

Guide of good practices in epidemiology

2025 Revision

ETHICS
SCIENCE
POPULATION
RECOMMENDATIONS
INTEGRITY
ONE HEALTH



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All the terms listed are defined in the context of epidemiological practice.

Acceptability: the way that a study and its implications will be received, tolerated or accepted by participants, the study population, health decision-makers, relevant professionals and any other person or organisation involved or affected by the study or its results.

Anonymisation: process by which the identifying characteristics of data are removed, so as to irreversibly prevent the direct or indirect identification of the individuals to whom they relate¹.

Archiving: the process of moving health data that is no longer used (study completed) to a secure long-term storage system that guarantees the integrity and traceability of the data so that it can be reused if necessary.

Artificial intelligence (AI): an automated system designed to operate at different levels of autonomy and capable of continuous learning after deployment. For explicit or implicit purposes, it deduces, from the inputs it receives, how to generate outputs such as predictions, content, recommendations or decisions that may influence physical or virtual environments⁶.

Bias: a systematic error in a study that distorts the results in a given direction and therefore undermines their validity. There are different types of bias, and these can exist at every stage of the study.

Big data: all available data, directly or indirectly related to health in the broadest sense of the term, collected from heterogeneous sources and in large volumes. This may be data on a very large number of participants or a large amount of data on a limited number of participants.

Biostatistics: scientific discipline consisting of analysing medical data using statistical tools.

Clinical research associate (CRA): a person who ensures the implementation and smooth running of clinical studies, guaranteeing compliance with regulations and quality criteria for the data collected. The CRA may also perform monitoring functions². The term epidemiological research associate (ERA) is also used for population studies outside a clinical context.

Cohort: study design in which participants are selected based on their exposure or non-exposure to one or more risk factors and are followed (prospectively or retrospectively) to identify events of interest that occur during the follow-up period. A generalist cohort is a study, often conducted on a large sample of the general population, covering a wide range of health issues.

Communication: any presentation, in any form, of the method, results of an epidemiological study and their interpretation to an individual or organisation not part of the study team and, more broadly, to the professionals concerned and the public.

Confidentiality: ensuring that all non-anonymised personal data is inaccessible through procedures designed to protect it.

Data collection: phase of an epidemiological study during which data relating to individuals or groups of individuals are collected.

Data manager: a person responsible for designing, structuring, managing and maintaining databases, ensuring their quality, consistency and harmonisation, in order to prepare them for future analysis. The term Data Steward is also used (their role is to guarantee the quality, consistency and compliance of data by organising, controlling and securing its lifecycle in order to reduce risks and optimise its use).

Data processing: all operations relating to the collection, recording, development, modification, storage, retention, archiving and destruction of data, as well as operations relating to the use of files, interconnections, comparisons, consultations or communications of data.

Data Protection Officer (DPO): a person responsible for the protection of personal data in accordance with the regulations in force (for example, in Europe, they verify compliance with the General Data Protection Regulation³ within the organisation that appointed them).

Deontology: all the duties and rules governing a profession or practice, in this case epidemiology as a discipline of research and application to population health.

Endpoint: a measured parameter used to evaluate the effectiveness of a clinical or public health intervention.

Epidemic: an excessive occurrence of cases of a disease affecting humans, animals or plants in a given place and period of time compared to the usual situation. Although the vast majority of epidemics are infectious in origin, they can result from other causes⁴.

Epidemiological or public health surveillance: the systematic process of continuously collecting, analysing and interpreting health data to produce results (information) necessary for the planning, implementation and evaluation of public health practices. Health monitoring (vigilance in some countries) is similar to surveillance but focuses on the evaluation of health signals or events, enabling early detection and thus allowing for a rapid response to protect the population from health threats.

Ethics: set of values, moral principles and reflections relating to human conduct/behaviour. In epidemiology, ethics can be individual or collective (at the population level), whether in a clinical, research or public health setting.

Expertise: a set of activities aimed at providing to a sponsor, in response to a question asked, with an interpretation, opinion or recommendation that is as objectively based as possible, developed from the best available knowledge and evidence, accompanied by professional judgement⁵.

Feasibility: analysis of the possibility of successfully conducting an epidemiological study, taking into account the scientific, technical, legal, organisational, ethical, financial and environmental aspects involved.

Funding body: any individual or organisation, regardless of status, that funds all or part of an epidemiological study.

General Data Protection Regulation (GDPR): European Union regulatory text that governs the processing of personal data and protects the fundamental rights and freedoms of individuals throughout the European Union⁶.

3. General Data Protection Regulation (GDPR) is defined in this glossary.

4. The term "epizootic" is used for animal diseases and "epiphytotic" for plant diseases, but in this document we will systematically use the term "epidemic" for simplicity.

Health data: data relating to the state of health or a factor related to the physical or mental health (past, present or future) of a natural person. Personal data is considered sensitive.

Information sheet: document given to study participants to explain what their participation in the study entails: objective, procedures, constraints, benefits, potential risks, etc. The information sheet should be short and easy to understand, without omitting any important details. It provides participants with the information they need to decide whether or not they wish to participate in the study.

