

7. EPIDEMIOLOGICAL RESEARCH

Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of the study to control health problems. “Study” includes surveillance, observation, hypothesis testing, analytic research and experiments. “Distribution” refers to analysis by time, place and class of persons affected. “Determinants” are all the physical, biological, social, cross-cultural and behavioural factors that influence health. “Health related states and events” include diseases, causes of death, behaviours such as use of tobacco, reactions to preventative regimens and provision and use of health services. “Specified populations” are those with identifiable characteristics such as precisely defined numbers. “Application of study to control health problems” makes explicit the aim of epidemiology - to promote, protect and restore health.” The Dictionary of Epidemiology (2001).

Epidemiological research is thus concerned, through the collection of data related to health, with the description of health and welfare in populations, and with the goal of improving health. Some epidemiological research may require a study of entire populations and go beyond an individual institution or organisation.

Epidemiological research is part of wider public health and health services’ research. It is concerned with improvements of health and welfare in human populations and with improving the efficiency and performance of human health services. Public health and health services’ research are often carried out with human participants, or data or biological samples from them, and such research provides important new knowledge that is not readily obtainable in other ways.

Public health surveillance should be distinguished from public health and epidemiological research. Its role is to monitor the health status of the community, known risk factors and emerging threats to community health. Its purpose is to facilitate a prompt, effective and corrective response. It may be carried out for reasons of disease surveillance, provision of information to government health services or to guide the development of health policy. Public health agencies generally are required or authorised by law to conduct health surveillance. However, under certain circumstances, public health surveillance data may be used for research purposes. Under such circumstances, considerations pertaining to data privacy and record review (Sections 7.3 -7.5 below) should be seen to apply.

In epidemiological research, medically relevant information about individuals and groups is accumulated. Features of groups of persons may be investigated whether or not the information was originally obtained for research purposes.

7.1 Categories of personal information

Epidemiological research includes the use of the following types of data:

- **Identified**

Data that allows the identification of a specific individual is referred to as ‘identified data’. Examples of identifiers may include the individual’s name, date of birth and address. In particularly small sets of data even information such as a postal code may be an identifier.

- **Potentially identifiable (coded, re-identifiable)**

Data may have identifiers removed and replaced by a code. In such cases it is possible to use the code to re-identify the person to whom the data relates so that the process of de-identification is reversible. In these cases the data is referred to as ‘potentially identifiable’.

- **De-identified (not re-identifiable, anonymous)**

The process of de-identification can be irreversible if the identifiers have been removed permanently or if the data has been de-identified. It should be recognised that the term ‘de-identified’ is used frequently in documents other than this statement, to refer to sets of data from which only names have been removed. Such data may remain ‘potentially identifiable’.

7.2 Approval by research ethics committee

All epidemiological research must be approved by a research ethics committee and should be conducted according to written protocols that state the aims of the study, the data that is required and how the data will be collected, used and protected.

When a research ethics committee considers a protocol for epidemiological research it must be satisfied that:

- The research complies with relevant South African legislation or approved policies dealing with the privacy and confidentiality of data;
- Researchers have the necessary facilities and skills in epidemiology to conduct the research;
- access to medical or other records for research should be restricted to properly qualified researchers;
- There is a scientifically acceptable process for the disclosure of information and dissemination of research results and, where there is to be selective disclosure of information, that there are scientifically justifiable reasons for so doing.

7.3 Consent

Informed consent of participants should generally be obtained for the use of identified or potentially identifiable data for all epidemiological research.

Special precautions should be taken to ensure that participants understand the information provided as part of informed consent, especially when research is conducted in cross-cultural settings, or in vulnerable communities.

Exceptions to this rule may be considered as indicated in Sections 7.5 and 7.6 below. Research participants have the right to refuse to take part in a study but they also have the right to accede. As a general rule only research ethics committees may deny participants the right to choose for themselves.

7.4 Data privacy

Privacy is concerned with protecting or limiting access to personal records containing confidential information. (See also Sections 2.7 and 9.2).

Data collected in epidemiological studies should preferably be in de-identified form. Data should be stored with personal identifiers (identified or potentially identified data) only if absolutely necessary and where approved by a research ethics committee in terms of sound justification. (See Section 7.5 below)

Identifiable personal data should never be stored in computers outside research establishments and the files containing personal identifiers should be stored in locked cabinets or rooms separately from the data used for analysis. Back-up copies must be subject to the same degree of data security and personal data should be sent only by secure methods.

Anyone who has a legitimate right to view the data must sign a promise of secrecy and may seek individual data only for legitimate research purposes.

7.5 Record review

Consent is not required for use of information in the public domain, although guidance may be needed concerning definition of what type of information about citizens is regarded as public.

Data gathered for administrative purposes or audit does not require the participants' consent if obtaining the consent could cause undue concerns, be impractical or too expensive. However, where publication of audited results may have potentially adverse consequences for study participants or for particular social groups, consent to use such data must be sought. Researchers should always seek the advice of a research ethics committee to decide whether record review requires individual consent.

