word”?
- In multi-national trials, what standards of care should be applied if the local standard means that pregnant women will not receive any treatment?

- What mechanisms ought to be considered to ensure that women in resource poor nations understand the nature and goals of the study and that consent to the research is voluntary?
- What procedures can or should be considered to ensure that pregnant women have access to appropriate AZT treatment during their pregnancy? What responsibilities do the researchers have in relation to the provision of care for women at the completion of the study?

## Case Study: Analytical Discussion

### Ethical Problems and Relevant Values

The collaborative international trials to investigate the effectiveness of alternatives to the 076 AZT protocol to reduce maternal-infant transmission of HIV resulted in heated debates among health professionals, ethicists, and policy makers worldwide. The primary ethical concern raised by critics was the use of placebo-controlled trials. Marcia Angell (1997), the editor of the *New England Journal*, suggested that the trials had the mark of the notorious Tuskegee study, a project funded by the U.S. Public Health Service to study the natural course of syphilis in poor African American men in the rural south. Angell believed that there was no need to compare shorter regimens of AZT with placebos. Lurie and Wolfe (1997) were equally harsh in their criticism of the studies. They argued that the research questions could be answered by equivalency studies in which the proven treatment was compared against alternative treatments and they also indicated that women and infants would die needlessly from HIV-infection if they were in the placebo control arms of the ongoing investigations.

Harold Varmus, director of NIH, and David Satcher, director of the CDC, countered these charges, noting that placebo-controlled trials are the definitive standard for determining the safety and efficacy of interventions (1997). Proponents of the placebo-controlled trials argued that the answers to the questions raised in the studies were not yet clear and therefore resulted in a state of equipoise, requiring the rigorous application of a placebo arm in the investigations. Moreover, proponents said that equivalency studies would require additional time because of the need for larger sample sizes, and they would be less conclusive.

Proponents and critics both evoked international guidelines for the ethical conduct of research with human subjects outlined in documents such as the Nuremberg Code, the Helsinki Declaration (being revised at the time of the debates), the Belmont Report, and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (also in revision) in stating their arguments.

A fundamental issue in this case concerns the complexities surrounding the meaning of “best proven therapeutic method.” Should it refer to the highest attainable standard *anywhere in the world*, or the highest attainable and sustainable therapy in the country where a study will be conducted? Another important ethical issue in the AZT placebo control studies to prevent maternal-infant transmission of HIV concerns the obligations of researchers to consider the availability of therapeutic interventions for research participants and the community once a study is complete. The 1993 CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects emphasizes that research carried out in developing nations must be responsive to the health care needs, concerns and priorities of the host country. The intention of the AZT trials for HIV-infected pregnant women was an attempt to respond directly to the devastating effects of the AIDS epidemic for poor women and children whose access to medical care and treatment is often severely compromised. Proponents of the trials have argued that it is vitally important to provide the highest level of therapy possible given the circumstances of the study in the host country and that if a therapeutic intervention is not sustainable, findings or products from clinical trials will not be applicable or available for the research participants and their communities.

Critics of the studies charge that, even if the alternative interventions were successful, in most cases, the cost of providing treatment (even though it would be minimal) combined with the absence of

clinical infrastructures would severely diminish the possibility for effective application of the research findings. Proponents, however, note that at least two of the countries where the trials were being conducted had the financial resources to provide short term AZT therapy if it proved effective, and that other resource-poor nations would be assisted by international agencies in securing and providing the drugs.

Although placebo-controlled trials to reduce maternal-infant transmission of HIV have ended, the debate continues (see e.g. Levine 2001; Macklin 2001). In particular, the revision of the Declaration of Helsinki has become the focus of considerable controversy over the meaning, interpretation, and application of standard of care and the obligations of researchers to communities once a study has ended. The new wording of paragraphs 29 and 30 are especially contentious for those involved in the debate. Paragraph 29 now states: "The benefits, risk, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists." Paragraph 30 is a new addition to the Declaration of Helsinki, "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study." Given the highly charged nature of the debates among health professionals, bioethicists, and policy makers internationally, it is unlikely that a general consensus on these issues will be reached in the near future.

### **Necessary Information**

In this case, the necessary information to be considered in the decision-making process regarding implementation of placebo-controlled trials to reduce perinatal transmission of HIV include extensive examination of the scientific evidence available and a robust exploration of existing guidelines for ethical conduct in international biomedical research. Additionally, the investigators must involve researchers from host countries in the design and implementation of the study and initiate a comprehensive review of the issues among established ethical and scientific advisory panels at participating institutions, and with relevant national and international organizations. It is important to note that these activities were implemented by the investigators working on the placebo-controlled trials. Despite their efforts to systematically address the complicated dimensions of the studies, controversy arose over conflicting opinions about the ethical appropriateness of conducting the studies.

### **Stakeholders to the Decision**

Public health professionals must be attentive to the views and concerns of the myriad stakeholders involved in the implementation of research such as the AZT trial to prevent maternal-infant transmission of HIV. The decision to go forward with the trial should be informed by the values and interests of: a) the pregnant women who would be directly effected by the study; b) the local community within which the study would be carried out; c) local researchers involved in the international collaboration; d) ethical review committees at the participating institutions, and if relevant, by national ethical advisory committees; and e) international advisory committees such as UNAIDS.

### **Available Options**

Thoughtful consideration of the recommendations and concerns of all interested parties provides researchers with a range of potential plans of action. In this case, a number of alternatives were possible, including those outlined below:

- Move forward with the placebo-controlled trials as originally planned, but only after intense review and approval by ethical boards at participating institutions, and national and international ethical advisory committees.
- Design careful strategies to ensure that consent among the women was truly informed and voluntary.
- Ensure careful oversight of the study by establishing an Advisory Board comprised of local researchers, community leaders, and international representatives.
- Revise the study design in order to compare the full course of AZT with alternative treatments throughout the duration of the pregnancy and after the baby is born.
- Postpone the implementation of the study until consensus is reached following a thorough debate among health professionals, ethicists, policy makers, and governmental authorities both nationally and internationally.

## Decision Process

In this case, the placebo-controlled trials of the effect of AZT on the prevention of maternal-infant transmission of HIV were implemented. The intense public and professional debate that followed was, and continues to be, reported in the media and scholarly publications. Consensus regarding the ethical appropriateness of these studies and others like it may not be attainable given the complexity of the issues involved and, in some cases, the sharp differences of opinions among interested parties. An important outcome of this study has been increased attention to ethical issues surrounding the design and implementation of biomedical international research, particularly in settings where individuals are vulnerable because of their poverty and lack of access to medical treatment.

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## **MODULE 4**

### **Community-Based Practice and Research: Collaboration and Sharing Power**

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Contemporary public health is dedicated to a community orientation and the premise that community-based activities are essential to sound practice and research. The central importance of community as a public health value is clearly reflected in the 2001 Public Health Code of Ethics and its accompanying statements. Five of the Code's twelve principles and six of its eleven key assumptions address the nature of community, the interdependence of individuals and groups, the links between communities and the environment, and the role of communities in public discourse and collaboration with public health organizations.<sup>1</sup> Defining public health as "what we, as a society, do collectively to assure the conditions for people to be healthy,"<sup>1</sup> the authors of the Code declare that effective public health practice and research depend on informed community trust and participation.

The practical ethical issues in community-based practice and research are as wide-ranging as community life itself. Many important ethical questions depend upon the meaning of community, but the word typically has no clear, consistent usage in public health, either as a social concept or as an ethical value. Moreover, identifying the key characteristics and rightful members of any particular community may raise ethical and political questions even before one considers the community's appropriate roles in assessment and priority setting, research, intervention, or public health policy.

This essay begins with an examination of some common definitions of community, community participation, and community representation, and considers the ethical presuppositions that lie behind the ways the terms are often used in public health. It then reviews how surveillance activities that focus on a given community may identify important public health problems and disparities within the larger population, and discusses the vital role of community members' own views and health concerns in assessment and priority setting. Next the essay reviews the tensions inherent in community-based practice by considering the ideals and experience of community-oriented primary care. Finally, it will address the increased emphasis on community participation in research and the challenge of applying research findings to interventions and ongoing practice in the participant communities.

#### **Defining Community and Communities**

The term *community* comes from the Latin root for "common" or "shared". The most general meaning of community is a group of people united by their common features. However, there is no agreement on precisely which common features create community, and the key features of even an established community may seem to vary when viewed by group members as opposed to outsiders.<sup>2</sup>

The theoretical public health literature on community is generally based in sociology. Early sociological efforts to describe communities focused on the importance of shared values and shared experience. Sociologists typically define a community in terms of group norms, personal relationships, and members' clear roles and expectations of each other. Health promotion researchers have identified six such aspects of community:<sup>3</sup>

- membership (a sense of belonging and clarity of roles)
- common symbol systems (language, religious rituals, national symbols)
- shared values and norms (from shared experience or handed-down belief)
- mutual influence of its members (based in communication)
- shared emotional bonds (a sense of personal connectedness)
- shared needs and a shared commitment to meeting them (a sense of “us” that transcends personal interests).

This set of characteristics also has parallels in the concept of the religious community of faith, which is characterized by fellowship, shared values, spiritual and emotional bonds, and mutual support. Many social scientists and ethicists maintain that human beings naturally seek community and are eager to experience the meaning and personal fulfillment that true community offers.

The use of the term community in public health practice often differs dramatically from the somewhat romanticized sociological notion seen in theoretical literature. Often the term is used to refer to a group of people from the same geographic location or catchment area (e.g., the westside community). It may also refer to a group with a common racial or ethnic background, socioeconomic status, religion, profession, health condition, or who share some other important experience (e.g., the African-American community, the indigent community, the Greek Orthodox community, the medical community, the HIV/AIDS community, or the women veterans' community). Public health agencies and practitioners typically use the word to refer to individuals and groups linked by one or more characteristics that, however vaguely defined, give them recognizable common needs and interests of concern to public health.

Often the intent of identifying a group as a community determines what features will be emphasized and who will be counted as a community member. Although self-defined communities figure prominently in the work of many public health agencies and professionals, many so-called communities are more rightly just “target populations”, constructs defined by the goals of a particular public health project or mandate (e.g., sexually active teenagers; households within 3 miles of a toxic waste site; the mentally ill homeless) rather than any natural social grouping. The description of a community targeted for public health practice or research may also be based on allegedly objective and readily measurable classifications, such as socioeconomic or demographic profiles, specific health conditions, or risk factors for disease. But because even these characteristics can be too complex to measure or verify, many projects define their communities of interest in terms of surrogate measures (i.e., income below 200% of poverty level, families of children enrolled in the local school district) or by arbitrary geopolitical boundaries (zip code, county, tri-state area) established by governments' or funders' priorities rather than characteristics that members of the resulting cohort would recognize as important to their identity.

Even within a “true” sociological community, professionals' views of the important relationships and commonalities among individuals and groups may be quite different from the views of the individuals

and groups themselves. Insiders typically see important distinctions between themselves and others who public health professionals might link as a community. For example, similarities of linguistic and ethnic heritage may link Hispanics of many national backgrounds, but their differing political and economic interests and cultural differences can significantly affect the cohesion of the “Hispanic community” as viewed from the inside. Similarly, the “public health community” of practitioners, researchers, and academics may appear splintered to insiders who emphasize such differences as discipline, professional training, and area of work. A true community can be quite diverse, because people of vastly different backgrounds can often create and maintain a sense of community when they have a common cause or a common adversary against which to define themselves and their goals. However, as common goals are met or the perceived benefits of solidarity fade, such a community may become divided or even dissolve. Because of the many forces that can affect a group's cohesiveness, community should be seen as a dynamic phenomenon in which change is both natural and expected.

Many people may consider themselves members of more than one community, or may fall under definitions of membership in several communities of interest to public health. Beginning with membership in a household, individuals are often formal or informal members of self-identified communities based in professional activities and the workplace, religious or spiritual beliefs and practice, sexual orientation, political affiliations, civic and charitable service, athletic activities, academic institutions or experience, social organizations or hobbies. Many individuals' community affiliations overlap and serve parallel interests. However, different communities' values and their expectations of members may also conflict, challenging individuals with multiple loyalties to choose sides or live with unresolvable ethical tension. Conflicting loyalties can be a risk for public health professionals when the goals and methods of public health practice challenge the traditions or beliefs of their religious, ethnic, or other value-oriented community. However, public health professionals who can successfully reconcile these tensions in their own lives can be quite valuable as interpreters and change agents who can negotiate the conflicts and facilitate understanding where others cannot work effectively.

Some uses of the term community in public health contexts are themselves ethically problematic. “The community” is often used as shorthand to refer to outsiders to public health — “them” in relation to public health professionals' “us”. This phrase can serve as a useful reminder that public health activities always take place in a community context and that professionals must always be aware of the community's response. However, it can also imply an adversarial or hierarchical relationship between public health professionals and the people they serve, a perspective that conflicts with the stated goal of collaborative, participatory public health. At times, it can also carry negative implications of the community's ignorance, misunderstanding, and apathy as opposed to the professionals' skills and knowledge and dedication to society's welfare.<sup>4</sup>

An even more ethically dangerous phenomenon is that public health practitioners and researchers may consciously or unconsciously use the concept of community as a marketing strategy to promote activities, perceptions, and goals to a target population. Referring to a cohort as a community can create the impression of underlying community values, norms, and expectations that hide “a giant reinforcement schedule.”<sup>5</sup> Use of the term community and its accompanying sense of mutual values and responsibility to encourage behavior change or acceptance of certain health values has been criticized as being cynically manipulative when it substitutes marketing and implied peer pressure for real moral and psychological support.<sup>5</sup>



## Community as a Public Health Value: Communitarianism and Public Health Ethics

The meaning of community as a central value in public health is at least as complex as its definition in practice. The preamble to the Public Health Code of Ethics states that one of the key principles “that follow from the distinctive characteristics of public health ...is the interdependence of people ... (which) is the essence of community.”<sup>1</sup> Community is an essential value for public health because “the health of individuals is tied to their life in the community.”<sup>2</sup> In this light, public health theorists and practitioners typically interpret the good of the community and the good of the individual as interdependent.

Unfortunately, public health’s community orientation is often misunderstood by ethicists trained in the principle-based frameworks of bioethics, which presume a certain natural conflict between the needs, interests, and goals of individuals and those of society at large. In mainstream bioethics, the principle of respect for autonomy requires that health professionals recognize and honor the right of individual patients to be self-determining, unless respecting one individual’s rights would violate the rights of another. Many bioethicists likewise emphasize the need for health practitioners and policy makers to avoid unduly restricting the rights of individuals in the just distribution of health-related benefits and burdens across society. In this context, critics of policies that seek community-oriented goals mistakenly label public health as “utilitarian”, in reference to the ethical framework that promotes the goal of the “greatest good for the greatest number” with less concern for individual rights than for social benefit.

While public health is not officially linked to any specific ethical theory or school of thought, its community orientation has many parallels to the philosophy of communitarianism. Communitarianism developed in the 1980s in response to a perceived overemphasis on individual rights.<sup>6</sup> Like public health, communitarian theory maintains that individuals are ultimately inseparable from community life, and that no one person and no one community can ever be completely self-determining. In contrast to more familiar ethical frameworks’ presumption of a natural antagonism between individuals and society—and particularly the state—communitarianism recognizes that human beings need *both* autonomy and social relationships. Communitarians insist that while individuals make their own moral choices, their moral commitments and values are shaped by community norms and experiences.

Traditional bioethics often interprets public health’s concern for community to be anti-individual, and its models for public health reflect a tension between individuals and society in which benefit is often a zero-sum game. For example, seatbelt legislation is often identified as a case in which the state enforces a paternalistic limitation of individual rights (to drive unrestrained) in pursuit of a greater social good (fewer collision-related injuries and lower related costs to society). In contrast, a communitarian approach to this issue focuses not only on the individual’s direct benefit from using seat belts, but also on the benefit that the individual enjoys as a member of a community that reduces driving-related injuries and deaths.<sup>7</sup> Communitarian models of ethical analysis are still relatively new, but a communitarian perspective on human dignity, social relationships, and community values can also suggest new approaches and strategies for resolving ethical controversy in public health practice and research.

## Community Participation and Representation

Ethical community-based practice and research depend not only upon a clear understanding of community and identification of the community’s interests but also on the way in which community participation and representation are understood. Community participation in public health appears both

as a grass-roots phenomenon linked to political activism and as a practical organizational effort to involve individuals and communities in promoting and protecting their own health. Just as there is no standard definition of community, the meaning of *participation* is ambiguous in many contexts where the term is often used. Community participation is commonly understood as the involvement of the community in the planning, organization, operation, administration, financing, and control of a project or enterprise. However, the goal of grass-roots community participation is not simply involvement, but rather the redistribution of power that deliberately includes traditional “have-nots” in the sharing of information, setting of priorities and policies, allocation of resources, and distribution of benefits and services.<sup>5</sup>

An early governmental step toward the promotion of community participation in public health programs came in the Economic Opportunity Act of 1964, which provided federal grants to state and local public and private non-profit agencies for community action projects, and which required “maximum feasible participation” by community members. Subsequent efforts to evaluate the effects of community participation in funded projects were frustrated by the wide variability in the definition, format, and implementation of relevant programs nationwide, and proponents of mandatory communication in federally funded activities were largely unable to respond when government requirements were cut back or eliminated. Moreover, the early efforts at engaging community participation in governmentally funded public health activities were criticized by grass-roots activists as mere tokenism that did not get the public very far up the “ladder of citizen participation,”<sup>8</sup> and which permitted “maximum feasible manipulation” of lay people rather than promoting partnership or citizen control.<sup>9</sup>

The concept of partnership or shared governance has been increasingly important in the literature on community participation over the past decade. The fundamental ethical challenge of authentic partnership and true sharing of authority with community groups lies in overcoming the significant disparity in power between community members and public health professionals, who have specialized knowledge, technical skills, and institutional or governmental support. Establishing a partnership requires mutual trust, which is built only over time and after visible results have been achieved. Sustaining a partnership in which collaborators have significantly different degrees of access to power typically requires ongoing financial, political, and community support, reinforced by demonstrated positive outcomes from the collaborative project. Important characteristics of authentic collaboration include the six “R’s” of participation: recognition, respect, role, relationship, reward, and results.<sup>10</sup> Without these components, the community is likely to discount the professionals’ sincerity and disengage from the project.

Because many communities of greatest interest to public health are precisely those whose members have limited technical skills, knowledge and access to power, promoting community participation in public health activities has necessarily involved professional efforts to empower individuals and the community at large. Empowerment relates to a person’s ability to affect his or her own situation. Individual, organizational, and community empowerment are interrelated in the development of social support and interpersonal, social, and political skills. Increasingly public health efforts to empower communities are also dedicated to capacity building, which typically involves the education, development, and support of community members who will then have the specialized knowledge, skills, and abilities to carry out the roles previously played by public health practitioners from outside the community. Capacity building creates a cadre of individuals who both understand the needs and values of the community as only members can and understand the theories and methods of public health that can help meet those community needs appropriately. The ethical advantage of capacity building is also

an important practical strength, as community members are ultimately able to work effectively toward their own goals without the potentially overpowering presence of public health professionals.

The effectiveness and ethical quality of community participation in any public health activity are also dependent upon the authenticity of the individuals and groups representing the community of interest. In theory, community representatives are able to provide insight into the norms, values, experiences, questions, objections, and appreciation of the community they represent, expanding, correcting, and ideally validating the approach taken by public health professionals in practice and research. Community representatives ideally serve as a bridge between their respective communities and the public health professionals with whom they work, representing the community to the professionals and the professionals back to their communities. However, in the same way that public health professionals often define communities based largely on the reason for engaging specific groups, professionals often identify community representatives in light of the purposes they are expected to serve. Even sincere efforts to include community representation in public health activities may result in tokenism if the primary purpose of inclusion is simply to satisfy external requirements for community participation or to secure the approval of proposed projects.

Engaging community representatives in a public health project is subject to logistical and ethical problems similar to those described in defining a community. Public health professionals who seek input from “average” members of the communities they serve may not be able to recognize the significant differences among members of even a small community, especially if that group is unfamiliar to or quite different from the professionals themselves. In an effort to identify “authentic” community members, public health professionals often look for individuals who are recognized as leaders or spokespersons for their group. However even identifying these individuals requires both an understanding of how the community perceives its own essential characteristics and recognizes who speaks for the community in its interaction with others. It also requires understanding of the group’s organizational and power structures. In more than a few situations, the official leaders of a given community have only titular or symbolic positions while others hold the true power or command the real respect of its members.

Similarly, an individual’s authority in one area of community affairs may not translate into authority in another, and an acknowledged community leader from an unrelated area may not provide the desired access to the group’s needs and views related to public health. Even powerful community leaders may be intimidated by health professionals whose work they may not fully understand and whose language and approach are unfamiliar. In order to maximize the effective participation of community representatives, it is essential for them to receive careful orientation to the project and to get to know its organizers. Ongoing education about the work in which they will be involved and its larger context can further empower community representatives, particularly when it is coupled with an active role for the community in defining its own needs and strengths, a process discussed below. Nonetheless, public health professionals should avoid the temptation to pick the most visible community members for multiple projects, as the repeated participation of a select few may not only exacerbate existing power differentials within a community, it may also create career community participants who are increasingly estranged from and resented by the group they are intended to represent.

The potential barriers to the effective involvement of community representatives often make it appealing to find health professionals from specific backgrounds to interpret the needs of targeted communities. In many ways this practice can provide a natural bridge between the professionals and the groups they

hope to serve. However, depending on the individual's background and the nature of the project, the socialization of professional training and work experience may distance professional members of a targeted community from the group's mainstream perspectives and even more so from its most vulnerable members. The difficulty of striking a balance in this regard argues for all but the smallest projects to include multiple representatives of any targeted community, in order to include a broader and ideally more representative spectrum of its voices. It also emphasizes the need for professionals to become more educated about the communities they serve in order to recognize important community characteristics and more easily overcome the barriers to community participation.

Since the end of the 1990s, two initiatives intended to improve the access of an increasingly multi-ethnic population to effective health services have also shown promise for increasing community participation in public health activities. The first is cultural competence education for professionals. Standards of cultural competence and related professional education are intended to improve public health professionals' recognition and understanding of the role of culture in health-related activities and the history, beliefs, values, and practices of members of the communities they serve. Concern for cultural competence was originally directed toward ethnic, religious, and linguistic differences in direct patient care, but increasingly the concept is being extended into social and political action and the organizational development of services and programs that accommodate communities' cultural differences.<sup>11</sup>

The second initiative is based in new federal standards for language assistance for people who use governmentally funded health-related services. These standards are aimed at institutions and agencies that provide health services, directing them to provide various forms of language assistance to individuals whose limited proficiency in English may be a barrier to their effective care.<sup>12</sup> The standards also apply in other settings where limited English proficiency affects some groups' access to health-related services. By facilitating communication and improved mutual understanding, language assistance and cultural competency programs should foster public health professionals' engagement of the diverse communities they serve and improve their ability to recognize changing community needs. Language assistance programs, in particular, should also expand many community groups' awareness and understanding of public health activities and ability to participate in them more fully.

### **Community Surveillance, Assessment, and Priority Setting**

Characterizing the health of the population through epidemiologic surveillance and identifying its health needs through formal assessment are essential public health activities that depend heavily on health professionals' presuppositions about distinctions and similarities among communities. Basic health statistics can be significantly affected by whether and how the larger population is analyzed by subgroups. Interpreting the meaning of such statistics, and identifying appropriate public health responses to them can also be affected by whether the members of the subgroups share community values or experiences. For example, the high low birth weight and infant mortality rates for the United States as a whole are often regarded as an embarrassing puzzle in light of national expenditures on prenatal and perinatal medical care. When national rates are evaluated by racial/ethnic group, socioeconomic status (SES), and age, the problem can be seen to affect young African-Americans of lower SES most severely, but the rates for all groups of African-American women are disproportionately higher than for their counterparts' from other racial/ethnic groups. In seeking to understand this disturbing phenomenon, public health researchers and women's health advocates have recently emphasized such potential causes as the experience of institutionalized racism and its associated stress

over possible biological or medical factors. Defining and measuring the experience of institutionalized racism and associated stress requires not only the observational and analytic skills of behavioral scientists and social epidemiologists, it demands the participation of the communities being studied and insight into community members' interpretation of their experiences.<sup>13</sup>

Community health professionals have long recognized that community members view health and illness and their respective causes differently than do practitioners and researchers. Even when community members and professionals identify the same health problems, needs, and resources, their emphases often differ. Professionals' emphasis on organizations and the delivery of service typically contrasts with community members concern for social, economic, and interpersonal issues. Knowledge of community members' subjective experience is considered essential for a comprehensive view of a community's health status, both in terms of the lived meaning of surveillance data and the importance attributed to specific health problems in daily life. But because of difficulties in involving the community at large in assessment and the logistical and ethical difficulties of identifying and engaging community representatives in the process, community assessment may be left largely to professionals in all but major projects or when funding guidelines require community participation.

In practice, community assessment and priority setting are twin components of health planning that inevitably affect each other. Formal assessment is typically based on an overview of a community's strengths and needs that effectively establishes some general priorities before the evidence is gathered, but funding for community projects requires data to support their feasibility and likely community benefit. Community members who enter into the assessment and planning process are typically much less concerned with developing and analyzing comprehensive and well-documented data and much more interested in action, change, and the provision of services. Maintaining community involvement in planning and priority setting often requires public health planners to balance their professional responsibility to use sound research methods and the need to provide meaningful opportunities for community participation that will keep community members interested and active in the process.

The best-known and most ambitious community-based priority-setting project in the United States, the Oregon Health Plan, illustrates both the ethical strengths and limitations of community involvement in planning for health services.<sup>14</sup> The Oregon Health Plan was the result of Oregon's 1989 revision of Medicaid in response to the state's growing number of uninsured residents. Under the plan all state residents who met federal poverty guidelines were eligible for Medicaid coverage, but fewer conditions and fewer types of treatment were covered under the revised system. In order to clarify which conditions and interventions should be covered under the plan, the state created the eleven-member Oregon Health Services Commission to develop a prioritized list that would be the basic benefits package. The Health Services Commission was created in part in response to the efforts of Oregon Health Decisions, a civic organization responsible for grass-roots education and community outreach centered around health care rationing. Between 1983 and 1984, Oregon Health Decisions conducted 300 community forums and town hall meetings designed to raise awareness of the practical and ethical issues related to health care rationing. The process involved some 5000 Oregonians and led to the 1984 Citizen's Health Care Parliament, which outlined the values that its participants believed essential to an acceptable rationing plan. In 1989 the Health Services Commission continued the community-based discussion in town hall meetings in every county across the state, discussing with participants how to allocate health care resources consistent with community values. The Commission subsequently used its findings to create a list of 709 condition-treatment pairs for which priority for coverage was based largely on the values and preferences expressed in the community forums.

From the outset the Oregon Health Plan was both hailed and criticized from many directions, but analysis of the priority list and the way in which it was developed received particularly strong criticism from some ethicists and community advocates. In particular, they pointed out that the community values and preferences that informed the prioritizing of coverage were not necessarily the values and preferences of Oregon's Medicaid-eligible population. The community forums and town meetings at which rationing, priorities, and values were discussed were typically attended by health care providers, and other educated, middle class Oregonians. Although organizations representing Medicaid patients took part in the discussions, only 5% of the participants were actual Medicaid recipients. Despite efforts to schedule sessions at convenient times for all community members and to publicize the meetings actively, members of the lower socioeconomic groups most affected by Medicaid's restructuring did not participate. Questions about the community that the Plan was meant to serve, the willingness and ability of health professionals and educated citizens to speak for the poor, and how the Commission might have engaged more participation from members of Oregon's lower socioeconomic groups continue to pose a serious challenge to health planners and the establishment of community-based practice.

### **Community-based practice**

Community-based practice, particularly the delivery of health services, is distinguished by both logistical and ethical aspects. Logistically, community-based practice is rooted in a particular, defined community, whose needs and goals define the purpose and activities of the practice. Ethically, community-based practice is committed to honoring the values and culture of the defined community being served and to shared governance of the practice itself. Community-based practice in this sense means the strategic and sustained cooperation of public and private health and social service agencies, neighborhood associations, local funders, businesses, schools and universities, consumer advocacy groups, public officials, and public agencies, which provide the resources and key players needed to maintain a comprehensive approach, a community focus and shared control, an epidemiological understanding of the community's health and well-being, and responsive and flexible interventions that recognize the importance of improving the health of both individuals and the community as a whole.

While few practices achieve this combination of ideals, across the country, diverse broad-based community partnerships such as Healthy Cities/Communities, Healthy Start, Ryan White Planning Councils, comprehensive community initiatives, and community health worker/promotora programs have made some inroads.\* One of the most successful models of community-based practice, community-oriented primary care (COPC), attempted to integrate community participation with clinical primary care and the basic features of public health. The history of COPC, which was quite popular in the United States in the 1980s, illustrates the ethical ideals as well as several ethical tensions inherent in community-based practice.

COPC was originally developed in 1940s South Africa by Drs. Sidney and Emily Kark and further developed in Israel. COPC was based upon the idea that decision making for health needs to hinge on an epidemiological understanding of the principal factors influencing health, including social, biological, and cultural characteristics and the natural and man-made environment. The Karks taught that health interventions should target both the individual and the community as a whole, and that the community should be involved in the promotion of its own health. In 1982 a U.S. Institute of Medicine

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\* See Best Practices sheet for general references on such programs.

(IOM)-sponsored conference on COPC defined the essential elements of COPC as (1) complementary use of epidemiology and clinical practice; (2) a defined target population, for whose health improvement COPC service takes responsibility; (3) defined health interventions based on epidemiological findings; (4) community involvement in its own health promotion; and (5) accessibility without financial, social, cultural, geographic, and other barriers to care.<sup>15</sup> Attracted to this model because of its comprehensive, democratic approach, many practitioners worldwide introduced COPC into public health practice, particularly in clinics for the indigent.

Over the past 20 years, however, COPC in the United States has come to be understood largely as a primary care medical practice with a geographically defined service area, where resource allocation and program design decisions are based at least in part on periodic health needs assessments. A few years after it defined a active role for communities in COPC, IOM reduced its definition of COPC to four key tasks performed by professionals: (1) defining and characterizing the community; (2) identifying the community's health problems; (3) modifying programs in response to health needs; and (4) monitoring the program's impact. Not surprisingly, today most U.S.-based COPC practices do not take a comprehensive approach to health that encompasses social, cultural, and environmental determinants, or target interventions to the health of the community as a whole (as compared to a large number of individuals). Similarly, although community health centers and other such practices may have consumer representation on advisory or governing boards, COPC practices today do not incorporate any significant degree of community involvement. Moreover, financial, geographic, cultural, and other barriers to access to health care continue to present tremendous challenges to indigent communities across the United States even where COPC programs exist.

The shift in COPC's ethical commitment to community participation and a holistic approach to community health may be the result of the persistent U.S. belief that health problems can be corrected by the delivery of professional health and social services and Americans' dedication to medical experts and institutions. Moreover, the dominant biomedical model of health and illness still overlooks the importance of connections among individuals for both creating and solving health problems, and doubts the wisdom or feasibility of sharing authority or responsibility with a given community for the promotion of its own health. And, perhaps most importantly, as the U.S. population grows more diverse and more mobile, the concept of "community" remains difficult to define in theory or practice, making community engagement particularly difficult to achieve. The original vision of COPC might well be highly effective if implemented faithfully, but the interaction of practical and ethical restrictions on its goals makes such implementation unlikely for the near future.

## **Community-Based Research**

The ethical issues in public health research, as in all human health-oriented research, relate primarily to the tensions between the real and potential benefits that research offers participants and the possible harms that the investigation may cause them.<sup>†</sup> Like epidemiologic surveillance, public health research attempts to answer questions related to the health of populations that may have markedly different answers for different communities. Nonetheless, presumptions about the similarities and differences between communities on which research agendas are built can pose ethical challenges for investigators and communities. The history of public health research is indelibly stained by the U.S. Public Health Service's 40-year study of untreated syphilis among poor, uneducated African-American men in Macon

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<sup>†</sup> Module 3 addresses the ethics of public health research in more detail.

County, Alabama, under the premise that the “Negro” biological response to syphilis was different from that of Caucasians.<sup>‡</sup> Despite national ethical standards that required the informed consent of participants over the four decades of the trial, researchers in the Tuskegee Syphilis Study betrayed the trust of the community and deceived individual participants by portraying the study as special medical attention.

Since the late 1960s, regulatory authorities have sought to protect research participants from study-related harms by through reinforced standards of informed consent for individuals enrolled in research protocols. In the late 1980s, however, AIDS activists demanded greater access to the therapeutic options offered only in drug trials. Their claims began a shift in the interpretation of informed consent from a largely defensive right to refuse experimental intervention to a positive right to be involved in research protocols as an informed partner.<sup>16</sup> Since the late 1990s federal regulations have reflected this new attitude, as evidenced by the substance and the language of new policies. Both governmental agencies and many researchers have abandoned use of the implicitly passive “research subject” in favor of the more active “research participant.”

“Participatory research” has gained particular currency for community-based studies. In the mid-1990s, international AIDS researchers faced significant ethical conflict in reconciling U.S. standards of individual informed consent with the accepted paternalism of medicine in most developing countries.<sup>17</sup> Some proposed models of community consent in which community leaders were asked to speak on behalf targeted participants.<sup>18</sup> Often the community members recruited for drug studies had no understanding of the western concept of self-determination and who respected the authority of community leaders to make important decisions in the group’s interests. For many ethicists this practice raised the crucial dilemma of how to respect individuals who do not believe in autonomy without supporting the potential exploitation use of vulnerable persons whose own interests might differ from those of their larger community. Although U.S. federal funding commits international research to U.S. ethical standards, the ethical controversy surrounding community consent remains largely unresolved, particularly with respect to privately funded drug studies.

In the United States, communities have begun to seek partnership with researchers in addressing health problems that they both recognize. Researchers, in turn, have realized the benefits of community participation in defining important research questions, implementing protocols, and interpreting results. The National Institutes of Health has increasingly called for protocol design to be consistent with the goals of participatory research, and recommends that applicants for certain federal funding consult published guidelines from the University of British Columbia on participatory research.<sup>19</sup> These guidelines highlight the importance of community involvement and partnership in health promotion research and define five basic categories for evaluating partnership and community participation:

- the **characteristics** of the participant community of interest;
- the **origins** of the research question and the **community’s support** for it;
- whether the research will **foster self-determination** among community members and **facilitate collaboration** with external resources;
- whether the community and the researchers can **learn about each other** during the process; and
- whether the participant community will **benefit from the research outcomes** and how.

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<sup>‡</sup> Module 2 discusses the history and legacy of the U.S. Public Health Service’s Tuskegee Syphilis Study in detail.



These criteria speak to the potential for researchers and communities to serve their mutual needs and link traditional concepts of research protection with new interpretations of collaborative trust.

## **Conclusion**

New attention to community in theory and practice offers the promise for a public health that is of the people and by the people as well as for the people. Integrated community-based efforts at surveillance, intervention, and research close an important circle for health professionals by bringing a wider range of knowledge, skills, and resources to bear on complex public health concerns and deepening broad commitment to solutions by involving people in decisions that affect them. For community-based research and practice to be successful, however, public health professionals must be alert to its inherent tensions and use conflicts to gain a greater understanding of how to balance the many worldviews, goals, and strategies at play. A strong mutual commitment to power-sharing and the collaborative process, and honest approach, careful attention to relationship, and the pursuit of “win-win” outcomes can go a long way to overcoming the many obstacles that remain.

# **Fact Sheet: Community-Based Practice and Research: Collaboration and Sharing Power**

## **Regulations and Guidelines**

Legal mandates, professional guidelines, and organizational standards on community-based practice and research, including related ethical issues, are decentralized and generally not coordinated. Funders and contracting agencies often place program-specific conditions on use of grant or contract funds, or recommend that projects incorporate principles of community-based practice or research or related guidelines.

For example, many federally legislated funding streams require community representation, in some cases with fairly specific representation formulas. Among many other examples, required vehicles for community representation include the community-level Planning Councils mandated by Ryan White CARE Act for local distribution of federal HIV/AIDS funding, the governing boards of Community Health Centers, and the planning and coordinating Community Consortia required of each local Healthy Start infant mortality initiative. In another vein, in partnership with a number of other public health agencies, the Centers for Disease Control and Prevention have drafted a set of Public Health Performance Standards for state health departments, local health departments, and governing bodies like Boards of Health. Among other purposes, the standards are intended to improve performance and increase accountability. As collaboration with the community is included in the draft standards, it is more likely than ever that all governmental public health agencies will be held accountable for community collaboration.

With some exceptions that are related to new technologies, the ethical issues that arise in community-based practice and research today are not new. Most relate to the difficulty in defining a community, identifying its leaders and appropriate representatives, and recognizing and addressing the tensions inherent in sharing power, knowledge, and responsibility in the pursuit of community health benefits. In practice, individual public health professionals may find themselves unable to conform to all relevant mandates. More commonly, unwritten organizational norms or individual job descriptions may conflict with the approaches and tasks necessary to interact successfully with the community.

## **Common terms**

Capacity building:	The provision and promotion of education and practical training within low- and unskilled communities, particularly with respect to essential health services. Capacity building is a strategy for community empowerment and fostering independence.
Communitarianism:	An ethical theory that recognizes the dual human need for autonomy and social relationships, and emphasizes the role of communities' values and experiences in shaping individuals' moral commitments. Communitarianism developed in the 1980s in response to liberalism's emphasis on individual rights. Communitarians believe that individual rights must be balanced with communal responsibilities.

Community:	A population or group defined by its common characteristics or experiences, particularly location or geographic origin; physical, behavioral, or personal characteristics (e.g., race/ethnicity, gender, age, sexual orientation, disability); beliefs, values, interests, norms or goals.
Community assessment:	Evaluation of the strengths, abilities, needs and goals of a particular group, population, or geographic area, typically with the goal of intervention to improve services or minimize the harm caused by intervention elsewhere.
Community governance:	Shared authority between communities and either private or public organizations over long-term issues of importance to the community, secured by a mutually desired outcome, such as funding, that depends of full community partnership.
Community health:	The health of an identified group; organized practices intended to promote, protect, and preserve the health of one or more defined populations
Community organizer:	Lay or professional person who works with one or more specific communities to define members' common goals, needs, problems and priorities, and design strategies and mobilize resources to achieve these goals and priorities.
Community-oriented:	An integrated system of clinical primary care and public health, primary care (COPC) which emphasizes continuity of care and focuses on the whole community and its subgroups in needs assessment, planning and providing services, and evaluating outcomes. COPC's five essential features are: a clearly defined target population for surveillance, care, and evaluation; complementary roles of epidemiology and clinical care; defined programs based in epidemiologic assessment; involvement of the community in health planning and health promotion; and accessibility to services without geographic, financial, socio-cultural, or other barriers.
Community participation:	The active involvement of the members of a community in the planning, creation, operation, and control of an organization, project, or service activity intended to benefit that community.
Community representative:	An individual who participates in an organization, project, or service activity as a member of a specific identified group or population, both to provide the perspective and knowledge of the group to the organization or activity and to convey essential information about the organization or activity to the larger group.
Culture:	As used here, a system of shared beliefs, values and behaviors and practices common to a particular group or population that results from group experience interpreted in light of beliefs about the purpose and meaning of life. With regard to health and well-being, culture includes ideas about definitions and causes of health and illness; beliefs about how to protect

and improve health; attitudes about when, how, and from whom to seek help; and appropriate ways of expressing (or not expressing) symptoms or suffering.

Cultural competence:	The knowledge, skills, and attitudes necessary to work effectively with persons from one or more cultures other than one's own. Since the late 1990s, many governmental and professional organizations have emphasized the need for cultural competence training to improve the ability of health-related organizations and individual health workers to provide high-quality services to diverse populations.
Participatory research:	Systematic inquiry with the active collaboration of the individuals or groups involved in or affected by the issue being studied, undertaken with the goal of education, intervention, and beneficial change.
Oregon Health Plan:	Oregon's 1989 revision of Medicaid in which all state residents who met federal poverty guidelines were eligible for Medicaid coverage, but with fewer conditions and fewer types of treatment covered. A list of 700 covered condition-treatment pairs and the priority for their coverage was based largely on values and preferences expressed by Oregon's citizens in community forums and public opinion polls conducted over several years.
Shared governance:	Collaboration of a broad range of stakeholders—public, private, governmental, lay, and professional, individuals and organizations—who take long-term joint responsibility to address issues of importance to the community.

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<sup>1</sup> <http://www.apha.org/codeofethics/ethics.htm>

<sup>2</sup> McQueen KM, McLellan E, Metzger DS, Kegeles S, Strauss RP, Blanchard L, Scotti R, Trotter RT. What is community? An evidence-based definition for participatory public health. *American Journal of Public Health* 2000; 91(12): 1929-1938.

<sup>3</sup> Israel BA, Checkoway B, Schultz A, Zimmerman M. Health education and community empowerment: conceptualizing and measuring perceptions of individual, organizational, and community control. *Health Education Quarterly* 1994; 21(2):149-170.

<sup>4</sup> Durant J, Hansen A, Bauer M. Public understanding of the new genetics. In: *The Troubled Helix: Social and Psychological Implications of the New Human Genetics*. T Marteau, M. Richards, eds. New York: Cambridge University Press, 1996, pp. 236-238.

<sup>5</sup> Jonas S. The question of community control. *American Journal of Public Health* 1971; 61 (10): 1934-1937

<sup>6</sup> The Communitarian Network, <http://www.gwu.edu/~ccps>

<sup>7</sup> Forster JL. A communitarian ethical model for public health interventions: An alternative to individual behavior change strategies. *Journal of Public Health Policy* 1982; .

<sup>8</sup> Arnstein SR. A ladder of citizen participation. *Journal of the American Institute of Planners* 1969; 35(4):15

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<sup>9</sup> Arnstein S. Maximum feasible manipulation. *City* 1970 (Oct/Nov): page numbers unavailable.

<sup>10</sup> Wolff T, Kaye G (eds.) *From the Ground Up: A Workbook on Coalition Building and Community Development*. Amherst, MA: AHEC/Community Partners, 1995.

<sup>11</sup> National Association of Social Workers. *NASW Standards for Cultural Competence in Social Work Practice*. Washington, DC: NASW, 2001. [http://www.naswpress.org/publications/standards/standards\\_cultural\\_competence/s01.html](http://www.naswpress.org/publications/standards/standards_cultural_competence/s01.html)

<sup>12</sup> Office for Civil Rights, U.S. Department of Health and Human Services. Title VI of the Civil rights Act of 1964; Policy Guidance Against National Origin Discrimination as it Affects Persons with Limited English Proficiency (65 Fed. Reg. 52762-52774).

<sup>13</sup> Reverby SM. More than fact and fiction: cultural memory and the Tuskegee Syphilis Study. *Hastings Center Report* 2001; 31(Sept-Oct): 22-28.

<sup>14</sup> Bodenheimer T. The Oregon Health Plan — Lessons for the nation (first of two parts). *New England Journal of Medicine* 1997; 337: 651-655; Crawshaw R. The Oregon Health Plan (letter). *New England Journal of Medicine* 1998; 338:395-396.

<sup>15</sup> Conner E., Mullin F, eds., Institute of Medicine. *Community Oriented Primary Care: New Directions for Health Services Delivery*. Washington, DC: National Academy Press, 1982.

<sup>16</sup> Arras JD. Noncompliance in AIDS research. *Hastings Center Report* 1990, 20(Sept/Oct): 24-32

<sup>17</sup> Levine RJ. Informed consent: Some challenges to the universal validity of the western model. *Law, Medicine & Health Care* 1991; 19: 207-13.

<sup>18</sup> Weijer C, Goldsand G, Emanuel EJ. Protecting communities in research: current guidelines and limits of extrapolation. *Nature Genetics* 1999, 23: 275-280.