Intervention: action aimed at reducing the impact of disease determinants, preventing their occurrence, halting their progression or limiting their consequences, including medical, environmental, social, legislative, economic, financial, behavioural and educational measures.

Investigator: a member of the study team who is ultimately responsible for the design, conduct, analysis, documentation and communication (through publication or other means) of an epidemiological study.

Law: the set of general and binding rules established and enforced by the state authority (or under its control) with a view to organising society.

Logbook: a tool in which epidemiologists record events and processes occurring in the environment and during the course of the study.

Metadata: data about data that describes its characteristics, facilitating its organisation, search and management, in particular by providing information such as the author, date, format or context of production.

Metrology: control principles and procedures to ensure reliability and maintain confidence in measuring instruments.

Monitoring (or quality control): activity consisting of verifying the completeness and accuracy of data transmitted by the investigation centres to the study promotor and ensuring that collection is carried out in accordance with the protocol, good practices and regulations. In animal health, this term may refer to the continuous monitoring of a population.

Participant: an individual included in a study whose personal data is collected.

Peer: an experienced epidemiologist who is recognised by the entire profession.

Peer review or validation: review of an epidemiological study by fellow epidemiologists (and sometimes other disciplines: biologists, field veterinarians, biostatisticians, etc.) who are independent of the study team and who critically assess or evaluate one or all stages of the study. Validation can take place at different stages of the study: beforehand as part of the protocol, afterwards to critique the results, and up until scientific publication.

5. Decree No. 2013-413 of 21 May 2013 approving the charter of health expertise provided for in Article L. 1452-2 of the Public Health Code - Légifrance, <https://www.legifrance.gouv.fr/loda/id/LEGISCTA000027435246>, (accessed on 26 July 2024).

6. Slightly adapted definition from the Regulation (EU) 2024/1689, art. 3. Definitions, <https://eur-lex.europa.eu/eli/reg/2024/1689/oj/fra>, (accessed on 17 April 2025).

Personal data: any data or set of data that allows, in any form whatsoever, directly or indirectly, the identification of the natural persons to whom it relates.

Pilot study: a preliminary study, replicating a large-scale epidemiological study on a small scale, which allows the feasibility, acceptability and measurement tools to be assessed, interventions to be tested and the study protocol to be refined.

Primary data: data specifically collected for the purposes of a study.

Promotor: person, public authority, department or organisation responsible for setting up a study. The term "agent" may be used in some countries (Canada).

Pseudonymisation: processing of personal data in such a way that the data can no longer be attributed to an identified natural person without additional information. This involves replacing directly identifying data (surname, first names, full dates, etc.) with indirectly identifying data (alias, sequential number, etc.). This process is less secure than anonymisation⁷ but allows individual data processing with the possibility of feedback to the participant.

Public health: the body of knowledge, expertise, practices and legal rules aimed at understanding, explaining, preserving and promoting the health of populations. The term "population" encompasses all populations, whether human, animal or plant (One Health).

Quality control: an overall programme or protocol designed to ensure compliance with reference standards, in particular those of good epidemiological practice. Quality control applies to all stages of the study, from the development of the study protocol to the publication of results, including the classification and archiving of data used or produced in the study.

Reference system: document containing a list of elements forming a reference system and providing guidelines on applicable methods.

Referral: request for health expertise commissioned by a public health authority.

Results: structured presentation of the data collected, after applying the analysis methods.

Scientific integrity: good scientific practices that guarantee the honesty and rigour of research activities.

Secondary data: data originally collected for reasons other than those of the study in which it is used.

Sensitivity analyses: analyses that examine the effects of a change in methods, values, variables or judgement criteria on the results.

Storage: the secure recording and retention of health data, making it accessible for the period necessary to achieve the purpose for which it was collected.

Study team: any form of organisation, regardless of status, including informal or ad hoc groups, participating in or contributing to the design, data collection, conduct, analysis, interpretation or publication, in whole or in part, of an epidemiological study, or responsible for processing data used or produced in the context of a study.

7. Anonymisation is defined in this glossary.

8. Regulation - 2016/679 - EN - rgdp - EUR-Lex, <https://eur-lex.europa.eu/eli/reg/2016/679/oj/fra>, (accessed on 17 April 2025).

9. PRISMA statement, <https://www.prisma-statement.org>, (accessed on 31 March 2025).

Subcontractor: any individual or organisation that manages or processes personal or non-personal data on the instructions and on behalf of the data controller.

Systematic review: a specific type of literature review that describes all steps transparently, from the question to the conclusion, using a rigorous, reproducible method based on a protocol to reduce the possibility of bias. The PRISMA framework incorporates these elements⁹.

Third party: any individual or organisation, regardless of status, that does not belong to the team responsible for the study.

Validity (internal and external): the ability of an object (measurement, tool, study, etc.) to correctly understand or measure a phenomenon or its real value, i.e., the accuracy of the object.

The internal validity of an epidemiological study is the ability to ensure that the results observed are attributable to what was measured and not to methodological errors.

The external validity of an epidemiological study is the ability to generalise a result to a specific target population.

