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Conducting research: practical steps

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SUMMARY

Developing a research protocol and obtaining funding for carrying out the research are only the first steps in doing research. Understanding the means to conduct the research is equally important. As research is a joint effort of a team, a mechanism of collaboration must be developed to engage all those with an interest in the research. This includes the community in which the research is to be undertaken, representatives of those who will participate in the research, the academic community who will be involved in the research, and those who will sponsor the research. These individuals can be formed into a 'steering committee' to guide the development, conduct, analysis and communication of the research. Careful consideration must be given to the benefits and risks of the research. These must be precisely spelled out in the research protocol, and all aspects of the research must be independently evaluated for technical competence, accuracy, communication and liability for injury by an ethics review committee. The research must follow precisely the protocol developed. Administrative procedures, including recruitment and management of staff, outlining standard procedures and quality assurance procedures must be clearly outlined and followed. Carefully handling the information collected in a research project is vital to ensuring the quality and validity of the research.

KEY WORDS: research; protocol; lung; education

WHO OWNS RESEARCH?

RESEARCH is an activity undertaken by a number of players working together; these include the investigators, their staff, the institutions they represent, those who provide the finances, the participants, their communities and the institutions in which the research is carried out.

As research is a partnership, ideally this should be explicitly affirmed in the formation of a 'steering committee' comprising representatives of all the partners. These include the investigators, the sponsors of the research, representatives of the community, and the regulatory or administrative agencies responsible for their health. This is vital in ensuring that the results of the research are communicated and that policy recommendations are implemented.

In carrying out research, the perceptions of the community concerning the health-related state and determinants under investigation need to be taken into consideration. This may require public meetings with members of the community to address their questions, to gain their co-operation and to explain the aims and procedures of the research.

The results of the research and clear recommendations for action must be communicated to the community and to those responsible for the health services in the community. Research investigations may sometimes uncover previously unknown disease or medical information of importance to the health of the participants. A well-defined plan of follow-up to deal with such instances, never breaching the confidentiality of individual participants, must be in place.

CAN RESEARCH HAVE NEGATIVE AS WELL AS POSITIVE EFFECTS?

Ethics review is essential for all biomedical research carried out on human subjects. This is normally undertaken by an ethics review committee. The committee's role is to satisfy themselves that all proposed interventions are acceptably safe for human subjects and to ensure that all other ethical considerations are adequately addressed. Membership of an ethics review committee should include a variety of health professionals with relevant competence and lay persons representing the community's cultural and moral values.

The basic principles of biomedical research involving human subjects are as follows:

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The protocol

- The research protocol must always discuss ethical considerations and adhere to the principles of the Helsinki Declaration.

Technical aspects

- Research must conform to accepted scientific principles and be based on experimentation or planned observation as well as knowledge of the scientific literature
- Research procedures must be fully described in a protocol
- Those carrying out research must be scientifically qualified and supervised by a competent medical person.

Credibility

- Accuracy and lack of bias in reporting the results of the research must be assured
- Researchers must always fully declare any potential conflict of interest
- Research that does not comply with these principles should not be published.

Communication and consent

- Subjects must be adequately informed of aims, methods, benefits and hazards
- Subjects must know that they are free to abstain or withdraw at any time without prejudice
- Subjects must give consent, based on full information, prior to participation
- Consent must be free and given to someone on whom the subject is not dependent
- Where legal incompetence prevents the subject from providing it, consent must be given by a legal guardian
- Consent for the research should be obtained from the leaders of community
- Even where community leaders give consent, individuals must retain the right to withdraw from the study, without prejudice.

Liability

- The value of the research must be in proportion to any inherent risk associated with the research procedures, and both must be clearly stated
- The interests of the subject must always prevail over the interests of science and society
- The integrity (including the privacy) of the subject must be ensured
- Responsibility for the well-being of the participants must always rest with the medically qualified individual and not the subject
- Those who suffer injury due to participation must be eligible for compensation
- Eligibility for compensation cannot be waived by the participant or guardian
- A mechanism for compensation is the responsibility of the sponsoring institution, organisation or person.

Additional principles apply when research is combined with patient care

- New tools for diagnosis or treatment may be used if they offer hope of saving life, re-establishing health or alleviating suffering
- The benefits, hazards and discomfort of new tools must be weighed against those of current methods
- All participants must be assured of access to the best methods of care
- Refusal to participate must not interfere with the delivery or quality of care
- Where consent is not requested, the reasons must be explicitly stated and a justification presented
- The research must promise potential value to the patient/community.