<sup>19</sup> University of British Columbia Institute for Health Promotion Research. Guidelines and categories for classifying participatory research projects in health promotion, in *Participatory Research in Health Promotion in Canada*. Ottawa, Ontario: Royal Society of Canada. [www.ihpr.ubc.ca/guidelines.html](http://www.ihpr.ubc.ca/guidelines.html)

## **Case Study 1: Providing Culturally Appropriate Services in a Changing Community**

**Our Covenant Health Center** is a 17-year old nonprofit clinic in an indigent, multi-ethnic neighborhood of a once-prosperous urban community. Our Covenant was founded as a free pediatric clinic by a consortium of churches after a sharp economic downturn left many area residents without jobs or health insurance. Through the leadership of a retired public health administrator and the volunteer efforts of other church members, the clinic grew steadily. After only a few years Our Covenant had expanded to provide a wide range of medical and social services for which patients paid on a sliding scale based on household income. By its 6th anniversary, Our Covenant had received funding from several private foundations and had hired a full-time administrator and several full- and part-time clinical staff. Our Covenant celebrated its 10th anniversary by moving into a renovated discount store building, which was donated by its owners to avoid a tax foreclosure.

The mission of Our Covenant Health Center is to provide community-based primary care for area residents, and the neighborhood has long viewed the clinic and its staff as important community assets. The 10-person board of directors includes 3 long-time community residents, and the community advisory board meets monthly to review operations and take part in planning. Both boards and the administration consider community capacity building to be one of Our Covenant's basic responsibilities. Two lay health workers were recruited from among neighborhood residents, and the veteran social worker/educator lives nearby. All three participate actively in the life of the community, visiting patients in their homes and conducting education and referral sessions.

Changing demographics have complicated Our Covenant's community-based efforts over the past few years. When the clinic was founded, the surrounding neighborhood and the clinic's patient population were a roughly equal mix of African-American and white Anglo families; today it is about 95% African-American. About 6 years ago, an influx of Mexican and Central American immigrants to the city brought new populations to the clinic. Soon the clinic needed Spanish interpreters to care for the many patients with limited English proficiency (LEP) coming from across the city. The administrator obtained private funding for 2 half-time bilingual clerks, but the availability of language assistance drew more LEP patients to the clinic, and their need for language assistance soon overwhelmed the bilingual staff members' abilities. To date the clinic has not had the money to hire additional interpreters or bilingual staff, and has relied instead on uncertified volunteers to translate.

After a month in which almost 60% of the patients spoke little or no English, the administrator concludes that the staff must be reconfigured to meet the clinic's current and projected need for bilingual services. She proposes that the social worker and one lay health workers each be made half-time, and that the clinic use the resulting salaries to hire a part-time bilingual social worker and a part-time Spanish-English interpreter. The board grudgingly agrees but the community advisory board objects. They insist that the social worker, an original member of Our Covenant's staff and neighborhood resident, should not be penalized for not speaking Spanish. The community advisory board points out clinic statistics that show that the majority of LEP patients come from outside the clinic's target population and that a growing number come from out of state. They propose that all patients from outside clinic's designated service area should be referred to other facilities.

- How should the board and administration respond to Our Covenant Health Center's changing patient population and the language assistance needs of the new patients seeking care there?
- How should new demand for services shape the clinic's approach to its community and original mission?

## Case Study 1: Discussion

This case addresses the dynamic nature of communities, the demographic and political variables used to define individual communities, and the how the need to tailor public health services to the cultural distinctions and differing needs of subgroups may affect an agency's structure and function. Discussion should focus on 1) how a public health entity defines the community it intends to serve, including the role that community members have in establishing such definitions; 2) how an identified community may include significantly different subgroups with apparently conflicting values and needs; 3) the meaning of cultural competence, its benefits and limits, and the practical ethical challenges of operating in a multi-cultural environment; and 4) the nature and limits of mission statements and concepts of organizational ethics.

### Background

No community organization can remain unchanged and be responsive to the needs of community dynamics. High rates of immigration have been a prominent feature of demographic change in the United States since the 1970s. Few areas of the country have been unaffected by the growth of Hispanic and Asian populations and the influx of immigrants with limited English proficiency (LEP). On a population level, this diversity has highlighted the role of culture in defining health needs and appropriate services, while on the individual level it has emphasized culture's influence on appropriate diagnosis and treatment. Public health agencies and community-based providers are increasingly responsible for meeting standards of cultural competence in treating the groups they serve, and for providing language assistance to LEP clients and patients.

Community organizations that serve growing immigrant populations may find their resources and identities strained as they attempt to meet immigrants' vast needs while meeting their original community missions. Moreover, long-term community residents may resent immigrants' use of already limited resources, straining the community relations essential to successful operations.

### Suggested Questions for Discussion

- What is the purpose of a mission statement for a community organization? When should a mission statement be changed and through what process? What external factors, internal features, and potential future needs shape the definition of a community organization and its services? What role should an organization's staff members play in defining, interpreting, and carrying out its stated mission?
- Are there valid grounds for a private, nonprofit primary care clinic to accept only specific groups of people as patients? *If so*, on what ethical grounds might a clinic such as Our Covenant refuse to treat certain individuals or classes of people? *If not*, why must a clinic treat everyone who seeks care? What are the limits of either position?
- Federal guidelines on language assistance call for health care providers to employ bilingual health professionals and/or certified interpreters. The guidelines insist that LEP patients' English-speaking family members should not be asked to translate for the patient and caregivers. What ethical and practical problems may use family members as translators cause? In addition to direct patient care, what other services and materials should be available for LEP



members of a service community? If a charitable organization or agency does not receive federal funding, how should it view federal standards and guidelines on quality of care?

- How can public health organizations and health care providers encourage their employees to gain “cultural competence” without unintentionally promoting cultural stereotypes that may lead to discrimination? Can an individual be “culturally competent” with respect to a specific group *without* speaking or understanding the group’s primary language? Is being bilingual an adequate measure of cultural competence?

## Case Study 2: Community Representatives on the Institutional Ethics Committee

Smith County Hospital is a 450-bed public hospital that serves a large multiethnic industrial town and the surrounding unincorporated area. The hospital draws patients from three outlying ambulatory clinics that the county operates, an active obstetrics service, and its emergency department, which maintains a Level I trauma center.

Smith County Hospital is preparing for an upcoming site visit from the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO). Since the early 1990s, JCAHO has called for hospitals to have a mechanism, process, or service such as an institutional ethics committee (IEC) that considers and helps to resolve ethical issues that arise in the care of patients, particularly in the area of terminal illness and care of the dying. At the last accreditation visit one JCAHO reviewer spent over an hour discussing the hospital's new IEC and its policies and practices. The hospital was not cited for problems with its IEC, but the reviewer strongly recommended that the committee's membership be made more multidisciplinary and more representative of the hospital's constituents. Since then, the IEC's chair, a general pediatrician, has recruited new members from almost every area and profession in the institution, as well as a lawyer from the Smith County Attorney's office. However, the IEC chair, the hospital's administrator, and the county attorney disagree about whether to include lay community representatives on the committee. They have put the issue on the today's IEC meeting agenda for a vote.

The IEC chair introduces the topic by reporting on the JCAHO reviewer's comments from two years before that the IEC needed one or more people from the community to bring a lay perspective to the IEC's discussion. The chair notes that, from his experience with the community advisory board of the county's pediatric clinic, the hospital has contact with many knowledgeable and dedicated community people who would be interested in serving on the IEC.

The administrator and the county attorney, however, draw a clear distinction between community advisory boards and the IEC. First, they argue, the IEC deals with complex information about individual patients and medical procedures that lay people don't understand. They worry that it would slow discussion to have to explain all the detailed medical issues to community representatives. Second, the county attorney insists, the IEC discusses cases that involve extremely sensitive personal information. Lay people don't have the ethical commitment to patient confidentiality that health professionals do, he claims, and there is no guarantee that community representatives won't talk to their friends and family members about what they've heard, especially if they know the patient. Moreover, there is no guarantee that community members won't go to the media if they learn about something that they think is unethical. Third, insists the administrator, many of the staff already on the IEC are members of the hospital's community and have friends and family members who are patients in the county health care system. They can represent the community even better than someone from the outside because they understand the hospital as well as the community's perspective. Finally, he points out, JCAHO does not *require* community representatives. He proposes that if this year's site visitor asks they can simply report that the committee considered the idea and decided not to add community members at this time.

- How should the members of the Smith County General Hospital ethics committee determine whether to include community representatives? If they choose to include community representatives on the IEC, how should such members be selected?

## Case Study 2: Discussion

This case addresses the role of community representatives on decision-making bodies that affect the public welfare and in government organizations in particular. Discussion should focus on 1) how to define a lay persons' qualifications to serve on a given specialty board or committee; 2) how to define what constitutes representativeness for any given community; 3) why professionals may fear lay participation in public health practice; and 4) how to maximize community representatives' contribution to the overall goals of the groups they serve.

### Background

The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) is a voluntary accreditation organization for hospitals and other in-patient health care facilities. JCAHO accreditation is required for such institutions to receive Medicare and Medicaid funding. Since the mid-1990s, JCAHO's standards have called for institutions to have a functioning multidisciplinary institutional ethics committee (IEC) to address ethical issues in patient care. JCAHO standards do not require hospital IECs to have lay community members the way that federal funding standards require community clinics to have community advisory boards, but they recommend that community representatives be included to provide insight into patients' perspectives on ethical issues.

Hospital IECs typically address ethical issues involved in caring for seriously ill and dying patients. Since the 1980s, IECs have served successfully to prevent and resolve ethical conflict between health care professionals and patients and their families. IECs often provide ethics education for hospital staff. They often help to write hospital policy related to medical care at the end of life (the use of advance directives and do-not-resuscitate orders, and withholding or withdrawing life support). Their best-known role, however, is in providing a setting for caregivers and patients and their families to work out controversial ethical issues in the care of specific patients. The IEC offers expert guidance on difficult ethical decisions, and most IECs provide an advisory opinion at the request of the person seeking consultation. Because many clinical ethical issues are highly personal and sometimes controversial, IECs observe strict guidelines on confidentiality. The qualifications for membership on IECs may vary between hospitals, but most members are chosen because of their clinical knowledge and professional dedication to good patient care.

### Suggested Questions for Discussion

- Defining Smith County General Hospital's community is essential for determining who might be a suitable community representative. Is it the entire population of people who live and work in Smith County? The population of indigent persons most likely to use the hospital? The Smith County residents whose taxes support the hospital financially? The patients who currently use Smith County General Hospital or its affiliated clinics?
- Which aspects of community life and which community perspectives might the IEC find useful in its consideration of ethical policy and practice? Given the size and multiethnic composition of Smith County, how many community representatives would be needed to represent the county's diversity? Could the authoritativeness of their views be confirmed? If so, how; if not, why not?

- What information and perspectives from the hospital might the IEC want community representatives to convey to the community? With which segments of the County's population might the IEC particularly want community representatives to be contact? How many representatives would be needed to represent the hospital to these groups?
- Can a health professional from a given community appropriately represent the interests and perspective of lay people from his or her community without being unduly influenced by professional attitudes and perspectives? If so, how can such professionals' best serve as "culture brokers?" If not, in what fundamental ways does the experience of health professions education and practice change people?
- What contributions might lay people make to the IEC beyond helping to satisfy JCAHO? What successful models of community representation might the IEC use in creating an effective system of lay membership? What institutional and interpersonal supports might certain lay members need to participate fully on the IEC?

### **Case Study 3: Community Participation in Epidemiologic Surveillance and Research Design**

Stillwater Springs is a small town about 45-minutes from the state capital. The town thrived during the early twentieth century as the home of one of the United States' most important lead mines, but the mine closed 30 years ago, and most of Stillwater Springs' residents left shortly thereafter. Over the past decade, however, a population boom and housing shortage in the capital city has brought many young families and retirees to Stillwater Springs because of its affordable housing and more relaxed rural lifestyle. In the past 5 years developers have built 3 new subdivisions at the edge of Stillwater Springs, several new businesses have opened, and voters recently passed a bond election to build a new elementary school. The capital city's newspaper has recently called Stillwater Springs one of the state's most promising communities for the future.

In the past several months, news reports about the end of an Environmental Protection Agency (EPA) Superfund cleanup at a lead mine in a nearby county have created controversy in Stillwater Springs. Many new residents have been surprised to learn that the town was an active lead-mining center for almost a century, and they worry that the nearby abandoned mine may expose them to health hazards. Most long-time residents can remember neighbors with seemingly unusual neurological conditions, but the town had no doctor for almost 20 years, and there is no county health department. Thus there are no central records detailing residents' health problems. Many parents insist that chronic underfunding and substandard programs are to blame for the school's poor academic ranking, but others privately suspect that chronic lead exposure may have resulted in mild mental retardation for some children. Although the mine is a frequent topic of conversation at community events, most residents don't know how to find answers to their concerns.

Brenda Curtis is a single mother of two young children and a resident of one of the town's new subdivisions. In college Brenda lived in an East Coast city where lead paint in old buildings posed a known health hazard, and she had worked on a lead poisoning education campaign as a community service project. From an EPA website Brenda learns that several old lead mines have been linked to elevated levels of heavy metals in the ground water and soil, and that people exposed to contaminated soil and water near old mines have been found to have unsafe blood lead levels. After reading that the risks of lead poisoning in mining areas are particularly high for preschoolers who spend a lot of time outside, Brenda takes her children to the pediatrician in the capital city for blood tests. Both children have slightly elevated levels of lead in their systems, but have no obvious symptoms of lead poisoning.

Armed with the children's test results and a packet of readings on lead poisoning from the Internet, Brenda goes door-to-door in her neighborhood, gathering signatures on a letter to the state health department's lead abatement program. The letter asks for an epidemiologic investigation of the community's health risks from lead, including blood testing of as many residents as possible, soil and water sampling, surveillance for neurological and developmental problems in area residents, and the creation of a database of all residents with high blood lead levels and their proximity to the mine. When the county newspaper reports on her effort, Brenda receives unexpected criticism from area business owners and residents concerned about the town's image and property values. The next week's paper carries a story on the EPA's 1985 decision that the Stillwater Springs mine did not meet the criteria to

be placed on the National Priority List of environmentally hazardous sites eligible for Superfund cleanup. The mayor of Stillwater Springs, who is often credited with the community's economic turnaround, is quoted in the article saying that the town is a safe and healthy place to raise a family.

When the state's lead abatement program director receives the letter signed by over 300 residents of Stillwater Springs, she is impressed with their initiative, but finds little reason to believe that the town is different from the many small mining towns across the state. She remembers vaguely hearing that in the mid-1980s EPA inspectors found no immediate health threat from the Stillwater Springs mine and gave it a better hazard ranking score than several other mines in the state. Still, as the letter points out, the recent construction may have stirred up lead-contaminated soil on previously unused property, creating a new risk of exposure.

The lead abatement program director wants to be responsive to this community's request for professional assistance in identifying a potential health threat that falls within her department's expertise. However, she knows that such an evaluation may be opposed by town leaders and others with a financial stake in the community's growth and prosperity, since the presence of toxic levels of lead will make Stillwater Springs an undesirable location. Moreover, the director knows that the environmental testing and epidemiologic work necessary to assess the potential health threat in Stillwater Springs will not be possible under the Health Department's projected 5-year budget. Even if she can find funding in the future, beginning assessment and surveillance there may snowball into demand for similar projects in many other communities at a cost that the state cannot afford.

- What steps should the lead abatement program director take in response to the letter from the Stillwater Springs residents?

## Case Study 3: Discussion

This case deals with community perception of health risks and the responsibility of public health practitioners and agencies to address community members' requests for assistance in identifying, assessing, and reducing threats to their welfare. Discussion should focus on 1) how public health agencies set priorities for research into health risks and the targets of epidemiologic studies, given limited resources; 2) how local, state, and federal agencies interact with each other and the communities they serve to evaluate and address multifaceted health problems; 3) how the interests of, and perception of risks and benefits to, any given community may differ among community members, as well as between community members and public health professionals; and 4) how to maximize effective interaction between communities and public health practitioners in designing and carrying out epidemiologic surveillance and research.

### Background

Mining was an important industry in many parts of the United States in the 1800s through the mid-1900s. New mining technologies in the late 1800s permitted excavation of multilevel tunnels and extraction practices that resulted in environmental contamination not only at mine sites but also in surrounding areas. Water accumulated in mine shafts typically contains high levels of dissolved heavy metals. When active mines pumped out this water, it often contaminated local ground and surface water. The practice of crushing rock taken from mines, both to extract metal ore and to make gravel for road construction, often created clouds of heavy metal dust that the wind carried for miles. Because lead is an element that does not break down in the environment, water and soil contamination is common in many areas where mining ended a generation or more ago.

Exposure to lead is a recognized health hazard, especially for children ages 1 to 5. In addition to the risk that small children will eat lead-based paint chips, young children's frequent hand-to-mouth contact puts them at risk of ingesting lead dust. Most children with lead poisoning have had chronic, low-level exposure to lead that can cause developmental and behavioral problems, lower IQ, and learning disabilities. Adults chronically exposed to lead may have neurological problems. More rarely, high levels of lead can cause mental retardation, seizures, coma, and death. Pregnant women may pass lead through the placenta, affecting fetal neurological development and growth. Because chelation treatment for lead poisoning is difficult and cannot resolve previous neurological damage, prevention is emphasized over intervention. Many public health agencies have programs in lead poisoning prevention and lead abatement. Epidemiologic work related to lead poisoning is typically carried out by local, county, and state health departments and children's clinics and hospitals. Its goals are usually to identify exposed individuals and groups at risk of poisoning, track the rates and health consequences of exposure, and locate sources of lead exposure for abatement and other prevention measures.

The U.S. Environmental Protection Agency (EPA) is a federal agency created in the 1970s "to protect human health and to safeguard the natural environment — air, water, and land — upon which life depends." EPA administers the Superfund Program, which was created by Congress in 1980 to identify, evaluate, and clean up the country's worst sites of hazardous environmental contamination from various sources. Sites suggested for the National Priorities List (NPL) of hazards warranting federally funded clean-up are announced in the *Federal Register* for public comment; EPA investigators then visit the site

to assess and score it under the Hazard Ranking System. High scoring sites may be targeted for immediate action to safeguard the health of the affected area's residents. However, the NPL is intended to provide information to state and local agencies and the public about sites that appear to warrant clean-up, and does not assign responsibility for clean up or legal liability for any harm.

### **Suggested Questions for Discussion**

- How do public health professionals' views of health threats and evidence of harm typically differ from those of members of the communities they serve? How do these differences shape public health professionals' interpretation of community concerns and requests for assistance? How are such discrepancies resolved in policy and practice? What responsibility do public health professionals have to community members to explain their conclusions and justify their actions?
- How might a health department's decision to conduct an epidemiologic survey create moral and legal obligations for governmental action far beyond the scope of the initial evaluation? How might internal interests affect an agency's willingness to undertake even a pilot epidemiologic project?
- How might external forces and interests influence a public health agency's decision to undertake epidemiologic assessment of a possible environmental health problem? Why might a community prefer to live in ignorance of a potentially remediable environmental threat rather than identify the nature and extent of the potential problem? What actions can public health professionals take to foster cooperation among community members in order to achieve high-quality surveillance?
- When several governmental agencies have jurisdiction over a broad-based public health problem, how is authority established among them? What response can the state health department's lead abatement director expect from environmental health officials at the federal and county levels if she proceeds with an initial survey of lead contamination in Stillwater Springs?



## Tools for Best Practice and Policy Assessment in Community-Based Practice and Research

The prescribed avenues for public health professionals to address the ethical issues in community-based practice and research vary widely. Nonetheless, for any project it is essential to identify and understand the written and unwritten ethical norms and values by addressing such questions as:

- What community is the focus our attention for this project? What criteria have we (public health officials) used to define this group as a community? Do they see themselves as a community with common interests, needs, and values? What other affiliations or divisions may be important to them?
- What previous experience do we have with community? Who among us has the best relationship with this group and what is it based on? In what other contexts do we interact with members of this community and how do those interactions affect the current project?
- Who speaks for this community and how were these spokespeople identified? At what point did they first become involved in the project? What was their original role in the project? How often do we communicate with community representatives or other community members about this project? Are these means of communication formal, informal, or both? What are our respective goals in this communication? Do both the community representatives and we attempt to include a wide range of community perspectives in this communication?
- What is the goal of our project and how was that goal identified? What role did members of this community have in defining that goal and the means of achieving it? What experience does the community have with this issue? How does this project relate to the community's other health priorities? How could community members modify the project if they chose to do so?
- How will participation in this project directly benefit the community and its individual members? How will the community and its individual members be empowered by participation in the project? How will the community's ability to learn about and act on other health issues be affected by participation in the project?
- Do we have a formal or informal agreement with the community about the ways in which knowledge gained from the project, including research data, may be used and how it may be disseminated?

The extent to which legal mandates or “expert” guidelines address community-based practice and research is also quite variable. However, professional and community groups have published a wealth of material intended to guide or facilitate community-based practice and research, both in print and online. A selected list of these “best practice” resources follows.

### Selected Resources

Campus-Community Partnerships for Health. *Partnership Perspectives*. San Francisco, CA: CCPH, 2000. <http://futurehealth.ucsf.edu/ccph/html>

Centers for Disease Control and Prevention/ATSDR Committee on Community Engagement.

*Principles of Community Engagement*. Atlanta, GA: Centers for Disease Control and Prevention, Public Health Practice Program Office, 1997.

Centers for Disease Control and Prevention, Public Health Practice Program Office. *National Public Health Performance Standards Program (draft)*. Atlanta, GA: CDC, 2000.

Institute of Health Promotion Research, University of British Columbia and the British Columbia

Consortium for Health Promotion Research. *Guidelines and Categories for Classifying Participatory Research Projects in Health Promotion*. Ottawa: Royal Society of Canada, 1995.

Mattessich P, Monsey BR: *Collaboration: What Makes It Work. A Review of Research*

*Literature on Factors Influencing Successful Collaboration, 2d ed.*, Saint Paul, MN: Amherst H. Wilder Foundation, 2001.

National Civic League Staff and the St. Louis County Department of Health. *A Guide to a Community-Oriented Approach to Core Public Health Functions*. Denver, CO: 2000.

National Association of Social Workers, National Committee on Racial and Ethnic Diversity. *NASW Standards for Cultural Competence in Social Work Practice*. June 2001. <http://www.naswdc.org/pubs/standards/cultural.htm>



## **MODULE 5**

### **Ethics and Infectious Disease Control: STDs, HIV, TB**

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In contemporary ethical theory, and biomedical ethics, strong emphasis is placed on the rights of the individual, on principles of autonomy and self-determination. But essential as those values are, the legitimacy of limiting them has long been recognized. When the exercise of one person's freedom results in harm to another, the state may intervene. The "harm principle" provides a widely recognized justification of imposing limits on autonomy. Given its most potent expression by the 19th century philosopher John Stuart Mill, the principle states:

*The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, both the physical moral, is not sufficient warrant.<sup>1</sup>*

This principle clearly provides an ethical foundation for establishing public health programs designed to limit the threat of infectious disease.

The public health authority to limit individual freedom when disease threatens has long been recognized in constitutional jurisprudence as well. Nearly 100 years ago in *Jacobson v. Massachusetts*, a case that centered on the question of compulsory vaccination, the Supreme Court held that the U.S. Constitution permits states to enact "such reasonable regulations [to] protect the public health and the public safety and" as long as such efforts did not "contravene the Constitution of United States, nor infringe any right guaranteed or secured by that instrument."<sup>2</sup> *Jacobson* also underscored the rule that courts should give deference to the government's exercise of the police powers designed to protect the public. Such measures could be invalidated only if they had no real or substantial relation to their purported goal. That standard of constitutional review would in later years be viewed as the least protective of individual right. Capturing the enormous scope afforded to the state acting in the name of public health, a treatise on constitutional law in 1900 asserted that before the demands of public health "all constitutionally guaranteed rights must give way."<sup>3</sup>

This extraordinary deference to government action prevailed throughout much of the 20th century, persisting into the late 1960's. The past three decades of constitutional development, however, particularly in the area of involuntary confinement of psychiatric patients, have seen increasing scrutiny of the exercise of the police powers of the state, raising questions about the constitutionality of statutes relating to communicable disease, many enacted before the profound shift in the balance between individual liberties and state authority.

As important to the transformations in the view of the state's authority has been the impact of the AIDS epidemic. In the early 1980's when the United States like other democratic nations had to confront the public health challenge posed by the new epidemic, it was necessary to face a set of fundamental

questions: Did the history of responses to lethal infectious diseases provide lessons about how best to contain the spread of HIV itself, a lethal sexually transmitted and blood borne virus? If AIDS were not to be so treated, what would justify such differential policies?

It was the specter of the most coercive of aspects of the public health tradition that concerned proponents of civil liberties and advocates of gay rights as they considered the potential direction of public health policy in the presence of AIDS. Would there be widespread compulsory testing? Would the names of the infected be recorded in central registries? Would such registries be used to restrict those with HIV infection? Would the power of quarantine be used, if not against all infected persons at least against those whose behavior could result in the transmission of infection?

Although there were some public health traditionalists who pressed to have HIV infection brought under the broad statutory provisions established to control the spread of sexually transmitted and infectious diseases, they were in a distinct minority. In the first decade of the AIDS epidemic an alliance of gay leaders, civil libertarians, and public health officials began to shape policy for dealing with AIDS that reflected an "exceptionalist" perspective. That perspective entailed the commitment to rely on prevention measures that were not coercive, and respected the privacy and social rights of those who were at risk. Mass education, *voluntary* testing and counseling were the centerpiece of the public health strategy that sought to avoid interventions that might "drive the epidemic underground." While the force of the exceptionalist perspective has waned since the 1990's as AIDS had been "normalized" the issues posed by the challenge to conventional public health practice remain pertinent: how should the claims of communal well-being be balanced against the claims of privacy and individual rights?

This module will center its discussion on the tension between the rights of the individual and claims of public health as they have surfaced in infectious disease control. The focus will be on: screening to uncover the presence of disease; surveillance and reporting of those with disease to public health registries; contact tracing; mandatory treatment of those with infectious conditions; vaccination of children to prevent the acquisition of disease; and quarantine or isolation of those whose biological condition or behavior pose a threat to the public health. Cases will be drawn from the AIDS epidemic, which provided an infectious disease threat to public health in the United States at a time when many had thought such challenges were all but relegated to history; resurgent tuberculosis in the late 1980's and 1990's, which compelled a contemporary reconsideration of practices which had served to lay the foundations of public health at the end of the 19th and the first decades of the 20th century; and mandatory vaccination policy, which at the end of the 20th century had begun to provoke renewed resistance echoing opposition that emerged a century earlier and set the stage for fundamental constitutional rulings on the scope of public health authority.

## Screening for Disease

During the 20th-century, screening for the presence of disease and at times occult infection has been a central feature of public health practice. Often such screening was mandatory or imposed as a condition for undertaking a desired course of action. Screening for venereal disease prior to marriage was imposed as a way of protecting unsuspecting spouses from infection. Screening children for entry into public school was imposed to protect classmates. Screening of newborns for inborn errors of metabolism was enacted to assure that needed remedial actions, dietary or otherwise, was taken. And of course screening for tuberculosis by X-ray and skin test became widespread, in schools and workplaces.

In each of these instances the determination to impose screening represented judgment that the claims of bodily integrity could be subordinated to the claims of the public health. When the rights of the individual in the context of public health were less robustly defined than became the case in the last decades of the 20th century such screening generally went untested. When challenges did arise they typically involved claims that the putative threat to the public health was overstated. It was thus possible to claim that respecting the rights of privacy did not entail a threat to the safety and well-being of the community or of those in need of the community's protection. At times determination could be made that screening programs that had served the public health were no longer warranted. For example, in recent decades premarital syphilis screening as a mandatory measure has all but vanished. Those who were getting married did not have syphilis and those with syphilis were not getting married.

The complex and volatile the issue of screening is highlighted by the furious debate that has centered on the HIV test. While there was no objection to the mandatory screening of blood donations in order to protect recipients, conflict emerged over screening in other settings. There were some who argued for wide scale testing without consent, for mandatory prenatal testing, testing of health care workers, the testing of newborns. In each case they asserted that the claims of public health took precedence over the right to privacy.

The insistence of public health officials, civil liberties advocates and AIDS activists fearful of how AIDS could provide the context for the deprivation of privacy rights led to a rejection of mandatory HIV testing, even as conservative political groups pressed for such measures. In lieu of such a course public health officials embraced the strategy of voluntary testing. Reflective of the impact HIV exceptionalism, testing was to be undertaken only after individuals had been fully informed of the risks and benefits of the HIV test and had given their explicit informed consent. With the advent of effective antiretroviral therapies in the 1990's there was increased pressure "to return HIV testing to the mainstream" to permit physicians to test with the presumption of consent and without elaborate pre-test counseling. More striking were the moves towards mandatory testing, to protect newborns, "innocent victims." Hence it was argued that pregnant women should be tested for HIV as they were tested for hepatitis B in order to permit interventions that could benefit and not yet born child.

The transformation in the debate surrounding HIV screening reflected an attempt to shift the balance between privacy rights and public health. It underscored the extent to which justifications for recourse to compulsion in public health are affected by the prospects of effective intervention.

In the end the ethical question posed by screening is: what prospect of effective public health intervention to protect the vulnerable, however defined, can justify the invasion of bodily integrity and privacy that is always involved in mandatory screening programs?

The ethical challenges posed by screening programs are illustrated by a proposal made in the year 2000 by the Institute of Medicine to require screening of some applicants for immigration the United States for latent TB infection.<sup>4</sup> After an exhaustive analysis the IOM concluded that the elimination of tuberculosis in the United States would necessitate more than the identification and treatment of individuals with active disease. Such efforts designed to protect third parties posed few ethical challenges. But were ethical and legal principles that justified screening for active disease sufficiently robust to justify mandatory screening for latent infection, infection that could only pose a risk to others were it to progress to active disease?

Since individuals with latent infection developed active infectious TB in only about 10% of the cases, the issues posed by the IOM recommendation were stark: Is it ever appropriate to use compulsory public health powers when the threat posed by an individual is merely statistical? How grave and how likely must the risk be? Is voluntary testing more ethically defensible? The IOM predicated its call for mandatory screening on its determination that mandatory treatment for latent infection could be justified. For the IOM the social benefit of radically reducing the burden of tuberculosis justified mandatory prophylactic therapy of new immigrants and hence mandatory screening. Relying on an expansive view of the ethics of public health law, the committee cited approvingly an analysis by professor Larry Gostin, "While traditional public health law focus principally on present infections, there is no reason to limit the direct threat doctrine in this way."<sup>5</sup> From an ethical perspective, of course, the question remains how to define what counts as criteria for being "reasonably foreseeable", so that it could provide Gostin with the justification for extending the direct warrant for intervention.

Finally, a critical question posed by the IOM report centers on the issue of who should be subject to mandatory screening. Efforts that were over inclusive—those that extended screening beyond what could be justified by the epidemiological profile of risk—unfairly imposed burdensome intrusions on privacy. Programs that were under inclusive—focused on fewer individuals than were at risk—could be viewed as invidiously discriminatory. The IOM chose to target immigrants from nations with elevated background rates of tuberculosis and from those nations that experience revealed contributed substantially to the burden of tuberculosis in United States. In so targeting the proposal for mandatory screening, the IOM sought to balance the need to avoid stigmatization of the vulnerable against the well established principle that the predictive value of screening programs is determined by the extent to which they are directed at populations at risk.

Decisions about how broadly to cast the net for screening are not, however, always dictated by epidemiological factors. When the Institute of Medicine itself issued a report on screening for HIV infection during pregnancy it recommended that voluntary screening be offered to all pregnant women in the United States despite the fact that HIV infection is found primarily among poor African-American and Latino women. That decision was in large measure dictated by concerns about how targeted screening could stigmatize the populations most at risk. Here then even in the context of a voluntary screening program we see a complex interplay of ethical concerns.

### **Surveillance and Name Based Reporting**

If mandatory screening raises questions about the circumstances under which the public health can justify intrusions on the body, public health surveillance poses questions of the tension between privacy, confidentiality and the public good. When does the state have the right to require physicians and health care institutions to report, by name, those with certain conditions? Do such requirements violate the confidentiality that serves as a foundation of the clinical relationship?

It was not until the late 19th century that systematic reporting of infectious diseases began. Since surveillance was undertaken not only to track patterns of morbidity and mortality but to initiate other restrictive measures, e.g. compulsory treatment, and quarantine, it provoked public and professional concern. Hence, physicians, on occasion, challenged the authority of the public health authorities to abridge the sanctity of the doctor-patient relationship in the name of surveillance. In New York City, for example, physicians opposed mandatory tuberculosis reporting and as a consequence it was necessary

to rely upon a voluntary reporting system in which doctors withheld the names of their private patients and reported only the names of the poor dispensary cases.

Eventually, despite such opposition, name based reporting was extended to a host of other conditions practically without any sign of protest. Recognizing that resistance could undermine their efforts, public health officials began to develop the legal and organizational capacity for protecting the confidentiality of names reported to health departments. But what appeared to be a matter of settled practice would become the subject of acrimony at the end of the 20<sup>th</sup> century. The AIDS epidemic provided the occasion for a furious extended debate on the logic and ethics of name based reporting, dramatizing the ways in which competing notions of privacy and public health could continue to affect public policy.

Soon after the first cases of AIDS were reported by the Centers for Disease Control in 1981, state health departments began to require that physicians and hospitals report by name those with the new disease. It is remarkable that given the intensity of the opposition that would emerge in the case of HIV reporting just a few short years later, little protest to the privacy-limiting act of name based reporting for AIDS emerged.

Once the capacity to test for the presence of the antibody to HIV became possible in 1985 it was only a matter of time before some public health officials sought to extend to such findings the reporting requirement that were in place for AIDS. Those who pressed for name-based HIV reporting asserted that reporting would alert public health officials to the presence of individuals infected with a lethal infection, would allow them to counsel such individuals about what they need to do to prevent further transmission, and would permit the authorities to monitor the incidence and prevalence of infection. Aware of concerns about privacy and confidentiality, the proponents of reporting underscored the existence of administrative, regulatory, and statutory protections of public health registries. There was no reason to believe, they argued, that state health departments would fail to protect the identities of those with HIV when they had protected those with AIDS, tuberculosis and other reportable infections.

The antagonists of name based reporting retorted that HIV was different. Social hostility and HIV related hysteria could lead to changes in policy, legislatively imposed, that would permit breaches which never occurred with other conditions. If that happened, those whose names were in registries would face the prospect of losing their jobs, their housing and perhaps their liberty. Aware of such opposition, many health officials in states with relatively large AIDS caseloads resisted HIV reporting. They believed that reporting would counterproductively drive people away from the testing and counseling essential to AIDS control in the United States. It did not matter that public health departments had an exemplary record in protecting name based reports. If those most at risk for HIV had fears about what could happen to them, that was all that mattered.

As therapeutic advances began to emerge in the late 1980's a number of public health officials began to argue that the time was right to extend to HIV the policies that existed with regard to AIDS itself. Most critically the CDC began to press for name-based reporting of HIV cases, as did the Council of State and Territorial Epidemiologists. Nevertheless, the resistance on the part of AIDS activist organizations and their political allies persisted. As a consequence HIV cases typically became reportable by name only in states that did not have large cosmopolitan communities, well organized AIDS constituencies or high AIDS caseloads.



It is striking feature of the opposition to reporting of HIV that it centered on the extent to which those whose names would be reported would be exposed to the possibility of great harms, acts of injustice, discrimination and stigmatization. By esting opposition to reporting on such possibilities—remote given the history of public health registries—a strategic determination was made that invoking the prospects of such danger would serve to effectively mobilize the communities most affected by HIV. An alternative would have been to underscore the fact that even were no harms to befall individuals whose names were reported to registries, they would nevertheless have suffered the injury of having their privacy violated.

As powerful new therapies emerged in the mid-1990s that fundamentally transformed the nature of HIV/AIDS, the effectiveness of the resistance to HIV reporting all but crumbled. While most states, including New York, adopted name-based HIV reporting, a few, including California and Maryland, chose to rely on coded unique identifiers. In so doing, they sought to meet the challenge of surveillance while protecting the privacy of those with HIV.

To those states that have chosen to use names, the history of public health surveillance and the contemporary experience with reporting—in cancer, occupational disease, and vaccine registries—suggested that there was no justification for treating HIV differently. For those states that had chosen to employ unique identifiers in lieu of names, the fears and concerns of those who had HIV provided a warrant for going beyond historical experience and convention.

In examining the possibility of alternatives to the use of name based reporting, it was necessary to consider the question of whether practices that emerged in an earlier era when concerns about privacy were more circumscribed needed to be rethought. Was it possible to merge the necessities of surveillance with contemporary conceptions of privacy? If the use of coded identifiers imposed additional costs, were these justified in the name of privacy? If surveillance that relied on coded identifiers was less effective than relying on names, was it nevertheless good enough given the value of privacy? Finally, the debate over HIV reporting surfaced questions about how public health officials should take into account the concerns of those whose privacy would be violated in the name of surveillance.

## **Contact Tracing**

Case-based surveillance serves not only to monitor epidemiological patterns of disease but as a trigger for contact tracing. In programs designed to treat and control sexually transmitted diseases (STDs), contact tracing has played a central role for more than five decades. Patients diagnosed with STD are urged to reveal the names of their sexual partners so that they may be examined and, if infected, treated. Contact tracing thus serves two functions: case finding and interrupting the chain of transmission. To encourage individuals to provide the names of their partners, a guarantee of absolute anonymity is provided: those who are notified are never informed of the identity of the person who provided their name. In this way, contact tracing has always been voluntary and has always rested on the foundation of confidentiality.

In the early years of the AIDS epidemic, contact tracing programs designed to reach sexual partners who unknowingly may have been placed at risk were greeted with protest. Despite the long history of such programs for STDs, proposals to initiate them were deemed coercive. They were viewed as an intrusion on the privacy of the notified partner. In the absence of a therapy for HIV infection, the

information provided by the public-health official was considered an unwelcome burden (Bayer and Toomey, 1992).

By the end of the first decade of the AIDS epidemic, most of the principled opposition to contact tracing had vanished, and public-health departments began to devote greater resources to such programs.

The issues raised by contact tracing are fundamentally different from those posed to the physician faced with an infected patient who makes clear the intention not to inform sexual partners of that fact. Does the duty to protect confidentiality take precedence over the obligation to protect unsuspecting partners? (Dickens, 1990). If a duty to protect exists, it requires that the clinician act despite the preferences of the patient. It may require that the identity of the threatening patient be revealed to the endangered party. Thus, the duty to warn is in all fundamental respects different from voluntary contact tracing.

As clinicians and public-health officials confronted this issue, they were faced with a dilemma that was starkly presented in the landmark Tarasoff case, in which the California Supreme Court held that a psychotherapist had a duty to protect or warn the potential victims of a violent patient. If it became known that under some circumstances clinicians would breach confidentiality, would this inhibit patient candor? Would such a reduction in candor, if it occurred, deprive clinicians of the capacity to affect patients' behavior? In short, might the duty to warn ultimately subvert the very good it was designed to achieve—enhanced public safety?

Faced with this complex situation in the context of the AIDS epidemic, many state legislatures opted to grant physicians a "privilege to disclose," thus freeing them from Tarasoff-like liability if they did not warn, as well as from liability for breaching confidentiality if they did warn. In a striking reflection of the concerns about privacy provoked by the AIDS epidemic, a number of states have prohibited physicians who do warn third parties from revealing the patient's identity to those being notified.

### **Monitoring treatment: The case of directly observed therapy**

In the face of infectious disease threats, public health departments have at times been involved in attempting to certify that those who could spread disease had undergone appropriate treatment. Treatment in this instance had to be understood as serving both the interest of the individual as patient and the broader community that would be protected from the transmission of disease. As the example discussed below will demonstrate, however, treating those whose conditions were infectious might not be sufficient.

In the late 1980's and early 1990's, the resurgence of tuberculosis in the United States and the pattern of drug-resistance made it clear to public health officials that strategies for managing the disease had failed. Those who began treatment but did not complete their therapy not only ran the risk of reactivating their disease but of developing resistance that could be very costly to treat and, in the case of those with compromised immune systems, could prove fatal. And, of course, drug-resistant disease could be transmitted to others.

Among the strategies designed to enhance patient compliance with treatment is directly observed therapy, a practice that involves having the patient take his or her medication in the presence of health care providers or other responsible parties. First proposed for individuals with poor records of

treatment adherence and for those whose demographic or psychological profile suggested a higher prospect of failure, directly observed therapy (DOT) has emerged as the standard of care for all tuberculosis patients.

From an ethical, legal, and constitutional perspective, the important question posed by DOT is not who should be *offered* the support provided by such supervision but whether such monitoring can be *imposed*. And if DOT were to be imposed, how broadly should such requirements be extended? To the extent that DOT was selectively imposed, what procedures, guided by what standards of evidence, should be used? While there were many who argued for the selective use of DOT in the case of those likely to be nonadherent, in the early 1990s such a posture was increasingly viewed as inadequate to the challenges posed by tuberculosis. There was no evidence that physicians or other health care workers could predict which of their patients could be trusted to complete their treatment. Efforts to distinguish among patients, using social or demographic factors, not only were unsuccessful, they ran the risk of being invidiously discriminating. As a consequence the argument for universal DOT gained increasing support. Three veterans of public health work in TB thus wrote:

*We believe it is time for entirely intermittent directly observed treatment programs ... to be used for all patients. Some argue that it will be impossible to treat every patient with directly observed therapy and that many people with tuberculosis do comply with treatment and would be offended by having to submit to direct observation while they swallow medications. Unfortunately, the literature is replete with studies demonstrating that professionals are not able to distinguish the compliant from the noncompliant.<sup>6</sup>*

Given the price of failure in morbidity, mortality and the cost of treating resistant strains of TB, they concluded, "We cannot afford not to try it."<sup>7</sup>

Calls for universal directly observed therapy provoked sharp opposition. First, it was argued that such an effort would entail an enormous waste of scarce resources. Funds that could best be used to provide services to those most in need would be diverted by the provision of service to those who would be compliant on their own. But most critically, universal directly observed therapy was challenged as an unethical intrusion upon autonomy, as " gratuitously annoying," as a violation of the constitutional requirement that the least restrictive alternative be used, and as contrary to requirements of the Americans with Disabilities Act that decisions involving restrictions on those with disabilities be based on an individualized assessment. One opponent thus stated,

*I cannot see how mandatory directly observed therapy can be reconciled with the principle of the least restrictive alternative in the exercise of governmental power since it would require the imposition of the coercive treatment regime on a class of people without any showing that they, as individuals, will fail voluntarily to follow course of medical treatment. Nor does it comport with basic constitutional due process principles which require individualized determination when state sanctions are imposed.<sup>8</sup>*

Legal commentators have generally rejected mandatory DOT as overly broad and as violative of constitutional principles. However this opposition to universal DOT should not be construed as a rejection of a mandatory DOT in all cases. The advocates of patients' civil liberties accept mandatory, court ordered DOT in cases of clear noncompliance, especially when the alternative appears to be involuntary confinement.

The issue posed here, therefore, is not whether tuberculosis patients should have a choice about whether or not to undergo therapy—there is universal agreement that the threat posed to public health necessitates that all patients with infectious TB be treated. Nor is the issue whether tuberculosis patients who are no longer infectious should be required to undergo treatment until cured of their infection. There is universal agreement that the threat to the public health justifies that imposition as well. What is at the center of controversy is the nature and scope of the mechanism that should be employed to assure that those who are in treatment adhere to the course of therapy required for their own good and that of the community. As we turn to the issue of quarantine we will have an opportunity to explore the question of the context within which the state may exercise the authority to deprive someone of liberty because of noncompliance with their treatment.