Value: quantity (e.g., number) or quality (e.g. gender) attributed to a variable.

Variable: any factor that may differ depending on the individual, time or place observed, i.e., a measurable characteristic or result that can take on different values.



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Justification

In 2007, the Association of French-speaking Epidemiologists (ADELF), the Association for the Development of Studies and Research in Occupational Health Epidemiology (ADEREST), the Association for the Study of Animal Disease Epidemiology (AEEMA) and the Association for the Development of Field Epidemiology (EPITER) adopted the second version of the recommendations on ethics and good practices in epidemiology (GPE)¹⁰ (the first version was adopted in 1998).

These same associations have decided to revise these GPE in 2024-2025 to take into account developments in epidemiological practice since 2007 and similar work carried out in other countries in Europe and internationally^{11,12}. This revision of the GPE targets the practice of the discipline in French-speaking countries.

Objective of the GPE guide

The purpose of this document is to highlight and contribute to the harmonisation of good epidemiological practices in French-speaking countries and to promote a better understanding of epidemiological practice and the principles that govern it. They are intended to facilitate dialogue between epidemiologists and their interlocutors, so that everyone can work together harmoniously, in accordance with the principles of epidemiology. These principles apply to all areas of epidemiology: human, animal, plant, environmental, etc.

10. Revue d'épidémiologie et de Santé Publique 56S (2008) S121–S148.

11. Hoffmann W, Latza U, Baumeister SE et al. Guidelines and recommendations for ensuring Good Epidemiological Practice (GEP): a guideline developed by the German Society for Epidemiology. European Journal of Epidemiology, 2019: 34:301–317. <https://link.springer.com/content/pdf/10.1007/s10654-019-00500-x.pdf>

12. Sandra Alba et al., "Bridging research integrity and global health epidemiology (BRIDGE) statement: guidelines for good epidemiological practice," BMJ global health, October 2020, vol. 5, no. 10, p. e003236.



The four associations tasked a project team with carrying out this review, under the supervision of a steering committee (SC) composed of one representative from each of their respective boards of directors. The project team was supported by a scientific monitoring committee (SMC) composed of 26 members from the four associations working in France, Belgium, French-speaking Africa (Algeria, Benin, Morocco, Democratic Republic of Congo, Senegal) and Canada (Quebec). The SC and SMC monitored the project through meetings held every six weeks, during which progress was presented and future directions and any disagreements were discussed, decided upon or resolved.

The project was carried out in several stages:

First, the project team conducted a scoping review of the scientific literature in English (searching the PubMed® database) and French-language documents (grey literature, existing guidelines and recommendations, etc.), from which it extracted 73 documents. Documents and publications were added during the drafting and peer review phase of the GPE (see below).

The project team, then conducted a series of qualitative interviews with 21 professionals in epidemiology and public health covering the fields of human and animal epidemiology (research, field epidemiology, surveillance, environmental epidemiology, social epidemiology, occupational health applications, public health decision support, animal health, etc.) working in the French-speaking countries and regions mentioned above. The questionnaire was developed following discussions with the audience attending the project presentation session at the 10th International Francophone Congress of Epidemiology and Public Health, held in Limoges in July 2024. The comments and discussions helped to identify the various topics to be addressed in semi-structured interviews. These interviews, with a median duration of 51 minutes (ranging from 30 to 67 minutes), were transcribed and then analysed using a systematically applied analysis grid (agreement, opposition, specific position). The analysis identified important themes and highlighted topics to be retained, deleted, modified or integrated. Finally, this process resulted in the drafting of a qualitative summary.

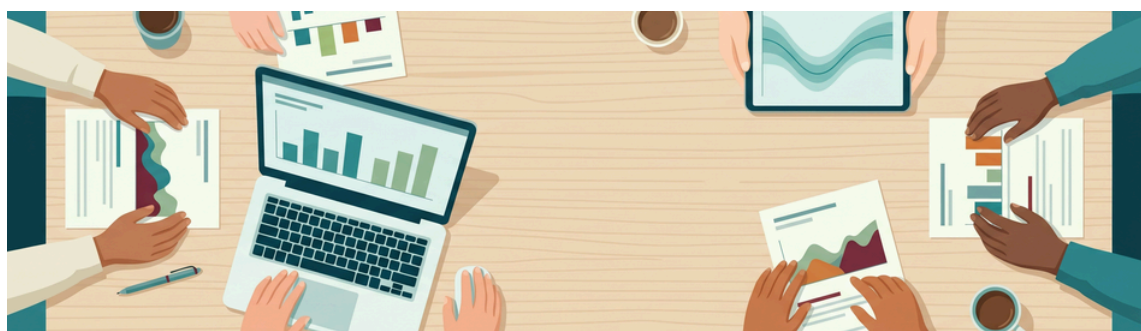
Based on the analysis of the literature review and the summary of the interviews, the project team, in close collaboration with the SMC, defined a nine-chapter outline for the new GPE and a standardised generic structure (rationale, objectives, recommendations) for each chapter.

