Good Epidemiological Practice

KIT Royal Tropical Institute

Contents

These are preliminary guidelines. They were first developed internally by KIT epidemiologists and were then presented to global health experts from all over the world for validation through a Delphi consultation process.

We are currently preparing a manuscript summarising the methodology followed and the resulting guidelines.

You are free to use these guidelines and we welcome feedback from all interested epidemiologists and researchers.

For any queries or comments contact Daniel Jeannetot (d.jeannetot@kit.nl), Masja Straetemans (m.straetemans@kit.nl) or Sandra Alba (s.alba@kit.nl).

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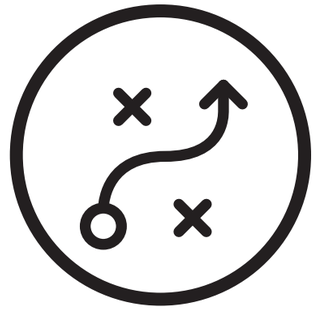
Standard 1: Study Preparation



Carefully prepare the study, in partnership with local researchers, by taking into account existing knowledge and resources and engaging with key stakeholders.

1.1 Plan and execute research in partnership with local researchers. When working in a setting where relevant epidemiological competences are limited or not available, consider what is in the study team's remit to strengthen local capacity
1.2 Identify and engage key stakeholders throughout the study with approaches based on their needs, competences and expectations. Key stakeholders include representatives of affected populations and end-users of research
1.3 Establish the knowledge gap by searching the literature (peer-reviewed publications and grey literature) as well as by consulting (local) experts, representatives of affected populations, and end-users.
1.4 Develop research questions and objectives in consultation with research partners and expected end-users
1.5 Select study design and research methods to best fulfil the study objectives and give due consideration to multi-disciplinary approaches
1.6 Before embarking on primary data collection, assess whether existing data could be used, fully or partly, to fulfil the research objectives
1.7 Assemble a study team with the right training, skills, experience and expertise mix to ensure a high-quality study conduct
1.8 Ensure data sharing and data ownership agreements have been agreed by all research partners, in line with national and international frameworks.
1.9 Develop fair publication plans and giving all partners the opportunity to contribute
1.10 Agree on work plans and governance structures with all study partners. Allocate adequate time, financial and human resources to all phases of the study.

Standard 2:
Protocol Development

Prepare a detailed research protocol and ensure it has been approved by relevant ethical review boards if it includes research concerning human subjects.

2.1 Prepare a detailed research protocol in consultation with all research partners
2.2 Write a clear and comprehensive analysis section which includes a description of how false-positive findings will be minimised
2.3 Consider disaggregating analyses by locally relevant equity dimensions
2.4 Strive for multi-disciplinary research and make sure that the protocol describes the purpose of combining different disciplines as well as strategies to integrate the different analytical methods
2.5 Strive to make study protocols publicly available, either on a publicly accessible website or in appropriate study registers
2.6 For all data collection and data use concerning human subjects, obtain ethical approval (or a waiver) ideally from all institutions and countries involved in the protocol. In case of multiple review and disagreement, the review of the country where the research is conducted should take precedence.
2.7 When working in a setting without ethical review boards or review boards with limited epidemiological capacity, consider what is in the study team's remit to strengthen local epidemiological capacity
2.8 If publication of data in online open access repositories is being considered, state it explicitly in the protocol submitted for ethical review and in the informed consent documents.

Standard 3:
Data Collection

Collect data using valid, user-friendly, culturally appropriate and technically sound procedures and instruments.

3.1 Use research instruments that are as valid and user-friendly as possible.
3.2 Ensure that research instruments are locally adapted and culturally appropriate
3.3 Provide concrete guidance for data collection in a document that is available to all data collection staff
3.4 Select data collection staff according to technical as well as cultural criteria. Clarify the roles and responsibilities for each person involved and provide adequate training and support
3.5 Pilot-test and, if possible, field-test all research instruments prior to the start of effective data collection
3.6 Ensure that data collection is conducted in a respectful and safe manner, in an environment which guarantees the confidentiality of respondents' responses
3.7 Put in place quality control mechanisms to ensure data accuracy, completeness and coherence.

Standard 4:
Data Management

Data management procedures should be put in place to ensure the quality and validity of the final statistical data files and to ensure that all data files are fully traceable and reproducible.

4.1 Put in place data management procedures before effective start of data collection and provide concrete guidance in a document available to all data management staff.
4.2 Create and pre-test a data entry application and a database prior to effect start of data collection.
4.3 Describe all variables in a codebook and consider preparing additional metadata documentation
4.4 Put in place quality control mechanisms s to ensure data validity, credibility, accuracy, completeness and coherence
4.5 Annotate all data cleaning and processing steps and strive for repeatability by means of stored programming code
4.6 For each data file define levels of anonymization and privacy protection as well as corresponding access rights in line with national and international frameworks.
4.7 At the beginning of the study, prepare an electronic secured study file including all study documentation and outputs at the beginning of the study. Regularly update this file and archive it the end of the study.
4.8 Retain source data safely, in their original form, preserving data confidentiality for as long as has been described in the protocol
4.9 Back-up data frequently (raw, final, and data cleaning/processing files) and consider submission to a trusted repository which stores datasets sustainably and with ease of reference.

Standard 5:
Data Analyses

Analyse data according to the pre-specified plan and integrate statistical analyses with approaches from other disciplines in the study.

5.1 Only work with personal identifiers that are necessary to answer the research questions
5.2 Conduct statistical analyses in accordance to the protocols pre-specified data analysis section (or data analysis plan). Justify and document major deviations.
5.3 Fully annotate all analysis steps and strive for repeatability by means of programming code
5.4 In multi-disciplinary studies, integrate statistical analyses with analyses from other study disciplines in an iterative process to coherently address the research objectives
5.5 Put in place quality control mechanisms to ensure that data has been correctly analysed

Standard 6: Dissemination

Report and disseminate results, preferably in the public domain, with means of communication which appropriately target key stakeholders.

6.1 Develop user-specific communication and dissemination plans in consultation with key stakeholders (representatives of the affected populations and end-users)
6.2 Report data reporting in a non-stigmatizing, non-discriminatory and non-identifying manner. Study participants may be identified (e.g. in quotes or pictures) if they have provided informed consent for identification
6.3 Conform to reporting guidelines for the given study design and methodology in academic publications
6.4 Put in place quality control mechanisms to ensure complete, accurate and understandable data reporting
6.5 Consider publication in indexed open access journals, and strive to also make corresponding datasets and programming code openly available
6.6 Upon study completion, consider publication of the archive in an openly accessible online repository. Consult key stakeholders and research partners to identify strategies within the study team's remit to encourage as much as possible re-analyses by local researchers.

KIT Royal Tropical Institute

P.O. Box 95001
1090 HA Amsterdam
The Netherlands

VISITING ADDRESS
Mauritskade 64
1092 AD Amsterdam
The Netherlands

TELEPHONE
+31 (0)20 56 88 711

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