Leading article

Ethics in survey research

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1. Introduction

The main objective of this paper is to explore the ethical considerations in relation to the procedures (research steps) of non-experimental (observational) and some mixed observational analytic studies with particular reference to community surveys. These include cross sectional, longitudinal, cohort and intervention studies.

The declarations and codes of conduct on medical ethics deal mainly with experimental research and especially the interaction with patients and medical professionals. However, if the term "patient" used, could be equated to individuals in the community (ill or otherwise) being researched, then the relationship becomes the interaction between study units and the researchers. If this be so, the same ethical considerations may be applicable in non-experimental studies.

Guidelines on ethics for non-experimental research are few, hence this attempt to do so, for consideration by those who undertake this type of research.

2. Ethics

Ethics or codes of conduct for societal living of human beings either written or unwritten have existed since man organized themselves into communities. They were initially based on habits and on value judgements and later became mores, which were more binding on society. The evolution has been from no ethical considerations to some, and in recent times, to a plethora of codes of ethical behaviour for the different types of professionals.

Ethics may be defined as the science of morals or code of behaviour based on moral principles. "Ethics deals with morals and good conduct. It frames codes, regulations and laws to maintain the desired standards of behaviour. Ethical behaviour however is the essence of a persons character; love and truth are its main ingredients"(1). Ethics is dynamic and may change with human behaviour, life styles and the sophisticated technology.

2.1. Declarations and codes of conduct

Around the 4th century B.C., Hippocratic ethics laid stress on beneficience, non- maleficience and confidentiality among others. The experiments on human prisoners conducted during the Second World War were revealed at the Nuremberg trial. The Nuremberg Code around 1948 states that no human may participate in an experiment unless freely consenting. The subject must be free from duress or undue influence and be capable of making a decision.

The Helsinki declaration was adopted at the 18th World Health Assembly, Finland in 1964 and amended by the 29th Assembly in Tokyo, Japan in 1975. It states "concern for the interests of the subject must always prevail over the interests of science and society, every patient including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method". The declaration of Lisbon in 1981 dealt with the rights of the patient.

The World Medical Association in the Geneva Declaration binds the doctor with the words "The health of my patient will be my first consideration" and the international code of ethics at the 35th World Health Assembly in Venice 1983, declared that "any act or advice which could weaken physical or mental resistance of a human being may be used only in his interests". This includes patients, controls, volunteers and the community as individuals and in groups.

2.2. The dilemma of the researcher

In recent times ethical considerations for research has become complex, complicated and controversial to the extent that some types of research on humans to elucidate certain problems has not been approved by ethical committees: hence the dilemma. It has been stated in recent times, "the ethical behaviour of doctors has come under close scrutiny with unhappy consequences. During the millennia in which medicine has been practised much has been written about ethics. There is no shortage of codes and declarations and of ethics committees to tell us what to do. These events raise questions about the status of the general principles of ethics and of the

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significance of particular assertions in that field. There is also the important question of whether or not there has been, or is any connection at all between utterances about medical ethics and behaviour of the members of our profession"(2).
An unusual definition states "ethics implied a state of goodness verging on saintliness to which we might aspire but are unable to achieve"(3).
To the aforementioned requirements, have been added, benevolence, which includes confidentiality, patient or subject autonomy, informed consent, distributive justice and integrity.
It has been stated that "medical ethics, like medicine itself, is a fusion of theory and practice, the theory may seem remote and abstract at times, nevertheless, it guides our reasoning. Even the most practical among us must resort ultimately to some philosophical construct, unless he or she is content to leave moral decisions entirely to intuition or visceral preferences"(4). It has also been stated that "perhaps the fundamental defect of applied ethics is its failure to recognize the pervasive need for judgment, sometimes these judgments are essentially pragmatic and strategic. Medical ethics, in this respect must be an amalgam of substance and procedure of morality and politics. The challenge is to weld substance and procedure in a manner that is sensitive and responsive to the issue that needs to be resolved, a challenge that is political and practical as well as theoretical"(5).
In view of the difficulties faced by researchers in conforming to the many requirements of medical ethics, medical deontology has come to the fore. This is defined as the "discipline in the study of norms of conduct for the health care professions including moral and legal norms as well as those pertaining more strictly to professional performance. The aim of deontology is therefore, the in-depth investigation and revision of the code of medical ethics"(6).