Each chapter of the GPE was drafted according to the standardised plan by the project team and was proofread as it progressed by four different volunteers, members of the SMC. Proposed changes were analysed by the project team and taken into account if deemed relevant, or if necessary, after discussion within the SMC with a decision based on consensus. In the event of disagreement, an alternative wording was proposed to reach a consensus within the SMC.

Finally, the GPE guide was proofread in its entirety by 10 volunteer members of the SMC and by the four members of the SC (some of whom had it proofread by members of their association who were not part of the SMC). The comments were considered by the project team, with discussion with the SMC where necessary, and were taken into account or not, with justification, before the SC validated the final version.

With regard to potential conflicts of interest and links, all SMC members were asked to sign a simple confidentiality and commitment statement to disclose any potential conflicts of interest or links. These were then dealt with on a case-by-case basis by the project team and, where necessary, members with actual conflicts of interest on certain subjects were required to withdraw from the discussion when these were being discussed. The members of the steering committee and the project team also signed this declaration. No potential conflicts or interests were reported or identified during the GPE review process.

This document is written in inclusive French language, based on the guide published by the High Council for Gender Equality¹³, while striving to be as readable and understandable as possible. This style of writing is more equitable and egalitarian, and allows all the people mentioned in the document to be represented.



13. Guide to public communication without gender stereotypes, <https://www.haut-conseil-egalite.gouv.fr/stereotypes-et-roles-sociaux/actualites/article/guide-pour-une-communication-publique-sans-stereotypes-de-sexe>, (accessed 14 May 2025).

Context of epidemiological practice

Epidemiology is a scientific discipline that studies the frequency, distribution and progression of diseases and health phenomena in populations, as well as the factors involved in their onset and the implementation of the necessary means for their prevention and treatment. This discipline includes, among other things, experimental research (such as therapeutic and community trials), quasi-experimental research, observational research, epidemiological surveillance, risk analysis, evaluation of actions and interventions, epidemiological and mathematical modelling, systematic reviews, and various forms of applied investigation aimed at improving the health of populations. Investigations may need to be conducted urgently, and GPEs must be able to be comply with and adapted to this constraint.

Epidemiologists, regardless of their status and the structure of their practice, are scientists whose studies, degrees, experience and professional practices have qualified to conduct epidemiological studies.

Epidemiologists, like scientists in other disciplines, must have as their ideals the practice of their discipline in complete independence and the contribution to improving knowledge and the health of populations.

Their behaviour must be fair and just and respect the principles of the discipline. Epidemiological investigation has an important role to play in a democratic society and everyone must contribute with their experience and skills. An epidemiological study or project is a better solution than abstention only if the results are scientifically credible (the validity and quality of the study are therefore particularly important) and benefit society or improve understanding of the occurrence of diseases in populations.

With the rapid development of big data on the one hand and artificial intelligence (AI) on the other, data processing is substantially increasing energy consumption. This dimension is a new focus that is now being incorporated into the revision of the GPE.



The scope of GPE guide

The recommendations apply to all forms of epidemiological practice, whether research, description of a health phenomenon, surveillance, evaluation or intervention, in human health as well as animal, plant or environmental health. All epidemiologists must comply with them, regardless of their mode of practice and personal or professional status, and regardless of the structure (public or private) in which they work. However, in exceptional cases, the context and nature of the study or epidemiological work may lead to some of these principles being adapted, subject to evaluation by expert peers.

These recommendations apply regardless of the promotor, funder and affiliation of the team conducting the study, whether they are from the public or private sector.

These recommendations apply to all forms of epidemiological studies, which generally pose little or no risk to study participants. However, epidemiological studies or parts of epidemiological studies may also be governed by other good practices (good clinical practices, good laboratory practices, good public statistics production practices, etc.), which must also be complied with. These apply from the early stages of the study, through the development of the study protocol, to its completion, reporting, publication, social promotion, communication of results, and storage and archiving of data and scientific documents related to it.



01.

Law, professional conduct, ethics and scientific integrity



The practice of epidemiology, whether for research or scientific study, surveillance, health security or protection of public health, must comply with the law, deontology, ethics and scientific integrity. These are essential and indispensable principles for the responsible conduct of epidemiology. The Council for International Organizations of Medical Sciences (CIOMS)¹⁴ has published international ethical guidelines for health research involving human subjects, in accordance with the revised Declaration of Helsinki¹⁵. This GPE guide applies to the practice of human, animal, plant and environmental epidemiology in French-speaking countries where these principles are shared. However, regulatory texts and their application vary from one country to another. For animal and occupational health, the principles are very similar to those for human health; specific features are mentioned at the end of this chapter.

Epidemiology has scientific and social value and must act for the common good and general interest, with the intention of doing good and no harm. All epidemiological studies, like all public health actions involving an epidemiological approach (surveillance, intervention, evaluation, expertise, etc.), must therefore be conducted in accordance with these principles, while also respecting human dignity, the autonomy of participants, the prevention of unreasonable risks and ensuring social and environmental justice. Its practice must comply with the regulations in force in the country or countries and the context in which it is carried out.