Research carried out in low-income countries that is sponsored from outside the country involves ethical considerations in addition to those outlined above

- The investigation may serve external rather than local interests
- External collaborators may lack insight into customs and legal systems
- Lack of long-term commitment to the community may jeopardise research
- Compensation for injury may result from a lack of accountability.

Ethics review procedures

- All research must be approved by both technical and ethical review
- Ethical principles in all research should conform to the Helsinki Declaration
- Independent ethical review takes place in the community involved in the research
- Standards of local ethical review must be as rigorous as those in the communities from which each of the investigators come.

Investigators and authorities in low-income countries should not agree to any research if there are no clear and stated benefits for the subjects, the local investigators and/or the community. The protocol of such studies should clearly specify the interests of each of the collaborating partners and evaluate the 'risks' and 'benefits' of the collaboration itself.

PROJECT MANAGEMENT: PRACTICAL ISSUES IN CARRYING OUT A RESEARCH PROJECT

Before starting on a research project, a research plan must be prepared, including a listing of all the tasks to be undertaken, identification of responsible individuals and a definition of personnel needs for carrying out the study. A calendar for carrying out the activi-

ties is then developed, including recruiting personnel, training, piloting techniques and procedures (if necessary), recruiting participation, doing the measurements, collating and checking the data, analysing the results, preparing the reports for the participants and community and preparing scientific reports of the results.

The responsibilities of each member of the research team should be written down. The responsibilities of the principal investigator include project management, quality assurance, public relations, ethics and analysis and reporting of the results.

The procedures of research must precisely follow those outlined in the protocol. The precise indicators for evaluating the quality of information and measurements need to be specified and the technique for recording and interpreting them defined. A number of steps are needed to ensure that the quality of the research is maintained.

Step 1

Pilot testing of untried methods must be undertaken in advance to ensure that they will work as planned. Similarly, all new equipment must be tested and questionnaires pilot tested to ensure that respondents are able to complete them as expected.

Step 2

Procedure manuals must be developed describing exactly how techniques are to be carried out. In addition, a careful plan must be developed and recorded for the management of data. Special attention must be paid to tracking of the data obtained, ensuring quality control of data, checking for errors and ensuring secure storage of the results.

Step 3

The staff who will be collecting the information must be trained for the study. For example, procedures for eliciting a clinical history are different from those for completing a research questionnaire.

Step 4

Periodic comparisons of data quality must be carried out when more than one person takes the measurements or when information is being collected at more than one centre. This ensures that results will be consistent across observers, or at least that you have a measure of the differences across centres or technicians.

Step 5

One final way to ensure high quality of data collected, especially for large projects, is to give responsibility directly to smaller research teams or to individuals and to give them recognition for this responsibility. It is often useful to decide in advance what reports (or what sections of one large report) will be produced from the project and to share the responsibility for these reports among the members of the research team.

The following measures will help to ensure that the study is carried out in time and on budget:

- Written schedule or timeline
- Periodic progress meetings or reports
- Individuals designated for ensuring that the schedule and budget are met
- Shared information on budget with all staff
- Separate budget for each team when the study is multi-centre or multi-team.

It is not uncommon for researchers to find themselves wanting to change some aspect of the protocol in the middle of a research project. Reasons for this may include the following:

- The methods do not appear to be working
- New information makes you question your hypothesis or your objectives
- The results appear to be suggesting conclusions about the original hypothesis.

The appropriate response is to stop the project temporarily and convene a meeting of your research team to consider the following options: to stop the study altogether or to decide to continue with the existing protocol. Changing the protocol mid-stream is not an acceptable option. Why not? Every study protocol includes a sample size/power calculation. If you change the protocol, you will end up with two small studies (each one with a slightly different protocol) instead of the one larger study you planned. These two smaller studies will have less (usually insufficient) power to address your objectives.

HOW DO YOU MANAGE THE INFORMATION COLLECTED?

The steps involved in checking, organising, analysing and reporting the results generally take at least as much time as does collecting the data.

The first step in data management is to review the raw data records for completeness and accuracy. For small projects, check and correct every paper record *before* its information is entered into a computer; for large projects, check a random subset of records, look for common errors, then if possible check and correct all records for the places where errors were commonly made.

Make changes to the raw data only for obvious errors, but do not make changes that require a value judgement that you cannot verify.

Some raw data can be entered directly into computer files. For other types of information, it may be easier to sort or classify the information into manageable groups and assign code numbers to each group. The code, rather than the name of the drug, is then entered into the computer.

Create a written codebook that provides a clear set of standard rules for turning the text information into

numeric codes. Coding systems may be very complex (e.g., several pages to describe treatment protocols) or very simple (e.g., '1' for females; '2' for males).

ALWAYS HAVE MORE THAN ONE COPY OF YOUR CODEBOOK!