## Quarantines

Ethical, legal, and constitutional principles have long recognized the authority of the state to confine individuals with dangerous infectious diseases because of the threat they posed to others. This power to deprive an individual of his or her liberty in the name of public health has vested public health officials with an authority that, from the perspective of the individual, may seem indistinguishable from that wielded by the criminal justice system. Yet, until relatively recently, the protections accorded to defendants in criminal prosecutions have not been extended to those viewed as a threat to the public health. As late as 1966 a California appellate court upheld the confinement of a TB patient pursuant to a statute that provided virtually no procedural protections for the patient. In its ruling, the court stated that regulations "enacted by the state under its police power and providing even drastic measures for the elimination of disease ... in a general way are not affected by provisions" of state or national constitutions.<sup>9</sup>

This broad deference to the legislature and to the exercise of public health powers would come to look archaic just a few years later as the jurisprudence of confinement underwent a radical revision in the wake of a series of far-reaching constitutional challenges to the power of the state to confine patients with psychiatric disorders. These cases, although framed in the language of law, embody important ethical considerations. In 1979 the Chief Justice of the Supreme Court would state in *Addington v. Texas*,

*This Court has repeatedly recognized that [confinement] for any purpose constitutes a significant deprivation of liberty and requires due process protection. Moreover it is indisputable that involuntary commitment to a mental hospital... can engender adverse social consequences to the individual. Whether we label this phenomena "stigma" or choose to call it something else is less important than that we recognize that it does occur and [has] a very significant impact on the individual.*<sup>10</sup>

In 1980 in the first reported appellate court decision upholding the procedural rights of tuberculosis patients, the Supreme Court of Appeals in West Virginia articulated a standard reflective of the U.S. Supreme Court's standards. The state's Tuberculosis Control Act was ruled unconstitutional because it did not guarantee the right to counsel, did not provide the right cross-examine, confront and present witnesses, and failed to hold the state to the stringent "clear and convincing" standard of proof required by the Supreme Court.

In 1993 when the Advisory Council on the Elimination of Tuberculosis recommended changes in state tuberculosis control laws it declared that commitment proceedings had to afford those who might be confined because of TB with a full range of procedural protections. Furthermore, in recognition of the liberty-depriving nature of compulsory hospitalization, the council asserted the importance of viewing such measures as a last resort after all less restrictive approaches had failed.

The council's incorporation of both procedural due process protections and the doctrine of the least restrictive alternative into its recommendations were specially crucial because it was calling for the expansion of existing tuberculosis laws to permit the involuntary isolation and detention of noninfectious patients who could not or would not adhere to regimens or to complete their TB therapy. This expansion in the conception of who posed a threat to the public health was driven by concerns about multi-drug-resistant tuberculosis and presented a move of great significance. No longer did the person to be confined have to represent an immediate threat of transmission, rather it was the prospect of reactivation and the prospect of the development of drug-resistance that provided the grounds for state intervention. Just as was the case with the IOM's call for mandatory prophylactic treatment of immigrants with latent TB infection, the concept of threat employed here was informed by population-based concerns. It was concern about the collective consequences permitting many individuals to conduct themselves in a way that posed some threat that motivated the extension of public health powers. This was a calculus far different from one that would center on the potential risk posed by a given individual.

In New York City, which confronted an outbreak of multi drug resistant tuberculosis (MDR-TB), the health department adopted regulations that permitted the confinement of those who it believed could not or would not complete their TB treatment. Among most significant features of those new regulations was a provision that would have permitted the imposition of quarantine even if the health authorities had not exhausted each and every element of the least restrictive approach. In the face of a public health threat officials asserted that they need not be required to wait for the patient to fail each set of interventions. In an ultimately unsuccessful challenge to these regulations civil liberties opponents sought to argue that while measures like those proposed by the municipal authorities might have been appropriate with contagious patients that was not the case with those whose TB was no longer infectious. Since there was no imminent risk in such situations it was more appropriate to protect the right of the patient against state authority.

Here again we can see how the concepts of risk, and of imminent risk, reflect more than a matter of measurement. As a trigger for state intervention, in this instance involving a deprivation of liberty, the concepts are suffused with moral considerations. In fact they compel us to confront the question of what threat, to whom, with what degree of certainty, and with what consequence all justify a limitation on freedom in the name of public health.

### **Vaccination Program**

To this point we have focused on public health interventions designed to discover or monitor infectious disease and prevent the spread of such conditions. It is now necessary to turn to the question of whether liberty-limiting interventions can be justified to prevent the spread of disease from those not yet infected and to protect those who might become infected in the future. These are the questions posed by compulsory vaccination programs.

In an analysis of the last phase of the smallpox eradication campaign in India a CDC officer assigned to the effort wrote,

*Infected villages were revisited—often repeatedly—to check [for cases that] had been left out. Almost invariably a chase or forcible vaccination ensued in such circumstances ... We considered the villagers to have an understandable but irrational fear of vaccination ... We just couldn't let people get smallpox and die needlessly. We went from door to door and when they ran, we chased. When they locked their doors, we broke down their doors and vaccinated."*

This striking description captures in an unvarnished way the extent to which concerns about disease prevention could provide a warrant for the untrammelled exercise of power. But even where the exercise of public health authority has not been used in so brutal a fashion, the history of vaccination is, in large measure, a history of the imposition of inoculations in the name of public health. In the United States, this issue was addressed by the U.S. Supreme Court in 1905. In a case noted in the introduction to this module *Jacobson v. Massachusetts*, the Court held,

In every well ordered society charged with the duty of conserving the safety of its members the right to the individual and respect of his liberty may, at times, under the pressure of great dangers, be subjected to such restraint to be enforced by reasonable regulations as the safety of the general public may demand.

Immunization in the United States has attained all-time highs. In 1998 the rates had reached 90% for 19- to 35-month-old children for most vaccines. To a very large extent this achievement can be viewed as a consequence of both persuasion—physicians routinely urge parents to immunize their children—and compulsion. All states require evidence of vaccination against a host of diseases including measles, polio and diphtheria. Children who are not immunized may not attend school or be registered in licensed day care centers. There are exceptions for religious reasons. 48 states permit parents to refuse immunization on religious grounds, and far fewer, 15 states, permit "philosophic exemptions." But such provisions affect only an extraordinarily small number of children. Nevertheless, it is worth thinking about the ethical justification for recognizing the religious and, for that matter, the broader philosophical exemption. At stake is the recognition that in matters touching on deeply held beliefs, the state should only with great reluctance intrude. But how much risk and to whom would be tolerable given such restraint? Do parents have a right to place their children at some risk by failing to immunize them? How much risk would be sufficient to tip the balance against parental religious beliefs? And what if the risk were not simply to the child but to others?

As a result of immunization programs diseases that were formerly a common occurrence among children have declined by well over 99 percent. For example in 1941 there were 890,000 cases of measles, and by the late 1990's the number had fallen to 89. In 1968 there were approximately 150,000 cases of mumps, by 1998 the number had fallen to 61. These achievements have, ironically, set the stage for the emergence of challenges to mandatory childhood vaccination.

As the experience of disease has receded, what has emerged is concern about the remote prospect of adverse reactions. With the possibility of disease so small why subject a child to any risk? The issue of vaccination places into sharp relief the clash between the rationality of public policy and rationality of decision making on the part of individuals for themselves or for those they have a duty to protect.

Because it involves children who cannot consent for themselves the issue of compulsory vaccination also raises questions about when the state may substitute its judgment for that of parents.

In an unusually thorough discussion of the ethical issues posed by childhood vaccination, Douglas Diekema and Edgar Marcuse have identified three broad questions that need to be considered:

First, do parents who withhold vaccination from their children harm them to such an extent that parental refusal ought to be overridden? Second, what duties do parents owe others in the community to avoid causing harm through an unvaccinated child? Third, does the social value of having a vaccinated population—for the sake of herd immunity and the eradication of disease—justify coercive efforts to vaccinate all children?<sup>12</sup>

In their analysis Diekema and Marcuse note that what makes the discussion of these linked questions so intriguing is the fact that immunization involves both a direct benefit to the individual child as well to those in the community who remain unimmunized who benefit from the immunization of the vast majority.

The question thus emerges of whether those who choose not to immunize their children and to rely on the benefits provided by herd immunity are "free riders"? From an ethical perspective the issue can be framed as one of justice and fair distribution of risks and benefits. Those parents who choose to immunize their children assume risks on behalf of the community that those who choose not to immunize can avoid. Finally, in this regard it is critical to recognize that the existence of free riders may erode the commitment to immunization, thus lowering the overall rate of protective coverage—undercutting the very foundations for herd immunity. Thus a paradox emerges: Herd immunity allows individuals to choose not to be vaccinated, but recognizing the right of parents not to vaccinate their children may subvert that very herd immunity.

The situation is somewhat different in cases such as measles, where immunization offers only imperfect protection. Thus the vaccinated remain at risk from the unimmunized who may develop disease. In such circumstances do the ethics of public health justify mandatory vaccination of all children for measles? What of the religious exemption?

## **Conclusion**

In the first years of the HIV epidemic it became a convention in AIDS advocacy and among some public health officials to assert that there was no tension between the claims of privacy and civil liberties on the one hand and public health on the other. The argument was that restrictions on rights were inevitably counterproductive to the pursuit of public health goals. It was with that perspective as a guiding principle that efforts were made to rethink public health practices that bore the imprint of their origins in the late 19th and early 20th centuries. Most provocatively this perspective informed the first formulations of the linkage between health and human rights. More radically, the human rights perspective, building on the long tradition of social medicine, underscored the extent to which the vulnerability to disease, including infectious disease, was rooted in poverty and social inequality. Tuberculosis provided the paradigmatic case. TB had declined in United States and elsewhere long before antibiotic treatment became available, and as Thomas McKeown had demonstrated, the fundamental cause of the decline of tuberculosis was the transformation of the social conditions under which people lived. Indeed tuberculosis in the contemporary period was largely restricted to the poor.

If health was in large measure a function of broad social conditions what role could be played by public health intervention? This is one of the great challenges of public health analysis. But to the extent that interventions are critical to protecting the public health, it is inevitable that decision makers will have to confront the question of how the interests and rights of the individual are to be balanced against the public good. Demonstrating the enduring nature of these issues is the very recent debate over the extent to which the threat of bioterrorism can justify the exercise of public health measures like name reporting, mandatory vaccination and quarantine in situations defined as a public health emergency. As should be clear, the very determination of what constitutes an emergency warranting such measures is more than a technical matter. It is suffused with value questions regarding the balance of risks and benefits, tolerable uncertainties, and our conceptions of rights.

In encountering these matters, careful ethical analysis can make a singular contribution to the practice of public health.

### **Cases In Infectious Disease**

The six case studies embedded in this essay that highlight critical ethical challenges in the ethics of infectious disease control are:

**1. *Screening for HIV infection and latent TB infection*** – Highlighting the tension between the integrity of the body and the imperatives of identifying those who harbor infections that may be transmitted to others.

**2. *Disease surveillance and the reporting of disease to public health registries*** – Highlighting the tension between the confidentiality of the doctor-patient relationship and the necessity to obtain accurate information about the incidence and prevalence of infectious disease.

**3. *Contact investigation and the duty to warn*** – Highlighting the tension between the desire of patients to maintain their privacy and the obligation of public health officials and others to want and protect those who may have been placed at risk.

**4. *Directly observed therapy for TB patients*** – Highlighting the right to refuse treatment and the risk poised by individuals whose untreated disease poses a risk to others.

**5. *Quarantine of individuals who could not or would not complete their TB treatment*** – Highlighting the tension between personal liberty and the *potential* risk posed by those with TB that has not been completely treated.

**6. *Mandatory childhood vaccination*** – Highlighting the tension between parental rights and the public health obligation to protect children from preventable disease and the public from infectious threats.

### **For Further Reading**

R. Bayer, *Private Acts, Social Consequences: AIDS and the Politics of Public Health*, Rutgers University Press, 1991 - Chapters 4, 5, 6.



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D. Diekema and E. Marcuse, "Ethical Issues in the Vaccination of Children," *Primum Non Nocere Today* (Elsevier, 1998), pp. 37-47.

S. King, "Vaccination Policies: Individual Rights v. Community Health," *BMJ* 319 (December 4, 1999): 1448-1449.

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<sup>1</sup> John Stuart Mill, *On Liberty* (Cambridge: Cambridge University Press, 1989), 13.

<sup>2</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)

<sup>3</sup> Cited in Merritt DJ: The Constitutional Balance Between Health and Liberty. *Hastings Center Report* 16: S2-10, 1986.

<sup>4</sup> Institute of Medicine, *Ending Neglect: The Elimination of Tuberculosis in the United States*, Washington DC: National Academy Press, 2000.

<sup>5</sup> Lawrence Gostin, "The Resurgent Tuberculosis Epidemic in the Era of AIDS: Reflections on Public Health, Law and Society," *Maryland Law Review* 54: 1-131.

<sup>6</sup> Michael D. Iseman, David L. Cohn, John A. Sbarbaro, "Directly Observed Treatment of Tuberculosis," *New England Journal of Medicine* 328;8 (1993): 576-578.

<sup>7</sup> *Ibid.*

<sup>8</sup> "Tuberculosis in the 1990s: Ethical, Legal and Public Policy Issues in Screening, Treatment, and the Protection of Those in Congregate facilities: A Report from the Working Group on TB and HIV." In United Hospital Fund of New York, *The Tuberculosis Revival: Individual Rights and Societal Obligations in a Time of AIDS* (1992). Dissent of David Hansell.

<sup>9</sup> *In re Halko*. 54 Cal. Report. 661 (1966)

<sup>10</sup> *Addington v. Texas*, 441 U.S. 418 (1979)

<sup>11</sup> Paul Greenough, "Intimidation, Coercion and Resistance in the Final Stages of the South Asian Smallpox Eradication Campaign, 1973-1975," *Social Science and Medicine* 41;5 (1995): 633-645.

<sup>12</sup> D. Diekema and E. Marcuse, "Ethical Issues in the Vaccination of Children," In *Primum Non Nocere Today* (New York: Elsevier, 1998), pp. 37-47.

## MODULE 6

### Ethics of Health Promotion and Disease Prevention

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*There is now widespread agreement among both the general population and health professionals that a good deal of disease is self-inflicted, the product of our own imprudent behavior. The premise that individuals contribute significantly to their own ill health or premature death appears unassailable in view of the mounting evidence relating various personal habits and lifestyle choices, such as poor nutrition, smoking, alcohol and drug abuse, failure to wear seat belts, and unsafe sexual practices, to major causes of morbidity and mortality.*

*While it is generally accepted that each of us is, to a certain extent, "dangerous to our own health," there is far less agreement on what can or should be done about making people less foolish. In particular, there is the question of how far government should go in fashioning lifestyles to minimize the physical and mental harm we inflict upon ourselves and others in society through risky personal choices. Where does personal choice and collective responsibility begin? How we reconcile two of our most prized social values, personal freedom and good health?*

—Howard M. Leichter, **Free to be Foolish.**

#### Introduction

The above-cited quotation sets the stage for the issues with which we will be concerned in this module. The issues posed can be reframed in the following way. What are the appropriate limits of the state in a liberal society in regulating, restricting or prohibiting behaviors that lead to premature morbidity and mortality; in shaping, molding or influencing the preferences and desires of its citizens; in protecting citizens from commercial influences that may encourage or sustain patterns of behavior that are antithetical to the goals of public health?

The contemporary discussion of these issues can be traced to a number of public reports that underscored the extent to which medicine can only play a limited role in affecting the patterns of morbidity and mortality in what was viewed as a post infectious disease society. In 1975 Marc LaLonde, Minister of Health for Canada, issued a landmark report, *A New Perspective on the Health of Canadians*, which boldly stated that unless the environment changed self-imposed risks reduced death rates could not be significantly improved. LaLonde was acutely aware of the ethical challenges posed by this orientation: "Whether and to what extent government can get into the business of modifying human behavior, even if it does so to improve health." These views and concerns were echoed in United States in the introduction to the 1979 Surgeon General's report *Healthy People*. Secretary Joseph Califano declared, "You the individual can do more for your own health and well-being than any doctor or hospital or exotic medical device." Like LaLonde, the Secretary underscored the ethical challenges signaling as well the treacherous political terrain. "There will be controversy—and there should be—

about what role government should play, if any, in urging citizens to give up their pleasurable but damaging habits. But there can be no denying the public consequences of those private habits. "

The scope and significance of the challenge posed by these public documents can most forcefully captured by the clash that emerged between those who saw in this new perspective a call for vigorous and legitimate governmental intervention and those who believed that represented the public health version of victim blaming.

No one more forcefully took up the banner for behavior change than John Knowles, a physician and Rockefeller Foundation president. In a widely read essay entitled "The Responsibility of the Individual" he took the opportunity to challenge a culture that fostered behaviors that caused illness and premature death:

*The idea of individual responsibility has been submerged in individual rights or demands to be guaranteed by government and delivered by public and private institutions. The cost of sloth, gluttony, alcoholic intemperance, reckless driving, sexual frenzy and smoking is now a national and not an individual responsibility. This is justified as individual freedom—[but] freedom in health is another man's shackle in taxes and insurance premiums. I believe the idea of a "right" to health [ought to be replaced by an] obligation to preserve one's health—a public duty if you will.*

These claims, which despite some recognition of the way in which broad social and institutional forces affected behavior, laid much of the responsibility for such actions on the individual. As a consequence they were viewed by many as an ideological strategy for relieving government of the obligation to assure the conditions of health or provide health care services to those were ill. It was a perspective, the critics noted, that despite the apparent attention to social conditions, tended to conceptualize behavior as the outcome of individual choices. Thus those who behaved foolishly had only themselves to blame for their condition. Finally, critics noted that the assertion that individuals had an obligation to be healthy had profoundly troubling implications. Just what was the source of this duty? Did each of us have an obligation to behave in every way possible to foster society's economic and social well-being? If there was a duty to be healthy was there also a duty to be productive?

However one framed the general issue, whether one saw the behaviors as a consequence of choice or as socially embedded, it was critical, as noted at the outset of this module, to confront the question of the role of the state. Because of the profound influence of individualism in American culture and politics it would be useful to begin this discussion with an oft quoted passage from John Stuart Mill's essay *On Liberty* where we encounter a robust defense of the individual against intrusions by the state.

*The only purpose for which power can be rightfully exercised over any member of the civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because in the opinion of others to do so would be wise or even right. These are good reasons for remonstrating with him or reasoning with him or persuading him or entreating him [but not for] compelling or visiting him with any evil in case he do otherwise. To justified that, the conduct from which it is desired to deter him must be calculated to produce evil to someone else. The only part of the conduct of anyone, for which he is amenable to society, is that which concerns others. In the part which*

*merely concerns himself, his independence is, of right, absolute. Over himself, over its own body and mind, the individual is sovereign.*

Before proceeding, it is crucial to understand the conceptual distinction being made by Mill. The target of his animus is paternalism—the attempt to impose limitations upon someone or to require actions by someone for his or her own good. Such impositions can be justified in two circumstances: (1) with children because it is assumed that they are incapable of deciding on their own behalf; and (2) with those who because of cognitive limitations cannot choose on their own behalf. The one exception that Mill makes only serves to underscore his position: one cannot sell oneself into slavery. One cannot do something that would forever preclude the exercise of one's freedom. (It is worth noting here that some have used this exception as providing a justification for paternalistic intrusions designed to prevent individuals from using addictive drugs or even smoking cigarettes. How far such an exception would go in eviscerating Mill's strong position on liberty is worth bearing in mind throughout this module.)

By contrast intervention is justified for Mill when one acts in a way that may pose a harm to others. Other-regarding harms are the appropriate target of government regulation. The shorthand for this justification has come to be known as the "harm principle." Conventionally put the principle asserts "your freedom to swing your arm ends where my nose begins." This apparently straightforward formulation opens the way to a series of questions involving the nature of harms that may be prevented. While the bodily injury entailed in a blow to the nose is clearly a harm for Mill, what about an injury that is threatened, one that is possible, or only remotely so, one that is merely statistical, smoking in an open-air café, for example? What if the potential harm involves an annoyance, for example the smell of smoke in an open-air stadium? What if an act that is self-regarding in terms of injury is other-regarding in terms of economic costs, for example smoking alone? The point here is to underscore the extent to which Mill's formulation can either serve to impose radical limits on what government can do in the name of public health, or if very broadly interpreted open the way to kind of interventions that would for all practical purposes eliminate the distinction between the realm of the private and social, between the self regarding and other regarding? After all, in a highly integrated society what action does anyone take that does not *ultimately* have an impact on "society"?

If Mill's antagonism to paternalism is understood as imposing severe limits on governmental intervention can it serve as a basis for an ethics of public health? If Mill's doctrine is very broadly construed does it compel justifications for public health that ultimately involve gross contortions, finding harms to others when they can only remotely be understood as such? In this module we will note how on several occasions the need to avoid the appearance of paternalism shaped and distorted justifications for state intervention in the name of public health. The alternative would be to embrace paternalism explicitly as a core value of public health. While such a strategy might be politically untenable it would open the way to a more candid discussion of the extent to which communal well being justifies limits on behaviors that impose harms to individuals themselves and only secondarily on others. That is the strategy adopted by philosopher Robert Goodin.

*We do not leave it to the discretion of consumers, however well informed, whether or not to drink grossly polluted water, ingest grossly contaminated foods, or inject grossly dangerous drugs. We simply prohibit such things on grounds of public health ... to a very large extent ... the justification of public health measures, in general, must be baldly paternalistic. Their fundamental point is to promote the well-being of people who might otherwise be inclined cavalierly to court certain sorts of diseases.*

Goodin's posture represents a bracing corrective and while he is acute in pointing out that instances of public health paternalism abound it is remarkable how often efforts are made to mask such interventions as ultimately involving the protection of third parties. This was the case as we will see below in the discussion of mandatory seat belt laws.

It is worth noting here that despite Goodin's embrace of public health paternalism he is quick to underscore that it is a "weak" form of paternalism that he advocates. He argues that in a fundamental sense his paternalism takes the most basic preference of individuals to live long and well as its starting point. It simply seeks to impose on the reluctant or the foolish interventions designed to secure those ends. "It is one thing to stop people who want to commit suicide from doing so," he writes, "but quite another to stop people who want to live acting away that they falsely believed to be safe." Provocative though this distinction may be, we should note that it provides a justification for paternalism that is breathtaking in its scope. Since we all want to be happy, fulfilled, healthy, what government intrusion could not be termed a "weak" form of paternalism? Is there something here that is akin to the paradoxical question asked in political philosophy "Can someone be forced to be free?"

With these preliminary observations in place, it is now possible to confront the ethical issues posed by government effort to affect behavior in name of public health. In this module we will examine efforts involving health communication campaigns (and censorship), taxation designed to discourage consumption, and prohibitions or mandates on certain behaviors. In each case we will be concerned with the impact on individual liberty as well as fairness of burdens.

### **Health communication campaigns and the censorship of advertising**

Health communication campaigns that discourage certain activities or encourage the adoption of others are the most common form of intervention designed to promote healthy behavior. They would at first appear to pose no ethical challenges. They provide needed information and thus enhance personal autonomy in the face of health risks. They may affect behavior that produces health related burdens for society. Thus such campaigns may limit the extent to which community may be compelled to tolerate negative externalities generated by those who engage in activities linked epidemiologically to morbidity and mortality. Finally, at an expressive level such efforts represent a public demonstration of the community's concern for the health and well-being of its members.

Yet even such interventions may raise troubling issues. Messages targeted at those most at risk may open the way to stigmatization and hence to the imposition of inequitable burdens. Two examples illustrate this point. In the context of the AIDS epidemic efforts to counter the tendency toward marginalization of those most at risk led to the creation of campaigns that suggested that everyone was at risk for HIV infection. While technically and biologically correct the campaign represented an epidemiological misstatement. In this instance a decision had been made to sacrifice veracity and perhaps effectiveness to protecting those most at risk for stigmatization. Was this determination to protect ethically warranted? The second case involved decision made by the New York State Health Department to require the posting of warnings at bars about the potential hazards of alcohol consumption during pregnancy. That rather straightforward effort to inform was greeted with dismay and hostility by advocates of women's rights who saw this health information message as stigmatizing, as reflective of a paternalistic assumption that women did not know what was in their best interest and the interest of their fetuses, as an invitation to meddling by bartenders and patrons. Were such

concerns of sufficient merit to warrant the scuttling of an effort that was viewed as pertinent to the public health?

In large measure critiques of health communication campaigns have centered primarily on the extent to which they have been understood to be a substitute for more effective public health interventions. But health communication campaigns can be successful. We know that the cumulative impact of many efforts over time is enhanced when novel messages, conveyed in a variety of media, have been supplemented by more personal interventions. Can such campaigns be too successful? Can they undermine autonomy by their efforts to reform the way in which we think about our health-related preferences? It is a striking feature of American fear regarding governmental intrusions that concern has been generated for some by the mere prospect of successful state sponsored programs to influence health-related behaviors. For commercial advertisers to advance exaggerated claims is almost expected. But were government to engage in similar levels of exaggeration, even in the name of public health, fears of unwarranted and dangerous manipulation would abound. Such reactions, if taken seriously, could place public health education campaigns at a disadvantage.

In light of these considerations is worth thinking about the ethics of social marketing. Is not surprising that public health officials have come to recognize that they had much to learn from the advertising industry. After all, years of efforts had created a vast industry designed to understand the wellsprings of motivation that could be tapped to encourage the purchase of products through the creation or manipulation of desire. If, for example, advertising could convince adolescents around the world that they wanted and needed Nike running shoes could they not be convinced that cigarette smoking was bad? Could not the manipulative capacity of advertising be mobilized for public health goals?

Whatever the answer to those questions will be--and the challenges of using advertising for public health goals may be substantial--social marketing raises critical ethical issues. Is the subversion of autonomy implicit in the manipulation of desire and preference ever justifiable? Can the protection of individuals from the manipulative activity of commercial advertisers justify counter-manipulation in the name of public health? Does such manipulation simply attempt to level the playing field? And does such an effort at balancing provided the ethical warrant for what otherwise might be considered morally troubling?

But if efforts at public health education raise important ethical challenges proposals to restrict advertising in the name of public health pose direct questions about the relationship between the community's well-being and freedom of expression. Here a discussion of the ethics of public health must inevitably engage American constitutional law. We will approach this issue through the case of proposed bans on cigarette advertising.

Efforts to impose radical restrictions--and even total bans--on cigarette advertising emerged in the mid-1980s. These initiatives had to confront an evolving constitutional debate over the extent to which commercial speech should be accorded protections under the First Amendment. In 1986 the American Medical Association called for a total ban on cigarette advertising and promotion and in so doing joined the American Heart Association and American Lung Association. In testimony before Congress the American Public Health Association stated, "Advertisements should be to promote good health products and not products that kill."

While proponents of the ban on all cigarette advertising and promotion sought to ground their arguments in a uniquely dreadful consequences of the sale and consumption of tobacco products many who opposed such efforts centered their claims on the uniquely important role of the First Amendment in American political culture. While the former believed it possible to prohibit advertising of cigarettes without unraveling the fabric of freedom of expression, even for commercial speech, the latter saw freedom as indivisible.

While support for an outright ban on advertising gained strength in the 1980's there was little evidence that such a move had anything like the necessary political support. It would require a reframing of the issue to make the call for restrictions more politically potent. That reframing gradually took place in the 1990's as the argument for restricting advertising and promotion increasingly focused on protection of children. At the heart of this reorientation was a pair of linked claims, one moral the other empirical. Children and young adolescents were incapable of making determinations on their own behalf and needed protection from manipulation by those who sought to stimulate their desires for harmful goods. Whatever the limits of paternalism in a liberal society, the exercise of the state's protective authority was certainly appropriate with those below the age of consent. Since cigarette smoking once commenced, was driven by the addictive power of nicotine, the exercise of restrictive and protective authority to prevent smoking was morally justified. That such measures would indirectly impose limits on advertising and promotion viewed by adults was a price worth paying.

The struggle between proponents of restrictions on tobacco advertising and advocates of First Amendment protection of such "speech" was played out against an ongoing controversy over the potential efficacy of advertising bans. The debate had both practical and constitutional implications. Certainly restrictions on advertising directed at youths could only be justified if, in fact, they affected patterns smoking. From a constitutional perspective the issue was crucial. The Supreme Court's jurisprudence on commercial speech restrictions stipulated that no matter how narrowly tailored, limitations could not pass muster if there was no evidence that they could achieve their goal. And here it is remarkable to note that despite decades of agitation for restrictions on advertising by public health advocates the evidence of efficacy had been very limited. This is the backdrop to the Supreme Court case *Lorillard vs. Massachusetts* decided in 2001. In that critically important case the Supreme Court stated that Massachusetts had failed to bear the burden of demonstrating that its restrictions on outdoor advertising designed to protect children would in fact achieve their goal. Hence there emerges a paradox: narrowly tailored restrictions on advertising designed to protect children are unlikely to be effective; those that might be effective are unlikely to pass constitutional muster.

It is here that we need to confront a critical set of ethical questions. Is it true that a vibrant democratic culture requires unfettered commercial speech? Is the protection of children through measures that burden the rights of adults morally acceptable? And perhaps most pertinent do adults have a right to be protected from the seductions offered by advertising? In short, questions of advertising restrictions force us to confront the limits of paternalism.

### **The wages of sin: taxes, consumption and the public health**

Given the focus of public discussion on the economic consequences of the relationship of personal behavior to morbidity and mortality it is not surprising that considerable theoretical attention has been devoted to the role of taxes as a critical element in health promotion efforts. Much of the concern has centered upon the issue of negative externalities, including the cost of health care and lost productivity.

Thus it was only natural that proposals were made to recapture those costs through excise taxes applied to products directly implicated in disease and early death.

From the point of view of economics such taxes would correct for market imperfections. They would pass on to consumers the true cost of their behaviors by having the price of a dangerous product reflect the costs imposed on society by the consumption of such a product. From an ethical point of view efforts were made to justify such taxes as central to a more equitable distribution of the burdens associated with certain behaviors. On the other hand, since excise taxes are always regressive, burdening the consumption options of the poor more than the well-off, it was argued that such levies rather than enhancing fairness would generate inequity.

The imposition of taxes in excess of those justified by calculable negative externalities, those downstream burdens that others are compelled to bear as a result of one's behavior, would require arguments that went beyond the claims of society in the face of such costs. Such efforts would entail paternalistic imposts designed to reduce consumption patterns deemed undesirable from the perspective of public health. Indeed such taxes drew the ire of J.S. Mill. In writing about proposals to tax alcohol in the 19th century he stated, "To tax stimulants for the sole purpose of making them more difficult to be obtained is a measure differing only in degree from their entire prohibition." We will discuss the issues posed here by the example of cigarette excise taxes.

It was not until the mid-1980s that the idea of using the power to tax emerged as a central feature of the anti tobacco campaign in United States. Faced with a challenge of affecting mass behavior public health advocates concluded that a substantial increase in tobacco excise taxes might be the most effective measure that state and local governments could take to advance public health. As the issue was joined it became necessary to address a host of both technical and moral issues: How would price increases affect the consumption of an addictive product? What was the elasticity of demand for cigarettes among those who might be poised to begin smoking, young smokers, those who had smoked for years? Would such excise taxes be inherently regressive and therefore inequitable? Did smokers impose collective burdens on nonsmokers because of the medical costs they incurred and did equity justify or require the internalization of such negative externalities? Was the imposition of excise taxes on cigarettes, at least in some part, an act of paternalism designed to place economic burdens on smokers in order to enhance the prospect of quitting? And if so was such paternalism morally justified?

Despite the recognition that increases in cigarette taxes could have a direct impact on tobacco consumption the public justification for such levies very quickly began to center on the social costs of smoking. Thus, for example, when California voters were asked to consider a ballot proposition that would have increased the cost of cigarettes by 25¢ a pack a coalition supporting the new tax declared: "The tobacco companies have said that a tax is unfair that taxes only smokers .... We say that for many years it was unfair that nonsmokers to have had to subsidize the smokers relative to their increased costs of medical care." The advocates of the proposed tax increase provided a second justification, one that focused on the need to protect those who were the appropriate targets of paternalistic intervention. The new resources generated by the levy would provide funds to educate children about the dangers of smoking. Furthermore increased prices for cigarettes would raise the barrier to consumption by children and adolescents. Taxes might be more effective than the already existent legal prohibitions on such sales.



A powerful indication of the extent to which tobacco activists wanted to avoid the taint of paternalism was the following observation made by Kenneth Warner, an economist and longtime proponent of aggressive anti-tobacco efforts on the part of government. Were taxes, he said, a way of asserting that "we know better than you" and that "we don't want people doing things the bad for themselves" he would oppose them. But taxes were not about protecting adults from their own choices but were rather a matter "discouraging children, the next generation from initiating its tobacco addiction."

Central to the moral arguments of the social costs of tobacco addiction were a set of assumptions about how smoking increased the cost health care. The evidence would, however, ultimately suggest that given the premature mortality associated with smoking the social cost argument far from definitive. Early death reduced social security payments, expenditures on nursing home care, and medical care late in life. Indeed by the year 2000 Kenneth Warner declared that claims that smoking clearly imposed costs on society in terms of expenditures was a "myth." In the end then a central justification for increasing taxes was brought into question. What remained was the claim that higher prices protected children. And once again the question posed for the ethics and public health would be on the extent to which the invocation of child protection could serve as the engine force for broad public health policies.

By the turn of the 21st century in a climate suffused with neo-prohibitionist trends regarding tobacco, it was, of course, possible to press for steeply increased cigarette taxes for purely fiscal reasons--increasingly burdening through a sin tax a product subject to wide scale marginalization.

It was a trend toward higher taxes and prices and the changing demography of smoking in America that provided the context for a question regarding equity and public health. Cigarette smoking by the end of a 20th-century was increasingly a behavior of the less educated and the less affluent. There was, in fact, a steep social gradient inversely relating smoking and class. Excise taxes that were, by definition, regressive were being borne by those least able to pay. Was such a burden inequitable or did it, precisely because of its potential impact on consumption, ultimately serve the interests of the least advantaged. If it did so, was the imposition of such burdens an expression of paternalism. Was such paternalism justified? Did the right to take risks, or enjoy dangers, and pleasures, without the intrusive concern of the state make such intrusions unacceptable?

Increased prices, unlike direct prohibitions ultimately leave to the consumer the choice of whether or not to purchase a product. Because they permit such choices while imposing burdens expressed through the market some have viewed them as a less troubling paternalism. But, at the end of the day, for those who must pay is such paternalism in fact less troubling? And while the case of tobacco may seem an especially appropriate target for health-inspired taxes would the extension of levies to high-fat foods sold by McDonald's, for example, be morally acceptable? To the extent that current policy does not cover all products linked morbidity and mortality can we conclude that the decisions are reflective of the pattern of an invidious discrimination, even moralism, masquerading as public health?

### **Restrictions, prohibitions, and mandatory behavior**

Whatever the ethical challenges posed by health education campaigns or by the use of the excise taxes they do preserve a realm of choice and hence avoid some of the obloquy that attends policies that unambiguously impose penalties for failing to behave in prescribed ways or for behaving in ways that have been proscribed. Prohibitions evoke the specter of Big Brother and of America's "noble experiment" with alcohol. Yet on a broad range paternalistic public health regulations are an accepted

part of contemporary life. Prohibitions on the sale or prescription of many intoxicating substances are challenged only by libertarians opposed, in principle, to any but the most limited restrictions on individual liberty. Pure food and drug laws, as well as legislation governing the use of potentially carcinogenic food additives are not only rarely opposed but often demanded by those committed to public health despite the clear impingement on liberty and autonomy of potential consumers.

It is only when government seeks to restrict the availability of a product well integrated into the social fabric, or when it plans to mandate behavior that is not already required that the ensuing controversy brings to the fore the ethical issues that undergird even the most widely accepted practices.

The debate surrounding mandatory motorcycle helmet laws, which occurred more than three decades ago, provides a unique window on the extent to which explicitly paternalistic measures can encounter opposition and as a consequence require justifications compatible with the individualistic trends in American culture. Hence the case remains of enduring significance. Stephen Teret has provided an analysis of the saga. In the nine years following the decision of the federal government to link highway funds to the enactment of mandatory motorcycle helmet laws, 49 states adopted the mandated requirements. Only California refused to do so. Utah limited the statutory requirements to highways on which travel exceeded 35 miles per hour.

Despite the vehement opposition to the statutes by representatives of cycling groups compliance with helmet requirements was nearly universal. As a consequence, deaths from motorcycle accidents declined dramatically. But because motorcyclists viewed mandatory helmet laws as unacceptable, a violation of their civil liberties, an intrusion upon their autonomy, and an example of unjustifiable paternalism, they brought suit in state after state challenging the constitutionality of the statutes. Only in Illinois did the court hold mandatory helmet laws unconstitutional. In one case that was pursued to the U.S. Supreme Court, the nation's highest tribunal refused to overturn a U.S. District Court holding that government could legitimately compel the use of helmets.

In their decisions, courts tended to avoid justifications that suggested a warrant for paternalistic intervention. Rather, they sought to demonstrate that the social impact of private behavior provided ample justification. Characteristic was the language used by a U.S. District Court in Massachusetts

From the moment of injury [society] picks the person up of the highway; delivers him to a municipal hospital and municipal doctors; provides him with unemployment compensation if, after recovery, he cannot replace his lost job; and if the injury causes permanent disability, may assume the responsibility for his and his family's continued assistance. We do not understand the state of mind that permits the plaintiff to think that only he himself is concerned.

Here in unvarnished words was a justification that relied on the harm principle conceptualized in terms of social costs. Strikingly absent was the will to assert that it was a legitimate social interest to protect motorcyclists from their own imprudent choices, a justification that might have articulated society's interest in preventing death and suffering regardless of its social costs.

What opponents of motorcycle laws had failed to do in the courts they succeeded in accomplishing in the Congress. The Secretary of Transportation was forbidden from using the power of the purse to force the states to impose protective requirements on motorcycles. Within three years of the 1976 congressional action 27 states had repealed their laws. As a consequence motorcycle helmet use

declined by 40 percent in the repeal states. The mortality toll began to rise in terms of medical expenses and lost productivity. So too did the toll in human suffering.

Here again we must address a set of critical ethical challenges: When can the state do just what Mill decried? Is an ethics of public health, focused on the well-being of populations, compatible with a Millian liberalism? How should we think about strained claims about third party costs and harms? When such claims are made despite the fact that they mask the true purpose of policy do they corrupt the discourse on public health? Would a public health that explicitly acknowledged the paternalism inherent in policy be more desirable or does such reluctance in fact serve important social functions?

## Conclusions

A theme that runs through virtually every policy debate involving health promotion and disease prevention is the fear of the slippery slope. If the state is justified in imposing limits on smoking or requiring motorcyclists to wear helmets will that inevitably open the way to a cascade of intrusions--some petty, some truly burdensome. Does the logic of public policy dictate that once the first step is taken down the road to paternalism there is no stopping point? Does consistency demand of a state that imposes restrictions on smoking that it impose restrictions on French fried potatoes because their fatty nature threatens health as well? On the number of hours each of us devotes to exercise? Alternately, is it possible that the invocation of the slippery slope rather than revealing an important truth represents a barrier to reflective consideration of the ethics of public health?

## Cases in Health Promotion and Disease Prevention

**1. *Health Communication Campaigns and the Censorship of Advertising*** – Using the case of tobacco highlights the tension between robust conceptions of freedom of expression and the claims that the protection of the public health requires bans or restrictions on advertising that may stimulate the consumption of tobacco products.

**2. *Taxes, Consumption and the Public Health*** – Increasing taxes on cigarettes to limit consumption highlights the tension between the claim that individuals have a right to purchase products that give them pleasure even if they produce illness and the public health claim that there is an obligation to inhibit behaviors that can predictably be the cause of morbidity and mortality. In this instance, the tax-induced increase in prices does not represent a prohibition but the creation of an economic burden that leaves individuals formally free to choose.

**3. *Mandatory Motorcycle Helmet Laws*** – This case places into bold relief the assertion that the protection of the public health, as represented in decreases in morbidity and mortality, may justify the imposition of outright prohibitions designed to protect individuals from their foolish choices, choices that incidentally may also produce burdens on society.

## For Further Reading

D. Beauchamp, "Community: the Neglected Tradition of Public Health," *Hastings Center Report* (December 1985) 28-36.

J. Moreno, R. Bayer, "The Limits of the Ledger in Public Health Promotion," *Hastings Center Report* (December 1985) 37-41.

R. Crawford, "You are Dangerous to Your Health: The Ideology and Politics of Victim Blaming," *International Journal of Health Services* 7 (1977) 633-680.

H. Leichter, "Saving Lives and Protecting Liberty: A Comparative Study of Seat Belt Debates," *Journal of Health Politics, Policy and Law* (Summer 1986) 323-344.

R. Goodin, *No Smoking* (Chicago: University of Chicago Press, 1989), Chapters 1 and 2.

R. Bayer, L. Gostin, G. Javitt, A. Brandt, "Tobacco Advertising in the United States: A Proposal for a Constitutionally Acceptable Form of Regulation," *Journal of the American Medical Association* 287; 22 (2002): 2990-2995.

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## **MODULE 7**

### **Ethical Issues in Environmental and Occupational Health**

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#### **Issue Essay**

US physicist Alvin Weinberg (1988) claims that today's environmental-health problems are relatively trivial. Although many aspects of human well being are influenced by the environment, Weinberg says that environmental-health problems (such as liquid and airborne wastes, stresses in the workplace, and unsafe food) are sensationalized by the hypochondria of laypeople. Weinberg believes that these contemporary hypochondriacs are driven by an hysteria analogous to the irrationality that drove fourteenth- and fifteenth-century witch hunts. Just as people eventually learned that witches did not cause misfortunes, Weinberg claims that the public must learn that various environmental problems do not cause the public-health problems often attributed to them. He says the public needs to come to its senses, just as those who killed more than a million alleged witches eventually came to their senses.

Public-interest activist and attorney Ralph Nader, however, thinks Weinberg is wrong (Nader 2000). He believes that many of today's public-health problems are substantial, increasing, and largely environmentally induced. The culprit behind this "corporate cancer," Nader believes, is the profit motive. Labor leader Sheldon Samuels (1988) agrees with Nader and claims that workplace health problems are increasing, largely because of an "industrial cannibalism," industries' killing their own workers in order to save money on pollution control.

#### **Background**

Who is right about environmental-health threats, the Alvin Weinbergs or the Ralph Naders of the world? Are environmental-health risks minimal, but fueled by public ignorance and hypochondria? Or are environmental-health risks massive, but covered up by vested interests attempting to reduce manufacturing costs? To answer these questions, it is important to examine environmental-health problems faced by at least three distinct groups--workers, the public, and the poor or members of minority groups.

Medical doctors long have realized that workers face special public-health threats as a consequence of workplace exposure to various environmental hazards. In 1472 a German booklet warned goldsmiths how to avoid poisoning by mercury and lead. And in 1556, the mineralogist Agricola wrote the first known review of miners' health problems. He noted that some women who lived near the mines of the Carpathian Mountains in Eastern Europe had lost seven successive husbands to mine-related accidents and diseases. Pleading with employers to make workplaces safer, in 1700 Italian physician Ramazzini wrote *Diseases of Workers* (Shrader-Frechette 2002, ch. 7).

More than two centuries ago, Percival Pott linked coal tars to the scrotal cancer that killed young chimney sweeps in England. Yet today thousands of coke-oven workers in steel mills around the world continue to inhale the same deadly substances, and they are dying of cancer at 10 times the rate of other

steel workers (Leigh 1995). Even in nations like the US, annual occupation-related deaths are approximately five times greater than those caused by the illegal drug trade and approximately four times greater than those caused by AIDS (Leigh 1995). A later case study will examine whether occupational health is getting better or worse and whether the current state of occupational health raises any important ethical issues, such as consent to higher workplace risks, that ought to be addressed.