Recommendation 1.1

All epidemiologists must comply with international texts and good practices promoting research studies on human beings and their equivalents for animal and plant studies, as well as with the guidelines of the country, province(s), territory(ies) or state(s), and the context in which it is carried out.



Recommendation 1.2

All individuals and organisations (study investigators, study team, promotor, funder, public or private body implementing the study) carrying out tasks listed in the study protocol are individually responsible for their own actions.

14. International Ethical Guidelines for Health-related Research involving Humans, s.l., Council for International Organizations of Medical Sciences (CIOMS), 2016. <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>

15. WMA - The World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, <https://www.wma.net/fr/policies-post/declaration-dhelsinki-de-lamm-principes-ethiques-applicables-a-la-recherche-medicale-impliquant-des-etres-humains/>, (accessed on 14 March 2025).

The promotor is a natural or legal person (institution or company) who initiates the study. They assume responsibility for it and ensure that it is funded. In practice, the promotor is responsible for the entire organisation, implementation and monitoring of the study. They work in collaboration with the investigator to put together the team responsible for conducting the study, obtain the approval of an ethics committee and authorisation from the competent authority, take out insurance if necessary, and report any adverse events that occur during the study to the competent authority. The investigator designs the study from a scientific and operational perspective, directs and monitors its implementation, and ensures its analysis and evaluation. For multicentre studies, each centre has an investigator who performs these functions for the centre's participants and reports to the promotor. He or she must demonstrate appropriate skills and experience in conducting epidemiological studies. It is his or her responsibility to ensure compliance with regulations, professional standards and ethics, and to ensure that the promotor's responsibilities are fulfilled.

These responsibilities are scientific, legal, professional and ethical in nature and involve compliance with all applicable legislative, regulatory and professional provisions. In addition to regulatory and professional aspects, any ethical issues that may arise during the study must be taken into account. It is therefore essential to define, in the study protocol, the responsibilities of the promotor, the investigators and the organisations involved, from the design stage of the study. Epidemiologists must ensure their independence and the absence of conflicts of interest with regard to the funders in the conduct of their work and maintain this throughout the study.

Recommendation 1.3

All funders and promoters of a study must be known; there is no justification for secrecy.

Recommendation 1.4

Epidemiologists must disclose in full any potential or actual conflicts of interest or links to the topics of their studies.



It is good practice for epidemiologists to report any potential conflicts of interest to the relevant ethical authority at their institution or the institution for which they are conducting the study (ethics officer, ethics committee or equivalent). It is up to this ethical authority to judge whether there is a real conflict of interest and to propose the necessary management measures to epidemiologists. The Organisation for Economic Co-operation and Development (OECD) states that a conflict of interest is a situation involving “a conflict between the public duties and private interests of a public official, where the public official has private interests that could improperly influence the way he or she carries out his or her duties and responsibilities”¹⁶. Some definitions also suggest declaring situations that may appear or be perceived to influence the investigator's role¹⁷.

This transparency towards society and the collaborators, institutions, funders or organisations with which epidemiologists collaborate helps to maintain confidence in this area.

Recommendation 1.5

The approval of an ethics committee or equivalent, depending on the context and country (Committee for the Protection of Persons, Committee for Research Ethics and Integrity, Scientific and Ethical Committee, Social and Economic Committee, Institutional Review Board, or any other authorised body) must be obtained before conducting any epidemiological study for research purposes.

Two exceptions to this recommendation have been identified. Firstly, in the case of animal health and regulated diseases, studies may be carried out without having to go through a committee. Secondly, according to the legislation in force, the processing of health data obtained during the practitioner's usual practice within the scope of its prerogatives does not require the approval of such a committee. This applies in particular to analyses for the purposes of care or treatment, health service management, surveillance or vigilance, prevention, occupational health or investigation in emergency situations (which require an emergency investigation to be set up, often in a complex context). In these specific cases, data protection rules apply in the same way as for epidemiological studies for research purposes (it is advisable to consult the data protection officer (DPO) of the relevant institution)¹⁸.

16. Conflict of interest policies and practices in nine EU Member States, https://www.oecd.org/fr/publications/politiques-et-pratiques-en-matiere-de-conflit-d-interets-dans-neuf-etats-membres-de-l-ue_5k40htrz63g8-fr.html (Conflicts of interest in the European Union: a comparative analysis of nine Member States), 31 December 2005, (accessed on 21 March 2025).

17. For example, in France, Law No. 2013-907 of 11 October 2013 on transparency in public life defines conflict of interest as “any situation of interference between a public interest and public or private interests that is likely to influence or appear to influence the independent, impartial and objective exercise of a function” (Article 2, 1°).