In many instances, it is advisable to choose codes *in advance* of collecting the data. Then provide this coding information to the person who will be collecting the data. This ensures that the interviewer (or person doing the transcriptions) will be sure to record the information in a way that makes coding possible later. Another option is to place the codes (and the coding rule) directly on the data entry form.

Coding should be checked just as you did for raw data.

Data can be entered into computer files in a number of different ways

- Direct data entry by computer as it is collected (e.g., a computerised questionnaire)
- Keypunching coded forms
- Optical scanning or bar codes.

A single data record is all the information you have collected about one person (assuming your unit of observation is an individual person)—like a *row* in a spreadsheet. A single variable is all the information—for every person in your study—you have collected about a particular characteristic—e.g., age, diagnosis, etc.—like a *column* in a spreadsheet.

After the data has been entered into computer files it must be checked again

- Checking for out of range and not valid values. For variables that are categories: have the computer produce a frequency distribution for each variable and examine the results. For variables that are continuous measures: have the computer produce a list of the minimum and maximum for each variable and examine the results. Ask yourself if the results make sense. For example, if the information does not match up with what you know about the study area, this might signal an important error in the way the data were coded or entered.
- Checking for non-sensible values. Have the computer produce a cross-tabulation of two variables. Look for logically inconsistent results (e.g., a person aged 12 years with 3 children).

Handling missing data

No matter how carefully you have collected and checked your data, there will still be some missing data. You must decide what to do about this. Data can be missing 'at random', meaning that the missing data are unrelated to other important factors in your study; or missing 'systematically', meaning that the missing data are related to some other important factor in the study.

The most common approach in health research is to delete from analysis every study participant with missing data. If you choose this option, you must consider that you now have a modified study population. Another option is to substitute a value for the missing ones. If you can demonstrate that the missing information is truly 'missing at random', you can substitute the mean value from all other subjects for the missing value. If you can estimate the missing or incorrect value with accuracy (based on other values not missing), then substituting the estimated value may be warranted.

RÉSUMÉ

Le développement d'un protocole de recherche et l'obtention d'un financement pour l'exécution de la recherche ne sont que les premières étapes de l'exécution de cette dernière. Il est également important de comprendre la façon de conduire cette recherche. Une recherche est l'effort commun d'une équipe et il y a lieu de développer un mécanisme de collaboration qui engage tous ceux ayant intérêt à la recherche. Ceci inclut la collectivité dans laquelle la recherche doit être entreprise, la collectivité académique qui sera impliquée dans la recherche et ceux qui la financeront. Ces individus peuvent constituer un comité de direction qui guidera le développement, l'exécution, l'analyse et la communication concernant cette recherche. Il faut considérer avec soin les avantages et les risques de la recherche ; ceux-ci doivent être exposés avec précision dans le protocole de recherche et tous les aspects de celle-ci doivent être évalués de façon indépendante en ce qui concerne la compétence technique, la précision, la communication et la responsabilité des préjudices par un comité de révision éthique. La recherche doit suivre avec précision le protocole élaboré. Les procédures administratives, y compris le recrutement et la gestion du personnel, la délimitation des procédures standard et des procédures du contrôle de qualité doivent être clairement définies et suivies. Un traitement soigneux des informations recueillies dans un projet de recherche est essentiel pour en assurer la qualité et la validité.

RESUMEN

La elaboración de un protocolo de investigación y la obtención del financiamiento para llevar a cabo la investigación son sólo las primeras etapas en la investigación. De igual importancia es la comprensión de los medios para dirigir la investigación. La investigación es el esfuerzo conjunto de un equipo y debe establecerse un mecanismo de colaboración para comprometer a todos quienes tengan un interés en la investigación, es decir la comunidad en la cual se llevará a cabo la investigación, los representantes de quienes participarán en la investigación, la comunidad académica implicada y quienes financiarán la investigación. Estos individuos pueden reunirse en un 'comité de orientación' para la elaboración, la realización, el análisis y la comunicación de la investigación. Debe prestarse atención particular a los beneficios y a los riesgos de la investigación, los cuales deben consignarse explícitamente en el protocolo de la investigación ; una comisión de ética independiente debe examinar todos los aspectos de la investigación para evaluar su competencia técnica, precisión, comunicación y responsabilidad por perjuicios. La investigación debe seguir precisamente el protocolo elaborado. Deben resumirse claramente y seguirse todos los procedimientos administrativos, como el reclutamiento y manejo del personal y deben sintetizarse los métodos de referencia y de garantía de calidad. El manejo cuidadoso de la información obtenida en un proyecto de investigación es fundamental para garantizar la calidad y la validez de la investigación.