In the area of public health, obviously environmental threats are being reduced, as compared to several centuries ago. In the middle 1800s communities in most nations established Departments of Public Health to monitor and regulate the health effects from environmental contamination such as polluted water. While progress in environmental health is obvious, it is less clear that some areas of environmental health are improving. For example, the World Health Organization claims that pesticide poisonings, especially in developing nations, annually cause about 50,000 deaths (Matthews *et al.* 1986). And the US Office of Technology Assessment asserts that up to 90 percent of all cancers are “environmentally induced and theoretically preventable” (Lashoff *et al.* 1981, pp. 3, 6 ff.). Experts agree that roughly one third of all cancers are caused by cigarette smoking (National Cancer Institute 1994), but they disagree about the causes of the remaining cancers. Some say a major culprit is industrial pollution, given that the cancer rate tends to track the rate of industrialization throughout the world (Epstein 1998; Walker 1998). Others say the greater culprit is lifestyle, such as eating too much fat, while still other medical experts say the predominant cause of cancer is genetic (Ames and Gold 2000). They point to the BRCA1 and BRCA2 genes thought responsible for 5 to 10 percent of all breast cancers. Whoever is right, the stakes are high. According to the National Institutes of Health, more Americans die each year from environmentally induced cancer than from murder. Cancer incidence in the US is increasing six times faster than overall cancer mortality is decreasing (National Institutes of Health 2000). A later case study will examine whether the cancer rate can be attributed, in large part, to environmental factors and whether there are ethical grounds, such as the right to life, and the right to equal protection, for additional investigation and regulation of these factors.

The environmental health of minorities and poor people is perhaps even more problematic than that of either workers or the public generally. A recent article (Navarro 1990) in *Lancet* pointed out that on average whites live 6 years longer than African-Americans in the US. The essay also noted that, for most causes of death, the mortality differentials between the two groups is increasing, not decreasing. Even worse, the article charged, is that the US is the only western developed nation whose government does not collect mortality statistics by class, that is, by income and education. When the author looked at class-based mortality data for the only diseases (heart and cerebrovascular ailments) on which the US government collects class-related information, the class data showed an even wider disparity than the race data. If the author is correct, then the public health of poor and minorities is getting worse and may point to crucial inequities in society. A later case study will examine allegations of greater numbers of environmentally-induced health threats among poor and minorities, that is, instances of alleged environmental racism or environmental injustice. It will also investigate whether there are ethical grounds for additional investigation and regulation of factors affecting the health of poor people and minorities.

### **State of the Debate**

The current debate over environmental threats to occupational, public, and minority health focuses both on the scientific facts (the magnitude of health risk) and on the ethical issues associated with those

facts. Normative controversies concern both the *content* of the ethical principles that should govern policy and decisions about environmental health and the scientific and evaluation *methods* that are most ethically defensible. Conflicts over the content of ethical norms focus on issues such as (1) rights to know, (2) autonomy and free informed consent, (3) equality, especially equal protection from environmental-health risks, and (4) due process. Controversies over the methods appropriate to ethical evaluation of environmental health focus on (5) the burden of proof, (6) stakeholder representation in environmental-health decisions, and (7) the legitimacy of using risk assessment and benefit-cost analysis in ethical evaluation of environmental-health problems.

Debates over (1) rights to know particular environmental threats to public health usually pit commercial interests against medical interests. On the one side, market proponents, like advocates of the World Trade Organization, argue that requirement of full labeling of food products, for example, regarding the presence of possible pesticides or growth hormones, amounts to an infringement on free trade (Hoekman and Mattoo 2002). They also claim that such labels put some manufacturers (who use more pesticides or growth hormones, for example) at an unfair competitive advantage, relative to manufacturers who do not use the pesticides or hormones. On the other side, public-interest groups, like the nongovernmental organization (NGO), Public Citizen, argue that all consumers have the right to know exactly what they are purchasing (Wallach and Sforza 1999). They also maintain that even Adam Smith argued that markets could be free and competitive only if there were full information available to consumers.

With respect to (2) autonomy and free informed consent, often the debate focuses on what serves the common good, versus what serves some private good or an individual's right to self-determination. On the one hand, many people (like businessman Peter Drucker (1991)) maintain that allowing free informed consent to every potential victim of an environmental health threat would be extraordinarily inefficient and might even lessen economic progress and thus harm the common good. They say that if most residents had to give free informed consent to siting a polluting facility nearby, then very few needed facilities could ever be sited, and the consequences would be economically disastrous, would harm the common good.

On the other hand, medical ethicists, like Tom Beauchamp and James Childress (1994, pp. 142 ff.), point to the fact that, as a result of the Nuremberg Accords, it is not permissible to experiment on anyone without his consent, and involuntary exposure to pollution may amount to an experimentation on people and to a potential violation of their rights to life. Arguing for free informed consent, advocates also note that typically pollution can be reduced to a level according to which it is easy to obtain free informed consent of exposed people, but that often industry is unwilling to pay the costs of reducing pollution. In such cases, some ethicists argue for expanding regulations that might help guarantee free informed consent to environmental-health risks (Cranor 1994).

Controversies over (3) equality, especially equal protection against threats to environmental-health risks, typically focus on whether decisions about environmental health should aim to maximize overall welfare, as utilitarians might propose, or on whether they should aim to ensure equal treatment among people, as egalitarians claim. Those, like economist John Harsanyi, who would likely find nothing reprehensible about siting most hazardous waste dumps in consenting minority communities, for example, typically maintain that the overall welfare of such communities can be improved because of such decisions (Harsanyi 1975, pp. 594-600). They say that increased support for the local tax base and



growth in jobs, available at the dumps, could offset any alleged inequality in the imposition of environmental health risks. They note that a bloody loaf of bread is better than no loaf at all.

However, those who are worried about equal protection, like philosopher John Rawls (1971), maintain that any choice (about siting most dumps in consenting minority communities) is unethical if it forces people to jeopardize their health, relative to others, because of factors that are largely beyond their control. Such inequality in imposing environmental-health risks, say egalitarians, also is inequitable because people are not really free to reject it, if they are powerless politically and economically, or if they must jeopardize their health in exchange for other basic necessities of life. Moreover, egalitarians argue that because rights to life, and to equal protection from environmental-health threats, are necessary for the exercise of civil liberties and for fulfilling the conditions of human life, people ought not be forced to give up such rights and protections.

If people are put at risk by an environmental threat to their health, ethicists also are divided on the issue of (4) due process and what, if anything, they deserve as compensation. On the one hand, more utilitarian (those who maximize overall average welfare) thinkers, like physicist Harold Lewis (1990), maintain that if people were allowed to exercise their due-process rights and were able to sue every source of potential health problems, then many societal resources would be wasted in lawsuits, and overall societal good would not be served. Moreover, they say that the burden of environmental health threats already is spread rather evenly to citizens, and therefore no one is put substantially more at risk than others are. Therefore, they claim, no one really needs to be compensated or to have his due-process rights enforced in this area.

On the other hand, medical and public-interest groups, like Public Citizen, assert that environmental-health threats are not distributed equally. They say often such threats are covered up and are more serious than people believe; that when people are harmed, they have due-process rights to redress (such as compensation) under the law. Moreover, without such redress, they say those who threaten environmental health have no incentives to improve their modes of behavior (Wallach and Sforza 1999).

One important area of due-process concerns, related to environmental health, is that of US weapons production. Under US law, defense operations that cause harm to citizens are typically not threats concerning which citizens can seek compensation. Because of the doctrine of sovereign immunity, according to which one cannot sue the sovereign or government, citizens have no rights to seek court action to protect their due process rights that may be jeopardized by the US government or its contractors. Yet current (year 2001) estimated costs to clean up the weapons-production facilities in the US, where thousands of communities are endangered because of chemical and radiological pollution, are approximately a trillion dollars. And US military contractors, such as Raytheon, McDonnell-Douglas, Westinghouse, Bechtel, Martin Marietta, and so on, are typically held not liable, by US law, even for intentional violations of public- and environmental-health standards at the facilities they run (US GAO 1999).

On the one hand, the rationale for exempting government contractors from responsibility for violations of citizens' due-process rights, to seek redress from injury caused by defense operations, is national security. Proponents of exemption also charge that everyone benefits from national security and defense, so everyone must be willing to pay the price (US Congress 1999). In addition, they argue that the health costs of defense are borne fairly equitably, across regions of the nation.

On the other hand, opponents of military violations of public-health and environmental standards argue that something is wrong when US defense activities harm the very people they are designed to protect (Rush and Geiger 1997-1998). They also point out that the US defense establishment is, by far, the largest and most serious violator of US public-health and environmental standards, and that the US has to be held accountable, on grounds of fairness, for obedience to its own laws. Critics of those who want to hold the defense establishment not responsible for threats to citizens' due-process rights, also argue that failure to hold it responsible has caused many needless threats to public and environmental health. For example, the US could have tested all nuclear weapons below ground, instead of above ground, and it could have avoided hundreds of thousands of additional US cancers caused by above-ground weapons testing. Because of the absence of liability and due-process claims against the government, the critics note that the US pursued the cheaper path of above-ground testing, of not warning civilians to stay indoors after the tests, and of not testing the weapons on the east coast, so that the fallout could drift over the Atlantic, instead of over the US.

Just as there is great debate over the content of the norms (e.g., individual rights versus common good) that ought to govern environmental-health decision-making, as in cases of weapons testing, so also there is controversy over the methods appropriate to ethical evaluation of environmental health. Primary among these debates is the focus on (5) the burden of proof. On the one hand, attorneys like Sander Greenland (1991) argue that, given US law, people ought to be presumed innocent until proved guilty, and therefore the potential victim of an environmental-health threat ought to bear the burden of proof in establishing his injury. Otherwise, they say that many innocent people and groups would face the impossible obstacles of trying to prove their innocence.

On the other hand, philosophers like Carl Cranor (1994) argue that, because the damage from environmental-health threats is so great, and because it is so difficult and expensive to prove causality in such cases, therefore the burden of proof should be on the "deep pocket," the party with the most resources and the party least likely to be vulnerable. According to Cranor, this least-vulnerable party is the person or group causing potential environmental-health threats. Such conflicts over who should bear the burden of proof in environmental-health disputes focus mainly on the common good, on equal treatment, and on fairness.

In debates over ethical strategies for decisions about environmental-health threats, many conflicts arise over (6) the necessity of stakeholder representation. (Stakeholders are those who stand to gain or lose as a result of particular environmental health threats. Often stakeholders are primarily potential public-health victims. ) On the one hand, groups like the US National Academy of Sciences, in its classic 1983 discussion of societal health threats, argue that decisions about the magnitude and importance of such risks ought to be made by experts, since only scientific experts have the requisite technical expertise (NRC 1983).

On the other hand, later committees of the US National Academy of Sciences, like the 1996 group studying democratic constraints on risk imposition, (NRC 1996) argue that environmental-health decisions are not mainly about technical matters. They say such decisions are mainly about whether the potential victim community believes the risks are worth the benefits. Hence the citizens' groups maintain that stakeholder representation is essential to democratic control of public health. Otherwise, they say, vested interests likely would dominate decisions about environmental health.

Ethicists concerned about environmental health also disagree over (7) the legitimacy of using risk assessment and benefit-cost analysis in ethical evaluation of environmental-health problems. That is, they disagree over the degree to which analytic methods ought to be used to resolve these problems. On the one hand, many economists and policy-makers argue in favor of such analytic techniques on the grounds that they systematize the problem under investigation, clarify it, and make it more tractable (Shrader-Frechette 1991). They also argue that, because society does not have infinite resources to correct environmental-health problems, therefore techniques such as risk assessment are necessary both to quantify the risk and to determine how to evaluate it. On the other hand, many environmentalists are opposed to any use of analytic methods in environmental-health decision-making (O'Brien 2000). They say that such techniques err both because they give control of public health to vested interests, rather than to potential victims, and because it is not possible to put a price on the value of life. They also say that the techniques fail to take account of many important ethical considerations such as consent and equity. Finally they complain that the techniques unfairly presuppose a largely utilitarian account of public policymaking.

### Policy Issues

In each of these areas of environmental-health debate, there are a number of concrete policy proposals that have been developed to address ethical aspects of environmental health. For example, one policy issue, regarding (1) rights to know, concerns whether the World Trade Organization ought to have the right to define accurate labeling on potentially dangerous foods as "impediments to trade." With respect to (2) autonomy and free informed consent, a crucial policy issue is whether representative democracy can adequately guarantee the free informed consent of potential environmental-health victims, or whether the victims themselves have the right to give or withhold free informed consent. For example, in the case of the proposed Yucca Mountain Nuclear Waste Repository, the US Nuclear Regulatory Commission, as a federal executive agency appointed by the President, claims the right to give free informed consent to the repository, whereas the residents of Nevada, 80 percent of whom oppose the facility, claim the right to withhold consent (Shrader-Frechette 1993).

On the issue of (3) equality and equal protection against environmental-health threats, one important current policy issue is whether all areas of the nation have equal rights to a liveable environment, or whether some people ought to have the right to trade the equal protection of their community health or environmental health for money. Is there a right to a liveable environment? Or is it a good that can be traded when necessary? Another policy issue is whether the US ought to require the same environmental-health standards for products manufactured abroad as for those manufactured in the US. Currently US manufacturers are held to higher standards of occupational health and environmental health than are the manufacturers from whom the US often imports goods and foodstuffs. Do these other nations have sovereignty over such decisions, or does the US have the right to demand the same safety standards of everyone who wishes to sell its products in the US (see Wallach and Sforza 1999)?

With respect to (4) rights to due process, an important policy issue is whether the US government ought to repeal the Price-Anderson Act. This law gives utilities protection against 99 percent of the costs of worst-case nuclear accidents, including costs and damages likely to threaten public health. Is the act constitutional, as the Supreme Court alleged, because no violations of actual due process, in the face of catastrophic accidents, have actually occurred? Or is the act a violation of due-process rights, rights that ought to be guaranteed in principle (Shrader-Frechette 1993, pp. 15-23, 96-98)?

With respect to (5) the burden of proof, an important policy issue is whether those who threaten environmental health, because of their products, ought to be held liable on grounds of considerably weakened evidentiary standards for proof of harm, or whether the current standards ought to be maintained. These current standards place the burden of proof on the potential victim. In the case of cancer, for example, it often is extraordinarily difficult for victims to prove what caused their disease, and most cancer outbreaks are recognized because of statistical associations that preclude proving that an individual cancer had a particular environmental-health cause (Cranor 1994).

In the area of (6) stakeholder representation in environmental-health decisions, one of the crucial policy decisions is whether all federal agencies who assess health risks ought to be mandated to change and therefore to follow the US National Academy of Sciences recommendation to give stakeholders equal weight (to experts) in decision-making regarding environmental health (NRC 1996). Many ethicists argue that justice requires not merely equal consideration of interests and equal treatment, but also equal voice in the decision about how to give equal consideration and equal treatment (Rawls 1971).

Finally, one of the crucial policy issues regarding (7) the legitimacy of using risk assessment and benefit-cost analysis in ethical evaluation of environmental and health-related problems is whether all federal health-related decisions require a cost-benefit justification, as the Bush Administration proposes, or whether justifications instead can be based purely on ethical criteria, such a rights to equal protection (O'Brien 2000).

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## Fact Sheet on Environmental Health

In evaluating the extent of environmental-health threats, it is important to realize that factual information, often used as a basis for ethical decisions about environmental health, may fall victim to a number of biases and values. For example, threats to environmental health may be described in problematic ways as a consequence of at least 4 factual difficulties, (1) framing problems, (2) low-power studies, (3) alternative statistical-epidemiological methods, and (4) arbitrary decision rules.

Any ethical decision about the magnitude of an environmental-health threat is subject to considerable uncertainty as a consequence of different *frames*. For example, if one evaluates environmental-health threats to coal miners in terms of the “frame” of tons of coal mined, the health of miners appears to be improving. That is, coal-mine deaths, per ton of coal mined, have been decreasing since 1950 in the US. However, if one evaluates environmental-health threats to coal miners in terms of the “frame” of numbers of coal miners, the health of miners appears to be diminishing. That is, coal mine deaths, per thousand coal-mine employees in the US, have been increasing since 1950. Note that the number of deaths remains the same in both cases, but the *significance* of the number changes, on the basis of the frame that is used to view the deaths (see NRC 1996, pp. 50-52).

One of the most common ways in which a polluter is able to claim that there is no environmental-health threat that results from his activities is by using *small sample sizes* or *low-power studies*. For example, if an excess of 1 in 10,000 workers exposed to y amount of vinyl chloride dies, within 5 years of exposure, of liver cancer, and if the epidemiological studies investigating this health effect employ a sample size of only 200, there is only a very small probability that the test will reveal a 1 in 10,000 chance of cancer for a 5-year study, given the low incidence of the excess cancer. The sample size is too small to be likely to reveal the risk. Similarly with low-power studies. For example, when John Todhunter of the US EPA in 1982 reassessed the data alleging the carcinogenicity of formaldehyde, he concluded that the data did not show the carcinogenicity of formaldehyde. These negative statistical results, this failure to show a statistically significant increase in cancers, as a result of formaldehyde exposure among DuPont workers, however, appears to be merely an artifact of the low power of the statistical tests that Todhunter used. The DuPont study had only a 4 percent chance of rejecting the null hypothesis (and therefore inferring excess cancers), even if there were a twofold increase in cancer of the pharynx or of the larynx in those exposed to formaldehyde. That is, the DuPont study had only a power of 4 percent to detect twofold increases in cancers. As this example shows, failing to reject the null hypothesis does not rule out excess environmental cancers unless the epidemiological tests are reliable. (For the DuPont and Todhunter assessments and discussion of these problems in the formaldehyde case, see Mayo, 1991).

Other *statistical-epidemiological methods* also can cause environmental-health threats to be overestimated or underestimated. For example, many industries are likely to claim that their employees are more likely to die at home than on the job, that their homes are less safe than the workplace. They often make such claims on the basis of the “healthy worker effect.” This effect typically is exhibited when an epidemiologist compares the cancers per x workers in a particular industry, for example, to the cancers per x members of the total population. However, there is a selection bias in comparing worker health statistics to those of the general population. The general population includes very young people, very old people, highly sensitive people, people too sick to work, and so on, whereas the worker population is in the middle-age group, a group which is generally freer of highly sensitive people or sick

people (or else they would not still be working). As a consequence, even workers with higher rates of occupationally-induced illness may appear healthier than the general population, simply because epidemiologists use a selection bias in comparing their health rates to those of the general population, a population that includes many more at-risk people than does the work population (Moeller 1997, pp. 43-44.)

Still another common difficulty that arises in evaluating environmental-health threats is caused by use of different *decision-theoretic rules* for evaluating the same data. For example, according to the US government's Rasmussen Report, the probability of a nuclear core melt, in a US reactor, is about 1 in 4 for all US reactors, assuming a 30-year lifetime for the reactors. Assessments conducted by the Ford Foundation and by the Union of Concerned Scientists (UCS), however, disagreed on the environmental-health risks associated with using nuclear fission, even though both studies used the same data about reactor-accident probabilities and about accident consequences. What accounted for the difference in the health assessments? The Ford research was based on the widely accepted Bayesian decision criterion that it is rational to choose the action with the highest expected utility, where "expected utility" is defined as the weighted sum of all possible consequences of the action, and where the weights are given by the probability associated with the consequence. The UCS recommendation followed the maximin decision rule that it is rational to choose the action that avoids the worst possible consequence of all options. Thus, for identical data, the chosen decision rule--with particular ethical presuppositions--determined the calculated environmental-health threat associated with nuclear power. (For discussion of the Rasmussen Report, the Ford Foundation Report, and the UCS assessment, including these decision-theoretic rules, in areas of environmental health, see Shrader-Frechette, 1991, pp.100- 130.)

As the preceding paragraphs reveal, it is important to evaluate the factual-scientific basis on which the environmental-health threats are assessed, prior to engaging in ethical evaluation, because decisions about the acceptability of a particular environmental-health risk are a function of many subtle factors. These include the actual magnitude or seriousness of the risk. Moreover, this magnitude and seriousness can be underestimated or overestimated, purely on the basis of considerations such as framing, the power of the studies, statistical-epidemiological methods, and decision rules.

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## **Four Case Studies on Environmental-Health Controversies**

In order to determine how the preceding ethical debates, policy options, and scientific methods play respective roles in controversies over environmental health, it is useful to examine, in more detail, several important environmental-health disputes. These concern, respectively, (1) environmental injustice in Homer, Louisiana; (2) escalating cancer rates, (3) endocrine disruptors, and (4) occupational health in the US.

For each case study, the issues of debate are introduced, and then readers are invited to consider various arguments, possible counterarguments, the need for additional information, the frames employed in the debate, relevant ethical values, and the interests of various stakeholders involved. References and citations for additional resources are provided. In addition, readers will find that every issue of the journal, *Environmental Health Perspectives*, provides additional information and potential case studies for discussion.



## Case Study 1: Environmental Injustice in Homer, Louisiana

Do all citizens have equal rights to protection against threats to environmental health? This question arises both because minorities and poor in developed nations bear greater-than-average environmental-health risks and also because those in developing nations bear greater health risks than those in the developed world, in large part because of the policies of developed nations. For example, according to the US General Accounting Office, roughly one-third of all US pesticide exports are products that are banned or not registered for use in the US because they are deemed too dangerous. Instead the US ships them abroad. As already mentioned, the World Health Organization estimates that approximately half a million cases of accidental pesticide poisoning occur annually, with a death-to-poisoning ratio of 1 to 10. This means that each year, about 50,000 people die annually from pesticide poisoning, most in developing nations. One person is poisoned every minute from pesticides in developing nations (Mathews *et al.* 1986).

Such disproportionate environmental-health impacts also affect those in the developed world. In 1983, African-American sociologist Bob Bullard largely began the whole area of study known as “environmental injustice” when he showed that (1996), from the 1920s through the 1970s, Houston placed almost all its city-owned landfills in African-American neighborhoods. Although they represented only 28 percent of the city’s population, African-American communities received 15 of 17 landfills and 6 of 8 incinerators. Bullard showed not only that minorities across the US faced disproportionate environmental-health threats from incinerators and toxic-waste dumps, but also that these added risks increased other public-health problems--such as crime, poverty, and drugs--in minority communities. Comparing pollution in different California ZIP codes, researchers likewise showed that in the dirtiest US ZIP code, in Los Angeles, industries release 5 times as much pollution as in the next-worst ZIP code. They concluded it is no accident that the dirtiest ZIP code is 59 percent African-American. Thus African-Americans appear to be victims of a special public-health problem, environmental injustice.

To understand alternative perspectives on the issue of environmental injustice, disproportionate environmental risks’ being imposed on poor people and minorities, consider a recent case, a proposal to build a multinational, highly-polluting, uranium-enrichment facility in an African-American community in Homer, Louisiana. One of the poorest towns in the US, Homer has a per capita income of only about \$ 5,000 per year. Members of the local community were able to oppose the proposed Claiborne Enrichment Center facility only because of help from outside experts, and their stopping the facility in 1997 became the first major environmental-justice victory in the US.

### Questions for discussion:

- Why would various parties want to locate a uranium-enrichment facility in Homer? Why might a multinational corporation want to build such a facility there? Why might residents welcome or oppose such a plan? Why would local businessmen or politicians welcome or oppose such a plan? Why would teachers, school administrators, and others concerned with public services welcome or oppose the building of such a facility?
- Why would “outsiders,” like environmental activists take an interest in Homer and the Claiborne facility? Who are the outsiders and insiders in cases of potential environmental pollution, and which should have the greater “say” in decisions about building a potential polluter? Why?

- What data should inform a decision about whether to build? In addition to scientific data about the facility and its environmental impact, what other data are relevant? How certain or uncertain are these data? In the presence of scientific, economic, social, or other uncertainty, who should bear the burden of proof and why?
- Can a community give informed consent to the initiation of a project like building the Claiborne facility? How would such consent be similar to a process of individual informed consent, and how would it differ? Consider what is discussed in Module 4 on community-based practice and research and on the process of sharing power within communities. Which methods discussed in that module might be useful in Homer?
- What would need to be disclosed and to whom in order for the community of Homer to make an informed decision about building the Claiborne facility? Are all of the issues to be disclosed factual, or are there ethical assumptions that need to be disclosed as well? Who represents the community in such a decision? Is it the community's decision to make?
- Consider some of the issues raised in Module 2 on the Tuskegee Syphilis Study and issues of race. What role does the predominant race of the residents of Homer play in the siting of the Claiborne facility there? Would you argue that the facility will benefit those of a minority group, African-Americans, or would you argue that they are being singled out to bear an environmental burden?

## Case Study 1: Discussion

Henry Payne (1997) argued that the proposed Claiborne Enrichment Center, in Homer, Louisiana, would have been desirable for the local African-American community but that outside environmental activists misled the community into criticizing the facility, which actually would be in the community's best interests. Payne argued that these activists prevented Homer citizens from getting the industry and the jobs that they want and need. He argued that the proposed facility would bring jobs and an improved economy to a poor area, and yet that it would cause no serious environmental harm. Payne takes, as facts, (1) that the facility would have benefited minorities nearby, (2) that these minorities wanted it, (3) that outside activists did not want the facility, (4) that the proposed plant would help the local economy, and (5) that the facility would cause no serious public health or environmental harm. In claiming (5), Payne assumed (a) that in a situation of uncertainty, with little scientific study, ethics does not require people to be "safe rather than sorry." He also assumed (b) that the absence of positive evidence of harm from the facility, or ignorance about the facility, was the same as a guarantee of safety about the facility. Thus he made the ethical assumption (c) that public health advocates bear the burden of proof in alleging harm from a proposed plant. Finally, Payne assumed (d) that the requirements (see Beauchamp and Childress 1994) of free informed consent (disclosure, understanding, voluntariness, and rationality) were met in the Louisiana case and that the minority community therefore actually consented to the proposed facility.

In assessing the adequacy of the Payne account, one would need to evaluate his factual assumptions (1)-(5) and his ethical assumptions (a)-(d). One also would need to take account of the fact that, in arguing for both his ethical and factual claims, Payne cited neither any scientific analyses nor any ethical and legal analyses to support his position. Instead, he relied on a commonsense assumption that manufacturing facilities bring economic benefits.

Addressing Payne's points, Daniel Wigley and Kristin Shrader-Frechette (1996), argued that both Payne's factual and ethical assumptions are wrong, and they therefore claimed that siting the Louisiana facility is not justified. Shrader-Frechette and Wigley challenged both the factual assumption (1) that the plant would have benefited minorities and (5) as well as the ethical assumption (a) that ignorance about the facility justified believing it was safe. Analyzing the required environmental impact assessment (EIA) for the plant, they showed that its proponents failed to consider a number of costs of the facility and that these costs were likely to exceed the associated benefits. In particular, they argued that the jobs created by the plant would go to skilled white labor and professionals, not to unskilled blacks, and that the EIA included no probabilistic risk assessment of threats posed by the facility. Instead they revealed that the EIA made purely subjective judgments about site safety.

Much of the Wigley and Shrader-Frechette (1996) analysis was devoted to showing that the EIA performed by the enrichment corporation (wishing to site the proposed facility) employed procedures that actually violated minority rights to free informed consent. In particular, Shrader-Frechette and Wigley showed, first, that the corporation did not disclose the actual nature of the facility to anyone, and instead asked citizens if they would like to have a manufacturing facility nearby. The company violated the disclosure requirement (for free informed consent), second, by covering up the radiological risks and health threats to be imposed by the facility and by failing to reveal that the onsite radiological wastes would not be covered by US government regulations. Third, the company did not reveal that the products of the multinational facility would likely be used abroad, not in the US. Nor did it reveal that

these multinational products would compete with higher quality US products, while Louisiana residents would bear the health risks of the facility. In addition, Shrader-Frechette and Wigley argued that the site EIS violated the criterion of voluntariness (for free informed consent) because the corporation polled only white residents living a great distance away from the proposed facility. It did not even seek the opinions of any of the minority residents who make up the entire population living within 5 miles of the plant. Thus, Shrader-Frechette and Wigley concluded that the Louisiana facility siting amounted to environmental racism or environmental injustice and that neither factual nor ethical arguments, given in the EIA, were capable of supporting it.

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Daniel Wigley and Kristin Shrader-Frechette, "Environmental Justice: A Louisiana Case Study," Journal of Agricultural and Environmental Ethics 9, no. 1(1996), pp. 61-82.

## Additional resources

Ruth Faden and Tom Beauchamp, A History and Theory of Informed Consent, New York, Oxford University Press, 1986. (on informed consent, voluntariness)

David Newton, Environmental Justice, Oxford, England, ABC-CLIO, 1996.

Iris Marion Young, Justice and the Politics of Difference, Princeton, Princeton University Press, 1990. (on the ways in which policies and practices affect differently situated people differently)

## Case Study 2: Escalating Cancer Rates: Assessing Vested Interests and the Published Literature

Early in the pages of *Silent Spring* (1962), her classic book publicizing health effects of the use of chemical pesticides, Rachel Carson claimed that Americans ought to revise the US Bill of Rights. She pointed out that, when America was founded, Thomas Jefferson and his colleagues thought that the greatest threats to the “liberty, equality, and fraternity”—preached by the French and embraced in the colonies—were kings and unjust political institutions. Therefore Carson says they wrote the *Constitution* and the Bill of Rights so as to protect people against government incursions on personal liberty, health, and equality. If our founding mothers and fathers were alive today, however, Carson says that they would take care to rewrite the Bill of Rights so that citizens are protected against industrial pollutants, like chemical pesticides. She argues that powerful corporations (and corporations are defined as “persons” under the US *Constitution*) constitute a grave threat to public health, public liberty, and public equality, and perhaps a graver threat than that of unjust government. Carson encourages public-health advocates to ask how there can be rights to liberty when dirty technologies take away the liberty to breathe clean air. Or how there can be rights to life, when hazardous wastes pollute the water that is necessary to life.

Not everyone would agree with Carson’s analysis of the threats to environmental health today. In the case of cancer, for example, the scientific community and the ethical community are divided on the causes of the diseases and on the appropriate ethical response to it. As already mentioned, according to the US National Research Council (1993), cancer will soon become the leading cause of death of Americans. Moreover cancer is not a disease of old age, as cancer victims die, on average, 15 years earlier than others. It is the leading cause of death of children between the ages of 2 and 18, and the leading cause of death of women in their thirties. In fact, since 1950, the cancer rate for children under age 15 has increased by 32 percent. Cancer incidence, in the general population, is increasing six times faster than overall cancer mortality is decreasing (NIH 2000).

Because cancer is one of the major environmental-health problems, it is important to identify its causes and to prevent them. The environmental and medical communities tend to agree with Samuel Epstein (1998), that industrial pollutants are the major problem, while the governmental and industrial communities tend to agree with Bruce Ames that genetics and lifestyle are the main causes of cancer.

### Initial questions for discussion:

- Why do you think that environmental and medical communities on the one hand, and governmental and industrial communities on the other, would tend to differ in their accounts of the causes of cancer? What interests are at stake for each “camp?” How do the influences on each camp affect the research agendas of each group?

Martin Walker (2000) uses the case of well-known British epidemiologist Sir Richard Doll to illustrate the thesis that scientists’ conclusions regarding the causes of cancer can be affected by their vested interests. Because many scientists obtain their funding from corporations, Walker (2000) and medical doctor Samuel Epstein (1998) argue that such scientists are pressured to defend positions favorable to industry. This can lead them to neglect or underestimate public-health risks caused by industrial practices and to overestimate natural causes of disease, according to Walker. In particular, Walker

(2000) argues that some prominent scientists (like Bruce Ames, Richard Doll, Richard Peto, and Lois Gold) who blame cancer on lifestyle and genetics are guilty of both ethical and scientific errors.

### Questions for discussion

- In the preceding paragraph, what is meant by “natural causes of disease?” With what are such “natural causes” contrasted?
- What sorts of scientific and ethical errors might a commentator like Walker have in mind when he suggests that some scientists ignore or underestimate public health risks of industrial practices?
- Are there changes that could be made in the way science is done that would reduce the likelihood that scientists would make these sorts of errors because of their “vested interests?”
- Can scientists and academics be truly “disinterested?” How can they reduce the degree to which they have vested interests or are insufficiently disinterested? If it is true that people always have interests and are always beholden to some people, projects, or priorities other than the pursuit of truth, is it better to be beholden to some people, projects, or priorities as opposed to others?
- What are the people, projects, and priorities that influence your research agenda and the conduct of your work? How do these influences affect the outcome of your research? What are the relevant differences among influences on the choice of research question, influences on the funding of some research projects (and not others), influences on the outcome of research (i.e., findings), and influences on the dissemination of research findings? Are some sources, types, and targets of influence more troubling than others?
- What are the strongest sources of influence on those you work with in your department, work unit, lab, or school? Would those sources of influence be subject to the sorts of criticism that Walker offers?
- It would seem ideal for those private parties (e.g., corporations) that impose potential health risks to fund research to investigate the magnitude of those risks and to monitor the public’s health. Should such private entities bear this responsibility? How could they discharge this responsibility without placing those who investigate such risks in a position of conflicting interests?

## Case Study 2: Discussion

On the ethical side, Walker says (a) that some prominent scientists cover up studies showing the negative health effects of industrial chemicals, for example, and (b) that instead of empirically investigating environmental-health effects, they typically rely instead on the mere opinions of scientific colleagues who are employed by (or subcontractors to) industries that use or manufacture toxic chemicals. In addition, Walker argues (c) that those (who blame lifestyle and genetics, not environmental pollutants, for most cancer) also are biased because their research is funded by vested corporate interests and not by disinterested scientific foundations. Finally, he claims (d) that disinterested academic and medical scientists have sharply criticized the methods used in such industry-funded studies.

On the scientific side, Walker says that a major reason the “cancer is caused by lifestyle not environmental pollution” advocates err is that they typically do not fund or do research on the epidemiological causes of diseases like cancer. Instead Walker says they tend to do only basic research on the theoretical mechanisms according to which cancer incidence occurs. Thus, he says they claim there is no evidence of environmental causes of cancer because they do not investigate possible environmental causes of cancer. In general, Walker accuses those (who say cancer is caused mainly by genetics and lifestyle, not environmental factors) of violating personal and professional ethical codes. They violate ethics, he suggests, by virtue of the fact that they tend to consider only the data and research that support the industry position, whereas they simply ignore all other information. In thus defending his view, Walker assumes that because vested interests tend to fund research that denies any environmental causes of many cancers, therefore that research is more suspect than that funded by disinterested government, academic, or medical agencies. He also assumes that the cancer analyses of public-health officials are likely to be more plausible than those of corporate-funded researchers.

In contrast to Walker, Bruce Ames and Lois Swirsky Gold (2000) claim cancer is caused mainly by naturally-occurring chemicals, genetics, and poor diet, not environmental factors. As a result, they contend that focus on environmental causes of cancer actually threatens public health and the common good because the focus does not address the main causes of cancer. Ames and Gold also maintain that investing public funds in research on the effects of synthetic chemicals damages public health by diverting resources away from more serious threats.

In presenting their case, Ames and Gold make both ethical and scientific assumptions. On the ethical side, they assume (a) that scientific research ought to address the most serious health threats first, namely those that kill the greatest number of people. They also assume (b) that those who create such health threats, or who profit from them, have no special ethical obligation to minimize those threats or to do research on them, provided that such threats are smaller than those arising from other social activities, like driving an automobile or smoking cigarettes. In other words, they make the ethical assumption (c) that the magnitude of public health threats, rather than the equality and fairness associated with their imposition, is what determines their societal importance. Pursuing this same magnitude or quantitative assumption, Ames and Gold argue that people worry needlessly about industry caused carcinogens (from things like toxic chemicals), because they say natural carcinogens in foods (such as coffee and peanuts) present greater risks than industrial substances. Following ethical assumptions (a), (b), and (c), Ames and Gold argue that public health officials ought to pay greater attention to natural carcinogens and less attention to manmade carcinogens. In other words, they make the ethical assumption (d) that private interests may contribute to public health risks, without ethical

violations, provided that the harm arising from their contributions is of a lesser magnitude than the dangers posed by natural sources. They also make the ethical assumption (e) that the liberty of private interests, operating in the market, is more important than mere possibilities of industrial harm, especially when the possible harm appears to be quite minimal, as compared to that caused by natural carcinogens.

## References

Bruce N. Ames and Lois Swirsky Gold, "Paracelsus to Parascience: The Environmental Cancer Distraction," *Mutation Research* 447, no. 1 (January 17, 2000), pp. 3-13.

Rachel Carson, *Silent Spring*, Boston, Houghton Mifflin Company, 1962.

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### Case Study 3: Endocrine Disruptors: Approaches to Uncertainty

Many of the threats to environmental health arise from chemicals, especially because in the US, there are about 80,000 different chemicals used in industrial and agricultural processes in the US, and only about 2 percent have been tested for toxicity, whereas only about one-half of one percent have been tested for carcinogenicity, in part because testing is so expensive. In recent years, the environmental health threat from chemicals has mounted, because very low doses of organic compounds (like chlorine), doses far below that found to induce cancer, are now thought to be responsible for reproductive-related disorders associated with endocrine disruption. Behaving as synthetic estrogens, these endocrine disruptors are believed to be responsible for the declining sperm count in males, a decline evident since the 1950s. As a result of many small doses of organic compounds, males of many species have become feminized and, as a result, the species have gone extinct. In other cases, the increase of estrogens has caused a variety of additional, reproductive-related cancers (Colborn *et al.* 1993).

Theo Colborn and her colleagues (1993) argue that large amounts of chemicals have been released into the environment since World War II. Many of these chemicals, Colborn argues, have disrupted the endocrine systems of animals. (The endocrine system consists of glands that regulate various bodily functions, such as growth, reproduction, and nutrition, by means of hormones). Because many human-made industrial chemicals act as synthetic estrogens, they can disrupt the bodily functions that natural hormones regulate. Even minute exposures to these artificial chemicals, at any point in life, can pass them on to offspring during pregnancy and lactation. Colborn and her scientific colleagues argue that such chemicals can have adverse effects on reproductive and immune systems in humans and wildlife, even at levels far below those necessary to induce cancer. As a consequence, she argues for caution in employing these chemicals, a caution that would require much tighter environmental regulation. Some of these endocrine disrupting chemicals include PCBs, dioxin, and DDT. Colborn and those who argue that even small amounts of such endocrine-disrupting chemicals are risky thus assume that ethics requires one, in the face of incomplete scientific information, to use the precautionary principle. (The precautionary principle specifies that positive evidence of societal harm is not necessary before one takes precautions to protect public health. The rationale for the principle is that if one always waits until conclusive evidence of definite harm is available, then many public-health threats would be so advanced that it would be far more difficult to stop them and to prevent catastrophe. Proponents of the precautionary principle also argue that failure to employ the principle would amount to using humans as guinea pigs in industrial and economic experiments. Finally, proponents of the principle argue that because vested interests are so powerful, they often keep government from doing the necessary studies to confirm public-health harms arising from activities of those vested interests. They note, for example, that less than two percent of industrial and agricultural chemicals (of the 80,000 to 100,000 currently in use) have actually been tested for any health effects. In the absence of complete scientific studies about some hazard, proponents of the precautionary principle say it is necessary to take extra precautions to protect public health).

Besides supporting the precautionary principle, Colborn and other scientists (who argue that even small amounts of endocrine-disrupting chemicals likely are dangerous) claim that much scientific and public-health evaluation of these chemicals has been scientifically inadequate. They say (1) endocrine-disrupting effects occur at levels several orders of magnitude lower than those needed to cause cancer, and that government currently requires no tests for such effects. Yet, they note (2) that laboratory tests

and field data have revealed endocrine-disrupting effects on other animals. Besides, they claim (3) that the best scientific explanation of the reason for the continuing decline in human sperm counts, since 1950, is that humans are responding in the same way, in response to these chemicals, as other animals. Factually, Colborn and her coauthors assume that seriously damaging effects of endocrine disruptors, on other species, argues for caution in exposing humans to these chemicals.

On the ethical side, Colborn and her coauthors recommend more study of potentially endocrine disrupting chemicals, as well as their precautionary regulation, for at least two additional reasons. (A) They say ethics requires one to be especially careful of low-dose chemical effects because they often are incurred during neonatal periods but not manifested till middle age; ethics requires extra precaution with effects that are delayed, and therefore hard to detect, and with effects that are most damaging to the most vulnerable individuals, namely developing children. (B) They also say that ethics requires one to be especially careful of these chemicals because their effects are permanent and irreversible.

## Reference

Theo Colborn *et al.*, "Environmental Endocrine Disruptors," Environmental Health Perspectives 101, no. 5 (October 1993), pp. 378-384.

## Questions for discussion

- The whole issue of endocrine disruptors raises the question of how to behave in the face of environmental-health threats that are uncertain, that have not been definitively proved. Should one be a health conservative and assume the worst, in order to safeguard the gene pool and future generations? Or should one be a health liberal and not take drastic and costly steps to reduce endocrine disruptors until the scientific data are clear? Whose interests are served by the "health conservative" and "health liberal" positions?
- In conditions of uncertainty, who in society should be most stringently protected from health risks: the majority, the average person, the least-well-off, the most vulnerable, those who protect themselves, those who are not themselves "risk imposers?" What values support protecting each of these groups: fairness, respect for autonomy, utility (promoting good), beneficence, equality?
- What are the arguments in favor of the precautionary principle? What arguments can be made against following it? In the case of endocrine disruptors, what factual disputes could be raised against Colborn and her colleagues? What ethically-based arguments could be raised against her advocacy of the precautionary principle in this case? What role should concern for economic progress play in arguments for and against costly plans to reduce endocrine disruptors? What role(s) does uncertainty play in arguments about both environmental and economic impact of endocrine disruptors and their reduction?
- In balancing risks and potential benefits, what, if any, special weight should be given to risks of harms that would be permanent and irreversible? How should risks whose associated harms do not manifest themselves for some time be treated in the balancing of risks and potential benefits?

### Case Study 3: Discussion

Those who tend to follow an egalitarian or contractarian ethical approach, like that of John Rawls (1971), argue that, in situations of scientific or medical uncertainty, one ought to be careful to protect the least-well-off, or most vulnerable, persons. These egalitarian ethicists attempt to follow the rule to treat people equally or consistently. One ought to follow a maximin decision rule, says Rawls, in situations of uncertainty characterized by (a) potentially disastrous consequences, (b) no overarching benefit to be obtained from taking the grave risk, and (c) little knowledge of the actual probability of disaster. The maximin decision rule specifies that, in situations of uncertainty, one's first or major goal ought to be not to treat people equally but to help the least-well-off people first. Ethicists who support use of egalitarian principle also say that it is not fair that one person should impose a potentially catastrophic risk on another, especially if the probability is uncertain, when the risk imposer gains from his action, while the risk victim may bear potentially great losses to which he has not consented and for which he has not been compensated.

On the other hand, those who tend to follow a utilitarian ethical approach, like that of John Harsanyi (1975), argue that following a maximin rule, in situations characterized by (a), (b), and (c) would be likely to thwart economic progress. They also say that following the maximin rule is not egalitarian but instead gives too much weight to the interests of potential victims. Finally they argue that rational people, in a high-risk situation of uncertainty, would be likely to maximize average expected utility and not follow a maximin rule. Rules to maximize average expected utility call for maximizing the average welfare of the average person. They do not call either for equalizing welfare or helping the worst-off.