A research ethics committee may approve the collection of data from records, either retrospectively or prospectively, that is identified or potentially identifiable if:

- It is satisfied that the scientific validity of the study would be compromised by de-identifying the data (i.e. that the objectives of the study could not be attained by de-identifying the data), or that
- An alternative study design which allowed for the use of de-identified data to meet the same objective was not possible, and that confidentiality of data collected could be assured.

Where data is collected from records, either retrospectively or prospectively, a research ethics committee may approve access to identified or potentially identifiable data without seeking the consent of those whom the data identifies, where the ethics committee is satisfied that:

- The procedures required to obtain consent are likely either:
 - to cause unnecessary anxiety for those whose consent would be sought; or
 - to prejudice the scientific value of the research;
- There will be no disadvantage to the participants, their relatives or any collectivity involved that will compromise their rights and dignity to an extent unreasonable and unjustified in terms of the benefits of the research;
- It is impossible in practice, due to the quantity, age or accessibility of the records to be studied, to obtain consent; and public interest in the research outweighs to a substantial degree the public interest in privacy.

7.6 Limited disclosure

For some epidemiological studies, non-disclosure of all the aims of the study may be permissible where full disclosure might bias the investigation or invalidate the hypothesis under investigation. In these circumstances, an independent research ethics committee may grant permission for such limitations, but only where based on careful considerations of the evidence that:

- Limited disclosure is justified in terms of the relative balance of benefits and harms;
 - the validity of the study clearly depends on non-disclosure;
 - the research is likely to yield considerable benefits to participants or other parties;
 - harm or potential for harm to participants are non-existent or minimal, and are outweighed by benefits;
- Respect for the autonomy of the participants is not unduly compromised;
 - there are no reasonable alternatives to meeting the study objectives that might better maintain participant autonomy;
 - that the extent to which participants' autonomy would be undermined by partial disclosure is not unreasonable.

7.7 Incentives

Research ethics committees should be satisfied that the conditions under which participants agree to participate in proposed epidemiological studies do not constitute undue influence that could

compromise the potential participant's ability to make independent informed decisions. While the nature of incentives in epidemiological research is very different to those existing in clinical studies, the principle applies equally that incentives should not result in undue influence on the participation of individuals, particularly those from vulnerable groups. In most public health studies participants have many opportunities to refuse participation and this should be clear in all aspects of research.

7.8 Obligations on epidemiologists

Where epidemiological research identifies the presence of a risk to the health and safety of particular participants or populations, the researchers should ensure that this information is not withheld from the populations or participants affected. Feedback to individual participants and, if necessary, family members and the community, of information relating to health risks should be included as part of the protocol and be required for a protocol to gain ethical approval.

Epidemiologists should also take into account the risk of publishing analyses that may stigmatize the group or groups in question.

Because epidemiologists are frequently occupied in research involving communities and groups with high disease burdens or risks, particular attention should be paid to ensuring that epidemiological research does not exploit the vulnerability of such groups (see Section 5). Rather, epidemiological research should seek to strengthen the capacity of vulnerable groups to reduce their vulnerability. Approval by a research ethics committee should be contingent on a consideration of the extent to which such responsibilities have been considered by the researcher, and where reasonably feasible, suitable actions incorporated into the research protocol.

7.9 Validity and ethical standards

Sound ethical practice demands that epidemiological research be conducted according to a rigorous scientific protocol to ensure that respondents are not asked to take part in a study that is fatally flawed in its design.

7.10 Conflict of interest

Researchers should have no undisclosed conflict of interest with their collaborators, sponsors or participants. Researchers must disclose actual, apparent or potential conflicts of interest to the research ethics committee and must publicly acknowledge all sponsorship of research. The research ethics committee is obliged to consider whether the apparent conflict of interest might compromise the scientific integrity of the study, and it must recommend appropriate remedial action and standards to be met in order for the study to be approved.

Results of a study, whether government- or industry-sponsored, should be the intellectual property of the investigators, not the sponsor, and all results should be published if they have scientific merit. Requests to withhold findings, to change or tone down the content of a report are not acceptable to good ethical epidemiological practice. However, sponsors or stakeholders should be afforded the opportunity to provide comment on research findings prior to publication, without any entitlement to veto, change the conclusions, or delay publication of results unreasonably.

Preferably, such considerations should be formalised by contract at the start of negotiations with the sponsor, whether private or governmental. There should be a written document stating that the results will be published regardless of outcome and that the independence of the investigator is acknowledged and will be maintained throughout the study.

7.11 Disclosure of research results

Researchers should not inform the Press about the findings of research unless the findings have been subjected to some form of peer review – that is, presented and discussed at a conference or have been published. Only for good reasons, such as emergency or epidemic, may this be waived. For example, investigators may discover health hazards that demand correction, and become advocates of means to protect and restore health. In this event, their advocacy must be based on objective scientific data only

Researchers should not exaggerate their results with the aim of increasing the likelihood of obtaining future research funding or making their paper more attractive to editors.