3. Community Surveys (Observational)

Surveys of population health is said to be "both the alpha and omega of health care by being a vehicle for both the discovery of need and the evaluation of the outcome of care and treatment"(7).
A survey is an investigation or inquiry to obtain information systematically and scientifically from groups or target populations on the status of the community and or on specific problems existing in such a community.
Community surveys are descriptive rather than analytic however they may be of the mixed type. The approaches used are qualitative, quantitative or both. They may be cross-sectional, longitudinal, cohort or field trials. Surveys in a community require consent not only of the study units but also of the community. The researcher should visit the area and make a "quick and dirty" situational analysis. He should identify the leaders and administrators in the area, inform them of the general purposes of the study, and obtain their approval and an assurance of community participation. Focus group discussions and Delphi techniques may be useful. If this step is not taken, it may lead to the premature abandonment of the study due to resistance by leaders and the community, and may therefore be unethical to publish only the available results.
In selecting the topic for research the Principal Investigator (PI) should consider its usefulness, practicability and feasibility. The study area, population and study units should be carefully selected and be relevant to the objective of the study. If there are study units that cannot be reached these are non respondents; ignoring this fact and generalization from limited data may be unethical.
It is stated, "scientifically unsound studies are unethical. It may be accepted as a maxim that a poorly or improperly designed study involving human subjects- one that could not yield scientific facts (that is reproducible observations) relevant to the question under study is by definition unethical. Moreover, when a study is in itself scientifically invalid, all other ethical considerations become irrelevant. There is no point in obtaining 'informed consent' to perform a useless study"(8).
The sample should neither be too large nor too small. A study with an overlarge sample may be deemed unethical through the unnecessary involvement of extra subjects and the corresponding increased costs. Such studies are rare; on the other hand a study with a sample too small will be unable to detect clinically important effects. Such a study may thus be scientifically useless and hence unethical in its use of subjects and other resources. Studies that are too small are extremely common, judging by survey of published research. The ethical implications however have only rarely been recognized (9).

4. Informed Consent

It is a universal medical ethic that informed voluntary consent be obtained in any type of study of humans, from participants, respondents, or guardians (if children are used), be it experimental or survey research. It may be verbal, especially for survey research, but often it has to be a written consent for most experimental studies.

In my experience of conducting field surveys, where the study population has to respond to questions directed at them, the introduction usually given to obtain informed consent is too brief and inadequate. The interviewer states that a study is being conducted and would the respondent answer a few questions. This may be considered to be unethical.

The requirements to obtain informed consent whether self or interviewer administered are as follows:

(1) Inform the respondent of the institution or organization conducting the research and the name of the team or principal investigator with his/her designation, either verbally or in writing.

(2) Indicate how and why the respondent was selected.

(3) The general purposes of the study (some ethicists call for more details).

(4) State clearly that all information given by the respondent will be treated as confidential.

(5) Inform the respondent of the right to refuse to participate or to answer certain questions without giving any reason (autonomy).

(6) State whether it will be one interview or more (give number) and the approximate time it will take.

(7) If the study involves the collection of samples such as urine, faeces or blood for examination this should be mentioned. If blood samples are to be taken, indicate the volume required, that standard and accepted safe methods will be used and that it will in no way cause harm (non-maleficence).

4.1 Related requirements

Ethical clearance should be obtained from an ethics and research committee when necessary. There is no place for coercion to obtain voluntary consent, some coaxing may be permitted. The respondent should not be under duress or obliged to respond because of the position held by the principal investigator, interviewer or other important persons in the community. Incentives, especially financial, should not be offered to obtain consent. However, out of pocket expenses may be reimbursed, if necessary.

In addition, at any stage of the study or after completion, it is improper, bordering on unethicality, for the PI or interviewer to inform any respondent that action will be taken to improve their conditions or their health; if prior decisions have not been taken and arrangements made for this purpose. The interviewers should be warned not to make any such promises in order to have a good response rate. It is unethical to raise false expectations in the participants which are unfulfilled.