Alicia Lubchenko (1990) and her colleagues, at the industry-funded American Council on Science and Health, argue that people need not be concerned about endocrine-disrupting chemicals, although these chemicals have been discovered to have an effect on wildlife. Lubchenko *et al.* say there is nothing to worry about, because humans are exposed to lower doses than is wildlife. Lubchenko *et al.* also argue that the chemicals are similar to estrogenic substances found in many plants, including those that humans eat, and that use of some estrogenic chemicals is decreasing. She argues that there is insufficient evidence to show that these chemicals actually harm humans. Lubchenko and her colleagues (who argue that so-called "endocrine disruptors" present no serious public health threats) thus disagree with Colborn *et al.* on both factual and ethical grounds. Factually speaking, Lubchenko assumes (1) that wildlife exposures to endocrine disruptors are greater than human exposures, even though Colborn denies this point, and even though humans are higher on the food chain than virtually all other animals observed to have endocrine-disrupting disabilities. (2) Lubchenko also notes that endocrine-disrupting chemicals are very weak, as compared to the normal human estrogens which they mimic, (3) that the link between specific chemicals and causal effects of endocrine disruption is controversial, and (4) that the many studies alleging a decline in male sperm counts also are controversial. In the face of their factual disagreement with Colborn *et al.*, Lubchenko and her coauthors make a number of ethical assumptions different from those of Colborn. They assume (a) that missing or controversial studies do not argue, ethically, for more regulation, or more precaution, regarding use of endocrine disruptors, whereas Colborn *et al.* argue that public health protection requires precaution, in the face of ignorance. Lubchenko *et al.* also assume (b) that if humans are naturally exposed to estrogens, therefore there is likely no serious harm and no ethical violation involved in exposing them to additional doses of synthetic estrogens, that is, to estrogen disruptors. Thus, even if Colborn and Lubchenko agreed on the

facts about endocrine disruptors, they still would disagree about the appropriate ethical response to this potential public-health problem.

## References

Theo Colborn *et al.*, "Environmental Endocrine Disruptors," Environmental Health Perspectives 101, no. 5 (October 1993), pp. 378-384.

John Harsanyi, "Can the Maximin Principle Serve as a Basis for Morality? A Critique of John Rawls's Theory," American Political Science Review 69, no. 2 (1975), pp. 594-602.

Alicia Lubchenko *et al.*, "Endocrine Disruptors," New York, American Council on Science and Health, 1999.

John Rawls, A Theory of Justice, Cambridge, Harvard University Press, 1971.

## Additional resources

Ronald Dworkin, Taking Rights Seriously, Cambridge, Harvard University Press, 1977. (on rights, economic analysis in assigning responsibility and legal liability)

Bernard Williams, Utilitarianism: For and Against, Cambridge, Cambridge University Press, 1973. (on utilitarian approaches in ethics)

## Case Study 4: Occupational Health in the US

One of the most serious questions of environmental health is whether everyone ought to have equal rights to protection against environmental harm, or whether workers ought to be allowed to trade some safety in exchange for higher wages. Elephant handlers at the Philadelphia Zoo, for example, receive an extra \$ 1000 per year, in exchange for the risks they face of being mauled by the elephants. On the one hand, in many nations of the world, there is no double standard for environmental health risks faced by workers, and pollution control is required to be as stringent for them as for members of the public. Countries that typically have no such double standard for workplace risk include Germany, Sweden, and Denmark, and the former Soviet states that are now republics. On the other hand, in the English-speaking nations of the world, as well as Norway, there does tend to be a double standard for workplace and public risk, in part because these countries have been influenced by the economic theories of Adam Smith. Smith argued that a compensating wage differential (CWD), or hazard pay, justifies higher workplace risks; he says that workers may accept higher risks if they freely consent to the higher risks they bear in the workplace (Shrader-Frechette 2002, ch. 7).

In most nations of the world, for example, nuclear workers follow the regulatory standards set by the International Commission on Radiological Protection (ICRP 1991), according to which nuclear workers are allowed to receive, each year, up to 50 times the dose of radiation that members of the public are allowed to receive. Proponents of the double standard argue that workers are compensated for the extra risk and also that it would be paternalistic not to allow workers to take the risks they want (Viscusi 1992). Otherwise, workers' autonomy would be violated. Proponents also maintain that allowing a compensating wage differential maximizes overall welfare in society, because some risky jobs need to be performed, and it is better for them to be performed voluntarily. Besides, they note that the CWD promotes efficiency because it allows people to make the tradeoffs that benefit them.

### References

International Commission on Radiological Protection (ICRP), 1990 Recommendations, Oxford, Pergamon Press, 1991.

Kristin Shrader-Frechette, Environmental Justice: Creating Equality, Reclaiming Democracy, New York, Oxford University Press, 2002.

Kip Viscusi, Fatal Tradeoffs, New York, Oxford, 1992.

### Initial questions for discussion:

- What arguments might be made *against* such a double standard regarding the degree of risk workers may incur as compared to members of the public?
- Think about products you are currently using or wearing. Do you believe that some workers involved in the products' production incurred greater risks than other workers or members of the public were exposed to? What was the nature of those risks? Do you believe those workers voluntarily consent to incur those greater risks? What information would you need in order to decide? How would you devise a compensation scale that reflected those differentials in risk? What factors would you take into account? What values would you employ to argue for your plan?

## Case Study 4: Discussion of Initial Questions

Opponents of the double standard claim that the higher risks to which many chemical and nuclear workers, for example, are exposed, harms not merely them but their children and the gene pool (Herbert and Landrigan 2000). All amounts of radiation are risky, and only 35 ev are sufficient to damage DNA. Opponents of the double standard also argue that workers typically have not given free informed consent to the higher risks, and instead that they have been forced to take risky jobs, not because they want them but because they are poor or in dire financial straits. Opponents of the double standard likewise say that often workers do not know the risks they face, so they have not really consented. They maintain, as well, that for poor people, non-unionized people (about 85 percent of the workforce in the US), people without college educations, old people, women, and minorities, there is no compensating wage differential, regardless of the risk. They claim that there merely appears to be a differential because all workers are lumped together, aggregated, and their pay averaged together, on the basis of the risks they face (Shrader-Frechette 2002, ch. 7).

### References

Robin Herbert and Philip Landrigan, "Work-Related Death: A Continuing Epidemic," American Journal of Public Health 90, no. 4 (April 2000), pp. 541-545.

Kristin Shrader-Frechette, Environmental Justice: Creating Equality, Reclaiming Democracy, New York, Oxford University Press, 2002.

## Case Study 4: Part 2

Much of the debate over the ethical acceptability of worker consent to the higher workplace risks they face is focused on the state of worker health. If worker health is actually getting better, then concerns about harm, consent, and compensation may be misplaced, while, if worker health is getting worse, then this fact lends credibility to these concerns. The US Department of Health and Human Services (HHS 1999) suggests grounds for believing that worker health is improving. It points out that, from 1933 to 1997, deaths from work-related injuries decreased from 37 per 100,000 workers to 4 per 100,000 workers. This improvement is attributed to a number of factors, including efforts by labor and management, improved education, stricter regulation, and development of safer equipment.

In arguing that worker health is improving, the US Department of Health and Human Services (HHS) makes a number of ethical and scientific assumptions. On the factual side, the HHS notes that US workplace fatalities have decreased, especially in coal mines. The HHS thus assumes (1) that a decline in fatal workplace injuries argues for an improvement in worker health and (2) that the decline in fatal coal-mine accidents is typical of the improvement in worker health and welfare.

### Reference

US Department of Health and Human Services (HHS), Achievements in Occupational Health, 1900-1999," Morbidity and Mortality Weekly Report 48, no. 22 (June 11, 1999), pp. 461-469.

### Questions for discussion

- Remembering the discussion of vested interests in case study 2 (on the reporting cancer rates and causes), identify the parties who have competing interests with regard to the data collected and reported by the HHS. Are there other data that you would want to use to assess trends in workplace safety?
- Remembering that choice of a frame used to conduct an assessment, such as an assessment of workplace safety, can affect that assessment, identify the frame being used in the HHS assessment and suggest other frames. What are the arguments in favor of the use of each frame?

## Case Study 4: Part 2 Discussion

On the ethical side, one can question whether the frame of fatal workplace injuries, however, accurately reveals an improvement in worker health and whether coal miners are accurate indicators of actual workplace conditions. According to Leigh (1995), only about 17 percent of workplace fatalities, about 17,000 per year in the US, arises from on-the-job accidents, like those documented by HHS. The remaining approximately 80,000 US workplace fatalities come from cancers induced by workplace exposure to hazardous substances (like radiation) and toxic chemicals. These 80,000 additional annual fatalities are much harder to detect, in part because there is no follow-up of employees who have retired, moved on, or quit work due to illness. Nor are there epidemiological studies or records kept of worker illnesses or cancers. If any records are kept, they are managed by the employers. Thus, the workers who succumb to latent, harder-to-detect cancers may represent a “silent majority” who (the HSS assumes) have no obvious health effects yet have much greater hidden health effects. If one assumes that the question of worker health can be “framed” purely in terms of acute problems, fatalities caused by on-the-job injuries, then the HHS may be correct that occupational health is increasing. If the frame is inaccurate, however, then the HHS may be incorrect. Likewise, the HHS may be incorrect to assume that coal miners represent typical groups in which workplace safety has improved. After all, coal mining has been known to be dangerous for centuries. Yet approximately 5,000 new chemicals, for example, are introduced into US industrial and agricultural processes each year, and most are not tested. If, as already noted, less than two percent of the approximately 80,000-100,000 industrial chemicals have been tested in any sense, then it may be that the largest workplace risks are in areas of unknown exposures and unknown effects, rather than in well-known areas of hazards such as coal mining.

Herbert and Landrigan (2000), however, offer grounds for questioning whether worker health is improving. Instead of focusing on acute problems, such as fatalities from workplace injuries, Robin Herbert and Philip Landrigan say that most workplace-related deaths are not from acute problems such as injury but from cancers, and that the cancers typically are not tracked or recorded as occupation-related. Herbert and Landrigan say that minorities are over-represented in jobs associated with toxic substances and that approximately 65,000 people die each year from occupation-related diseases, mainly cancer. They argue that, at least on the cancer front, workplaces are not safer, and that occupational health will improve only if there are better industrial-hygiene controls and substitution of less harmful products for toxic chemicals.

### References

Robin Herbert and Philip Landrigan, “Work-Related Death: A Continuing Epidemic,” American Journal of Public Health 90, no. 4 (April 2000), pp. 541-545.

J. Paul Leigh, Causes of Death in the Workplace, London, Quorum, 1995.



## Case Study 4: Part 3

In arguing that worker health is not improving, Herbert and Landrigan make a number of ethical and scientific assumptions. On the scientific side, they assume (1) that the frame of fatalities induced by workplace injuries is not an adequate measure of worker health and safety and (2) that until technology and manufacturing change radically, to use safer products and processes, worker health and safety will not improve substantially. Herbert and Landrigan also make the scientific or factual assumption (3) that because so little good data on workplace-induced disease exists, and because many workplace-induced diseases are not uniquely caused in the workplace (people have other exposures to chemicals and hazardous substances), it is very difficult to get firm data on workplace hazards. Nevertheless, they say it is clear that acute injuries (the frame used by HHS) grossly underestimates workplace caused deaths. Thus they tend to accept the workplace fatalities given by Leigh (1995).

### References

Robin Herbert and Philip Landrigan, "Work-Related Death: A Continuing Epidemic," American Journal of Public Health 90, no. 4 (April 2000), pp. 541-545.

J. Paul Leigh, Causes of Death in the Workplace, London, Quorum, 1995.

### Questions for discussion

- What ethical or value-laden assumptions are implicit in Herbert and Landrigan's argument that worker health is not improving?
- Is it of ethical concern if particular groups within American society—e.g., minority group members, women, or the poor—bear a disproportionate burden of workplace injuries? Which ethical values support such concern?
- Is there is a responsibility to protect workers from workplace hazards? If so, who bears (or shares) that responsibility? Does it matter whether the workers are citizens, legal or illegal residents, or workers in other countries?
- If it would be of ethical concern that particular groups within American society bear a disproportionate burden of workplace injuries, does the same concern arise if particular groups within global society bear such a burden, e.g., particular nations, regions, or groups within other nations? If workplace injuries are of concern internationally or globally, what recourse to remedies do individuals, governmental agencies, and organizations within the US have?

## Case Study 4: Part 3 Discussion

On the ethical side, Herbert and Landrigan assume (a) that completeness requires one to take account of latent, hard-to-identify cancer fatalities, induced by workplace exposures and (b) that fairness and justice require one to examine the health of minorities and the poor, because their workplace health threats are more severe than those faced by non-minorities and by middle-class workers. They also claim that there are ethical problems associated with claiming that US worker health is improving, especially given the fact that many US industries engage in an export of hazards so as to avoid US regulations. Herbert and Landrigan believe that this "export of hazards" is one reason that the International Labor Organization affirms that there are about a million workplace-related fatalities in the world annually. This number, they say (Herbert and Landrigan 2000) is more than double the number killed annually in wars throughout the world, and more than 100,000 greater than those killed in automobile accidents.

### Reference

Robin Herbert and Philip Landrigan, "Work-Related Death: A Continuing Epidemic," American Journal of Public Health 90, no. 4 (April 2000), pp. 541-545.

### Additional resources

Peter Dorman, *Markets and Mortality: Economics, Dangerous Work, and the Value of Human Life*, Cambridge, Cambridge University Press, 1996.

Elaine Draper, *Risky Business*, Cambridge, Cambridge University Press, 1991.

Ruth Faden and Tom Beauchamp, *A History and Theory of Informed Consent*, New York, Oxford University Press, 1986. (on informed consent, voluntariness)

Charles Levenstein and John Wooding (eds.), *Work, Health, and Environment*, New York, Guilford, 1997.

David Newton, *Environmental Justice*, Oxford, England, ABC-CLIO, 1996.

## **Tools for Best Practice and Policy Assessment**

In creating a case study of one's own, on topics of environmental health, one might focus on a number of key ethical themes, such as consent, equity, or compensation. With respect to consent, several types of cases lend themselves to discussion, especially those dealing with siting a LULU (locally unacceptable land use), a hazardous facility such as a waste dump. Virtually every community has some LULU, and there are many LULUs that deal with issues of national interest, such as the proposed Yucca Mountain High-Level Nuclear Waste Repository in Nevada. Because there are so many controversial sitings that allegedly threaten public or environmental health, it should be easy to investigate whether the conditions for free informed consent are actually satisfied in one or more of these proposed sitings.

With respect to equity and equal protection, it might be useful to discover, in one's own community, whether the poorest-income areas are those with the highest levels of air pollution. There are databases, some on the Internet, that show toxic releases in different areas. Air sampling is also an empirical strategy that might be used. By sampling air and by examining problems associated with "medical geography" databases, it should be possible to see whether there are potential problems of environmental injustice and whether there are any offsetting benefits (such as cheaper housing prices or increased employment) that might compensate for the alleged inequities in environmental-health protection.

Compensation issues in risky workplaces might be addressed by cases investigating environmental health in local places of employment. It might be instructive to determine, for a given workplace, whether there is indeed a compensating wage differential, and what its level is. It also might be instructive to examine whether, apart from compensation, workers in risky jobs have been adequately informed about the relevant environmental-health risks. Virtually all of the case studies related to environmental and occupational health can be addressed by examining some of the readings selected in the case studies for this module, and then following those investigations as a model for how one might examine ethical issues. The cases, however, will be more interesting if students address issues, pollutants, workplaces, and problems faced in their own communities. Such emphases will bring ethical issues "home."

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# **MODULE 8**

## **Public Health Genetics: Screening Programs and Individual Testing/Counseling**

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### **Issue Essay**

Advances in genetic science provide new insight into the complex, interactive roles that genetic and environmental factors play in morbidity and mortality, and they consequently create innumerable opportunities for disease prevention and health promotion. Should genetic information and genetic interventions, however, be used routinely in public health—like other health data and services—or are they different? Answers to this question essentially frame the ethical debates about public health genetics.

While some people argue that the uniquely personal nature of genetic information requires an individual rights approach that limits public health use, others view genetic data as just another type of population data that can be collected, aggregated, and used along with other surveillance and environmental data to produce social utility. Still others focus on the significant power of genetic advancements to improve individual lives and, from a distributive justice perspective, emphasize public health's responsibility to not only ensure access to genetic information throughout the population but more importantly to provide genetic services for the disadvantaged. Public health must address these and other competing ethical claims when developing public health genetics policies.

### **Public Health Ethics**

Public health genetics has been defined as “the application of advances in genetics and molecular biotechnology to improve public health and prevent disease.”<sup>1</sup> As with public health generally, it is teleological (end-oriented) and consequentialist—it draws on a population-wide analysis to identify strategies for improving the health of the entire population, in contrast to the patient-centered focus of clinical genetics.

Several of the major ethical principles or considerations that animate public health include: producing population benefits, preventing and removing harms, and producing the maximal balance of benefits over harms and other costs (utility). These values provide a *prima facie* warrant for public health action.



Newborn genetic screening programs are just one example of public health interventions justified by these values.

Other general moral considerations in public health, however, are recognized as setting limits or constraints on what may be done in pursuit of population health and social utility. These concerns include respecting individuals' autonomous choices and actions, protecting privacy and confidentiality, distributing benefits and burdens fairly, and maintaining trust with the community. Unlike with public health interventions directed at the entire population, such as water fluoridation, genetic interventions are at their core individually focused, requiring the collection of individual-specific data and often targeting individuals and groups at risk for genetic conditions. Thus, public health genetic interventions have the potential to cause or increase social harms, especially when the targeted individuals or groups have been vulnerable in the past to discrimination or social stigmatization because of race or ethnicity. For this reason some critics maintain that few, if any, government-sponsored public health genetics interventions are appropriate. This perspective often is based on a balancing of the potential population benefits of genetic interventions with what these critics consider to be the stronger moral claims against the intervention which arise from the risk of social harms and from individual interests in autonomy, privacy, and confidentiality.

For some genetic interventions, such as newborn screening, ethical considerations such as respect for individual autonomy, privacy, and confidentiality, therefore, may act as ethical constraints on public health action. This perspective is evident in arguments that call for requiring explicit informed consent from parents for all newborn screening programs, even though requiring consent will likely lead to a decrease in both population and individual benefit because some infants will not be screened. Ethical justification for this position is based both on (i) a heightened autonomy interest, because the potential social harm to individuals from the misuse of genetic data is judged to be greater than with other types of medical data, and (ii) a related need to explicitly involve individuals in genetics decisions in order to maintain trust with community members, who are partners with public health officials in defining and achieving population health benefits.

These autonomy-based ethical arguments are countered generally in public health genetics policies by claims that genetic science fundamentally challenges and requires new specifications of the concept of autonomy. After all, by establishing the genetic links among individuals, families, and groups, genetic science generates new questions and insight about moral obligations to those who are genetically related—and to the public in general. Given humans' common genetic heritage and the fact that genetic advancements result from (and often *depend* on) the analysis of population data and the collective efforts of scientists and organizations, this perspective suggests that individual interests cannot easily be separated from population benefits, and that even individual interests are supported in the long run by acknowledging the weight of moral claims to produce population health benefits.

This perspective, based on the view that genetic science heralds a new era of medical and pharmacogenetic treatment, may even lead to ethical claims that human genetic data are a form of common property that should be collected and analyzed for purposes of social utility and population health. With this line of argument, for instance, genetic data from newborn screening programs might be viewed as common property; thus, being screened and providing genetic data for population-based surveillance to allow for analysis of genetic/environmental interactions might be considered an

obligation of citizens for the social good, similar to the obligation to submit to compulsory immunizations or to pay taxes.

It is common in public health practice for conflicts to arise among important moral considerations such as, in newborn screening programs, between producing population benefits and respecting individual liberty (by requiring parental consent). To help determine whether promoting public health with a particular program warrants overriding conflicting values such as individual liberty, Childress, Faden and Gaare, *et al.*, propose five “justificatory conditions” or criteria. These are 1) effectiveness (the public health program will likely realize its goal); 2) proportionality (the probable benefits of the program outweigh the infringed general moral considerations); 3) necessity (the program is essential to achieve the public health goal); 4) least infringement (the program is the least restrictive alternative); and 5) public justification (public justification can be given).<sup>2</sup> An ethical analysis of newborn screening programs using these criteria would be aided by empirical data, as well as public consultation. For example, information about parents’ willingness to give consent if the screening programs were voluntary would provide evidence about whether the mandatory programs satisfy the least infringement condition.

## **The History of Eugenics**

A long shadow is cast on public health genetics by the history of eugenics, a social movement of the early 20<sup>th</sup> century that carried to an extreme the impetus to improve the human population through government interference in reproduction and in the selective transmission of genes to future generations. Although people often remember eugenics as an evil Nazi project to purify Germany’s gene pool, it was in fact widely popular in the U.S., Europe, and other countries as a way to cure social ills such as drunkenness, criminal behavior, and poverty. Groups with divergent political views, including Progressives, reformists, feminists, and successful capitalists, believed that society ought to foster the breeding of those with favorable traits (positive eugenics) and discourage or prevent the breeding of the biologically inferior (negative eugenics).

Although eugenicists varied greatly in their particular beliefs and approaches, class and race prejudices were pervasive. In Northern Europe and the United States, eugenicists generally “favored standards of fitness and social value that were predominantly white, middle-class, Protestant....”<sup>3</sup> Positive eugenics programs rarely went beyond providing encouragements, such as “Fitter Family” competitions or family allowances. Negative eugenic projects, however, led to coercive measures like the eugenic sterilization laws enacted in Northern Europe, including Denmark, Sweden, and Germany, and in more than two dozen American states by the mid-1930s. The constitutionality of these laws was upheld in the 1927 U.S. Supreme Court decision, *Buck v. Bell*. The court’s now-dubious opinion, written by Justice Oliver Wendell Holmes, stated that “(t)he principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes,”<sup>4</sup> and explicitly proposed the worrisome connections between public health and eugenics.

## **Public Values and Accountability**

The integration of genetics into public health practice today must be understood in the context of significant progress made during the last 50 years in scientific and technological knowledge and in the development of national and international norms for medical research, professional ethics, and reproductive rights—all of which provide safeguards against a revival of eugenic policies. For instance, public health ethics increasingly acknowledges the partnership between public health professionals and

the community in jointly defining goals and articulating values. (This is similar to the evolution that occurred in clinical medical ethics during the last half-century, in which the doctrine of informed consent, based on respect for the autonomy of individual patients, increasingly established the patient as a partner in defining his or her treatment plan.)

The public health/community partnership extends not only to defining community health problems, collecting and interpreting data, and designing appropriate interventions but also to jointly developing policies, regulations, and laws to protect individual and group interests that may be adversely affected. When considering public health genetics policies, many public health professionals and researchers explicitly address the history of eugenic abuses. For example, the Association of State and Territorial Health Officers' (ASTHO's) public health genetics policy statement includes a section on eugenics that states:

In the early to mid twentieth century, approximately 30 states enacted eugenics laws to limit the transmission of perceived undesirable characteristics such as mental retardation by restricting the reproduction of affected individuals. There was little scientific evidence by current standards that would have indicated that a person with one of the targeted traits would have offspring with the same condition; however, tens of thousands of women and men were involuntarily sterilized as a result of these laws. A situation like this must never be allowed to occur.<sup>5</sup>

Condit, Parrott, and O'Grady are even more specific, identifying at least three lessons learned from the past: Genetic information can be used to stigmatize; genetic information should be used to benefit individuals; and "genetically based decisions must be made by individuals, based on their own values and preferences, not on externally imposed criteria, whether or not these criteria are perceived to be true and just by socially sanctioned experts."<sup>6</sup> They question public health choices that favor financial concerns about efficiency over individual rights, and suggest, for instance, that voluntary newborn screening programs may be superior to nonvoluntary approaches, in part because research suggests that parents who voluntarily involve their families may be "more likely to follow through on treatment regimens because they understand and are committed to their value."<sup>7</sup>

An ethical analysis of a genetic intervention by a public health agency, then, might begin with the following questions: *What is at stake in the situation? What is at stake in alternative courses of action? Who are the critical stakeholders?* A stakeholder is anyone who might be affected by the decision, and part of the analysis would include consideration of the costs and benefits of an action for each stakeholder as well as the nature of the relationships with and among stakeholders. With questions of genetics, for which "stakeholders" can include distant relatives or future generations, a stakeholder approach to understanding and balancing the conflicting moral obligations and principles provides a useful framework for identifying ethically relevant considerations.

This "ethics process," especially when it is public and includes actual stakeholders (when possible) rather than representatives speaking on their behalf, can facilitate real understanding. Ethical deliberation also can illuminate questions that can be addressed by empirical research (e.g., assessing the actual risk of genetic discrimination) and the need for legislative action (e.g., anti-discrimination laws). Public health policy evolves as empirical evidence about the effectiveness and the social effects of interventions accumulates, and as societal responses change.

For *government* public health officials, public health ethics requires a process of public accountability. At a minimum, their accountability involves “transparency in openly seeking information from those affected and in honest disclosure of relevant information to the public.”<sup>8</sup> For genetics and other issues about which there is ethical disagreement, public health ethics also requires a fair process, which—as defined by Norman Daniels in a different context—includes: (1) transparency and publicity about the reasons for a decision; (2) appeals to rationales and evidence that fair-minded parties would agree are relevant; and (3) procedures for appealing and revising decisions in light of challenges by various stakeholders. As Daniels explains, “Since we may not be able to construct principles that yield fair decisions ahead of time, we need a process that allows us to develop those reasons over time as we face real cases.”<sup>9</sup>

## Public Health Genetics

The role of governmental public health agencies in addressing genetic advancements encompasses the three core functions defined for public health practice by the Institute of Medicine:

- Assessment (of data on the population’s health)
- Assurance (of high quality health services)
- Policy development (to serve the public interest by promoting the use of scientific knowledge)

The Centers for Disease Control and Prevention (CDC), in addition to state and local health departments, currently have oversight of large health care databases, including birth and death records, disease registries, and statistics on reportable diseases, and with these data, they determine the need for and benefit of population interventions, such as educational programs on nutrition or screening programs for high blood pressure or cancer. Khoury, Burke, and Thomson call for the collection of additional surveillance data “to determine the population frequency of genetic variants that predispose people to specific diseases, both common and rare; the population frequency of morbidity and mortality associated with such diseases; and the prevalence and effects of environmental factors known to interact with given genotypes in producing diseases.”<sup>10</sup>

Current birth-defects surveillance illustrates the value of such population data—for instance, in understanding the etiology of certain genetic conditions or birth defects clusters, such as those caused by new teratogens in the environment or health services. Botto and Mastroiacovo point out that population monitoring was useful in identifying valproic acid as a cause of spina bifida and the association of a cluster of limb anomalies among infants with their mothers’ chorionic villus sampling (CVS). They suggest that international comparisons of the prevalence of neural-tube defects, for instance, may provide insight about gene-environment interactions, particularly if prevalence data are integrated with population data on genetic variation (e.g., the frequency of polymorphisms of folate-related genes) and dietary intake (e.g., micronutrient consumption).<sup>11</sup>

Identifying the connection between environmental risk factors and inherited susceptibility to cancer also has been called a “new paradigm” for cancer prevention and control, and Coughlin and Burke describe the need for additional population-based molecular epidemiologic research to explore these connections. They hypothesize, for instance, that for women at risk of breast cancer, gene-environment interactions between gene mutations and nongenetic factors, such as ionizing radiation or cigarette smoking, may be identified and lead to new targeted prevention programs.<sup>12</sup>

These examples illustrate the vagueness of the term “genetic condition.” While it often refers to relatively rare conditions in which a single gene is implicated (e.g., Huntington’s Disease), public health genetics has a much broader focus. In fact, because virtually all human disease involves both genetic variants and environmental factors (broadly defined to include infectious, physical, and social factors), viewing any particular condition in public health as “genetic” is as much a matter of public choice and ethics as it is genetic science.

Some scientific distinctions about genetic disorders and causation may not even be helpful in determining the appropriate role for public health. An example is the distinction medical geneticists make between disorders resulting from single-gene variants, such as PKU and hemochromatosis, and other disorders associated with susceptibility genes, such as colon cancer and breast cancer. Khoury, Burke, and Thomson describe the complexity of genetic labels by pointing out that even many of the classic single-gene metabolic disorders are the result of both a deficiency in a nutritional enzyme and a dietary exposure to one or more chemicals (e.g., phenylalanine and phenylalanine hydroxylase deficiency in PKU; iron intake and mutations in the HFE gene in hereditary hemochromatosis).<sup>13</sup> They quote Rothman: “It is easy to show that 100% of any disease is environmentally determined and 100% is genetically determined as well. Any other view is based on a naive understanding of causation.”<sup>14</sup> Given the pervasive role of genetic factors in human disease, then, the more important issue involves not whether some disorder is labeled “genetic” rather than behavioral or environmental but instead, when and how to use genetic information and technology effectively, and ethically, in public health policy and practice.

Tobacco use, commonly viewed as a behavioral or environmental problem, illustrates this point. Even though more than 90% of lung cancers may be caused by smoking, only 10-15% of smokers develop lung cancer, which suggests “the interaction of smoking with other factors including genetic ones.”<sup>15</sup> If a genetic test became available to determine an individual’s susceptibility to cancer from exposure to tobacco smoke, what would be an appropriate public health response? Would including the genetic test be justified as part of the state newborn screening program, so that public health professionals could alert parents to take particular precautions to protect the child from second-hand smoke? Would the state be justified in following up later in childhood and targeting particular anti-smoking interventions to middle-school children with genetic susceptibilities? Would the public health department be justified in requiring genetic analysis of lung cancers in the cancer registry, so that family members could be told of their potential susceptibility—and, if so, should such notification be mandatory or voluntary? Should public health departments provide access to genetic tests for susceptibility? If so, should they collect the data in order to target education and behavior modification interventions to those at special risk, including the family members of those tested?

In answering many of these questions, scientific assessments of the magnitude of genetic susceptibilities may be less important than the ethical considerations. These include concerns about individual rights, such as liberty of action and the risk of discrimination, stigmatization, and social harm, in addition to concerns about ensuring equitable access to services and maintaining public trust. Determining whether to use genetic technology and genetic information about tobacco in a public health program requires examining the social, economic, and political implications of such a decision. There are implications for individuals, such as the potential for discriminatory use of genetic information in insurance and employment, as well as widespread social effects, such as a potential public perception that tobacco use is merely a genetic problem of a subgroup of the population. This in turn may lessen a sense of

collective responsibility for addressing the underlying economic and political issues related to tobacco production and use.

A complex web of individual and group interests, benefits, and costs is involved in these questions, and the public health agency provides a public structure to facilitate transparent ethical reflection, deliberation, and consensus-building. Public health accountability ensures that tradeoffs and balancing of ethical claims will be made openly, with explicit acknowledgement that individuals' fundamental well-being and values are at stake and that reasons, grounded in ethics, will be provided to those potentially affected by the decisions. At the same time, public health ethics with its population perspective focuses attention on the level and distribution of well-being throughout the population and "makes explicit the competition for scarce resources that has proven difficult to address in the patient-centered maze of medical ethics."<sup>16</sup>

## Genetic Testing

Genetic tests are rapidly being developed and marketed for clinical diagnosis, treatment, and prevention, and are now available for hundreds of inherited and chromosomal disorders and genetic predispositions. A genetic test is defined as:

*[T]he analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting the risk of disease, identifying carriers, and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and carrier screening, as well as testing in high risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes. Tests conducted purely for research are excluded from the definition, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes...Some, but not all, predictive genetic testing falls under the rubric 'genetic screening,' a search in a population for persons possessing certain genotypes.*<sup>17</sup>

The 1997 Final Report of the Task Force on Genetic Testing (established by the National Institutes of Health-Department of Energy Working Group on Ethical, Legal, and Social Implications of Human Genome Research) provided extensive recommendations on the safety and effectiveness of genetic tests, as well as the overarching principles excerpted below as guides for future policy:<sup>18</sup>

***Informed Consent.*** The Task Force strongly advocates written informed consent [for genetic testing]. The failure of the Task Force to comment on informed consent for other uses does not imply that it should not be obtained.

***Test Development***—Informed consent for any validation study must be obtained whenever the specimen can be linked to the subject from which it came.

***Testing in Clinical Practice***— (I) It is unacceptable to coerce or intimidate individuals or families regarding their decision about predictive genetic testing. Respect for personal autonomy is paramount. People being offered testing must understand that it

is voluntary. Their informed consent should be obtained. Whatever decision they make, their care should not be jeopardized.

(2) Prior to the initiation of predictive testing in clinical practice, health care providers must describe the features of the genetic test, including potential consequences, to potential test recipients.

*Newborn Screening*—(1) If informed consent is waived for a newborn screening test, the analytical and clinical validity and clinical utility of the test must be established and parents must be provided with sufficient information to understand the reasons for screening. By clinical utility, the Task Force means that interventions to improve the outcome of the infant identified by screening have been proven to be safe and effective.

(2) For those disorders for which newborn screening is available but the tests have not been validated or shown to have clinical utility, written parental consent is required prior to testing.

***Prenatal and Carrier Testing.*** Respect for an individual's/couple's beliefs and values concerning tests undertaken for assisting reproductive decisions is of paramount importance and can best be maintained by a nondirective stance. One way of ensuring that a non-directive stance is taken and that parents' decisions are autonomous is through requiring informed consent.

***Testing of Children.*** Genetic testing of children for adult onset diseases should not be undertaken unless direct medical benefit will accrue to the child and this benefit would be lost by waiting until the child has reached adulthood.

***Confidentiality.*** Protecting the confidentiality of information is essential for all uses of genetic tests. (1) Results should be released only to those individuals for whom the test recipient has given consent for information release. Means of transmitting information should be chosen to minimize the likelihood that results will become available to unauthorized persons or organizations. Under no circumstances should results with identifiers be provided to any outside parties, including employers, insurers, or government agencies, without the test recipient's written consent.

(2) Health care providers have an obligation to the person being tested not to inform other family members without the permission of the person tested, except in extreme circumstances.

***Discrimination.*** No individual should be subjected to unfair discrimination by a third party on the basis of having had a genetic test or receiving an abnormal genetic test result. Third parties include insurers, employers, and educational and other institutions that routinely inquire about the health of applicants for services or positions.

***Consumer Involvement in Policy Making.*** Although other stakeholders are concerned about protecting consumers, they cannot always provide the perspective brought by consumers themselves, the end users of genetic testing. Consumers should be involved in policy (but not

necessarily in technical) decisions regarding the adoption, introduction, and use of new, predictive genetic tests.

### **Public Health Genetic Testing**

The formulation of sound public health policy regarding genetic testing and screening programs requires an on-going, systematic, evidence-based analysis of the benefits, risks, and costs of genetic tests and follow-up interventions. Multidisciplinary research and perspectives from history, cultural anthropology, economics, psychology, and other disciplines provide important information. Given that the risks and harms of genetic testing are primarily psychosocial, empirical evidence is necessary in order to assess whether the tests are justified—that is, whether the probable benefits outweigh the probable harms or costs. As Beauchamp and Childress point out, the probable benefits also “vary from genetic condition to condition, depending on whether the screening and testing are for disease, disposing condition, or carrier status, whether preventive or treatment measures are available, whether the information is important for reproductive decisions, and the like.” They summarize: “For any genetic screening or testing, fundamental questions concern who will use the resulting information, how they will use it, and for what purposes.”<sup>19</sup>

As with any public health decision, critical questions involve (1) deciding what factors to include in the calculations of costs and benefits (e.g., whether to include in the cost calculations the future lost productivity of children who die or suffer disability as a result of not being screened as newborns) and (2) determining how to value the costs of social stigma that may result from targeting particular groups at high risk.

The following types of genetic testing are especially relevant to this discussion.

***Newborn Screening Programs for Phenylketonuria (PKU).*** These programs were among the first genetic screening programs developed in the United States and, along with testing for hypothyroidism and hemoglobinopathies, are now conducted in all 50 states and the District of Columbia. Widely touted as a public health success, they identify infants with the hereditary metabolic disorder so that special dietary treatment can prevent life-long mental disabilities. However, commentators have criticized the way the PKU screening programs were initially developed and their legacy of mandatory newborn screening without parental consent.

The PKU programs were established throughout the United States during the 1960s and 1970s, without the initial support of the American Academy of Pediatrics and the medical community in general, without prior controlled clinical trials, without appropriate empirical evidence about the optimal diagnosis and management of PKU, and without adequate treatment programs. Even today, the economic impact on and financial support available for U.S. families affected by the disease are not well documented. The fact that testing for a rare condition affecting fewer than 400 American infants a year attracted such a groundswell of support has been attributed in part to the advocacy of various groups, such as the March of Dimes Birth Defects Foundation and the National Association for Retarded Citizens (now the ARC), which proposed model legislation to create public programs and conducted lobbying campaigns. Other support came from PKU clinicians, parents, and the Kennedy Administration’s Presidential Advisory Commission on Mental Retardation, which hired an advertising group to develop a public campaign advocating mandatory screening.<sup>20</sup>



Given the widespread public acceptance of PKU screening, many states also began screening for sickle cell disease (SCD) in the early 1970s. SCD, an autosomal recessive hemolytic anemia that occurs most frequently in African Americans, causes serious infections, life-threatening splenic sequestration and severe anemia, stroke, and respiratory problems. When SCD screening laws were first introduced, they varied greatly, with some targeting special populations and some including newborns, preschool children, and even individuals seeking marriage licenses. New York's statute, for instance, required screening for urban school children but not rural ones. Most laws did not include confidentiality provisions; the result, in some cases, was stigmatization, charges of racism, and documented discrimination, especially in the military. An Institute of Medicine Report (IOM) states: "Initial supporters of SCD screening were spurred on by the success of PKU screening, but the clear difference between SCD and PKU was not fully appreciated until later. There was no intervention for SCD at this time other than counseling to avoid marriage or pregnancy (prenatal SCD screening was not feasible)."<sup>21</sup>

The National Sickle Cell Anemia Control Act, enacted in 1972, made federal funding for screening contingent on programs being voluntary. However, since a prophylactic regimen of penicillin in infants was shown in the 1980s to significantly reduce the morbidity and mortality of SCD, and a National Institutes of Health consensus panel in 1987 recommended universal (not targeted) newborn screening, about 40 states and the District of Columbia have now adopted universal newborn screening programs for SCD. The IOM report summarizes the lessons learned from the early sickle cell screening programs as follows:

*The experience with SCD screening in the 1970s illustrates the difficulties that can arise when the goals of screening programs are not clearly specified, when there is no treatment that improves health outcomes, and when the intervention is not acceptable to the target population because of stigma and discrimination....The change in approach to SCD screening over time, as new facts and treatment opportunities emerge, illustrates that programs must have the flexibility to change over time, as the situation changes.*<sup>22</sup>

These early experiences led to numerous multidisciplinary policy statements, beginning with a National Academy of Sciences report in 1975, all of which recommend that empirical research on the benefits and risks of a particular genetic test be undertaken before mass screening programs are established. The 1997 Report of the National Institutes of Health-Department of Energy's Task Force on Genetic Testing, for instance, stated the newborn screening tests must have primary benefit for the infant identified and are not justified solely to determine the carrier status of the infant or parents.<sup>23</sup> Others have called for assessing the community's interest in and acceptance of a genetic test, particularly if a particular group will be targeted for screening; assuring laboratory quality; addressing issues of education, informed consent, privacy, and confidentiality; assuring the availability of follow-up services; and assessing the costs and the priority of the particular test, given the limited financial resources.<sup>24</sup>

Newborn screening programs currently vary greatly among the states, so that the 4 million infants born annually in the United States are tested for different conditions depending on where they are born. Mounting pressure from parents, advocacy groups, medical professionals, and test manufacturers is being exerted on state legislatures to increase the number of conditions included in state screening programs, while numerous groups are calling for national standards so that all newborns in this country will have equitable access to appropriate newborn screening and its potential benefits. The 1994 Institute of Medicine Committee on Assessing Genetic Risks recommended that three conditions be met before a newborn screening program is initiated: (1) The identification of the genetic condition provides

a clear benefit to the child; (2) a system must be in place to confirm the diagnosis; and (3) treatment and follow-up must be available for affected newborns.<sup>25</sup> In fact, however, state newborn screening policies are influenced by many other factors, such as community values; political and economic conditions; and the availability of health data, public health personnel, laboratory facilities, and technical capabilities within the state.

A Report from the Newborn Task Force on Newborn Screening in 2000 explicitly recommended that “public health agencies must involve health professionals, families and the general public in the development, operation, and oversight of newborn screening systems.”<sup>26</sup> Current controversies focus on the role of various stakeholders in allocation and financing decisions related to screening programs, particularly given the cost of follow-up programs that must be supported by state health departments and the need to balance resources among competing community health needs, including screening and services for other genetic disorders. Particular attention is focused on the methods and role of cost-effectiveness analysis in determining which tests to include in newborn screening programs and on the appropriateness of informing and seeking consent from parents for newborn screening.

The ethical issue of informed consent for newborn screening was addressed by the American Academy of Pediatrics in its 2001 policy statement, “Ethical Issues with Genetic Testing in Pediatrics.”<sup>27</sup> The report provides the following analysis:

A persistent ethical issue in newborn screening is whether screening should be voluntary or mandatory. Whether programs are voluntary or mandatory has significant implications for informed responses to test results and for the integration of new tests into established programs. A voluntary approach in this context entails an informed decision by parents about newborn screening. Wyoming and Maryland are the only 2 states that require informed consent for newborn screening, although 13 other states require that parents be informed about newborn screening before testing (18). A mandatory approach in this context requires an explicit refusal of screening by parents who object to this intervention. All states except South Dakota permit parental refusal of newborn screening for religious or personal reasons (18).

*The principal ethical justification offered for mandatory screening is the claim that society's obligation to promote child welfare through early detection and treatment of selected conditions supersedes parental prerogatives to refuse this simple medical intervention (19). An opposing argument maintains that parents traditionally have broad discretion for making health care decisions for their children. Although parents do not have the prerogative to forgo effective treatments for life-threatening conditions, they generally have the prerogative to pursue a variety of options in less threatening circumstances, including options that some medical professionals would consider unwise. Furthermore, it is argued that the great majority of parents will continue to be supportive of newborn screening when they are informed adequately of the risks and benefits (20).*

*With continued broad public support, approaches involving informed consent (that is, parental permission) (21) may fulfill the important goals of the programs and enhance program quality while respecting traditional parental prerogatives to be informed participants in health care decisions for their children. In a study of newborn screening in Maryland involving informed consent, the majority of women preferred that permission be asked before screening, and the informed refusal rate was only 5 per 1000 infants (22). In the Maryland study, the consent*

*process typically took 5 minutes or less of staff time. Additional research to develop and evaluate models of parental education and consent will be valuable.*

*Two potential advantages of obtaining informed consent for newborn screening include more prompt and efficient responses to positive results and an ability to incorporate experimental tests into established screening programs. Under current programs, the information provided to parents about newborn screening is often minimal. A significant source of problems in newborn screening programs is slow or uninformed responses to test results by parents and physicians (23). If an informed consent process promotes more thorough understanding of the implications of the tests, slow or inappropriate responses to positive results may decrease. Second, advances in genetic research will offer many additional tests for consideration by newborn screening programs (24). The relative risks and benefits of new tests will be uncertain until adequate clinical research has been conducted. In these circumstances, experimental tests should be offered on a voluntary basis with informed consent. Experimental tests could be integrated more easily in screening programs that routinely sought informed consent for newborn screening tests.<sup>28</sup>*

Additional ethical questions about informed consent arise regarding the storage and later use of newborn blood spots to evaluate the effect of genetic variation on population morbidity and mortality. While informed consent is universally understood to be required for genetic research, no consensus exists regarding informed consent standards for the use of stored samples—especially anonymous ones—to conduct epidemiological studies based on large-scale screening and/or surveillance data. Khoury, Burke, and Thomson describe the “debate about the practicality of re-contacting subjects from population studies (for informed consent); whether or not genetic studies pose more than ‘minimal risks’ to subjects; the definitions and desirability of ‘anonymization’ of existing samples; and whether or not coded but ‘linked’ or linkable’ samples can be used.”<sup>29</sup> Balancing the potential harms to individual interests with the potential benefits to individual and population health requires a systematic assessment of the benefits, risks, and costs to individuals, perhaps through pilot demonstrations; an evaluation of methods for maintaining privacy and confidentiality within public health registries; and an exploration of ways to minimize the potential stigmatization of population subgroups.