[https://www.google.com/url?](https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://www.legifrance.gouv.fr/loda/id/JORFTEXT000028056315&ved=2ahUKEwj5w72c9eyTAxUJT6QEHCuFKSYQFnoECCcQAQ&usg=AOvVaw2H7PCUNmBh1DPW7ryGYwHs)

[sa=t&source=web&rct=j&opi=89978449&url=https://www.legifrance.gouv.fr/loda/id/JORFTEXT000028056315&ved=2ahUKEwj5w72c9eyTAxUJT6QEHCuFKSYQFnoECCcQAQ&usg=AOvVaw2H7PCUNmBh1DPW7ryGYwHs](https://www.legifrance.gouv.fr/loda/id/JORFTEXT000028056315&ved=2ahUKEwj5w72c9eyTAxUJT6QEHCuFKSYQFnoECCcQAQ&usg=AOvVaw2H7PCUNmBh1DPW7ryGYwHs)

18. See recommendation 1.8 of this chapter, “Law, ethics and professional conduct,” and recommendation 5.8 of the chapter, “Data collection, acquisition, management, storage, archiving and sharing.”

If healthcare professionals involved in processing such data obtained in the course of their normal practice intend to use it for research and publish the results, the opinion of an ethics committee should then be sought for.

The practical arrangements vary depending on the country and the nature of the study (e.g., interventional, observational, with or without biological sampling, use of secondary data, or studies involving humans, animals or the environment). It is always advisable to refer to good practices in this area in the country, province(s), territory(ies) or state(s) where the work is being carried out.

Epidemiologists have an obligation to reduce the risks of physical, psychological and social harm, including unanticipated harm, from an epidemiological study. This principle applies to all stages of the study, including the communication of results. The opinion of an independent ethics committee guarantees this fundamental right for participants and, more broadly, for the groups or populations involved in the study.

These rules apply to all fields of epidemiological study. For studies conducted in the workplace, the joint social dimension (including employee and employer representatives) must be integrated.

Recommendation 1.6

Participation in an epidemiological study must be voluntary, without external pressure or undue influence.

Where incentives are offered, they must always be evaluated. For example, a reasonable balance must be found between reimbursement of travel expenses and excessive remuneration for study participants. It is also important not to overlook the cultural aspects of the country where the study is conducted with regard to financial considerations. It is the responsibility of the competent independent ethics committee to monitor and judge this balance.

Recommendation 1.7

The free, specific, informed and unambiguous consent of participants must be obtained before data collection and must be demonstrable at all times. In some cases, consent may be considered to have been given by the participation of the person itself (e.g., telephone surveys without number registration) or by non-objection (e.g., surveys reusing recorded data).

For non-interventional research involving the reuse of health data or biological samples that have already been collected, for which obtaining individual consent would require an unreasonable effort, or even be impossible in the case of old data, compared to the general interest of the research, specific consent is not necessary. General information may be sufficient (derogation from the obligation to provide information and obtain individual consent). This decision is the responsibility of the ethics committees and the authority responsible for the protection of personal data¹⁹.

In clinical studies, any participant may refuse to give their consent, modify it or withdraw it without this having any impact on their care or resulting in any disadvantage. A participant must be able to withdraw his/her consent at any time and their recorded research data, if not completely anonymised, must then be deleted.

Except in situations defined by law or regulations (mainly immediate life-threatening emergencies and mandatory reporting of disease), individual consent cannot be waived in order to collect epidemiological information from persons under investigation in an emergency. It is recommended that this situation be anticipated by a generic protocol for emergency studies, with the approval of an ethics committee, the competent authority where applicable, and, for countries where this applies, the authority in charge of the General Data Protection Regulation (GDPR) and the organisation's DPO.

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Recommendation 1.8

Epidemiologists must take appropriate measures to protect the privacy of individuals and to avoid the risk of breaching the confidentiality of all information concerning research participants during and after the study.

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19. In France, this is the responsibility of the National Commission for Information Technology and Civil Liberties (CNIL).

The right to confidentiality of personal data must be respected. As the regulations in force may vary depending on the country where the work is carried out, it is advisable to refer to them. This recommendation applies to the security and protection of personal data collected and to the protection of the individuals concerned, throughout the study and when the results are published and communicated. In some studies (e.g., studies involving follow-up of participants or studies involving biological sampling and analysis), it is necessary to have an identifier in order to contact participants again. In this case, the database must not contain the participants' identifiers but a secure correspondence code that allows the investigator to link the code to the participants' identities. This can be managed by a trusted third party independent of the investigator, who is the only one to hold this correspondence. This need for identification of participants in a study and how it is managed must be justified in the protocol.

Particular attention must be paid to epidemiological studies with a small number of cases (e.g., case series, investigations of clustered or aggregated cases, or tabulations stratified according to time, place and person characteristics) where there is a risk of identification through detailed description of the results (a situation described at risk of revealing the identity of individuals). It is necessary to consult data protection experts, such as DPOs, to ensure compliance with the rules in force in the country or countries concerned and to ensure that the disclosure of results does not cause harm to the community.

Recommendation 1.9

Where possible, representatives of the populations concerned and end users of the research should be involved throughout the study, taking into account their culture and communication methods and adopting approaches based on their needs, skills and expectations.

Participatory approaches enable stakeholders to be involved and help to develop an epidemiological study that is best suited to the population concerned. This can be done, for example, in the form of advisory committees, qualitative approaches (group discussions, etc.) or co-construction. If appropriate and if it does not lead to recruitment bias, non-scientists may participate in the selection of participants and the planning and implementation of data collection, in accordance with the principles of confidentiality and independence.