5. Study Design

5.1. Cross sectional

A cross sectional study is usually a one time single group; it is an analysis of the situation at a point in time (point prevalence). It may also collect some information retrospectively for a short recall period (period prevalence). If two or more groups are used they should be comparable. It may be unethical to use selected populations or to apply different methods of investigation between them leading to differences that may not reflect the true position. Ethical considerations are few in this type of study. However, if the study is repeated informed consent should be obtained on each repeat occasion.

In the analytic cross sectional study, information is obtained in retrospect on the relevant independent variables from those exposed and non-exposed. The groups are compared for probable associations so as to formulate hypotheses for further study (here the independent variable is not manipulated). If the recall period is long, then some of the information may not be accurate and of doubtful reliability. It may be unethical to use such data. If confounders are not controlled or accounted for in the planning stages or by statistical procedures during the data analysis, inferences may be faulty and be unethical.

5.2. Longitudinal (prospective)

In a longitudinal study one or more groups of study units are followed or observed for a specified period of time. The term cohort is generally used restrictively to refer to an analytic longitudinal study. These may be either concurrent or historical. In the latter, information is obtained from secondary data available prior

to the start of the study. If such data are unreliable or incomplete, it is unethical to use them.

The cohort may be a closed fixed type where replacement of losses is not permitted or the dynamic type where this is possible. In the former if the losses are higher than scientifically permitted then it is an unsound study and is unethical. In the latter if permitted replacements are not made from an oversample drawn in the same manner as the study sample, but taken at will by the PI or interviewer it is unsound and unethical.

Mixed analytic studies may be individual or group based. "Most individual based analytic studies may be categorised as cross sectional, cohort or case control studies or as combinations of these types. A group based analytic survey is a comparison of groups of populations. It is a survey of a group or groups, not a group of individuals" (10).

During the period of follow-up of two groups, if conditions have changed in one and not in the other or different changes have occured in either group, it will be unethical to make inferences, ignoring these changes.

5.3. Intervention Studies

Cross sectional, longitudinal or cohort studies of single or more groups, conducted in the community may evolve into being intervention studies. The intervention may take many forms such as educational, food supplementation, fluoridation of water supplies,or changes made in the environment. The purpose is to test the effect on the outcome of that particular intervention. If a single group is used the procedure is either an intervention followed by a post test, or a pre test, intervention and post test; the latter being better. If two or more groups are used, the same procedure as for a single group is adopted, but with the control group not having the intervention.

In intervention studies it may be unethical to assume that the intervention has been effective without a follow up which indicates that the intended change or outcomes have been realized and whether it is due *per se* to the intervention without other factors coming into play.

If in a single group a post test is being done immediately or shortly after the pretest and if the score is higher than at the pretest, is it ethical to infer that the intervention was effective? If two post tests are taken within a suitable interval between these and the score at the second was considerably less than at the first it is unethical to use the first only and state that the intervention was effective. If two post tests are done, but the same conditions and methods were not used it may be a faulty study and findings are erroneous and may be considered unethical.

If two groups are used, one of these will be the control, without the intervention. It may be considered unethical to deprive the controls of the benefits, however small, especially when it is a food intervention. This may be overcome by giving food supplements also to the controls, but such that this will not affect the objectives of the study.

An educational intervention package should be relevant and the expected outcome or effect should be defined. If it is poorly constructed, the inferences on its effect may be faulty and therefore considered unethical. In addition if an over enthusiastic researcher includes in the package, certain aspects of knowledge, practices and behaviour, which may lead some study units (e.g. children on sexual matters) to unacceptable experimentation by them, it may be considered unethical.

5.4 Preventive field trials

Preventive trials involve ethical considerations. Exposure of the study group to the possible hazards of a trial is only justifiable by the benefits which a successful outcome to the trial may confer on the reference population. Use of a control group may also raise ethical issues, such as in a trial of a vaccine. "The investigator may have good evidence at the onset of the trial that the vaccine confers some degree of protection. In order to quantify the degree of protection by means of a trial, it is necessary to deny the vaccine to the control group"(11).

In all such field studies informed consent of the communities concerned is necessary. They should be made aware of the study, benefits, possible hazards similar to those described in the section on informed consent.