***Predictive Genetic Testing to Learn the Risk of Future Disease.*** These tests can reveal the presence of genetic disorders presymptomatically, as in the case of hereditary hemochromatosis, or can reveal susceptibility to certain diseases, such as with BRCA1 breast cancer or colon cancer. Genetic testing or screening is most appropriate when early treatment or other modifiable risk factors allow for behavior change or preventive interventions that can reduce the probability of harm, and when an assessment of the benefits, harms, and costs of testing and population screening programs provides the basis for the public health policy. Ethical issues are often related to the potential psychological harm to individuals, family members, and family interactions and relationships that may result from testing, inaccurate or misunderstood results, and the potential misuse of genetic risk information in insurance and employment discrimination.

Hereditary hemochromatosis (HH), a common adult-onset genetic disorder for which screening tests and treatments are available, illustrates the challenges for public health policy making. The disorder, which is estimated to occur in one out of every 200 to 400 people of European heritage, causes

excessive iron storage and can lead to damage of the liver and other organs, arthritis, and diabetes in many but not all affected adults. Treatment by removing iron from the blood is safe and effective and can lead to a normal life expectancy if initiated before organ damage has occurred. Many in the medical community, as well as patient support groups, advocate population screening. However, universal screening for HH was rejected by a 1997 consensus panel, in part because of inadequate clinical knowledge about the natural history of hemochromatosis, uncertainty about the proportion of people with genetic risk who will develop the complications of iron overload, and concern about possible genetic discrimination.<sup>30</sup> The president of the American Society of Human Genetics challenged the consensus statement and argued that the potential to prevent disease outweighed the various problems. Other commentators also have expressed similar concern: “We are facing the dilemma of waiting until all requisite information about diagnostic process and therapeutic indications is available or cautiously initiating a more vigorous screening program that will detect unsuspected disease with potential morbidity and mortality, realizing that unnecessary therapy and anxiety may occur.”<sup>31</sup> One worry in particular about HFE mutation testing for hemochromatosis is the possibility that follow-up treatment will be initiated in individuals who may test positive but who may never develop the iron overload condition. The Centers for Disease Control and Prevention recommends, instead, iron overload testing (not genetic testing) for individuals who have affected blood relatives. CDC experts believe that “strategies are needed to disseminate information to family members about their genetic risk and to aid their efforts to be tested, and that this “must be accomplished in the course of patient care.”<sup>32</sup> Public policy regarding HH population screening shows the complexity of initiating population genetic screening programs, given the need to evaluate the predictive value of the test, measure the benefits and harms of testing and not testing, protect against genetic discrimination, and act without complete knowledge.

With the proliferation of genetic tests comes a number of particularly challenging issues regarding the benefits of tests for disorders for which there currently is no clear treatment. These issues include (1) the difficulty of assessing the results of many genetic tests and providing helpful information about genetic risks and (2) the appropriate role for government regulation of commercial tests with uncertain predictive accuracy. Genetic tests available for breast cancer and Alzheimer’s disease, for instance, indicate only a propensity or increased probability of developing the diseases, while even tests for other disorders that are completely penetrant (i.e., always result in disease), such as Huntington’s Disease, do not provide information about severity or onset of the disease, which can be highly variable.

Consequently, providing genetic information does not always influence individuals to undertake prevention activities. Andrews describes the complex reactions and psychological harms that can result from genetic testing. She writes: “In fact, there is evidence that the stress created by genetic information can actually lessen the likelihood that the individual will engage in surveillance strategies and monitor himself or herself for early signs of the disease.”<sup>33</sup> Andrews also points out other potential harms that may arise from the misinterpretation of a negative test result, including a false sense of security. Numerous ethical questions arise regarding the benefits and harms that result from such tests; the appropriateness of commercial marketing of these tests, particularly given the fears associated with certain genetic conditions; and insurance reimbursement or government financial support for the tests and for follow-up prophylactic interventions, such as removal of breasts.

Predictive genetic testing of children and adolescents for late-onset disorders, such as Huntington’s Disease and hemochromatosis, raises unique ethical questions because testing in childhood limits the child’s freedom of choice later in life to decide not to be tested (many adults choose not to be tested,

so consent cannot be presumed) and subjects the child to the risk of stigma and discrimination. The American Academy of Pediatrics' policy states that, unless there is anticipated benefit to the child or the availability of interventions that can be initiated in childhood to reduce morbidity and mortality, "genetic testing for adult-onset conditions generally should be deferred until adulthood or until an adolescent interested in testing has developed mature decision-making capacities."<sup>34</sup>

***Reproductive Testing and Prenatal Screening.*** These tests raise particular challenges for public health practice and policy, such as ensuring that the reproductive freedom of vulnerable individuals is adequately protected; clearly defining and implementing nondirective goals for genetic counseling programs; and developing assessment tools for cost-effectiveness evaluation of public health prenatal screening programs. Family history has long provided clues about an individual's risk of genetic disease, but hundreds of genetic tests are now available to clearly identify people who are carriers of genetic conditions that may be passed on to their children, including Tay-Sachs disease, muscular dystrophy, cystic fibrosis, and sickle cell anemia. Many people emphasize that carrier testing and genetic counseling can provide significant benefit to individuals by enhancing their capacity to make informed choices about reproduction. The information about genetic risk presents individuals with numerous options: prior to conception they can decide whether to conceive and/or whether to use reproductive technologies to decrease the risk of transmitting a genetic condition, and after conception they can decide whether to abort an affected fetus.

Providing universal access to low-cost public health carrier screening and reproductive genetic counseling would therefore seem to be desirable from an individual rights perspective (because it facilitates informed reproductive choice for more people and would reduce suffering of future generations) and from a public health perspective (because it would tend to reduce the prevalence of disease and disability). However, universal access to genetic counseling has been challenged on the grounds that it could tend to erode the reproductive freedom of vulnerable individuals. Benkendorf, Peshkin, and Lerman raise concerns that vulnerable individuals may not understand that they are free to refuse recommendations provided by public health programs and may also feel pressure to act on information about abnormal genetic results in ways that are "inconsistent with their values."<sup>35</sup>

Others explicitly challenge the motives for government genetic counseling programs and the presumption that individual and social interests are congruent. Diane B. Paul, for instance, writes: "Today, everyone favors increasing the choices available to women. But fostering reproductive autonomy is rarely if ever the primary goal of governments when they choose to fund genetic services. That states expect to save money is evident in the arguments actually made to legislatures, which are typically framed in cost-benefit terms. Thus it seems that the new consensus on reproductive autonomy rests on the old assumption that families will ordinarily make the 'right' decisions."<sup>36</sup>

In response, some people point out that reproductive freedom can be threatened not just by the state but also by market forces and societal pressures. Underwriting and reimbursement policies of health insurance companies, marketing and pricing by for-profit genetic testing and technology companies, the rhetoric of advocacy groups, and the beliefs held by religious groups are among the many factors that may exert a strong influence on individual reproductive decisions. Calling for expanded clinical genetic services "at public expense if necessary," Buchanan, Brock, Daniels, and Wikler suggest that the state can remove potential pressures to curtail reproductive freedoms—by providing prospective parents with

both adequate information and “alternative means of having children, when the more customary methods threaten genetic harms.”<sup>37</sup>

Because of public funding and the ethical requirements of public accountability, public health initiatives are subject to greater public review and evaluation than private programs. Measuring the benefits of reproductive genetics programs and justifying their costs present yet another challenge, especially using conventional cost-effectiveness evaluation methods. If the goal of these programs is to enhance reproductive decision making, Lin-Fu and Lloyd-Puryear point out the inappropriateness of measuring the costs of the programs against the number of women who undergo amniocentesis or chorionic villus sampling. They question whether public health officials will “deviate from conventional cost-benefit analysis” and consider a sufficient justification for funding a program to be providing the public with “a basis for informed decision making.”<sup>38</sup>

Given their policy development role delineated by the Institute of Medicine, public health professionals increasingly must work with professional organizations and consumer groups to decide when and how to integrate genetic advances into public health. These decisions must be based on at least the following considerations: an epidemiological assessment of the impact or likely impact of a genetic variation on the disease risk; the degree to which the genetic risk or condition is modifiable or treatable; the degree to which the public regards public health action by government as appropriate for the particular condition; and justification that the particular intervention is ethical.

### State of the Debate

Current debates in public health genetics about genetic testing focus generally on defining, measuring, and balancing competing moral values, particularly population benefit, individual interests, and distributive justice. Underlying the discussion about ethical principles and frameworks is the fundamental question of genetic exceptionalism—that is, whether to treat information derived from genetic testing as different from other health-related information by, for example, providing genetic-specific privacy and antidiscrimination laws.

In support of this position, Ronald Green and Mathew Thomas recognize five unique aspects of genetic information: (1) DNA’s informational nature; (2) its longevity; (3) its potential use as a personal identifier; (4) the familial risks indicated by the information; and (5) the effects on communities.<sup>39</sup>

George Annas also argues that genetic information is “uniquely private” and in need of special legislative protection. He suggests that a person’s genetic information can be viewed as a coded “future diary,” which should be considered “as personal and private as a diary about that person’s past.”<sup>40</sup> Annas describes four different ways of thinking about privacy in this country: private information, private relationships (husband-wife), private decisions (such as reproductive), and private places (such as bedrooms). Since genetic information involves three of these four, Annas suggests that genetic information may be “more powerfully private than other types of information.” He goes beyond the usual concerns about the use of genetic information in employment and insurance discrimination because that “discussion assumes that information has already been collected, analyzed, and stored somewhere.” Annas asserts:

*I believe that if you are really interested in genetic privacy, you have to protect people before the information has been collected by giving people a choice to participate or not. To make*

*privacy protection more meaningful, the law should make it clear that each of us owns our DNA.*<sup>41</sup>

Challenging Annas's use of the term "future diary," which "implicitly supports genetic exceptionalism," Douglas Ginsburg argues that our genetic information is much less diverse than written personal diaries and that "the secrets that our future diaries are supposed to hold, like our family histories, speak only to probabilities." Acknowledging that genetic exceptionalism is psychologically compelling, Ginsburg concludes that "the questions that genetic information raises are not sufficiently different from those raised before—either qualitatively or as a matter of degree—to justify the creation of unique legal solutions – solutions likely to serve only to press the popular debate ever more toward the reductionist forms of genetic exceptionalism."<sup>42</sup> Thomas Murray also challenges the basis of genetic exceptionalism as an "overly dramatic view of the significance of genetic information in our lives" and argues that "the more we repeat that genetic information is fundamentally unlike other kinds of medical information, the more support we implicitly provide for genetic determinism, for the notion that genetics exerts special power over our lives."<sup>43</sup>

Burris, Gostin, and Tress suggest that genetic information "is more like, than different from, other health information," and that genetic illnesses may even require less legal protection than sexually transmitted diseases, which often carry a stigma because of their transmission through voluntary risky behavior.<sup>44</sup> They raise arguments similar to those used against HIV exceptionalism:

*On a practical level, we must be cautious that the very people whom policymakers hope to encourage to take advantage of genetic testing may become more reluctant because of the heightened focus on its exceptional nature. Treating genetics as distinct from the rest of medicine may enhance the stigma of genetics testing, even as legislators attempt to remove its stigmatizing effects. This can create public fears and misapprehensions about genetics that could discourage individuals from seeking testing and treatment and thwart future scientific progress.*<sup>45</sup>

Another related normative issue is whether decisions about whether or not to integrate genetic advances into public health practice should focus primarily on their potential long-term benefits for population health, or instead on the potential social harms for individuals and groups. While both harms and benefits are assessed in all ethical analyses, approaches vary in their emphasis, particularly in situations of scientific uncertainty. A decision about whether to incorporate genetic information into existing surveillance systems on infectious disease and cancer illustrates the complexity of such an analysis, since both the benefits and harms are uncertain and difficult to quantify. Given the lack of empirical data, the critical question becomes which side bears the burden of justifying public health action or non-action.

Those who support the collection of additional surveillance data on genetics cite the potential (though unknown) opportunity costs of not acting and emphasize the population health benefits and prevention programs that would be possible with new knowledge about gene-environment interactions. Others believe that the potential harms for individuals are so great that clinical trials and empirical studies must first be conducted to evaluate and eliminate any social harms that might arise with the collection of genetic data. Disagreement focuses, in part, on the extent to which genetic information in public health data banks can be protected from breaches of confidentiality and misuse.

Different frameworks for balancing benefits and harms have been put forward. On one hand, Lori Andrews describes a fundamental rights approach to genetic policymaking, in large part to protect against harm. She explains that the fundamental rights model is appropriate for health care services, such as reproductive services, “that are central to our notions of ourselves” and that have “an impact on how the individual is viewed and treated by social institutions.”<sup>46</sup> Andrews suggests that genetic testing currently is being made available and used without appropriate understanding of and protections against potential negative psychological and social impacts, such as discrimination against individuals and minority groups. The fundamental rights approach, emphasizing individual rights and the need to protect individual freedom, thus gives great weight to individual decisions to voluntarily choose or reject genetic health services and to individuals’ access to extensive information about genetic services.<sup>47</sup>

Andrews raises special concerns about the potential negative impact of genetic services on women and vulnerable populations, such as people of color and individuals with disabilities, and calls for careful examination of the differential impact of genetic interventions on particular groups. Citing empirical research on differential medical treatment of women and minorities, and the history of the eugenics movement, Andrews maintains that individuals in disadvantaged groups “are most likely to have their individual decisions overridden, sometimes on the patronizing grounds that it is for their own good, other times for the supposed good of society.” She argues that “allowing individuals in disadvantaged groups to make informed, more autonomous choices could reduce the resulting stigmatization and inequalities.”<sup>48</sup>

Another ethical perspective focuses more on equal opportunity, maximizing the benefits from genetic science, and recognizing society’s obligations, grounded in requirements of distributive justice, to provide access to genetic services. This approach emphasizes the significant impact of access to genetic services on an individual’s fair access to equal opportunity (which can be severely limited by pain and disability), the potential to prevent grave harm, and the recognition that genetic technology has been created in part with public investment and financial resources from the population as a whole. Buchanan, Brock, Daniels and Wikler urge “maximum progress in developing the genetic techniques and safeguards against exclusion” and propose that “public policy should try to ensure that the benefits of genetic therapy and (particularly) enhancement are not distributed along class lines or selectively to those who already enjoy greater opportunity.”<sup>49</sup>

While acknowledging the concerns of disability rights groups that genetic interventions could further disadvantage those with genetically related disabilities, Buchanan *et al.* contend that this is not an inevitable consequence of genetic progress. They write:

*The problem lies not in our genes, but in their interpretation on a social level. One way we can resist the genetic determinism that constitutes part of the threat of greater discrimination is to demonstrate that we can, as a society, accommodate genetic advances while integrating, rather than marginalizing, people with disabilities.*<sup>50</sup>

These philosophers describe a potential role for the state (to balance market-based inequities) in providing access to genetic services with public funds. They argue that recognition of this role for the state “is not incompatible with a proper respect for reproductive freedom in particular and for liberty generally,”<sup>51</sup> and suggest that future public policy should focus on ameliorating the conditions of those



with disabilities and enacting protective safeguards. Several commentators point to the positive effects of federal protections, such as the 1990 Americans with Disabilities Act (ADA) that protects against employment discrimination for disabled workers who are otherwise qualified to do a job. Policies continue to evolve regarding the extent to which genetic conditions or genetic predispositions without any symptoms are considered disabilities under the ADA, but the law demonstrates society's ability to mandate the inclusion of and reasonable accommodation for those with particular needs or vulnerabilities.

Another set of background normative issues focuses on concerns about genetic reductionism and the identification of families, groups, subpopulations, or communities for public health targeting based on a genetic condition or genetic risk. Targeting particular subgroups with an elevated genetic risk is arguably justified because of the costs of universal screening for genetic conditions that have a very low incidence in the general population. However, concerns arise that increased use of genetic data and targeting will lead to victim-blaming and a public perception that health and illness are individual concerns.<sup>52</sup>

Clayton describes the risks and limitations of targeted public health interventions in general (especially for vulnerable subgroups at risk for stigmatization and discrimination) and the challenges of targeting subpopulations when genetic risk factors may have some correlation with race. Even though she points out that "genetic variation and community, population, and even race do not correlate very well," Clayton nonetheless proposes consulting communities to address the possibility of group harms and to acknowledge the significance of group identities and interests for some members of society. Community consultation, she says, "will provide several important benefits: (1) to understand the group's concerns and to develop responses; (2) to help investigators focus on the consequences of their research for the subjects; and (3) to capitalize upon the teachable moment of research to educate the group about genetics, perhaps mobilizing them to participate in a more informed manner in political debates about the appropriate use of genetic information."<sup>53</sup>

Others, in contrast, note the wide variation of beliefs and experiences within communities and reject the notion of community consent or a strong role for group involvement, proposing instead that *individuals* take into account the risks and benefits of genetic research and testing for their families and communities. Dena Davis, for instance, points out that "even within the most traditional and isolated of communities, a person still has multiple identities based on, for example, age, gender, and profession." She concludes that "(o)nly the individual can decide how her values will adjudicate among the many communities to which she belongs."<sup>54</sup> Others, however, focus on the family unit as having a more significant role regarding genetic information. For example, Doukas and Berg explore the creation of a family covenant for genetics that defines expectations among family members regarding autonomy and benefit and promotes discussion within families about the competing ethical claims and conflicts that arise over genetic testing and information.<sup>55</sup>

These different positions highlight the fact that genetic testing and screening provide information that may have significant implications for family members and particular communities. Courts have begun to address the issue of a physician's duty to warn their patient's family members (who are not their patients) about increased risk of genetic disease. In *Safer v. Pack*,<sup>56</sup> for instance, a New Jersey court focused on the foreseeability of the risk of avoidable harm; the fact that individuals or groups at risk can be easily identified; and that the harm can be averted or minimized by warnings. As genetics continues to be further integrated into public health practice, policies must address the claims of family members

and groups for access to shared genetic information; for warnings about genetic conditions that become known to professionals based on collected genetic data; and for protections from potential social harms. The degree of risk and the severity of the potential harm that can be averted will be significant factors in developing policies.

## Fact Sheet on Genetics/Gene Testing and Screening

*Excerpts adapted from the New York State Department of Health Task Force on Life & the Law Report, "Genetic Testing and Screening in the Age of Genomic Medicine," Executive Summary, pp.1-3 (<http://www.health.state.ny.us/nysdoh/taskfcr/screening.htm>)*

### Genes and Chromosomes

- Genes are the blueprints of heredity. Genes are made of hundreds to thousands of DNA bases. The human genome consists of tens of thousands of pairs of genes. Each person inherits one copy of each gene from each parent.
- Genes are organized along string-like structures called chromosomes. Each individual inherits two sets of twenty-three chromosomes, one from each parent: two sets of twenty-two autosomes and one set of sex chromosomes (X, X or X, Y).

### Genetic Variations, Mutations, and Human Disease

- The DNA base sequence of human genes is about 99.9 percent identical among individuals. About 1 of every 1,000 DNA bases varies among individuals, accounting for inherited differences in traits and disease susceptibility.
- Changes in a DNA base sequence, called mutations, account for inherited gene variations. Mutations may be harmful if they prevent a gene from making a normal copy of its specific protein. These mutations can cause, or increase susceptibility to, specific diseases.
- Single-gene diseases are relatively rare diseases that result when a person inherits one gene with a harmful mutation or a pair of genes in which each has a harmful mutation. Inheritance of these mutated genes generally results in a 100 percent chance of developing a specific disease. Single-gene diseases include autosomal dominant diseases (e.g., Huntington disease), autosomal recessive diseases (e.g., sickle cell disease), and X-linked diseases (e.g., Duchenne muscular dystrophy).
- Most diseases result from a complex set of both genetic and environmental causes. Inheritance of some harmful gene mutations increases the chance, although it does not ensure, that a person will develop a specific disease. These mutations are called inherited susceptibility mutations.

### Genetic Testing

- Genetic testing for inherited genetic variants is performed for several purposes: diagnosis of individuals with symptoms, determination of future disease risks in asymptomatic individuals, determination of genetic risks for progeny, guidance of medical treatment, research, and individual identification.
- Genetic testing for inherited genetic disease risks is an analysis of DNA, chromosomes, or gene products to provide specific information about variations in the number or form of genes or chromosomes in an individual or his or her progeny.

- Genetic information is information about specific variations in genes or chromosomes learned by genetic testing or by other means.
- *DNA-based testing* directly analyzes the DNA base sequence of a gene.
- *Phenotypic testing* identifies specific inherited gene variations indirectly, by detecting specific variations in the structure of a protein encoded by a gene or variations in a protein's enzyme activity.
- *Karyotype* analysis and fluorescent in situ hybridization analysis detect variation in form or number of chromosomes.
- New testing technologies that will promote genetic testing in health care include DNA chip technology and tandem mass spectrometry.

### **Assessing the Accuracy and Usefulness of Genetic Tests**

- Analytical validity of a genetic laboratory test is a measure of how well the test detects what it is designed to detect. It encompasses analytical sensitivity (the probability that the test will detect a gene variant it is designed to detect when present in a sample) and analytical specificity (the probability that the test will be negative when a specific variant tested for is not present in a sample).
- Clinical validity measures the extent to which an analytically valid test result can diagnose a disease or predict future disease. For predictive genetic tests, it includes positive predictive value (the ability to predict that an individual will develop a disease) and negative predictive value (the ability to predict that an individual will not develop a disease).
- For DNA-based testing, clinical validity is limited by genetic heterogeneity and incomplete penetrance. *Genetic heterogeneity* means that different mutations in a specific gene, or mutations in different genes, are associated with the same disease. *Incomplete penetrance* means that within a population, not everyone who tests positive for a specific gene mutation will develop the associated disorder.
- Utility of a test is a measure of how useful test results are to the person tested. Clinical utility is a measure of how a test may guide clinical decisions. In some circumstances, predictive genetic testing may not provide medical preventive or treatment options but may help reduce anxiety and/or aid planning for the future.

### **Predictive Genetic Testing to Assess Reproductive Risks**

- Reproductive genetic tests detect heritable genetic variations that are associated with disease. This type of testing includes carrier testing, prenatal testing of fetal cells, and pre-implantation testing of embryos formed by in vitro fertilization.

- Reproductive genetic tests generally are offered to individuals and couples who are at increased genetic risk for a specific disorder based on family history or membership in a racial or ethnic group that has identified genetic variants that increase risk for a specific disease.
- Carrier testing generally is performed to determine the risk of a healthy individual or couple of having a child with a recessive disorder. It may be performed before or after conception.
- Prenatal testing of fetal cells includes amniocentesis and chorionic villus sampling.
- Pre-implantation testing of embryos formed by in vitro fertilization is performed using single cells removed from individual embryos to detect specific gene mutations or chromosomal anomalies.

### **Predictive Genetic Testing to Assess Future Disease Risks in Healthy Adults**

- Presymptomatic genetic testing is predictive testing of apparently healthy adults to determine whether they are at risk for a single-gene disorder. These disorders occur with virtually 100 percent incidence in persons who have inherited a specific gene mutation.
- Susceptibility (predispositional) testing is predictive genetic testing of apparently healthy adults to determine whether they are at increased risk, relative to the general population, for a specific future disease. A positive test result (finding a mutation) does not necessarily mean that a person will develop a future disease.
- Pharmacogenetic testing is genetic testing of individuals to guide their pharmaceutical or other medical treatment. Pharmacogenetic testing seeks to promote a favorable response and to prevent an adverse response to a drug or other treatment based on genetic predisposition.

## Case Study 1: Cystic Fibrosis Carrier Screening

You are the nurse practitioner who directs one of the health department's largest prenatal clinics serving a diverse urban population, and you have received the following memo. What would be your position on cystic fibrosis carrier screening and why?

To: Senior Health Care Professional Staff  
From: Director, Division of Maternal and Child Health, State Health Department

*The state health department has become aware of new guidance from the American College of Obstetricians and Gynecologists, calling for widespread cystic fibrosis (CF) carrier screening. In light of the new recommendations, the state health department must consider whether to revise its screening policies for pregnant women who receive care in health department prenatal clinics.*

*The current department policy is that high-risk families (those with a family history or child with CF) are referred to a genetics clinic for genetic counseling and testing for CF, if indicated. (The prenatal clinics routinely screen all obstetrical patients for a number of conditions that include rubella, syphilis, and hepatitis B. Targeted sickle cell testing is done for African American patients and others in high risk groups, with follow-up referrals to private genetic clinics funded by the health department, when needed.)*

*Newborn screening for cystic fibrosis currently is not included in the state newborn screening program. Participants in the 1997 Centers for Disease Control and Prevention workshop, "Newborn Screening for Cystic Fibrosis: A Paradigm for Public Health Genetics Policy Development," recommended that several states conduct research/pilot studies to assess the benefits of newborn screening for CF, but evidence is still inconclusive.*

*About 15,000 maternity patients receive care in the state health department clinics each year. About 9,000 (60%) of the patients are Caucasian or another race or ethnicity considered at higher risk for carrying the CF gene. The cost of a test for CF carrier status is about \$250.00. If both parents test positive, a follow-up genetic consultation would cost about \$1,200. At this time, the only targeted testing routinely done in the health department prenatal clinics is for sickle cell anemia. About 6,000 (40%) of the obstetrical patients in the health department prenatal clinics are African American and they routinely receive the targeted sickle cell test, which costs about \$4.00 per test. (Sickle cell has a prevalence rate of about 1 in 600 in the African American population and a carrier rate of about 1 in 12.) The benefit of carrier testing for both sickle cell and cystic fibrosis is the provision of increased information to pregnant couples so that they have the opportunity to learn all they can before their delivery dates in order to make informed decisions and plans.*

*The maternal and child division is calling a meeting of senior health professionals in the division to discuss whether CF carrier screening should be provided. Please review the following material and prepare a brief statement of your perspective on the issue, particularly focusing on the ethical issues.*

## I. Recommendations from the American College of Obstetricians and Gynecologists

### *"Ob-Gyns Offering Large-Scale Cystic Fibrosis Screening"*

([http://www.acog.org/from\\_home/publications/press\\_releases/nr12-12-01-2.cfm](http://www.acog.org/from_home/publications/press_releases/nr12-12-01-2.cfm))

*Washington, DC* --The nation's obstetrician-gynecologists have initiated one of the first clinical changes in the US arising from discoveries of the human genome project. In recent weeks, ob-gyns began to greatly expand the number of couples offered genetic screening for cystic fibrosis (CF) during preconception or prenatal care, thanks to tests made possible by genetic research.

"The genetic revolution has begun," announced Michael T. Mennuti, MD, of The American College of Obstetricians and Gynecologists (ACOG), speaking today at an ACOG press briefing in New York City. "The advances of the human genome project have moved from the laboratory to the obstetrician's office. With these changes come new options and new decisions for expectant couples."

ACOG now recommends that ob-gyns make DNA screening for cystic fibrosis available to all couples seeking preconception or prenatal care -- not just those with a personal or family history of carrying the CF gene, as previously recommended. ACOG has distributed physician and patient education materials to its 40,000 members to help implement this major screening change.

Couples who learn they both carry the CF gene would have a 1 in 4 chance of delivering a child with cystic fibrosis. CF can bring pulmonary and gastrointestinal symptoms of varying severity, but most CF cases are associated with substantial illness and shortened lifespan and require lifelong medical care. Since the discovery in 1989 of the gene, called CFTR, that causes the autosomal recessive genetic disorder of CF, more than 900 mutations of the gene have been identified. Screening is now available for the most frequent CF mutations.

Among ACOG's new recommendations:

- Testing will be made available to all couples, whatever their risk for carrying the CF gene, through information brochures on CF given to couples seeking preconception or prenatal care. These materials explain the relative risks for carrying CF, screening options, and what steps are next should a couple learn that they carry the CF gene.
- For couples in ethnic or racial groups considered at higher risk for carrying the CF gene -- Caucasians, particularly those of European or Ashkenazi Jewish descent -- physicians will specifically offer screening and will follow up with inquiries about the couple's decision on whether to be screened.

"Our approach may become the prototype for future screenings for other genetic diseases," notes Dr. Mennuti, the secretary of ACOG who co-chaired a steering committee on the project.

CF is one of the most common genetic disorders in Caucasian populations, carried by about 1 in 29 Caucasians. CFTR is much less frequent in Asian Americans (carried by 1 in 90), in African Americans (1 in 65), and in Hispanic Americans (1 in 46).

Physicians and patients will need to discuss whether it is worthwhile for a couple to be screened. "Should a couple learn that they both carry the CF gene -- which gives them 1 in 4 odds of having a child with CF -- they must make the personal decision whether to continue or terminate the pregnancy," says Dr. Mennuti. He notes that some couples will want to continue the pregnancy and learn all they can about the health needs and treatments for children with CF. "Testing provides the opportunity for such couples to learn all they can before their delivery due date," notes Dr. Mennuti.

To help physicians and patients with these decisions, ACOG and the American College of Medical Genetics (ACMG) issued a guideline publication for physicians, *Preconception and Prenatal Carrier Screening for Cystic Fibrosis*. A companion brochure for patients, [\*Cystic Fibrosis Carrier Testing: The Decision is Yours\*](#), uses a question-and-answer format to help patients sift through information about their chances for carrying the disease and whether they should have testing. [\*Cystic Fibrosis Testing: What Happens If Both My Partner and I Are Carriers?\*](#) uses a similar format to explain the implications of test results and direct patients to appropriate counseling experts.

Francis S. Collins, MD, PhD, director of the National Human Genome Research Institute, told ACOG members at their 50th anniversary meeting in April that the human genome era in medicine "will have profound implications for all branches of medicine, but perhaps particularly so for obstetrics and gynecology." "It's not surprising that the impact of the human genome project will first hit home during prenatal care visits across the United States," adds Dr. Mennuti. "As we increase our ability to screen for more and more genetic diseases, the obstetrician's office becomes the first arena where individuals confront the new dilemmas presented by 21st century science."

ACOG's initiative is the final phase of a three-year project with ACMG and the National Human Genome Research Institute.

**2. Excerpt from "Access to Genetic Services in the United States: A Challenge to Genetics in Public Health,"** by Jane S. Lin-Fu, M.D. and Michele Lloyd-Puryear, M.D., Ph.D., in *Genetics and Public Health in the 21<sup>st</sup> Century*, ed. Muin J, Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, pp. 286-287.

### **Race and ethnicity in public health genetic programs**

In the United States, although racial designation in census data is based on self-identification, racial classification in the social context has no biological basis. Despite this illogical and offensive approach, the U.S. census and other governmental data sources continue to tabulate data according to race and ethnicity as defined by the 1977 U.S. Office of Management and Budget Directive No. 15.

The incidence of diseases often varies among different racial and ethnic populations, and it is common for public health programs to target high-risk groups who often are minorities. Although the method of reaching out to each community should be culturally appropriate, the actual test and treatment or prevention measures used are generally the same for all racial and



ethnic groups. This one-size-fits-all approach, however, may present a problem in public health genetic programs.

In planning for public health genetics programs, not only must one bear in mind that the frequency of genetic disorders is often very different in different populations and the genotype-phenotype correlation may vary from group to group, but common mutations for the same genetic disease often differ among racial and ethnic populations. A single public health policy on a genetic disease for all racial and ethnic groups may be neither prudent nor ethical. The 1997 National Institutes of Health Consensus Development Statement on Genetic Testing for Cystic Fibrosis [CF] (23) is a clear example.

The Statement recommended that genetic testing for CF should be offered to adults with a positive family history of CF, to partners of people with CF, to those seeking prenatal care and to couples planning a pregnancy. It did not recommend offering the CF test to the general population. The Statement acknowledged the wide range of test sensitivity in different population groups using current technology, nonetheless made no special recommendation for groups for whom the current CF test is of extremely low sensitivity. In the United States, the incidence of cystic fibrosis is much higher among European Americans (1/3,300) than among African Americans (1/15,300) or Asian Americans (1/32,100). Because of differences in mutation, the sensitivities of current cystic fibrosis tests vary widely, ranging from 90-95% among U.S. European Americans to 30% among Asian Americans. Thus offering CF testing to couples planning for a pregnancy or women seeking prenatal care, regardless of race or ethnicity, utilizing tests for the predominant mutations in U.S. European Americans would have an extremely low cost-benefit ratio in certain minority populations such as Asian American and Hispanic (24). More important, offering a genetic test of extremely low sensitivity to certain racial and ethnic populations raises the ethical issue of equity and questions the wisdom of such across-the-board one-size-fits-all genetics public policy for all U.S. populations. In CF testing, assuring true informed decision through effective counseling is a particular challenge for the Hispanic and Asian American populations. These two minority groups have the lowest test sensitivity (57% in Hispanics and 30% in Asian Americans) yet both have a very high proportion of immigrants who face severe linguistic and cultural barriers in accessing any service. Since offering a genetic test of 30-50% or even 75% sensitivity in a broad-based program should have been unacceptable to most public policy-makers, one must question what is an acceptable sensitivity level when genetic testing is recommended without regards to race and ethnicity? If one truly considers all human beings as equal, regardless of race and ethnicity, then shouldn't public health policies and programs on genetic testing seek a test sensitivity of 90-95% for all racial and ethnic groups and not just for the majority population? If this is deemed impractical, and public health programs decide to offer a test with less than 90% sensitivity to certain minority populations, is this ethical and how should people in these communities be counseled? Is equity in fact achievable in one-size-fits-all genetics public policies?

### **3. Recent Research: Cystic Fibrosis Carriers Unlikely to Inform Many Family Members of their Genetic Risk (<http://www.cdc.gov/genomics/update/text/ginl.htm>)**

WASHINGTON, D.C., Nov. 6, 2001 – On the heels of new guidelines from three major medical groups calling for widespread cystic fibrosis (CF) carrier screening, new research suggests that

individuals found to be CF carriers are unlikely to inform many at-risk family members of their status. Several CF papers are being presented here today at the 20th Annual Education Conference of the National Society of Genetic Counselors (NSGC). A report on the largest ethnicity-based prenatal screening program in an HMO setting also is being given today at the meeting.

Just a few weeks ago, the National Institutes of Health, American College of Medical Genetics and the American College of Obstetricians and Gynecologists issued joint guidelines calling for CF carrier screening to be offered to every Caucasian who is pregnant or considering having a baby.

CF is a chronic, progressive illness that causes serious breathing and digestive problems resulting from build-up of sticky mucus in the lungs, pancreas and other organs. The average life expectancy for a person with CF is 32 years. About 1 in 25 Caucasians are carriers of CF, the most common severe recessive condition in individuals of Northern European ancestry. Approximately 1 in 2,500 babies born in this country each year will have CF, which can occur only when both parents are carriers. Genetic testing can identify carriers and determine how likely a couple is to give birth to a child who has CF or will be a CF carrier.

***Carriers Should Be Educated about CF Risk, Importance of Notifying Family Members***

"Many people have never heard of CF and mistakenly believe that if it's not present in their immediate family they are not at risk," said Kelly E. Ormond, genetic counselor and director of the graduate program in genetic counseling at Northwestern University Medical School, Chicago.

Ormond conducted a study to determine how likely CF carriers were to inform immediate and extended family members of their carrier status and whether the presence of a family history of CF affects the likelihood that a carrier will notify at-risk relatives.

"It's important not only to inform relatives if you discover you're a CF carrier, but to explain the implications as well," Ormond said. "Individuals with a first-degree relative who is a CF carrier have a 1 in 2 risk of being a CF carrier themselves. If a second-degree relative is a CF carrier, the risk is 1 in 4; and if a third-degree relative is a carrier, the risk is about 1 in 8."

The Northwestern University study sought to determine the notification attitudes and practices of 48 CF carriers with 871 first-, second- and third-degree relatives. CF carriers who had a family member affected with CF informed 100 percent of their living first-degree relatives (parents, children, siblings and half-siblings); whereas, CF carriers without a family history only informed 84 percent of living parents and 56 percent of siblings.

The most common reasons for sharing CF carrier status with parents and siblings were closeness of social relationship and the birth of an affected child with CF, according to Ormond. Two-thirds of children at risk for being carriers had not yet been informed of carrier status, primarily because they were too young.

CF carriers with a family history of CF informed 68 percent of second-degree relatives (uncles, aunts, nieces and nephews) and 50 percent of third-degree relatives (first cousins). Carriers

without a family history of CF only informed 21 percent of second-degree relatives and 3 percent of third-degree relatives.

***Largest Prenatal CF Carrier Screening Program Finds Pre-Test Education is Essential***

During the NSGC meeting, Sharon Ungerleider, genetic counselor with Kaiser Permanente of Northern California, reported on the nation's largest ethnicity-based prenatal CF carrier screening in an HMO setting.

Since 1999, Kaiser Permanente Northern California Region has offered CF genetic screening to all pregnant women who identify either themselves or their partners as having Caucasian ancestry. A woman is tested first and when a mutated, or damaged, CF gene is found, the male partner is offered CF screening to help determine the likelihood that the fetus will be affected. Kaiser tests for 37 CF mutations; current guidelines recommend screening for 25 mutations. Of the 27,507 Kaiser members who have been screened to date, 952 female carriers and 27 male carriers were identified. All 27 high-risk couples were offered genetic counseling and prenatal testing.

"It takes two mutations to have a child affected with CF, but just because you're both carriers doesn't mean you will definitely have a baby with CF," Ungerleider said. "There is a 1 in 4 chance that the child will have CF. There is a 1 in 2 chance that the child will be a carrier, just like both parents, and there is a 1 in 4 chance that the baby won't have CF or be a carrier."

Pre-test education is extremely important when helping couples understand their CF risk and the significance of their genetic test results, according to David R. Witt, M.D., medical geneticist and director of Kaiser's regional CF screening program in Northern California.

"There is a spectrum of CF in terms of the severity of the disease that is influenced by the particular mutations that are present," Dr. Witt said. "Severe mutations represent about 90 percent of all mutations, and mild mutations represent about 10 percent. If a couple has one mild and one severe mutation, the mild mutation gives some protection with the gastrointestinal aspects of CF, but the lung aspects of the disease can still go either way in terms of severity. Explaining the expected impact of the mutation findings in terms of the future child's clinical course is a difficult but critical part of genetic counseling."

Knowing whether you're a carrier gives you options you wouldn't otherwise have had, Ormond said. "Your partner can be tested. You can have prenatal diagnosis if you're expecting a child. If both partners are CF carriers, couples planning a pregnancy can consider alternate methods for getting pregnant, including egg or sperm donation or pre-implantation diagnosis."

*(Co-authors on the paper on the topic being presented by Ormond are P.L. Mills, L. Lester and L. Ross. Co-authors on the paper on the topic being presented by Ungerleider are Dr. Witt and J. Coppinger.)*

## **Case Study 2: Ethical Implications of a Decision on MCADD Screening of Newborns**

As Director of the State Health Department, John Jamison has responsibility for the state's Newborn Screening Program, which currently screens every infant born in the state for six disorders, including phenylketonuria, hypothyroidism, and hemoglobinopathies. The state's newborn screening program has had a quiet and respected history in the state up until now, unlike some other health department programs, such as the state cancer registry that was a recent focus of legislative hearings and a public outcry over privacy concerns.

The nurse practitioner who directs the newborn screening program, Sally Scott, has just reported that pressure is building for the addition of new testing for genetic disorders to the battery of required state screenings for newborns. Sally says pressure is coming from many sources, including individual parents, powerful advocacy groups within the state, and even some physicians. A coalition of these interested parties has just met with her and requested the state health department's support for a bill to add a test for one particular disorder this legislative session – the test for Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCADD). The group intends to issue a press release within two or three days and plans to publicize whether the state health department is supportive of the test.

Sally believes the test for MCADD is likely to garner more attention and support from the public and the press than other newborn screening tests, because MCADD increasingly has been mentioned as a potential cause of Sudden Infant Death Syndrome (SIDS).

Sally met with Jamison yesterday for guidance. She warned him that MCADD is just the latest, in what she believes is becoming a continuing and growing problem for the state health department regarding genetic screening for newborns. As director of newborn screening for the last five years, she has been receiving frequent inquiries about the possibility of expanded newborn genetic screening, both for particular disorders and for predisposing conditions.

Jamison asked Sally to get back to him today with as much relevant material as she can quickly find, so that they can review the data and discuss the options with the department's epidemiologist, health policy analyst, and the Director of the Division of Maternal and Child Health.

At the meeting Sally presents the following information.

The State legislature, with guidance from the health department when appropriate, has the authority to establish newborn screening policies, including deciding which disorders should be included among the battery of newborn screening tests.

Currently parental consent is not required for the newborn screening tests in the state. All newborn screening tests are conducted by the state lab, which reportedly discards newborn blood samples after the initial testing.

The state newborn screening program provides follow-up notification of positive tests, counseling, and in some cases, state-provided treatment when newborn conditions are identified. These costs generally are not covered by health insurance.

The annual cost of the newborn screening program in the state is now \$2.5 million.

MCADD is a type of fatty oxidation disorder where an enzyme defect in the fatty acid metabolic pathway inhibits the body's ability to utilize stored fat. Initial clinical presentation occurs from two months of age to two years, and has not been found in children post-adolescence. An initial event of MCADD is usually triggered by prolonged fasting, which can lead to vomiting, lethargy, coma, apnea, cardiopulmonary arrest, and sudden death. Up to 30 percent of initial events result in death and lead to a misdiagnosis of SIDS in up to 5 percent of cases. One recent publication suggested that up to 50% of infants with MCADD died as a result of their first acute episode and in these cases, MCADD was diagnosed postmortem.

Current data suggest that the incidence of MCADD varies in the U.S. between a homozygous prevalence (individuals presenting with MCADD) of between 1 in 6,400 to 1 in 20,000 and a heterozygous prevalence (asymptomatic carriers of MCADD) of 1 in 6,900. The newborn screening data from three other states that currently test for MCADD show a per year incidence that ranges from 0.0001 in one state to 0.00003 in another state. A routine blood sample drawn at time of birth and processed via a Tandem Mass Spectrometer (TMS) can reveal MCADD gene involvement. Follow-up testing can confirm diagnosis. The state laboratory, however, currently does not have equipment to conduct these tests.

*Treatment:* Some studies suggest that early detection and follow-up treatment that could be as simple as eliminating prolonged periods of infant fasting could be life saving. Recent studies suggest that intravenous infusion with 10% dextrose will generally cause rapid improvement after an acute event. Other treatment options such as 150 mg per day of L-carnitine or cornstarch mixed with liquid at bedtime could prevent acute events leading to hospitalization or death. L-carnitine treatment has been recommended for the first three years of life for MCADD patients with confirmed diagnoses.

*Expected Outcome of the Newborn Screening Test:* Given current estimates of incidence rates, screening all infants in the state could result in approximately 8-10 confirmed cases/year. An estimated 30-50% of patients with MCADD die within their first two years; so about 4 lives are projected to be saved per year in the state.

### **Approximate Costs of MCADD Screening**

Given the state's annual birth rate of over 100,000, two tandem mass spectrometers will need to be purchased for the state lab at a total cost of about \$700,000. Annual operating costs for the systems would be about \$50,000. Two additional lab specialists would cost about \$80,000. Additional nursing time for assessment of laboratory results, follow-up, and outreach programs would cost between \$75,000, which would not be covered by insurance.

A fee of \$4.00/test would be added to the total cost of the current set of newborn screening tests, and would be billed to insurance carriers (this covers machine use cost, allowing for machine depreciation), for an additional annual screening cost of about \$500,000. (This raises the annual cost of the state program to \$3 million.)