Recommendation 1.10

If the scientific literature indicates or suggests inequalities (social, gender, etc.) for a given subject or issue, epidemiologists should take these dimensions into account in their studies.

Recommendation 1.11

When an epidemiological study is conducted within a particular community (defined by ethnicity, social group or organisation), it must be organised according to ethical rules that respect the moral values, material interests and specific regulatory provisions of that community, to the extent permitted by the general ethical and scientific requirements and rules set out in this text.

Recommendation 1.12

Epidemiologists must be aware of their own biases and do everything possible to limit them in order to strive for a neutral and objective scientific approach.

Epidemiologists operate in a social, political, economic and cultural context and are influenced by values, norms and even ideologies. Personal biases (which may be shared within members of a team) may exist and must be recognised in order to adopt the most objective and neutral professional stance possible towards them and ensure the quality of the study conducted. A collegial approach, i.e., one in which decisions and guidelines concerning the study are not taken solely by the investigator but involve representatives of the study population, helps to limit these biases and strive for greater objectivity.

Recommendation 1.13

Epidemiologists must be aware of the potential risks associated with the use of AI. In particular, care must be taken to ensure that it does not contribute to exacerbating social inequalities in health through biases against socially disadvantaged people, as indicated by research on this matter.

The use of AI can be very useful in conducting epidemiological studies, particularly in reviewing scientific publications, but algorithmic biases²⁰ can lead to discrimination. Therefore, the risks of bias should always be assessed using a reference method²¹. AI must not replace humans under any circumstances; it is always up to epidemiologists to reflect and make decisions.

20. Bias in algorithms - Artificial intelligence and discrimination | European Union Agency for Fundamental Rights, <https://fra.europa.eu/en/publication/2022/bias-algorithm>, 29 November 2022, (accessed 17 April 2025).

21. For predictive models using AI, see for example: Karel G. M. Moons et al., "PROBAST+AI: an updated quality, risk of bias, and applicability assessment tool for prediction models using regression or artificial intelligence methods," *BMJ*, 24 March 2025, vol. 388, p. e082505.

Epidemiologists are responsible for the results produced by AI. Good practices, ethics and current regulations regarding its use must be respected²².

Recommendation 1.14

Epidemiologists must optimise the use of resources and consider ways to reduce their environmental impact at all stages of an epidemiological study.

This involves, for example, determining the usefulness of the study, identifying and considering the reuse of existing and accessible data²³, or avoiding the use of AI (which is very energy-intensive) if other more frugal solutions exist. Epidemiologists should also consider the emissions generated by their travel to conferences and other scientific events, and limit them as much as possible.

Special cases

- For epidemiological studies involving animals, the rules and good practices that apply are very similar to those for human populations. They aim to ensure the welfare of animals used for scientific purposes, while ensuring the quality and reliability of the data obtained. A particular aspect of animal epidemiology is that animals cannot give their consent directly. Therefore, the responsibility for providing consent for the participation of animals lies with the owners or legal keepers of the animals. For animals without owners (stray or wild animals), it is important to establish a clear ethical and professional framework for optimising the use of animals due to the total absence of consent. The same applies to studies in plant epidemiology in the absence of owners.
- For studies involving medicinal products for human use, refer to Good Clinical Practice (GCP)²⁴.
- For pharmacoepidemiologic studies, refer to good practices in pharmacoepidemiology²⁵.
- For non-clinical trials, i.e., animal trials or in vitro models, refer to the OECD's good laboratory practice guidelines²⁶.

22. In the European Union, reference should be made to the AI Act, available in French here: Regulation - EU - 2024/1689 - FR - EUR-Lex, <https://eur-lex.europa.eu/eli/reg/2024/1689/oj/fra>, art cit.

23. See recommendation 5.2 of the chapter entitled "Data collection, acquisition, management, storage, archiving and sharing".

24. Légifrance, "Decision of 24 November 2006 laying down rules of good clinical practice for biomedical research involving medicinal products for human use".

25. Guidelines for Good Pharmacoepidemiology Practices (GPP) - International Society for Pharmacoepidemiology, <https://www.pharmacoepi.org/resources/policies/guidelines-08027/>, (accessed 28 June 2024).

26. OECD, OECD Principles of Good Laboratory Practice, s.l., OECD Publishing, 2003. https://www.oecd.org/content/dam/oecd/en/publications/reports/2005/12/good-laboratory-practice_g1gh5db5/9789264012837-en.pdf

- For non-clinical safety testing of chemicals, refer to the ANSM's good laboratory practice guidelines²⁷.
- For epidemiological studies in hierarchical institutions and populations (armed forces, police, prisons, private companies, etc.) and more generally in environments where access to the target population of the epidemiological study requires prior authorisation from hierarchies exercising authority over the study participants, epidemiologists must take all necessary precautions to ensure that access to the target individuals likely to be included is not biased. Participants must be free to express themselves and under no circumstances be influenced by the hierarchy, so that those included respond sincerely and are not subject to bias. Interviews and data collection must not take place in the presence of representatives of the hierarchical authority. Participation must be voluntary and those approached must be assured that there is no risk of sanction, whether for participating or refusing to participate.
- Epidemiological studies in the workplace are not subject to any specific regulatory, ethical or deontological requirements. Nevertheless, voluntary and informed participation, the provision of information to groups and individuals in the workplace, data channels²⁸ and the visibility of results both within and outside the company are important factors to consider.