Studies to provide normal values and to detect abnormal values may be considered unethical and hence full and complete voluntary informed consent should be obtained, especially if it involves invasive procedures.

In a preventive therapeutic trial, one group is given the therapy while the control group is given a placebo, this may be unethical unless the participants have been informed of this procedure before the study, and consent obtained.

6. METHODOLOGY

6.1. Data collection

Information collected in survey research may be primary or secondary data. Primary data are obtained by face to face interviews with respondents or by remote control methods such as by telephone and other electronic devices. They may also be obtained through a self-administered questionnaire or check-list where the interviewer is not present, or if present, such as at a group self-administration, only for supervision.

The instrument for primary data collection which is usually a questionnaire should be well constructed, especially so if it is a self-administered one, and should be relevant to the objectives of the study and the respondents. A poorly constructed questionnaire will lead to erroneous answers being given by the respondents and thus inferences drawn may be faulty and, therefore, publishing such findings may be unethical.

The research design usually designates the respondent. If the required respondent is not available at the time of the visit, the interviewer may use a substitute not permitted as a proxy in the protocol. The respondent may be helped by others (family members present) with the answers during the interview, the respondent nodding assent. In these situations the answers obtained may not be those of the designated respondent. The problem is greater when self-administered. The questionnaire if completed may not have been by the designated respondent. It may be by another or the answers may be by consensus of family members. In both situations, the findings are flawed and the inferences drawn, erroneous. If the non-response rate is high (usually higher when self administered) then the study becomes useless. Consideration should be given by the researcher as to the ethicality of publishing such studies.

Secondary data refers to information maintained prior to the study. The sources may be medical records such as case notes maintained in Bed Head Tickets (BHT), records maintained in preventive clinics, doctors' surgeries, data stored in tapes, computers and other electronic devices. They could also be records or part of a record kept by users of health care for their edification and or to facilitate follow up by the health care providers. Secondary data obtained from the routinely kept records are not in a format pre-designed for the purposes of the study. There may be missing data and inaccuracies; resulting in incomplete data. If these are considerable it becomes unrepresentative. Sometimes the researcher may correct the recorded information using her judgement thus introducing a bias. These deficiencies lead to a poor study and is unethical.

The persons extracting data from the documents may differ in what they perceive, interpret and record. It may then not be a true reproduction of what is in the original. In addition, if a reliability test is not done on a random sample, rechecking the original and that transcribed, the findings may be flawed and hence may be considered unethical.

There are special methods of data collection used by ethnographers and social scientists which may be related to health, or even used by health professionals for an indepth observational study. The two methods are either non-participant or participant observation. In non-participant observations the observer is on site, observes the activities performed by an individual or a group, for a period of time on one or more days without communication with those observed who may be aware or not aware of the presence of the observer. In participant observation, the researcher lives with and forms part of those observed, participates in their activities and communicates with them. Therefore, those observed are aware of his presence but will not know the purpose of his participation. The initial observations made by them are usually short notes, which they later expand on. They may also use more structured formats for this purpose.

In obtaining data using these approaches, the ethical considerations are whether in the non-participant approach, it is "spying " on the privacy of the observed especially if the observed is unaware of the presence of the observer; and in the participant approach, whether the observer is "putting on an act" giving a false impression of the observer's genuineness in participation. These may be considered unethical; however, this is a controversial subject.

6.2. Interviewers and interviewing

When an interviewer administered questionnaire is to be used, it is important that the PI selects suitable interviewers considering the objectives

and the study units. They should be adequately trained in the content of the questionnaire and in the technique of interviewing. The PI or a field supervisor should monitor the work of the interviewers, especially to check whether interviews have taken place. A dishonest interviewer may complete some of the questionnaires in her own home, resulting in false data which makes the study unethical.

If an interviewer is unable to extract reliable information from respondents, due to various reasons, then the inferences drawn may be faulty. It is unethical to present such data.

The question arises, whether during training, the interviewer should be told the details of the specific objectives. Some ethicists say that it should be given. However, it may bias the interviewer to record answers in favour of such specific objectives that may have been stressed by the researcher. The ethicality of non-disclosure may be considered.