Follow up confirmation testing for identified newborns will cost about \$6,000 a year. Treatment for MCADD for the 8-10 patients a year would cost about \$2,500 total, much of which would be covered by insurance.

Without early detection of newborn screening and preventive treatment, approximately four MCADD patients in the state each year will be expected to experience acute episodes of undiagnosed MCADD resulting in hospitalization. Based on cost analysis from another state, the average acute episode results in a seven-day NICU stay and a seven-day pediatric ward stay, with a total cost of about \$33,000 per episode. From a pure dollar outlay, adding this test will cost more to the state than the cost of treating those children with MCADD when they have acute events. This concludes Sally's report.

Jamison thanks Sally, and turns to the other three professionals at the meeting for their reactions. The health policy analyst quickly responds, "Sally's cautious approach to this question is well-founded because the issue of newborn genetic screening is potentially explosive. We cannot be in a position to go against the tide of these powerful advocacy groups, because they could create a media circus and undermine our position and support in the legislature on a number of important public health initiatives. This could result in cuts to our budget on critical issues -- on teen education for sexually transmitted diseases, for instance, and other public health programs that operate just below the public radar screen. As long as the newborn test is valid and preventive treatment is available, the health department must support the test and I think..."

The Director of the Division of Maternal and Child Health interrupts, "I disagree. My programs are significantly underfunded, and my staff overworked. I would like to initiate numerous new programs, some requiring far less money than this screening program. This new test will mean that I will have to reassign one or two of my staff nurses to run this program, which will require assessing the laboratory test results and following up with patients and physicians. Better funding of current programs or new programs we are planning for would result in saving the lives of many more than four newborns a year and additionally would result in a significant reduction in child and mother morbidity. I believe the health department should not be pressured into supporting particular programs without careful analysis of other potential uses of the funds."

The epidemiologist concurred, "I believe we should do a study about this screening program, including assessing other uses for health department funds and also our own study of the intervention's effectiveness, which is not clear to me. We might undertake a pilot test of the MCADD test and the preventive interventions. We could randomly screen a group of newborns in the state by sending their newborn blood samples to outside labs, and then divide positive babies into one of two groups: a treatment group who are given the L-carnitine for three years and a control group. This seems to me the only way to justify the program -- with good science." The health policy analyst shakes his head, "Would you tell the parents of the control group babies that their children might be at increased risk for a disease that kills? Would you get informed consent from parents in the pilot screening program?"

Jamison holds up his hand. "There seem to be numerous ethical questions arising in our discussion. Let's explicitly address them. What are the ethical issues in this case as you see them and what are your positions?"

## Considering the Ethical Issues Involved in MCADD Screening

### *Assessing the Public Health Problem*

- What is at stake in the current situation? Is public health department missing SIDS cases? How should the health department make decisions about the use of limited resources to benefit the public? Are there other concerns?
- What role does the public have to play in this issue? Should there be public discussion? How could that discussion be elicited?
- Are commercial interests at stake? Has the company that manufactures the TMS machine been involved in discussions to date? Should it be?
- Who are *all* the stakeholders in this decision? Do any of the stakeholders have conflicts of interest? What are these? Do any have conflicts of obligation?
- Are there issues of power involved in the ongoing debate? Where is the interface between public health and politics in this situation?
- Is there money available to do the testing? What are the alternative uses to which it might be put? Are the MCADD advocates aware of those facts?

### *Advocacy*

- Do the roles and duties of advocates of MCADD testing differ from the roles of health department staff? Should they be different?

### *Ethical Issues*

- What specific ethical issues are involved in a decision to test (or not test) for MCADD? Specifically, what harms, risks and benefits may be involved for individual children, parents, other individuals and for the population at large?
- If money is diverted from other possible lifesaving uses to MCADD testing, should the harms, risks and benefits of the other intervention *not selected* be taken into account?
- What are the moral claims of the various stakeholders?
- Are there any other ethical issues that might be involved?
- Have any discussion of screening ethics occurred in the other states where MCADD testing is done? What were the considerations in those settings?

## Case Study 2: Discussion

### Ethical Problems

This case study presents John Jamison, Director of the State Health Department and Sally Scott, who directs that state's Newborn Screening program, with several dilemmas about how to respond to requests to take a position on the inclusion of an additional test in the state's current newborn screening program.

Each is aware that three other states currently include MCADD screening for newborns, making the option of adding it a technically feasible one. They are aware of the test's potential for saving the lives of several newborns in the state each year through use of the test. However, both are aware of other possible policy and ethical dilemmas.

First, although data are available from which to conduct a cost-benefit analysis, available data do not include any information on false negative or false positive screening tests. What information about false positive and false negative MCADD screening tests should be included in the direct cost-benefit figures?

Second, the source of funding for adding any new screening test is not obvious. While the actual costs of the laboratory tests will be covered by private insurance for those who have coverage, there still remains the significant costs for the health department to pay a staff nurse to interpret all of the laboratory results and do the followup, which insurance does not pay for. In addition, the state health department is responsible for the costs of the laboratory tests for the state's uninsured population. If adding a new test required diversion of resources from other current state programs, resulting in fewer children benefiting from those other programs, should that lost benefit be included in the cost-benefit analysis?

Third, state employees are being pressed to support legislation to further the goals of one advocacy group, the MCADD screening lobby. How should Jamison and Scott decide what position to take with the MCADD test?

### Relevant Values and Key Stakeholders in the Decision

In addressing this issue, Jamison must address the concerns of multiple stakeholders. Jamison is aware that different values lie behind the positions taken by various stakeholders, including his own staff. Advocates for MCADD screening, including perhaps parents of affected children, would like to totally eliminate morbidity and mortality related to MCADD. Advocates' position seems to give priority to *beneficence*. In the name of *autonomy*, some persons would like to limit newborn screening programs to tests done with parental consent. Manufacturers of testing equipment would like to increase the market for their product(s).

Jamison is also aware that roles and duties of health department staff differ from the roles of MCADD advocates. State health department staff must be concerned with values of *efficiency*, e.g., cost per MCADD case detected, and *utility*. Health department staff, including Sally Scott, must also be concerned with *non-maleficence* and *justice*, since they have to balance the value of a new screening test with the opportunity costs of other programs that might have to be cut to allow inclusion of the MCADD test. Specifically, health department staff would appear to have a *conflict of obligation*



between children/parents who might benefit from MCADD testing and children/parents who are beneficiaries of current programs that might have to be cut to allow MCADD screening.

Director Jamison has to include the concept of planning for an orderly decision process for this and future decisions. Finally, it is not yet clear what values might inform the responses of the state legislature, which will have to ultimately decide, based on Jamison's recommendation and on lobbying pressure, whether the MCADD test should be included (and perhaps whether new funds to pay for it should be added.)

### **Necessary Information**

In considering his decision, Jamison clearly needs objective information beyond the list of stakeholders and their values. The costs of MCADD screening (in equipment, staffing, etc.) and the benefits in terms of cases detected and lives saved are a starting point. In addition to the information already available, these data should include the frequency of false positive and false negative MCADD screening results. State health department staff is the best initial source for such information although information from manufacturers and from the coalition could also be reviewed. Similarly, if funds to pay for MCADD screening are not currently available, the *opportunity costs* of other programs to be cut must be included in the information. Specifically, what are the options for internal redirection of funds are what would be the program impacts of such redirection? Should the impact on other public health programs be made public, so that other stakeholders who may be adversely affected can take a position?

Jamison is also interested in knowing the position of the American Academy of Pediatrics (and its state affiliate chapter) on MCADD screening. He would also like to know more about how MCADD decisions were made in the states where its use has been discussed. (These states include not only the three states where MCADD testing was included but also any states where decision were made to *not* include MCADD testing.)

Finally, Jamison could consider discussing the MCADD screening issue with members of the legislature who ultimately would be making the key decisions about the testing program.

### **Available Options**

In considering any recommendation to the legislature, Jamison must consider each of the several options available:

- Do not add MCADD screening at this moment. Cost-benefit analysis may support this position in that costs for treating children with MCADD may be less than screening costs. (Note: This does not take into account the deaths.)
- Defer a decision while collecting additional information through additional study of MCADD testing.
- Add MCADD screening using current resources (Some other activity or program has to be cut to cover the health department's costs of nursing staff assigned to this program.)
- Add MCADD screening once new resources can be identified. This approach could perhaps include a form of partnership with the coalition.

- Consider a more comprehensive review of the state's approach to newborn screening: Because of Sally Scott's sense that more new screening tests and more advocacy will be coming in the near future, Jamison and Scott could also consider an option of asking for a review of state newborn screening policy. Outside experts in various fields could inform both the MCADD decision as well as provide recommendations for how the state should approach the issue of considering other new newborn screening tests as they come along.

### **Process for Arriving at a Decision**

In addition to discussions with his own staff, Jamison should be sure that he and his staff have heard from as many of the stakeholders as possible. Specifically, meeting with representative of the advocacy coalition can help inform his position. That discussion could include the issues and values at stake as well as options for moving toward consensus on an approach to adding a new test. During this meeting, in addition to hearing the coalition's perspective, a process of compromise could be discussed.

Jamison might also consider holding a public hearing on the MCADD issue either through the state health department or jointly with the state legislature.

### **Questions about options**

- What ethical justifications support each of the options, i.e.,
  - to support MCADD now?
  - to not support MCADD but use funds elsewhere?
  - to study the issue further?
  - to partner with advocacy group to raise external funds for MCADD testing?
- What is the appropriate role for the State Health Department in resolution of this issue?
- What roles could the State Health Director play in the resolution of this issue?
- Would a legal opinion from the department's legal counsel be helpful in resolving this issue?
- Would having the State Health Department proactively bring this issue to the legislature be helpful?
- Would an external ethics consultation be helpful?

### **Case Study 3: PKU and Follow-Up**

Dr. Susan McManus, director of the Adamsville Tri-County Health Region, asked to make a presentation at the monthly meeting of the state health department executive committee, which includes Dr. John Jenkins, the commissioner of the state health department, and the directors of the major state health divisions, including epidemiology and surveillance, maternal and child health, laboratory services, public clinics, and health policy.

Dr. McManus, herself a pediatrician by training, had been frustrated for a number of years about the continual cutback in preventive services available for maternal-child health care and had just become aware of yet another case of an infant born in her district with an easily preventable birth defect. The infant was born with microcephaly because her mother did not follow a special diet for Phenylketonuria (PKU) during pregnancy. This was the fourth such PKU-related case in her region in the past five years. Having done some research, Dr. McManus knew that her health district population could have an elevated risk for PKU because of the high population with Scot-Irish family backgrounds, and she was concerned that the state health professionals may not consider this problem significant from a state perspective.

Recent national attention about the problem of dietary control among pregnant women with PKU published by the Centers for Disease Control and Prevention, however, gave her the courage to institute a new policy in her health district, and she wanted both to notify the state health department heads and to enlist their support for her project.

As head of the one of the largest health districts in the state for ten years, Dr. McManus enjoyed a good personal relationship with many leaders in the state health department and felt comfortable beginning her presentation with the story about the infant recently born with microcephaly.

It was a heart-wrenching case. The mother was 21 years old, unmarried, and had discontinued formula use for PKU in early adulthood because of limited financial resources. She reported that she had not fully understood the importance to her infant's health of following the PKU diet, and was devastated when she found out that she could have easily prevented her infant's condition. While she expressed a strong willingness to adhere to the diet during pregnancy, her lack of transportation, financial constraints, and inability to take time off from work prohibited her from accessing care at the nearest metabolic clinic, which was 3 hours away. She did meet with local health department staff several months into the pregnancy to acquire formula, but it was too late. PKU was included in her prenatal medical records, and she was referred to a maternal-fetal specialist; however, her blood phe (phenylalanine) levels were not monitored and she was not referred to a metabolic clinic.

Dr. McManus looked her colleagues in the eye and said, "I am determined to prevent future cases like this one and I have an idea. I have decided to begin an on-going tracking system of these young women until they reach child-bearing age in order to provide special education to them about the importance of maintaining a special diet during their pregnancies. One way is to have a nurse visit with the child and her family each year. Another way is to maintain a record of the child's physicians or clinic, and send advisory letters to physicians to be included in the child's health records. In addition, for those infants/children who do not remain in contact with the health agency, the program will begin an

aggressive outreach to locate the young women when they turn 16 in order to provide them with the educational information about their condition and an appropriate diet during pregnancy.”

Dr. McManus looked at her colleagues: “Before you respond, I want to assure you that because I am initiating this program in my health district, the state will not be under pressure to adopt such a policy for all regions, since the population in my district is at greater risk of PKU because of their genetic backgrounds.

I’m sure you all have some concerns about my program, such as questions about targeting the young women in my health region and about the confidentiality and consent for the use of newborn genetic information. I am essentially creating a PKU registry, based on the newborn screening data, and I understand the public’s great sensitivity to public health registries. But I believe for my county the registry is justified by the increased risk and gravity of the harm that can be prevented. I would like to end my presentation by summarizing a recent report from the Centers for Disease Control and Prevention.” She then summarized the following report.

**Excerpts from “Barriers to Dietary Control Among Pregnant Women with Phenylketonuria – United States, 1998-2000” MMWR 2/15/2002/51(06);117-120.**

“Newborns in the United States are screened for phenylketonuria (PKU), a metabolic disorder that when left untreated is characterized by elevated blood phenylalanine (phe) levels and severe mental retardation (MR). An estimated 3,000--4,000 U.S.-born women of reproductive age with PKU have not gotten severe MR because as newborns their diets were severely restricted in the intake of protein-containing foods and were supplemented with medical foods (e.g., amino acid-modified formula and modified low-protein foods) (1--4).

When women with PKU do not adhere to their diet before and during pregnancy, infants born to them have a 93% risk for MR and a 72% risk for microcephaly (5--6). These risks result from the toxic effects of high maternal blood phe levels during pregnancy, not because the infant has PKU (5--6). The restricted diet, which should be maintained for life, often is discontinued during adolescence (5--10).

This report describes the pregnancies of three women with PKU and underscores the importance of overcoming the barriers to maintaining the recommended dietary control of blood phe levels before and during pregnancy. For maternal PKU-associated MR to be prevented, studies are needed to determine effective approaches to overcoming barriers to dietary control.

During the fall of 2000, CDC conducted an interview-based study of women with PKU who were aged >18 years and pregnant during 1998--2000 (index pregnancy), regardless of dietary management or pregnancy outcome. Women were recruited from three metabolic clinics that provided services funded by state and private sources and were interviewed using a structured questionnaire that was completed in person or by telephone. Medical records were requested to document timing of diet initiation, control of blood phe levels (defined as 2--6 mg/dL), and pregnancy outcome. The study protocol was approved by CDC’s Institutional Review Board, and informed consent was obtained from each respondent.

A total of 30 women met the interview criteria; two could not be contacted. Of the 28 remaining women, 24 were interviewed (17 in person and seven by telephone). The median age was 28 years (range: 22--38 years); 75% were married, 96% were white, and 50% had a high school education or less. A total of 51 pregnancies had occurred among 24 women. Among the 24 index pregnancies, 18 (75%) resulted in live-born infants; 11 (46%) pregnancies were intended.

The use of formula-based medical foods before conception was reported more often among the 11 women who were trying to conceive than among those who were not (risk ratio=3.5; 95% confidence interval=1.6--10.2). Use of modified, low-protein medical foods to diversify the diet was reported only among women trying to conceive. No difference was reported in avoiding high-protein foods between women who were and who were not trying to conceive. One woman remained on the restricted diet throughout adulthood; 23 women had been off the diet for 6--24 years (average: 16 years). At the time of the interview, 17 (71%) women were not using medical foods (65% because of the unpleasant taste). A total of 22 women had resumed the diet before or during their index pregnancy, eight (33%) women had contacted the metabolic clinic before conception, and 11 (46%) had contacted the metabolic clinic after conception but by week 10 of gestation. Of the 22 medical records available, 12 (55%) records indicated controlled blood phe levels before 10 weeks of gestation.

All of the women expressed confidence in their metabolic clinic staff's knowledge of a phe-restricted diet and maternal PKU; eight (33%) perceived that their obstetricians were knowledgeable about maternal PKU. Approximately equal numbers of women used public assistance and private insurance to cover the costs associated with clinic visits (Table 1). Costs of medical foods were more often covered by public assistance than by private insurance (Table 1). Among the 13 women who used public assistance, nine (69%) reported that proof of pregnancy was required to receive services. When the data were stratified by state of residence, women in state C had the lowest rate of live births resulting from their pregnancies, lowest use of formula before pregnancy, fewest women achieving metabolic control before 10 weeks' gestation, and longest commutes to a metabolic clinic (Table 2). These differences were not significant by Fisher exact test."

Dr. McManus looked around the table of state health professionals, and smiled. "What do you think of my idea?" she asked. The room was quiet.

Dr. Jenkins shook his head, "Your idea raises many questions we have been struggling over and, quite frankly, avoiding. Should we keep identifiable genetic data from the newborn screening tests, or alternately, keep the blood samples as we do now in case they would be useful for surveillance in the future? And, as your program idea brings up: Should we allow, or perhaps are we ethically obligated to, follow-up on the test results years later, when the infants are able to understand the medical information themselves? Do we have a duty to these infants?"

Dr. Jenkins looked around the room at his staff. "What do you each think? What are the ethical issues here?" Should we allow this program in one region, targeted at this one particular group, to go forward?

## Case Study 3: Discussion

### Ethical Concerns

Dr. McManus is clearly aware of the various ethical issues at play.

First, acquiring and keeping information on individuals without their explicit consent could be perceived as a privacy (autonomy) threat to those persons. Part of this concern is the issue of contacting these phenylketonuria (PKU)-affected people who may be unaware that they have PKU and, more important, that their children are at grave risk.

A different perspective on the same issue is whether the state has an obligation to be sure that PKU-affected persons, detected in a state-supported screening program as children, are aware of their condition as they enter adulthood and their childbearing years. This obligation could be construed as an obligation to the children of persons with PKU as much as to those identified persons themselves.

One large generic ethical issue is regarding ownership of the information on individual citizens collected in a state-run or state-supported screening program.

Another practical consideration is that of reliably identifying “at risk” pregnancies prior to the actual risk period. Some at risk women are likely to have changed their names when married and thus undetectable by name based screening during pregnancies.

Another ethical issue involves the strength of the requirement to assure access to appropriate interventions once “at-risk” pregnancies have been identified.

Another issue is that of justice. This program is to be implemented in only one part of a state. Although the program suggested by Dr. McManus for her health region could be viewed as a pilot program for the state that could be extended if judged successful in an evaluation, it is worth considering the justice issues of a limited access program.

A final issue with ethical dimensions is that of the age for aggressive outreach (16 years). Is that age adequate to reach all females at risk before they become pregnant? What are the issues involved with choosing a younger age?

### Relevant Values and Stakeholders

Dr. McManus and the various program directors have a number of values to incorporate into whatever decision they make. One issue is *beneficence*, in terms of the need to protect children from untreated PKU. Identifying high-risk pregnancies and preventing disease among children “at risk” is a socially useful goal that could also benefit individual children and parents.

Another issue is that of risk to the affected women’s other relationships in various ways. For example, is there a risk involved in spouses or prospective spouses becoming aware that a woman has PKU? Is there a risk of discrimination from an insurance company’s becoming aware of PKU in a prospective customer?

Another issue is the state's obligation to assure freedom from future PKU, having identified it in the maternal generation. Is the state permitted to retain these records and conduct follow-up activities? Is, in fact, the state not only permitted but *obligated* to carry out follow-up in order to provide education and warnings?

From a societal standpoint, which health care professional or person should have a duty to warn? Who is in the best position to prevent harm?

### **Necessary Information**

Having information about existing PKU follow-up programs or similar follow-up programs from other states could provide both a framework for discussion in this state as well as experience in dealing with ethical concerns raised.

In addition, it could also be helpful to obtain new information as it becomes available from this state or elsewhere on adverse outcomes of potentially detectable but undetected PKU cases. Any new evaluations similar to that published by CDC would also be useful.

One additional piece of information includes the numbers of affected children born each year and the length of time needed to reliably determine benefits, costs, and any other adverse effects from the program.

Finally, a very clear description of the system used to protect the privacy and confidentiality of persons whose name is in this registry would be helpful. This should include information on confidentiality agreements signed by employees with access to the data as well as plans for follow-up of persons who move to known addresses in other health regions or states.

What would be the response if the mother of an affected child refused follow-up? Would the girl herself be contacted at some point? At what age?

### **Available Options**

In considering next steps, there may be several options:

- Allow Dr. McManus to do exactly what she has suggested, testing the effectiveness of several ways to stay in touch with affected girls and their families. This could be done as a formal research study.
- Conduct the program as suggested but have it done as a pilot program of the State Health Department.
- Carry out the program state-wide. This step would considerably shorten the time required to know whether the program is effective at ensuring follow-up.
- Tell Dr. McManus not to do the program.
- Defer a decision until an external Committee can discuss and provide guidance.

### **Process for Arriving at a Decision**

Dr. McManus and the State Health Director were clearly hoping for a discussion by senior state health officials present at this meeting. Although necessary, is that discussion sufficient? Could there be any value in having a broader public discussion of this issue among health officials (e.g., professional groups) and among the public? Would that answer differ as a function of whether this program is conducted in a region vs. the entire State? What might be the issues raised by those particularly concerned with privacy and confidentiality issues? What information would be needed to reassure them? Is the successful implementation of confidentiality protections for other public health registries in the state evidence that supports this proposal?



## **Case Study 4: State Genetics Commission: Ethical Implications of Informed Consent in the State Newborn Screening Program**

As the health commissioner of the largest city (population 5 million) in the state, you have been appointed by the Governor to a Blue Ribbon Commission on Ethics and Human Genetic Technologies to study and report on genetics issues in state health policy, as well as related issues in genetic reproductive technologies. The 15-member Commission includes representatives from a range of governmental, for-profit, and public interest groups, a number of whom you are developing collaborative partnerships with, such as the state hospital association and the largest health insurer in the state.

The Governor has asked the commission to explore the ethical issues and make recommendations on the major issue currently pending in the state legislature: should parental informed consent be required for the state newborn screening program?

Given that the legislature is expected to hold hearings within the month, each member of the Commission was asked to bring a statement of ethical concerns and a short position statement to the first commission meeting.

You have consulted the director of the city's department of maternal and child health and your health policy analyst and learned the following:

The current state law authorizes the state department of health to establish, maintain and carry out a newborn screening program to detect hypothyroidism, PKU, hemoglobinopathy, congenital adrenal hyperplasia (CAH), and maple syrup urine disease; and additionally to provide each infant determined to be at risk with a screening test for sickle cell diseases. The state legislature currently determines which tests will be administered under the newborn screening program, with consultation from an advisory board of the state health department.

The newborn screening requirements do not apply to infants whose parents object for religious or personal reasons. However, parental consent for newborn screening currently is not required, and even though newborn testing may not be conducted over parental objection, virtually no parents raise the issue or object to testing.

Currently only a few states require informed consent (that is, parental permission) for newborn screening, while about a dozen other states require that before testing is done, parents must be explicitly informed about newborn screening.

Your health policy analyst provided the following background information about informed consent.

- Analysis of informed consent generally focuses on five elements: competence, disclosure, understanding, voluntariness, and consent. Beauchamp and Childress include these elements, when they write: "One gives an informed consent to an intervention if (and perhaps only if) one is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention." They also acknowledge that in some circumstances obtaining consent that satisfies these rigorous standards may be

excessive or impossible to implement and that an alternate framework based on social or institutional rules of consent may be appropriate. They explain: "We should evaluate institutional rules not only in terms of respect for autonomy but also in terms of the probable consequences of imposing burdensome requirements on institutions and on professionals. Policies may legitimately account for what is fair and reasonable to require of health care professionals and researchers, the effect of alternative consent requirements on efficiency and effectiveness in delivering health care and advancing science, and the effect of consent requirements on the welfare of patients." \* In some circumstances, patients do not expect to be asked for or to give full and rigorous informed consent, for example, as with a routine battery of blood tests; consent in these circumstances is presumed or implied because testing is routine.

- In the context of screening, Gostin describes five forms of screening and consent:\*\*
  1. Compulsory Screening (with no informed consent), authorized by state legislation under its police powers, for specific circumstances, such as when a person is exposed to blood borne infections, or for certain class of persons, such as newborns, inmates or prostitutes.
  2. Conditional Screening, which make benefits contingent upon screening, as in the case of requirements for a PPD tuberculin test in order to work in a school or nursing home.
  3. Routine Screening with Advance Notification (Opt-In), which involves offering screening tests to a population, with patients not given the test until they have consented or "opted in."
  4. Routine Screening without Advance Notification (Opt-Out), which involves routinely or automatically screening individuals in a population (who may not be aware of or understand the purposes of the screening tests), unless patients explicitly refuse to have the test.
  5. Voluntary Screening, which requires full and rigorous informed consent.
- Regarding parental consent for newborn screening in particular, some commentators raise ethical arguments that focus on the role of the state to protect children from harm and suggest there are compelling arguments against a policy requiring parental consent or honoring parental refusals of screening for some conditions; others focus on the important role of parents as caretakers and highlight the clinical value of involving parents in newborn screening decision making; and still others focus on the potential value of more public participation in the policy-making process for newborn screening programs so that questions about parental consent will be addressed by parents and consumers in a public policy-making body.

What position would you take on the issue now pending in the legislature? Why?

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\* Beauchamp, T. and Childress, J., *Principles of Biomedical Ethics* (5th Ed.), (Oxford and New York: Oxford University Press, 2001) p.78-79.

\*\* Gostin, L, *Public Health Law*, (Berkeley and Los Angeles: University of California Press, 2000) pp.193-195.

## **Case Study 4: Discussion**

### **Ethical Concerns**

This case study presents you, as a health commissioner and as a member of the Governor's Blue Ribbon Commission, with an opportunity to elicit and express opinions about the informed consent process in the state's current newborn screening program. You are aware that the focus in this case is on currently available and validated newborn screening tests rather than new or still experimental tests.

You are aware of at least two large and partially overlapping ethical concerns in this situation.

The first concern addresses balancing the autonomy or respect for autonomy of those involved as participants in the screening process with the obligation of the State (i.e., the government) to reduce preventable morbidity, i.e., society's disease burden, by identifying disease risk among those not yet affected.

A second ethical concern involves clarifying the potential beneficiary or beneficiaries of the newborn screening process and being sure that whatever consent process that is put in place protects the interest of all parties, including the pregnant woman or new mother, the fetus or infant, the father and the society at large.

### **Relevant Values and Stakeholders**

In addressing this informed consent issue, the Commission must identify various stakeholders and address their concerns and interests. Advocates for women who are either tested themselves or whose newborns are being tested are appropriately concerned with respecting the autonomy of those women to consent to or refuse the screening process. They point out that the State's interest in reducing disease among its citizens may not automatically override maternal autonomy. Advocates may be concerned about a coercive nature to the screening process, especially when children of ethnic minority or poor women are being tested.

Others may raise opposite issues, concerned that the interests of children may not always be best represented by decisions of their mothers, especially when the information transmitted as part of the informed consent process is uncertain.

A related value raised could be that of competence of women to give what is essentially surrogate consent for their children. For example, what are the issues involved in having a new mother who is herself a minor give or refuse consent for screening for her newborn child. Is a woman giving or refusing consent in this setting also consenting or refusing on behalf of the child's father? Does the answer to that question vary when the parents are not married? Can a child damaged by a disease which might have been detected except for refused consent by his/her mother have a valid claim against her mother once the child becomes an adult. In a related question, what is the state's obligation to provide support to a child or family if a child becomes ill in a setting of refused consent?

### **Necessary Information**

In considering this issue, you, as a health director and as a member of the Blue Ribbon Commission, can be informed by several kinds of information.

In terms of objective information, information on the frequency and severity of conditions being screened for can help provide a context for consent discussions. Such information should include not only assessment of medical consequences but also information on treatment cost of disease in unscreened persons as well as costs among persons whose disease was detected earlier by screening.

Information from your state and from other states on the frequency of refusal of consent—as well as the consequences of refusal—can provide additional perspective on the magnitude of the problem.

Information from the State's attorney general or other legal counsel can be helpful in understanding the boundaries of the Commission's – or the State's - decision-making ability. The State Constitution may provide guidance about the limitations of unconsented testing as well as guidance on the State government's responsibility and authority to act on behalf of the community. That official can also provide opinions about options for considering justifications for religious or other refusals should mandated testing be recommended.

Finally, opinions on informed consent can be solicited from parents providing - or refusing -- consent as well as from persons affected by disease that might have been prevented had newborn screening been done.

Arguments generally raised in public AGAINST requiring consent from parents focus on the fact that the benefits of screening are obvious and substantial, relative to potential harms; that no “reasonable” parent would refuse screening (perhaps raising questions of child neglect); that obtaining consent from each parent is difficult, costly and an unwarranted expenditure of time and money; and that the history of newborn screening has led to the current expectation that newborn screening is routine and that parental consent is appropriately “presumed.” Some of the arguments raised in public FOR requiring parental consent include: parental consent is necessary because refusal to newborn screening is not unreasonable, given that many conditions for which newborn testing is done are rare and that newborn screening does have adverse consequences, particularly psychological harms associated with false positive tests; that long-term parental care taking is enhanced when parents are included in all clinical decisions about their children; and that the process of obtaining consent does not have to be time-consuming or burdensome for health care professionals but rather can be part of an educational process that enhances the health professional-patient relationship.

### **Available Options**

In considering consented screening recommendations to the governor, you and the Commission must consider each of the options available, which include:

- Mandatory screening without consent. This process could still allow for a refusal of conscience for religious or other reasons.
- Presumed consent, which includes public awareness of the screening program and testing unless objection is raised.
- Explicit consent, including a counseling and consent process with each new mother.

Within each of these options, a second set of options must be prepared to address procedures should there be a difference of consent opinion between the two parents.

### Process for Arriving at a Set of Recommendations

In addition to collecting and discussing the objective information described earlier, you could encourage the Commission to hold open hearings where various opinions can be solicited and heard.

The state's legal counsel can be helpful in clarifying within the recommendations a set of procedures for deciding on the competence for consent of underage persons as well as options for including fathers in the consent process.

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<sup>1</sup> Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, "Genetics and public health: A framework for the integration of human genetics into public health practice," in Genetics and Public Health in the 21<sup>st</sup> Century, ed. Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, p. 5.

<sup>2</sup> James F. Childress, Ruth R. Faden, and Ruth D. Gaare, *et al.*, "Public Health Ethics: Mapping the Terrain," Journal of Law, Medicine, & Ethics, 30, no. 2 (Summer, 2002), p. 173.

<sup>3</sup> "Out of Eugenics," in The Code of Codes, ed., Daniel J. Kevles and Leroy Hood, Massachusetts, Harvard University Press, 1992, p. 9.

<sup>4</sup> *Buck v. Bell*, 274 U.S. 200 (1927)

<sup>5</sup> Association of State and Territorial Health Officers (ASTHO), "Public Health Genetics Policy Statement," PHG-I.4.6, p. 49, ratified October, 2001, [http://www.astho.org/pubs/consolidatedpolicy.html#PHG-I\\_PubHealthGenetics](http://www.astho.org/pubs/consolidatedpolicy.html#PHG-I_PubHealthGenetics).

<sup>6</sup> Celeste M. Condit, Roxanne L. Parrott, and Beth O'Grady, "Principles and practices of communication processes for genetics in public health," in Genetics and Public Health in the 21<sup>st</sup> Century, ed. Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, p. 550.

<sup>7</sup> *Ibid.* 555.

<sup>8</sup> Childress, Faden, and Gaare *et al.*, p. 174

<sup>9</sup> Norman Daniels, "Accountability for Reasonableness," British Medical Journal, 321 (2000), p.1301.

<sup>10</sup> Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, "Genetics and public health," p. 9.

<sup>11</sup> Lorenzo D. Botto and Pierpaolo Mastroiaco, "Surveillance for birth defects and genetic diseases," in Genetics and Public Health in the 21<sup>st</sup> Century, ed. Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, p. 125-126.

<sup>12</sup> Steven S. Coughlin and Wylie Burke, "Public health assessment of genetic predisposition to cancer," in Genetics and Public Health in the 21<sup>st</sup> Century, ed. Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, pp. 151-165

<sup>13</sup> Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, "Genetics and public health," p. 7.

<sup>14</sup> Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, "Genetics and public health," p. 7, citing Rothman, KJ. Modern epidemiology. Boston: Little, Brown, 1986, p. 14.

<sup>15</sup> MJ Khoury, JF Thrasher, W Burke, EA Gettig, F Fridinger, R. Jackson, "Challenges in Communicating Genetics: A Public Health Approach. p.3. Centers for Disease Control and Prevention website. <http://www.cdc.gov/genomics/info/reports/program/communicate.htm>

<sup>16</sup> Scott Burris, Lawrence O. Gostin, and Deborah Tress, "Public health surveillance of genetic information: Ethical and legal responses to social risk" in Genetics and Public Health in the 21<sup>st</sup> Century, ed. Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, p 539.

<sup>17</sup> Neil A. Holtzman and Michael S. Watson, eds., "Promoting Safe and Effective Genetic Testing in the United States: Final Report of the Task Force on Genetic Testing" (ELSI, September 1997). P. 6. [http://www.nhgri.nih.gov/ELSI/TFGT\\_final/](http://www.nhgri.nih.gov/ELSI/TFGT_final/).

<sup>18</sup> *Ibid.*, pp. 8-9.

<sup>19</sup> Tom L. Beauchamp and James F. Childress, Principles of Biomedical Ethics (Fifth Edition), New York, Oxford University Press, 2001, p.301.

<sup>20</sup> American Academy of Pediatrics Newborn Screening Task Force, "Newborn Screening: A Blueprint for the Future,"

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Pediatrics 106, No. 2, August, 2000, p. 389-390. See also, Diane B. Paul, The Politics of Heredity, New York, State University of New York Press, 1998, pp.173-186

<sup>21</sup> Michael A. Stoto, Donna A. Almaro, and Marie C. McCormick, editors, Reducing the Odds, Washington, D.C., National Academy Press, 1999, pp. 27-29.

<sup>22</sup> *Ibid.*, p. 29.

<sup>23</sup> Holtzman and Watson, eds., "Promoting Safe and Effective Genetic Testing" p. 27-28.

<sup>24</sup> National Research Council, "Committee for the Study of Inborn Errors of Metabolism," Genetic Screening: Programs, Principles and Research, Washington, D.C., National Academy of Sciences, 1975.

<sup>25</sup> L.B. Andrews, J.E. Fullerton, N.A. Holtzman, and A.G. Motulsky, eds., "Assessing Genetic Risks. Implications for Health and Social Policy," Washington, D.C., National Academy of Sciences, 1994, cited in American Academy of Pediatrics Newborn Screening Task Force, "Newborn Screening: A Blueprint for the Future," Pediatrics 106, No. 2, August, 2000, p.391.

<sup>26</sup> American Academy of Pediatrics Newborn Screening Task Force, "Newborn Screening: A Blueprint for the Future. Executive Summary: Newborn Screening Task Force Report," Pediatrics 106, No. 2, August, 2000, p. 387.

<sup>27</sup> Committee on Bioethics, American Academy of Pediatrics, "Ethical Issues with Genetic Testing in Pediatrics," Pediatrics, 107, No. 6, June, 2001, pp. 1451-1455, (Website, <http://www.aap.org/policy/re9924.html> )

<sup>28</sup> *Ibid.*, p.1453

<sup>29</sup> Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, "Genetics and public health," p. 9

<sup>30</sup> Arno Motulsky and Ernest Beutler, "Population Screening in Hereditary Hemochromatosis," Annual Review of Public Health, 2000. 21 (1): 65-79

<sup>31</sup> *Ibid.*, p. 79.

<sup>32</sup> Michele Reyes and Muin Khoury, "Screening for Iron Overload due to Hereditary Hemochromatosis," Centers for Disease Control and Prevention Website, <http://www.cdc.gov/genomics/info/factshts/hemoscreen.htm> , 4/13/02

<sup>33</sup> Lori B. Andrews, Future Perfect, New York, Columbia University Press, 2001, p. 42.

<sup>34</sup> Committee on Bioethics, American Academy of Pediatrics, "Ethical Issues with Genetic Testing in Pediatrics," Pediatrics, 107, No. 6, June, 2001, p.1451-1455, website citation, <http://www.aap.org/policy/re9924.html>, p. 6

<sup>35</sup> Judith Benkendorf, Beth Peshkin, Caryn Lerman, "Impact of genetic information and genetic counseling on public health," in Genetics and Public Health in the 21<sup>st</sup> Century, ed. Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, p 365.

<sup>36</sup> Diane B. Paul, The Politics of Heredity, New York, State University of New York Press, 1998, p.149.

<sup>37</sup> Allen Buchanan, Dan W. Brock, Norman Daniels, and Daniel Wikler, From Chance to Choice, Genetics & Justice, Cambridge (UK), Cambridge University Press, 2000, p. 325.

<sup>38</sup> Jane S. Lin-Fu and Michele Lloyd-Puryear, "Access to genetic services in the United States: A challenge to genetics in public health," in Genetics and Public Health in the 21<sup>st</sup> Century, ed. Muin J. Khoury, Wylie Burke, and Elizabeth J. Thomson, New York, Oxford University Press, 2000, p.286.

<sup>39</sup> Ronald N. Green & Matthew Thomas, "DNA: Five Distinguishing Features for Policy Analysis, II Harvard J. L. & Tech. 571 (1998) in Lori B. Andrews, Maxwell J. Mehlman and Mark A. Rothstein, Genetics: Ethics, Law and Policy, St. Paul, Minn., West Group, 2002, p. 608 (note)

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## **MODULE 9**

### **Public Health and Health System Reform: Access, Priority Setting, and Allocation of Resources**

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Humans live in a threatening world. Individually and collectively we respond to threats. We protect. We run. We fight. We repair. We build shields, weapons, and walls. Cultural, socio-political, and historical forces shape the social institutions that protect both individuals and groups from harms. The health system is an organized set of societal responses to the health problems that threaten human well being (Fields 1973).

The object of interest in public health is protection from threats to health. The ethics questions explore our relationships in community and our obligations within community. Which protections from what harms should we expect as members of a community? How seriously does solidarity oblige us? What does it oblige us to assure to one another? How do we distribute both the benefits and the burdens of having an effective system for protecting health? How do we exercise our community responsibility politically?

Individuals and communities as well as institutions and culture stand in dynamic relationship. Historical choices affecting these relationships are essential aspects of an adequate analysis of the ethics of access to health care and allocation of social resources for health (Walzer 1983, Starr 1982 and 1994). The concepts of social solidarity, wisdom, prudence, and fairness are central to our analysis. We note that access arguments tend to flow from assumptions about rights or common good or enlightened self-interest. Allocation arguments tend to rest on assumptions about societal wisdom and affordability of programs. We argue that questions about health systems lead to political process questions about democratic participation and representation (Garland 1994). Because of the complex and technical nature of health policy, a partnership between experts and the general public is a desirable strategy for reasonable public participation in this process (Garland 1999).

***Protection against morbidity and mortality.*** The health system is a social mechanism devised to deal with morbidity and mortality as they affect the physiologic, psychological, institutional, and cultural domains of human activity (President's Commission). Those components of well being comprise society's notion of health and disease. All of these domains change over time under their own dynamics as well as under the influence of specific health related forces. Our central collective responses to morbidity and mortality have produced the social institutions of medicine and public health. In addition to these central activities, a host of community-based services and various forms of alternative and complementary medicine also serve important protective and rehabilitative functions. All of these



elements constitute the full health care system about which questions of the ethics of access and allocation arise. Throughout the essay we will use the expression “system of health protections” in an expansive sense to refer to all forms of societal response to morbidity and mortality in the community. We include in this meaning those responses that are simply compassionate without possibility of protection or cure (for example, providing palliative care to dying persons).

The medical literature gives ample documentation of the genetic and environmental factors that act at the physiological and psychological levels to produce disease. From the time of Rudolph Virchow in the 19th Century, social factors have been recognized as contributing to the occurrence of illness, disability, and other threats to well being. Epidemiologists increasingly explore the complex interplay between biomedical individualism and a profusion of social factors. Contemporary researchers are elaborating the theoretical underpinnings of the web of causation model and exploring the thesis that social conditions are fundamental causes of disease. In this view, social, economic, and political factors profoundly affect the distribution of health-related conditions and the genetic and environmental factors associated with them.

#### Key Questions to Identify Frame of Reference

*We will highlight several key questions for exploring the ethics of access to health system benefits and the allocation of societal resources to maintain the system. We will introduce the questions in relation to specific aspects of the issues. The accompanying fact sheet for this module will gather all these questions in one place and connect them to the three cases for discussion. The first two key questions are useful for uncovering the general frame of reference that underlies thinking about problems in access to care and resource allocation.*

- 1. Which of the many threats to human health and well being deserve organized response from the health system?*
- 2. Which social factors that threaten health (e.g., poverty, risky behaviors, environmental degradation) should be countered with social interventions to limit their impact?*

These same social, economic and political factors also affect the distribution of the organized responses to these health threats – both in terms of the distribution of goods and services and in terms of the ability of those in need to access those goods and services. Research into effective interventions to protect health and to counteract pathologic events points to the need to address both individual and social domains. In addition, the health services research literature documents the role of social and behavioral factors in determining the way individuals and groups seek and obtain health services. The challenges of social wisdom, prudence, and fairness require crafting health care access solutions in the context of social norms, structures, and practices (Garland 2001).

***Dynamic relationships and historical choices.*** The links between medicine and public health have not been strong over the past century. The growth of science and technology and the related increase in the power of diagnosis and treatment partly explain this phenomenon. The medical profession has moved toward a narrower focus on the individual both in its practice and in the ethical implications that come to bear on practitioners. Despite this, the perspectives and practices of medicine and public health complement one another.

Medicine carries out its social function of protecting and improving health by focusing on providing care and services for individuals with health-related conditions. This tends to focus on the biologic and physiologic and on the psychological and behavioral domains, although medicine incorporates recognition of the importance of prevention and of social factors in both health and illness. Public

health carries out its social role by focusing on identifying and ameliorating environmental factors that prevent or allow disease and injury to affect the health of individuals and communities. It also focuses on the early identification of, and interventions for, health-related conditions at the community level. These complementarities and the origins of both medicine and public health in social practices make it imperative that they work together. It also makes health policy about access and allocation of resources more complex. It is hard to determine when one passes from health protection to economic policy or social policy.

Practitioners and researchers in public health and medicine have unique and critically important perspectives on the core functions of public health (assessment, assurance, and policy development). Each of these functions has its complement in the practice of clinical medicine. The unique social position of these professionals within the formal institutions of health care especially equip them to advocate for systemic change as a means of improving the health of the communities in which they live and serve. Social responsibility imposes a moral obligation on health professionals to be engaged in addressing issues such as access to care, the just allocation of health resources, reduction in poverty and the effects of poverty, and education of the public about health risks.

There is a tendency in American health policy discussions to reduce all of health policy to decisions about medical care. This recurrent conceptual problem leads to a distorted definition of the problems and an excessively narrow selection of policy alternatives. The discussion of “health insurance” is a vivid example of this conceptual problem. For the most part health insurance covers medical care for illness and injury. Debates focused on how to extend health insurance to all members of the American community hide an important fact. Access to insurance that pays for medical care is only part of the larger ethical problem of access to health protections. Similarly, questions about allocating resources for medical care are only part of the ethical problem of resource allocation in pursuit of the community’s health.

During the 20<sup>th</sup> Century, most advanced industrial nations determined that all their citizens should have access to medical care. That expression of social solidarity is usually understood in terms of a guaranteed right to medical care possessed by every citizen. Some nations took the path of making medical care delivery a government function (for example, Great Britain or the Scandinavian countries). Others made health insurance the focus of government intervention (for example, Canada or Germany). The United States, however, determined that access to medical care would remain a private good for most citizens. The government assumes a collective responsibility for securing access for some citizens through programs such as Medicare, Medicaid, the Indian Health Service, the Veterans Administration System, the military, and prisons. For the rest of the citizenry, however, access to medical care (except for emergency care) is left to the market. People get medical care they can pay for and this payment is usually mediated by insurance plans or prepayment schemes.

Although tax deductions encourage Americans to purchase health insurance, buyers and sellers in the marketplace primarily determine how health insurance is distributed in America. (Note: We deliberately use the misleading expression “health insurance” because it is the common name for this product. It is important to remember that health insurance is mostly for medical care and hospital services. “Health care” is a much larger frame that includes social, economic, and legal domains that have significant impact on human health.) Historically, America adopted the social practice of distributing health insurance through employment status, so that employers (not the employees who become insured) are

often viewed as the purchasers of health insurance. American employers manage the purchase of health insurance for their employees through a system of benefits that accompany salaries. A result of this market-based approach is that some 15 % of the American population makes a decision not to buy health insurance. Most often they simply do not consider health insurance as an expenditure option because they lack the financial resources to afford it (Schroeder 2001).

Numerous public opinion polls taken during recent decades show that a solid majority of Americans want health care access to be universally guaranteed. This is evidence of the moral sentiment of the American citizenry regarding solidarity and health care as part of the security and welfare we expect as members of our society. Because America distributes health insurance mainly through employment, the extension of health insurance coverage functions as a surrogate for guaranteeing access. The majority of uninsured persons work in low-income jobs that do not include health insurance as part of the total compensation. These persons do not fit into the categories for which government sponsored coverage is available. Many states are experimenting with tax-supported subsidies to assist families with limited incomes to purchase private health insurance. Still, the United States has not yet produced a political solution that can accomplish universal coverage through employment driven health insurance or through the creation of new government programs.

**Central ethical concepts.** What concepts help analyze the ethics of access to health care? On what basis and by what methods should we allocate collective resources for health care? What can guide us in setting priorities among needs for health care resources? We propose that social solidarity, social wisdom, rights, societal obligation, fairness, and justice are the most important ethical concepts to apply to this area.

**Solidarity.** The first important concept for exploring the ethics of access to health care, social solidarity, comes from the meaning of membership in a community (Walzer 1983). Solidarity is both moral sentiment and norm. Solidarity arises from the sense of belonging. It expresses itself in loyalty and self sacrifice for those we acknowledge to be “one of us.” Security and mutual welfare are primary benefits of membership in a community. We rely on one another for these essential goods of human thriving. We come to human awareness in community. First we know family and gradually the circle enlarges to bring us awareness of many others with whom we share our lives. In community we find shelter, nourishment, attention to suffering, values, and knowledge. In society we live, build, reproduce, suffer, and die. Shared life builds social solidarity among members of the same community. In relation to threats to health, organized health care is the societal response to suffering and death.

#### Key Questions About Social and Historical Context for Health Policy

1. *How can we keep in mind medical care, public health, and other social factors that influence health while pursuing questions of social obligation regarding health protections?*
2. *How can we keep ideas of social obligation relevant to historical and cultural patterns of response to health threats?*

How the response to suffering and death takes shape depends on social decisions made in government, in economic structures, in law, and in intimate familial choices. Over time a community's responses take institutional form. Some widely available protections and services come to be seen as basic needs that the community feels obliged to meet. Through various social processes, a community determines who are its members and whose needs it must meet. Society determines how strong its commitment will be (Walzer 1983). In contemporary parlance, society sets priorities to guide the use of its collective resources. The underlying justification for institutional policies derives from the shared health needs, common exposures to health risks, socially produced health benefits, and caring response to pathology. Health investment includes conducting research in an attempt to generate the information needed to demonstrate and improve the effectiveness of both preventive and treatment practices.

#### Key Questions About the Foundation of Health Security in Community Solidarity

1. *What obligations arise from social solidarity among members of a community who face common threats to health and well being?*
2. *Who counts as a member of the community with respect to health protections?*
3. *What information does a community need about its health to design an effective health protection system?*

***Rights, Societal Obligation, and Self-Interest.*** Moral arguments about access to health care follow several pathways. Some invoke the concept of human rights. This argument asserts that basic human needs (such as food, shelter, education, justice) create an obligation on society to provide some level of common access to these fundamental goods. Access to these is a matter of right inherent in all human beings. Creating social mechanisms for the distribution of access to these goods (including health care) is a primary obligation of civil society (Mann 1999). Other approaches simply assert that the basic needs ground a generalized obligation on society to assure access to health care for all its members. This is an argument based on common good grounds. Access to health care is an element of the common good that improves the general well being of all members of society. It is a benefit of social life that ought to be pursued by society because it is achievable and possible. (President's Commission, Walzer 1983.) Another line of argument appeals to self interest of members of society. A significant stable level of access to medical care makes human existence more secure for each member of society. In this argument, the pursuit of individual well being is the ground for the obligation to take social action (Churchill 1994). All three of these lines of reasoning are too often narrowly focused on medical care rather than the full frame of health care.

***Social Wisdom.*** Reflections on wisdom come after a prior societal determination to guarantee access for all to health care (whether as a matter of right, or common good, or individual self interest). Social wisdom directs us to shape our systems of health care so that we accomplish what we value. The scope of a mutual guarantee of health care has to be defined so we can commit sufficient collective resources to the system. For example, in the last twenty years, neonatologists have made remarkable strides in delivering effective care to endangered neonates. Yet during the same period, rates of prematurity and low birthweight have been rising. A narrow focus on medical care access and allocations prevents society from focusing on social and economic factors that lead to these birth conditions. As a matter of social wisdom, the public health frame will look for some way to reduce this increasing flow of patients to costly neonatal intensive care units (Lantos 2001).

A subset of wisdom is the challenge to our social prudence to build sustainable systems of protection and care. Prudence is the social virtue that looks ahead in time to determine what resources we need keep our system working. What portion of services available in the medical marketplace merit guaranteed access? What counts as the basic or adequate health care we want to guarantee? What is required to achieve our social goals and sustain them over time? For example, American health insurance plans have favored low deductibles and co-insurance arrangements, despite the fact that economic researchers have demonstrated that this approach fuels unnecessary use of health services and makes costs very difficult to control.

***Fairness.*** Given a determination that all members of society should have guaranteed access to adequate health care (the solidarity, wisdom, and prudence questions), how should we distribute the benefits of these systems equitably and share equitably the burdens of financing our mutual protection and aid? The problem of equitably distributing both benefits and burdens arises from our reciprocal commitments to one another in community.

To resolve problems of fairness we always have to consider both the distribution of benefits and the distribution of burdens. For the distribution of health care benefits (guaranteed health care services) fairness calls for equitable access based on health care need. Equality among citizens follows on universal coverage. No citizen would be excluded (the solidarity question), although some needs (e.g., experimental treatments, cosmetic surgeries) might be excluded from the guarantee (the wisdom question). The benefit side of the fairness puzzle must look carefully at the content of the adequate care package. Does the benefit package favor certain health problems over others on some basis other than the core values of the community for health care? Historically, mental health has been less well served than physical health. This may represent a professional and social prejudice unfairly affecting persons with mental health problems. The critique from the perspective of fairness needs to look for this problem.

The fairness question also requires an examination of the delivery systems for health care. There may be geographic barriers experienced by some members of society. Examples might be rural health care where the need for transportation and relative thinness of health care resources can make care inaccessible for some members of society even though care is theoretically guaranteed. Unless carefully attended to, the delivery system might incidentally incorporate linguistic and other cultural barriers to adequate health care that will affect some but not all members of society.

The other side of the fairness question focuses on the distribution of burden. Here income and health status are essential elements of the analysis. Income level is highly relevant to the problem of fairly sharing the burden of financing access for all. Tax based systems can achieve more or less fairness. Progressive taxation schemes (higher tax rates for higher income households) seek to achieve equality through inequality. By setting unequal levels of monetary contribution, progressive schemes approach equality of burden. Higher levels of contribution will be less burdensome for wealthier households. A straight proportional contribution (imposing the same percentage rate on all income levels) seeks equality of burden by a different form of unequal contributions. Equal contribution (the same absolute dollar amount irrespective of income level) starts with the goal of equality of burden, but easily results in significant inequality of burden across income levels.

Government sponsored programs use tax based contribution schemes. For example, Medicare is federally financed through Social Security taxes and provides health insurance for the elderly, persons with disabilities, and persons with end-stage renal disease; Medicaid provides coverage for certain persons with low incomes and is financed by matching funds from various state and federal taxes and revenues. Fairness evaluations of tax based systems need to explore the degree of burden experienced across income levels (Reinhardt 1993). Most taxes that support health programs are progressive, although some regressive tax programs (e.g., tobacco taxes) are also in vogue. Insurance premiums use the equal contribution standard. Premiums often adjust for age, health status, gender, and geographic location. Recent legislation at federal and state levels has ruled out some of these ways of adjusting premiums as unfair. Deductible, co-insurance, and co-pay mechanisms redistribute contributions from premiums (all members of a specific group) or taxes (all taxpayers) to those who use the health care system. The more severe the need (acute or chronic) the heavier the redistribution burden these mechanisms produce. The social ethics evaluation of fairness needs to examine the effects of the initial distribution and redistribution methods built into various financing programs.

#### Key Questions for Analyzing Ethical Reasoning About Access and Allocation

1. *Which path of argument seems most persuasive in grounding the social obligation to provide for health protections (human rights, common good, enlightened self-interest)?*
2. *What does social wisdom indicate are the essential elements of an adequate health system?*
3. *What are the major indications of fairness in the distribution of the benefits of the system of health protections?*
4. *What are the major indications of fairness in the distribution of the burden of maintaining the system of protections?*

***Democratic process in health policy: participation and representation.*** It is essential to recognize that ethical solutions about access and allocation have to be joined to political solutions. Without this pragmatic link, ethical analysis and argument will not drive institutional arrangements. They may help us think more clearly about a problem but they remain hypothetical. They will not affect the life of the community in a material way unless joined to political process (Starr 1994, Garland 2001).

The movement into political process makes the ethical question more complicated. The work of developing a balanced interpretation of ethical concepts becomes engaged with economic effects, social power, and political ideology. It is not merely a question of the more rational or more efficient path. In the political arena one has to search for the path that leads to an acceptable outcome, even when that outcome is not the preferred outcome from a philosophical point of view.

In the context of American democracy (as practiced in local and regional communities), representation of the public interest in shaping and implementing health protections becomes a critical matter. In representative democracy, the elected officials are expected to act on behalf of their constituents but also on behalf of the whole community. How they form their conscience leaves considerable room for interpretation and persuasion. In the matter of access and allocation, the benefits and burdens of coverage and cost control make for contentious discussions.

Advocates of public participation argue that the citizenry should take on the responsibility of defining and promoting the common good. But the citizens are caught in the same conflicting currents of benefits and burdens that affect elected representatives. Theoretically, open dialogue about matters of shared interest (such as the system of health protections) can lead to finding better political solutions. The principle benefits hoped for from broad public participation are clarification of key values and commitment to pursue the common good ahead of private good.

#### Key Questions About Politics and Community Responsibility

1. *What are the central political concerns that need to be incorporated into modification and maintenance of the system of health protections?*
2. *How should community responsibility figure into political processes regarding health protections?*

The Oregon Health Plan (see case study below) is an example of an organized approach to define adequate health care using public discourse to define core values. It has succeeded to some degree in moving toward a politically effective definition of adequate health care. Similarly, the unsuccessful Clinton health reform plan called for a high-level national committee process to define basic health care (*Health Security*, Starr, "Logic").

***Experts and the general community.*** In 1983 the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission) proposed an ethical framework for pursuing the definition of adequate health care. For the Commission, a proper definition would reflect the kinds of services generally covered in market-driven health insurance, the informed opinion of clinical experts about efficacy of various services and standards of practice, and the relative value of health care in relation to other social benefits that rely on collective resources. This approach uses the market to help identify society's values about health care. It calls on experts to evaluate efficacy of specific services and relative importance for health. In addition to the market information (average benefit levels), several forms of social discourse and input can help determine the underlying values that should set the standard for wise use of collective resources (Garland 1994). A related ethical question asks what is required to achieve our social goals and sustain them over time. Social prudence requires policy that acknowledges fiscal constraints and the importance of developing policies that can guide ongoing institutions.

Moving from the ethics of access to the ethics of allocation of resources calls for careful attention to the data on which policy makers rely. Allocation of resources in pursuit of access requires the ability to achieve valued outcomes in sustainable systems. The systems have to distribute benefits and burdens fairly. To do this, society must have a way to determine the relative value of specific interventions in medical care and health protection efforts. Society also must be able to assess the relative value of various health-related institutions in the light of their effect on the general health status of the community and their contribution to the compassionate response to disease, trauma, and care for chronically ill or dying persons. To manage health care systems in pursuit of solidarity, wisdom, and fairness, leaders need data from quantitative epidemiology (knowledge of the distribution of disease and identification of probable causes). Quantitative data is useful but not enough to guide ethical discourse at the policy level. Complementary qualitative data from the stories of individuals living out health care relationships with one another and among various social institutions help policy makers understand the human value dimension of health care organizations. The capacity to care simultaneously for individuals and the community drives the assessment of needs and services. Knowledge of the values of the

community related to health and illness should guide the social ethics of health care provision. Scientific knowledge and technical capacity determine how society can respond to health protection opportunities and threats.

Allocation decisions affect which kind of protections or responses to pathology will be present and distributed in the community. Organizational preferences, individual choice, and social interests are in constant tension in the pursuit of fair allocations for health care. Social institutions suited to identifying the health interests of various parties or constituencies involve democratic and political process as well as judicial resolution of controversial claims. Emerging forms of deliberative process can enrich the function of political process in the pursuit of fairness, wisdom, and sustainability of the health system (Fleck 2002, Goold, Biddle, and Danis 2000, Lenaghan 1999, Garland 1999).

Participatory or deliberative democracy is an exercise of social responsibility. Three major goals define this process: education of the public, transfer of information from the public to policy leaders, and enhancement of the sense of responsibility in the community. Each of these goals is variably present in public participation activities. Some emphasize the education of the public about significant issues (for example, the National Issues Forum). Other programs seek to develop input to policy makers on specific issues (for example, the Oregon Health Decisions program, or a public opinion survey concerning a specific issue). The Oregon program also sought to build a sense of community responsibility for the Oregon Health Plan.

Several problems accompany the practice of deliberative democracy and public participation in health policy (Daniels 1992). The content of policy problems in the health arena are always very complex. Many critics say that the public is too ill-informed to have reliable input. They feel that legislators or other policy leaders should seek input from experts. Being elected or appointed by elected officials is enough input from the public to satisfy the conditions of democracy. In addition, most health legislation and policy activities have opportunities for public hearings or statements from the public during their work process. Finally, the legislative process is well attended by lobbyists who represent both special interests and public interest groups. These people, it is felt, are more informed and focused in their input, and therefore, more useful than general public input.

We advocate general public involvement in health policy, but hold that it is important to structure it carefully to fit the circumstances of the general public. Leaders should not seek from the general public answers to questions better asked of experts. They should structure the encounters (community meetings, focus groups, surveys) to identify values relevant to the issue at hand. All members of the general public are able to give meaningful answers to questions about what makes health care important to them. This input helps the leaders specify the value-goals they should pursue. This information can help shape the questions leaders should ask of relevant experts (Garland 1999). Involving the public is a form of exercising community responsibility for the common good. This approach creates a partnership between the public and technical experts. The community

**Key Questions About Public Participation and Technical Expertise in Health Policy**

1. *What benefits and risks are associated with public participation in the design of health policy?*
2. *What benefits and risks are associated with the design of health policy by technical experts?*



meetings and telephone survey used in the prioritization process for the Oregon Health Plan are an example of the partnership approach.

Experts in economics, insurance, epidemiology, clinical care, and public health have specialized knowledge relevant to health policy design. Data and expert opinion from these sources are essential to rational policy choices. Providers of special expert information, however, do not constitute the appropriate source for the articulation of community values. As members of the community, these technical experts represent only a narrow segment of the population. They are not a representative group. They tend to define problems from their specialized field. This leads to putting the perspective of the special field ahead of the values of the community. Priority should be given to articulating the social goals valued by the community. With a clearer view of these values, the experts can help leaders find the most effective or efficient way to achieve society's goals. The distinction between means and ends is an important one to bear in mind throughout the policy development process.

## Conclusion

The ethics of access to health care in a community and of the allocation decisions required to maintain the system of health protections lead to fundamental questions about the meaning of life in community. Health systems are a social response to common threats to individuals in the community. The degree of social commitment to defending against these threats becomes a matter of social and political choice. Who is included in the community, what threats merit social defenses, how fairness will guide both benefits and burdens, and how the necessary political dimension of health policies, form a multi-dimensional frame for this examination. We derived a checklist of twelve questions that can guide the evaluation of a specific proposal for health protections reform (for example, the Oregon Health Plan or the Clinton Health Proposal). The same questions can easily be reformulated to guide an assessment of the status quo.

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## Fact Sheet: Access and Allocation

### A. National Health Expenditures

America spends \$4,637 per person on health -- more than any other nation. Still 41.2 million, or 14.6% of the U.S. population in 2001 had no third party coverage for personal health services (private insurance or coverage under a governmental program).

Source: U. S. Census bureau (<http://www.census.gov/hhes/www/hlthin01.html>)

Total expenditures for health exceed one trillion dollars. The following table shows some of the categories of health spending. Personal health services account for 87% of the total. By contrast, government public health programs account for only 3% of the total health care pie. The table below shows information about US spending for health in 2000.

National Health Expenditures (selected categories)	Dollars (in millions)	Percent of total (Items do not total 100%)
Total	\$1299.5	100%
Hospital Care	412.1	32%
Physicians and Clinics	286.4	22%
Dental care	60.0	5%
Nursing Homes	92.2	7%
Home Health Care	32.4	2%
Prescription Drugs	121.8	9%
Government Public Health	44.2	3%

Source: Centers for Medicare and Medicaid Services (<http://www.cms.hhs.gov/statistics/nhe/historical/t1.asp>)

#### *Selected Web sources of information on allocation and access:*

Centers for Medicare and Medicaid Services – <http://www.cms.hhs.gov/>

Kaiser Family Foundation – <http://www.kff.org/>

Health Affairs – <http://www.healthaffairs.org/>

## **B. General Questions for Analyzing Access and Allocation Issues**

The following questions provide a general strategy for focusing discussion about specific cases. Use them to see if the discussion touches on all the points you think are important when considering access and allocation. Modify the list to fit your approach to ethical decision-making. A checklist allows you to keep track of important matters that are easy to forget in the course of working on a complex issue.

### ***Frame of reference questions***

- Which physiologic or psychological threats to health and well being are at issue in this proposed change?
- On which social factors that affect health (e.g., poverty, risky behaviors, environmental degradation) does this proposal focus?

### ***Questions about scope of concern and historical context***

- How broadly does the problem case construe the social obligation to provide health protections (medical care, long term care, public health, social factors)? What part of the full range of health care does this case seek to change?
- How does this proposal fit into its own historical and cultural contexts? What historical antecedents bring this case to critical status?

### ***Questions about how community solidarity functions in defining health policy issues***

- How seriously does this proposal take the obligation of social solidarity among members of the community (human right or some lesser obligation)?
- Who counts as a member of the community this proposal seeks to protect (eligibility requirements)?
- What information or assumptions about the community's health is this proposal based on?

### ***Questions about ethical concepts and argumentation***

- What vision of an adequate system of health protections is at issue in this case? What view of social wisdom does the case problem assume? What kind of social obligation is at issue in this case (human rights, common good, enlightened self-interest)?
- How does this case deal with problems of fairness in the distribution of benefits and of burdens?

### ***Questions about community responsibility, political ethics, and technical expertise***

- What are the central political concerns involved this case (power issues, status issues)? Which stakeholders have power? Which ones don't?
- What role should public participation play in this case (surveys, hearings, forums)?
- What role should technical experts play in this case?

## C. Fact sheet for Case Study I—The Oregon Health Plan

### *1. Goals of Oregon Health Plan (first legislation 1989)*

- Coverage for all Oregonians (17% of population uninsured in 1989)
- Control costs of Medicaid
- Establish priorities for health services (guarantee the most important services)
- Prefer managed care delivery systems and administrative streamlining
- Private insurance reforms
- Mandatory coverage for employed persons
- Employers contribute to premiums
- Guaranteed insurance for persons unable to get private health insurance because of pre-existing conditions (High Risk Pool)

### *2. Target population: about 350,000 uninsured persons*

- Medicaid: anyone with income below the Federal Poverty Level
- One third of the uninsured to be helped by Medicaid
- Two thirds of the uninsured to be helped by private insurance reforms

### *3. Funding*

- Medicaid uses state and federal funds (40% state and 60% federal)
- Employment-based insurance would require contributions by employer (at least 50% of premium for employee, nothing for dependents).

### *4. Responsibilities*

- Health Services Commission: creates and maintains prioritized list of health services
- Legislature
  - Establishes Medicaid budget by “drawing a line” on the list
  - Needed to pass legislation to implement the mandatory insurance program\*

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\* The mandatory insurance strategy was never implemented because of complex federal laws protecting employee benefits. This part of the strategy was eventually repealed and partially replaced with a program to offer subsidies for insurance premiums to low income families. Current reforms (2002) seek to expand that subsidy program and require further waivers from the federal government.

## **D. Fact Sheet for Case Study 2—Using Intravenous Immunoglobulin (IVIG)**

### ***1. Clinical Facts***

- The FDA lists 6 approved (“label”) indications for IVIG use for which reasonable supportive evidence exists.
- Different institutions vary considerably in how IVIG is used even for these labeled indications (e.g. some provide routine initial prophylaxis for bone marrow transplant recipients, others limit use to prophylaxis for certain high risk recipients or treatment of specific clinical indications).
- Anecdotal reports and small clinical studies have led to a profusion of “off-label” uses. There is little supportive evidence for most of these off-label uses, but for some there is good evidence of effectiveness (both published and by clinical experience)
- For most indications (label and off-label) no data exist to support any particular treatment regimen.
- Current rationing of product occurs implicitly by a first-come-first-serve basis coupled with the “squeaky wheel” phenomenon.

### ***2. Administrative Facts***

- Several clinical units are frequent users of IVIG for quite distinct clinical indications (bone marrow transplants, neuro-muscular disease, infectious diseases, hematologic diseases, and immunologic diseases).
- The pharmacy administration had exhausted all available resources for the supply of additional product.
- Attempts to address the demand problem through provider education and by asking for provider justification for each prescription had failed to change IVIG use patterns.
- Current policy is simply “first come, first served” until the supply of IVIG is exhausted.

### **E. Fact Sheet for Case Study 3—Cutting a State Health Department Budget**

The state public health agency is required to show the public health service consequences of a 15% reduction in its budget. The agency delivers its public health services through five service centers. Here is a summary statement of the services selected to feel the effect of the reductions. Other activities of each of the centers would remain unaffected by the proposed reductions.

- Impact on Administration and Special Programs: reduce funding to county health departments to make flexible strategies for local priorities.
- Impact on Center for Child and Family Health: eliminate teen health advice line and 4 high school based teen clinics; reduce support for maternity and well child care for families with low incomes.
- Impact on Center for Disease Prevention and Epidemiology: stop paying for drugs used to treat Hepatitis A and TB; eliminate support to counties for STD, HIV and TB case management programs.
- Impact on Center for Environment and Health Systems: eliminate some staff consultants on environmental issues; eliminate staff and subsidies for Emergency Medical Systems program; introduce fees for monitoring of public drinking water systems.
- Impact on Public Health Laboratory: eliminate free tests for parasites, syphilis, flu and other respiratory viruses; cease participation in U.S. and WHO influenza surveillance program.

## Case Study 1: The Oregon Health Plan

For this case discussion, we will focus on the question of rationing health care that played a central role in the health care reform carried out in Oregon during the 1990s.

In 1989 Oregon passed several pieces of legislation that formed the basis of the Oregon Health Plan (OHP). The program aimed at achieving access for all Oregonians to affordable medical care. At the time, it was estimated that 350,000 Oregonians (of a population of 1.2 million) lacked coverage. The vast majority of these persons had incomes below or near the Federal Poverty Line (FPL). Although the reform seeks primarily to expand access to health care, it achieved considerable notoriety as a program that “rationed health care.”

The Oregon legislature, led by Senate President John Kitzhaber, MD, crafted a two-part strategy to get to universal coverage. First, Oregon Medicaid was redesigned so that everyone below the Federal Poverty Line, for example, a family of three with an income of \$14,628 (in 2001 dollars), would be eligible for coverage. Income only, with no additional categories would be the basis for eligibility. By contrast, traditional Medicaid is a program in which income plus some category, particularly families with dependent children, constitute eligibility. In 1989, eligibility for Oregon families had fallen to 58% of the FPL so that a family of three with an annual income above \$ 8, 484 (in 2001 dollars) would not be poor enough to qualify for Medicaid.

Medicaid is a federal-state partnership program in which federal dollars match state dollars based on a federal formula that factors in the relative wealth of the state. In 1989 Oregon received \$60 for every \$40 it put into Medicaid. A major part of the politics of the Oregon reform focused on satisfying the concerns of the federal government to maintain the matching federal dollars. The use of categories is a central feature of the federal Medicaid rules.

The second strategy required all Oregon employers to participate in the purchase of health insurance for their workers. Initially the program would be voluntary, but if employers did not reach the target, the requirement would become a mandate. Employers who did not participate in the purchase of health insurance for their employees would pay a special tax that the state would use to purchase insurance for those left out.

Based on population demographics, the Medicaid reform was expected to bring coverage to one third of the uninsured and the employer-sponsored insurance would bring coverage to the remaining two thirds.

Three other goals of the OHP were definition of an adequate health care package, improved control of the Medicaid budget, and a fair distribution of the burden of paying for universal coverage. The adequate package goal was pursued through the formation of a prioritized list of health services. The use of the list to structure Medicaid required an agreement with federal Medicaid administrators to exempt Oregon from the usual Medicaid rules (called a “waiver”), since the federal rules considered some services mandatory and others optional. Oregon felt a prioritized list would better approximate an adequate health care package, since some optional items (like hospice care, organ transplants, and dental care) were more valuable than some mandatory services included in a general category of physician and hospital services. (Several states besides Oregon currently have waivers so they can test local experiments with their Medicaid programs.)



Improved control over Oregon's Medicaid expenditures was expected to result as the legislature used the list to determine Medicaid budget ("drawing a funding line on the list") and from administrative efficiencies carried out by the Medicaid Agency. In 1989 the legislators held high hopes for a cost control strategy of using managed care for Medicaid clients.

A special committee, the Health Services Commission, was established to create the prioritized list. The list's first use was to give the legislature a tool for budget allocations. The Commission's role is to identify the relative value of various health services. The legislature's role is to identify the relative value of health care among other uses of the state's resources (for example, education, transportation, economic development, environmental protection, and non-clinical public health services).

Its second use was to set a benchmark for those private insurance packages that would qualify as meeting the employer mandate requirement. The benchmark role was intended to prevent employers from fulfilling the letter of the mandate by selecting cheap plans that offered inadequate coverage (thus failing to meet the spirit of the law—health protections).

The law required the Health Services Commission to hold public hearings and community meetings to identify the values that should guide the prioritization process. Two civic organizations, Oregon Health Decisions and the Oregon Health Action Campaign partnered with the Commission to design, publicize, and report the results of the community meetings. The Commission also held public hearings and commissioned a random sample telephone survey to complement the community meetings. All of these public involvement modalities focused on community values rather than specific services. The public was asked, "What makes health care important to us?"

The Commission also recruited more than 50 teams of clinicians to provide input on the probability that specific treatments for specific conditions would achieve results matching the values of the community. Each item on the prioritized list consists of a diagnosis and treatment pair (or groups of such pairs). All services available in the medical marketplace were open to inclusion on the list. The Commission used the *International Classification of Diseases* and the *Current Procedural Technology* to establish the range of condition-treatment pairs. The task of clinical experts was to help identify what services were likely to pay-off in terms of the community's values for health care.

The Commission created its own methodology using mortality, morbidity, treatment effectiveness, and costs as primary points of reference. Values derived from the community meetings, survey, and hearings guided their interpretations. The list that finally received approval from the Federal government for a waiver from the usual Medicaid rules had the following logic. First, the lines would be ordered in terms of the probability of the treatment being life saving. Lines with higher probability of saving life come before those with lower probability. The Commission believed this ordering serves two values expressed by the public: life saving and effectiveness of treatments. Second, among those items with identical probability of saving life, the commission placed lower cost services ahead of higher cost services. This incorporates the community value of cost-effectiveness.

The third ordering principle required the Commission to intuitively place items that served important values identified by the community that were not covered by the first two principles. These values included the following. "Compassion" led to placing hospice and other palliative services high on the list. "Prevention" and "Effect on the community" led to placing maternity care, and many screening and

early intervention services high on the list. “Maintaining function” led to placing many mental health services and substance abuse rehabilitation services in secure positions.

Post script: The Medicaid program began operation under federal waiver in February 1994. The list is revised every two years. The entire list currently consists of 743 lines and is funded through line 574 (about 80% of the list). The employer mandate strategy failed politically in 1996 and has been replaced with a small subsidy program to aid families with incomes above federal poverty to purchase health insurance. Additional support for universal coverage comes from a federally stimulated program in 1998 to secure health insurance for children.

### Questions for discussion

- Critics have attacked the Oregon Health Plan for rationing health care “only to the poor.” They assert that the good idea of extending health coverage to more poor persons was corrupted by reducing benefits only for the poor (current Medicaid clients) and using those savings to fund care for other poor persons (new Medicaid clients). Fairness, they argue, would require that all citizens submit to the rationing of health services in order to extend coverage to more of the poor. Supporters of the Oregon Plan have responded that all the poor are better off because the extended income range will provide continuous coverage for current clients when their income improves. They argue further that the more rational benefit package (based on the list) is a better one than the traditional Medicaid package. What are your thoughts about the dangers of rationing medical care only among Medicaid eligible persons? How would you argue in favor of rationing medical care?
- Critics have objected that the community meetings were not sufficiently representative of the people whose lives were affected by the Oregon Health Plan. They argue that meetings should have been exclusively for persons below the Federal Poverty Level. Instead, although the meetings did include people with incomes below the federal poverty level, most of the people at the meetings were from the middle class and therefore their values were not relevant guides for setting priorities. This, say the critics, makes the community values of little relevance to the Medicaid reform. Supporters have responded that values about access to health care are widely distributed so the values of the middle class participants are quite relevant to this issue. They also point out that the discussions did not ask people, “What services do you want?” Instead they asked “What makes health care important to us?” What do you think of this criticism and response? What do you think is an ideal solution to this question of representation in public participation efforts?
- Some critics opposed the Oregon Health Plan because it is incremental rather than radical. “Being successful with a plan like this,” they argue, “only delays America achieving true universal coverage based on progressive financing through taxes. Efforts put into plans like Oregon’s distract America from the search for real solutions to the central problem of health care.” What is your position on whether incremental reform is a barrier to needed radical reform?
- For several decades, public opinion polls have shown that Americans believe in the ideal of universal access. In recent years, opinion also supports significant reform of the system. Still,

America continues to have almost 20% of its population uninsured for health care. How do you interpret this contradiction between public opinion and public action?

- Some people argue that getting universal coverage won't do much to help the health status of the population. Health is more seriously affected by social causes (obesity, poor nutrition, poverty, stressful lifestyles, violence) than by access to medical care. What are your thoughts on this critique?

## **Case Study 2: Multiple Claims and Commitments in a Health Care Institution**

This case explores the organizational ethics of dealing with a scarce resource within the context of a single health care institution. Different clinical units had differing clinical reasons for using this scarce resource for their patients. How do you think about resolving conflicting moral claims?

Intravenous immunoglobulin (IVIG) is a pooled and concentrated blood product. A single unit of human immune globulin comes from 100,000-300,000 units of donated blood. The FDA has identified six approved or “labeled” medical conditions for which IVIG is licensed and for which there is general agreement among clinicians and variable amounts of supporting evidence. Intravenous immunoglobulin has also been used and recommended for a host of “off-label” (i.e. non-approved) indications, for only a few of which is there good supporting evidence. Clinicians are free to use an approved substance for “off-label” indications, although they incur greater risks of malpractice action in the event of bad outcomes.

A nation-wide shortage of IVIG developed in the mid-1990s resulting from problems with both supply and demand. Growing concern about the possible risks of transmitting Hepatitis C and human forms of spongiform encephalopathy (Creutzfeldt-Jacob Disease) by blood products was largely due to reports of either disease or positive tests for disease in individual donors whose donated blood was traced to pooled blood products. These reports were all the more compelling because they occurred in the wake of the HIV threat to blood products in the 1980s.

Concerns about the safety of the nation’s blood supply led to a marked increase in regulatory activities by the FDA around IVIG and its production. Manufacturers were required to make major changes in production processes in order to correct deficiencies. This in turn required manufacturers to stop or slow production, which had a prolonged negative impact on the output of final product. Some manufacturers discontinued production altogether—and substantial amounts of product were either recalled or withheld because of relatively conservative criteria for defining and increased risk of transmission, adding to problems with supply. These events contributed to the current critical shortage as well as decreased the long-term potential for recovery of supply.

In addition to the constraints on supply, demand increased markedly in response to research studies and anecdotal reports of IVIG use that expanded the list of off-label indications for IVIG. These off-label uses are not only numerous but often involve high dosage regimens that consume large quantities of product. The shortage of IVIG became an issue at the Kos University Memorial Hospital (KUMH), a large academic health center, during the late 1990s when the pharmacy began to experience a marked increase in the cost of IVIG (from \$15 to > \$40-50 per gram) and then reached a point where minimal quantities could be obtained at any cost.

The usual sources of IVIG began to dry up, requiring considerable ingenuity to keep KUMH supplied with enough IVIG to meet its ongoing need. By January 1998 the shortage had reached critical levels and the pharmacy looked to the administration for a solution.

## Questions for Discussion

- Suppose you were the responsible hospital administrator involved in this shortage problem. How would you organize your thinking about this dilemma? What are your ethical obligations and what process would you call on to serve those obligations?
- Now suppose you were a clinician-leader in one of the specialties that regularly uses IVIG. How would you organize your thinking about this dilemma? What are your ethical obligations and what process would you call on to serve those obligations?
- Who are all the stakeholders that need to be involved in dealing with this problem? How would you most effectively engage them? What rules of discourse do you think ought to guide the process of developing a new institutional policy about clinical uses of IVIG?
- What are the ethical constraints faced by each of these stakeholders and how do you think each defines the ethical issues she/he faces? What are the ethical stories or central ethical metaphors (for example, healer, administrator, patient advocate) that each stakeholder uses to define the ethical context within which she/he works in thinks about that work?
- What information do you need to factor into your solution?
- What are the wider ethical implications of this problem? How do you think those implications are likely to be framed at different levels of the health care system? Do you think the treating physician should be concerned with shortages for other physicians and patients in KUMH? Or other hospitals served by the same regional blood supply system? Or the national supply system? Or the international supply system?
- What strategies for discourse and decision should the administrative staff use in addressing this issue? What are the ethical implications of how one uses data at different levels of decision making?
- What is the ethical justification for your recommended strategy?
- What do you think is the nature of what one might call an “ethical perspective” on allocating scarce medical resources?

## Case Study 3: Making Cuts in a Health Department Budget

### Frame of reference

A public health agency budget is the locus of allocation decisions. Ethical reflection on allocation decisions enters reality by working out a practical resolution of conflict among public health values in the context of an agency's budget. On a regular basis, state public health agencies set budgets and must deal with fiscal constraints on what they can do. This case explores the ethics of identifying places in a hypothetical state budget where administrators propose cuts to services that can produce an overall reduction in expenditures of 15%. In the aftermath of September 11, 2001 and the subsequent recession, most states across the country faced severe shortfalls. The 15% budget reduction imagined here is not an unusual scenario.

### The North Upland Public Health Budget

North Upland has a state population of 4 million. Immigration from other states and foreign countries exceeds emigration from North Upland to other states and countries. In terms of per capita income it falls into the middle tier of states. The state has a lower percentage of persons without health insurance than the national average. In the past few years it has moved from one of the lowest rates of unemployment in the nation to one of the highest.

The N.U. Health Department organizes its activities around five Centers: 1) Administration and Special Programs, 2) Child and Family Health, 3) Disease Prevention and Epidemiology, 4) Environment and Health Systems, and 5) the Public Health Laboratory.

The North Upland State Health Department has proposed a two-year budget of \$49,139,000 for 2002-04. The total budget of the Health Department is composed of 62% state general funds (\$30,447,000) and 38% federal funds (\$18,661,000). Federal funds are tied to specific programs. The Governor of North Upland has asked all state agencies to construct a budget showing what they would cut if faced with a 15% reduction in state general funds. The list below shows more than \$4.5 million in cuts proposed by the Health Department along with a narrative showing the anticipated consequences for the health of the population if these cuts are made.

### Proposed budget cuts and their consequences

1. From the Office of the Administrator and Program Services  
(\$1,000,000 cut from a budget of \$6,667,000)
  - Reduce general purpose public health support payments to counties  
*Savings:* \$1,000,000  
*Impact:* This will reduce funds counties use to make flexible adjustments to various public health activities based on local priorities.
2. From the Center for Child and Family Health  
(\$1,692,000 cut from \$11,280,000)

- Eliminate Teen Health Information Line  
*Savings:* \$97,000  
*Impact:* Would cut in half the capacity of the major metropolitan county health department to answer calls from an estimated 4000 teens on a variety of health issues.
  - Eliminate funding for 4 High School Based Clinics  
*Savings:* \$415,000  
*Impact:* Would probably result in closure of these programs which will have to be fully funded by the School District which faces severe loss of revenue at this time.
  - Reduce support for Perinatal Clinical Services and case management  
*Savings:* \$870,000  
*Impact:* Reduce support for counties to provide maternity and well baby services and case management for clients with complicated cases. Involves and estimated 10,400 mothers and babies.
  - Abolish state funding portion of the Child Health Program  
*Savings:* \$310,000  
*Impact:* Reducing payments to counties for this service affects a variety of well-child programs provided free of charge through county clinics. Examples: SIDS prevention, nutrition services, injury prevention, dental health education, adolescent health promotion. Counties would have to come up with the funds or eliminate services.
3. From the Center for Disease Prevention and Epidemiology  
(\$1,035,000 cut from a budget of \$6,900,000)
- Eliminate provision of specific medical supplies and services.  
*Savings:* \$425,000  
*Impact:* The state would no longer provide immune globulin used to prevent the spread of hepatitis A or drugs used to treat persons with active or latent TB. The state currently provides free treatment for 1570 persons with active or latent TB and 2900 persons exposed to Hepatitis A. In the future, persons in need of these drugs will have to pay for them or receive them through some private charitable source.
  - Reduce special payments to Counties for HIV/TB/STD programs  
*Savings:* \$610,000  
*Impact:* This will eliminate the HIV case management program for persons with HIV and TB. It will diminish the capacity to notify sexual partners of persons who have been diagnosed with a sexually transmitted disease.
4. From Environment and Health Systems  
(\$495,000 cut from a budget of \$3,300,000)
- Eliminate staff in the Environmental Services and Consultation Office  
*Savings:* \$165,000  
*Impact:* This will reduce the capacity of the office to enforce restaurant, pool, and

lodging standards throughout the state. It will also eliminate direct service for environmental health issues in twelve counties that now rely on the state office. This funding might be replaced by increasing licensing fees to restaurants, swimming pools and public lodging businesses.

- Eliminate staff and subsidies in Emergency Medical Systems program.

*Savings:* \$165,000

*Impact:* This will affect the ability of the program to oversee training certification, professional standards, investigation of complaints, and statewide system development and coordination. Subsidies (reduced licensure fees) will no longer be provided to small, primarily volunteer, ambulance services in rural areas.

- Initiate fees for Public Drinking Water Systems

*Savings:* \$165,000

*Impact:* Replaces state dollars with new fees on systems (requires new specific legislation). Federal matching dollars (1:1) will be lost if replacement money is not available. Reduces the ability of county water programs to monitor safe drinking water standards.

5. From the Public Health Laboratory  
(\$ 344,000 cut from a budget of \$2,300,000)

- Eliminate free parasite testing.

*Savings:* \$114,000

*Impact:* The lab would no longer provide at state expense testing for parasites such as Giardia (900 cases reported in 1998), Cryptosporidium, and many others. This will require local health departments to pay for tests needed to detect and control community outbreaks or identify the source (e.g., food handlers, day care centers).

- Eliminate free syphilis testing.

*Savings:* \$115,000

*Impact:* We will no longer provide screening and confirmatory tests for syphilis at state expense. Local health departments, charity clinics, family planning clinics, and correctional institutions will have to pay for tests needed to detect, monitor, and control syphilis. We anticipate an increase in the number of cases and severity of disease in those infected.

- Eliminate free Influenza cultures and other respiratory infectious agents

*Savings:* \$115,000

*Impact:* We will no longer test at state expense for influenza and other respiratory viruses. We will no longer participate in the U.S. and WHO influenza surveillance program. We will rely on others to detect a change in the flu strain that might affect citizens in North Upland.



## Case Study 3: Discussion

The ethical pattern involved in this case involves “least harm” decision-making, where harm is identified by loss of valued outcomes as a result of budget reductions. An agency typically projects its budget by assuming the continuation of the activities carried out with the resources of previous budget. The agency then makes the case for two potential steps. It may propose to discontinue or reduce a previous activity. It may propose to initiate some new activity. The situation we will consider raises questions involved in reducing and discontinuing activities.

The case discussion should look at both the content (the reasons that support the choice) and the process by which the identification of reductions takes place. The content aspect considers ethical categories such as common good, fairness, justice, and rights. The process aspect considers democratic values such as participation, voice, representation, and sacrifice.

### Context

Although the case provides little information about context (social, economic, political, historical) for these decisions, your discussion should explore what context issues you believe are essential for analyzing the case from the perspective of ethics.

Are there population health factors (e.g., age, state wealth, endemic diseases, environmental threats, etc.) that would be important considerations in selecting which of the programs would be cut? (Remember, 85% of the budget is still funded.) Draw up a list of important population health factors you think must be considered in this decision.

From a population perspective, what values do you want to use to guide the selection of budget cuts? The North Upland Health Department states that its mission is: “To protect, preserve, and promote the health of all the people of the state; to prevent unnecessary death and disability, improve the health status of all N.U. inhabitants, and to reduce the per-capita cost of illness care for all North Uplanders.” Does this capture all the values you want to bring to bear on allocation decision-making? Make a list of any values you don’t want to be left out of the consideration.

### Ethical content

- What are the principles you would use to guide choices and evaluate the results of these budget choices? Try to articulate the rules or “guidelines” you think ought to be used to see that budget reductions deal with the following ethical concerns.
- How should we make sure that the cuts are *fair* to all involved?  
(State the decision-rule you think should be followed to achieve a *fair* decision.)
- What can we do to make sure that the cuts meet the requirements of *justice*?  
(State the decision-rule you think should be followed to achieve a *just* decision.)
- How can we be assured that the cuts serve the *common good*?  
(State the decision-rule you think should be followed to achieve a decision that promotes or

protects the *common good*.)

- What other ethical norms do you believe are essential to making an ethical decision about reducing (or expanding) a public health budget?  
(State the decision-rule you think should be followed to achieve a decision that incorporates these other norms.)

### **Ethical Process**

- This part of the discussion focuses on *how* the decision is made. Process ideas will focus on who should have a *voice* in the decision, how *representation* of stakeholders is achieved, what *rules of discourse* are followed, and how a *conclusion* is reached.
- Who do you think should be consulted about these cuts? How should they be notified?
- How should inputs be sought?
- How should the decision maker use the inputs?
- How should the input process (or debate) be brought to a conclusion so a decision can be made?