6.3. Reliability

In community studies, where an interviewer administered questionnaire is used, it is usual to conduct a reliability or repeatability (test-retest) test on a random sub-sample of study units. The same questionnaire or certain questions therein are repeated. The respondent should be the same as before especially if certain questions refer to that respondent. Informed consent should be obtained giving a suitable explanation for the repeat. The repeatability could be done while the study is in progress or after. The time interval between the first and the repeat interview should be considered. An index of agreement is calculated.

The ethical considerations revolve around answers to the following questions:

1. Will repeating the questionnaire to a reluctant respondent, who is unable to understand the reason for it, especially if inadequately explained, cause psychological trauma?
2. If the respondent is not available could a substitute be used, or should it be considered as a non-response?
3. Will the interviewer having for perusal the previously completed questionnaire, (an incorrect procedure) merely duplicate the findings?
4. If the interval between the first and the repeat is either short or long and varying between groups, will the information be reliable?
5. If the agreement index is low for some questions, should they still be used in the analysis?
6. If the non-response rate is high in the randomly selected sub-sample, could this be ignored?

7. Results

If there is a large amount of missing data especially to questions that are important to draw inferences based on the objectives and hypotheses, the study has to be considered as an incomplete one. It is unethical to present only that part of the data which lead to the rejection of the null hypothesis.

If the analytic methods are incorrect then the findings are faulty. It is stated "The mishandling of statistical analysis is as bad as the misuse of any laboratory techniques. Both can lead to incorrect answers and conclusions and are thus unethical because they render them valueless"(12).

If the study involves a score system and amalgamation of rows is required, the cut off point may be selected in a way that would be advantageous for a desired interpretation. To adjust the results to suit the purposes of the study may be unethical.

To generalize from unrepresentative samples or faulty techniques of sampling is unjustifiable and unethical.

In presenting a graph it is not justifiable to manipulate the axes (x,y) to serve the purposes of the researcher. This will mislead the reader and hence is unethical.

Information that may identify a study subject such as name, initials, medical record number should not be given, unless written permission of that person is obtained. Reproduction of tables, graphs, diagrams, photographs, copied from other sources should be acknowledged in the proper manner. If photographs of study subjects are presented, information that may identify such persons should be withheld and in addition the customary "blotting out at eye level" should be done.

If accepted standard formats, questionnaires, check lists, tests and procedures are used, they should be acknowledged and the references given. If apparatus and instruments that are patented or carrying expressed considerations are used, this should be acknowledged and their names and addresses should be given. If a laboratory has performed tests at your request, this should also be acknowledged.

8. Limitations and Conclusions

The limitations of the study, if any should be mentioned giving reasons. If there are many, especially related to important data, then the study is useless.

It is dishonest and unethical to draw conclusions from non-existing or manipulated data. It is unethical to make conclusions based on a flawed methodology, inadequate data and findings that are scientifically unacceptable.

If respondents or participants wish to know the findings of the completed study, it may be considered unethical not to provide them with the information.

9. Writing and Publishing

It may be unethical if an attempt is not made by the PI to publish a scientifically completed survey research study where many respondents participated. Plagiarism, which may be defined as writing and publishing borrowed thoughts or work done by others, as your own, is unethical.

Writing and publishing more than one article on the one study, using different titles, changing words, sentences and paragraphs is unethical. However, if there are clearly defined sub-studies within the one study, writing more than one article may be justifiable if reference is made to the initial article and also a statement made that the study units are the same.

It is unethical to publish the same article in different journals without informing the editors that this article has been published or has been accepted for publication by another journal. However, if one editorial board has rejected the article in its present state, giving reasons, corrections could be made and the article submitted to another journal for publication.

The International Conunittee of Medical Journal Editors states "when submitting a paper an author should always make a full statement to the editors about all submissions and previous reports that might be regarded as prior or duplicate publications of the same or very similar work. Copies of each material should be included with the submitted paper to help the editors decide how to deal with the matter. Multiple publications, that is the publication on the same study more than once, irrespective of whether the wording is the same, are rarely justified"(13).

It is unethical and illegal to contravene the rules on the Protection of Intellectual Property Rights".

10. Conclusion

The ethical considerations mentioned in this article are not meant to be a code or rules and regulations in the conduct of survey research. These may be used as guidelines - hence the inclusion of some open questions.

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