Specific data protection regulations in different countries

In Europe : GDPR; European regulations on the European Health Data Space : https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=OJ:L_202500327

In France : Data Protection Act (LIL); Act on research involving human subjects, known as the Jardé Act (2012); CNIL/CESREES : <https://www.health-data-hub.fr/depot>

In French-speaking Africa : the Francophone Association of Personal Data Protection Authorities (AFAPDP) : <https://www.afapdp.org/documents/biblio>

In Morocco : Law 09-08 and Decree No. 2-09-165 of 25 Joumada I 1430 (21 May 2009)

In Quebec : Personal Information Protection Act : <https://laws-lois.justice.gc.ca/fra/lois/P-21/textecomplet.html>

In Belgium : Data Protection Authority : <https://www.autoriteprotectiondonnees.be/citoyen/page-d-accueil>

In Switzerland : Federal Data Protection Act (FPA) No. 235.1 of 25 September 2020 : <https://www.fedlex.admin.ch/eli/cc/2022/491/fr>

27. ANSM, Good Laboratory Practices, <https://ansm.sante.fr/documents/reference/bonnes-pratiques-de-laboratoire>, 6 March 2025, (accessed 3 April 2025).

28. The CNIL publishes a guide for occupational health and safety services (SPST), <https://www.cnil.fr/fr/la-cnil-publie-un-guide-pour-les-services-de-prevention-et-de-sante-au-travail-spst>, (accessed 16 April 2025).

02.

Purpose of the study and questions addressed



Once the objectives of the study have been defined, the research or study questions must be specified and formulated in an explicit and operational manner. The research or study questions may be a subset of the general objectives or, where applicable, intermediate objectives in their direction. These questions are the starting point for any scientific study and will guide and justify the next steps in the study, as described in the protocol.

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Recommendation 2.1

Any study or work of an epidemiological nature should begin with a review of the literature²⁹, which will help to define, refine and justify the research or study questions and hypotheses. This review also helps to avoid redundancy with existing studies.

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A study must address a knowledge gap and a scientific or operational need. Epidemiologists must be able to demonstrate the scientific or public health necessity of the study they wish to conduct. It may also involve confirming the results of other studies, as the replication of results in another context is an argument for causality, or studying or analysing a risk in a different context or from another perspective (geographical, social, environmental, occupational, etc.). If the aim is to set up or evaluate a surveillance system, its usefulness must be justified in relation to one of the objectives of surveillance^{30,31,32}.

In all cases, the purpose of the literature review is to provide an overview of the current state of knowledge – or “state of the art” – on the subject under study, to identify gaps or uncertainties in published scientific work or work available in grey literature, and to identify biases and difficulties encountered. This review of scientific literature must extend to study protocol submission platforms to ensure that no equivalent study is underway during the same period.

Epidemiologists can also consult with other epidemiologists who have already addressed the subject to gather their opinions, which could limit the pitfalls already encountered when conducting research or studies on the same subject.

29. To determine what type of knowledge synthesis to produce, refer to the tool provided by the website: Right Review, <https://whatreviewisrightforyou.knowledgetranslation.net/>, (accessed on 17 April 2025).

30. Jean-Claude Desenclos and Gilles Brückner, "11. Surveillance" in *Traité de santé publique*, s.l., Lavoisier, 2016, pp. 79-94.

31. François Dabis and Jean-Claude Desenclos, *Field Epidemiology (2nd edition): Methods and Applications*, s.l., John Libbey, 2017, 809 p.

32. Barbara Dufour and Pascal Hendriks, *Surveillance épidémiologique en santé animale*, 3rd ed., Versailles Maisons-Alfort, Éd. Quae AEEMA, 2011.

 Recommendation 2.2

Research, study, investigation or surveillance questions must include the notions of population, period or duration, geographical area and comparison. They refer to the precise wording of the objectives in the protocol. For surveillance systems, the period or duration is not defined because it is continuous overtime by nature.

 Recommendation 2.3

The purpose of epidemiological work is multiple but must always aim to improve knowledge of health issues in populations and their determinants.

Apart from descriptive epidemiology, the ultimate goal of epidemiology is to investigate causality by testing hypotheses, for example, the cause of a disease (aetiology) or the cause of the success or failure of an intervention. although an observational study cannot conclude to causality, it provides contributions or factual elements which, when taken together with results of other studies, help to establish causal links or aid in understanding them. In this perspective, it will be useful to refer to one or more causality models with an analysis based on a causal diagram, in particular directed acyclic graphs (DAGs)³³.

An epidemiological study may serve different purposes, but whether these are clinical, scientific, preventive, environmental, risk assessment, political or social, they must be made explicit in the description of the research question and its justification. Regardless of the purpose and scope, the same scientific, ethical and regulatory requirements apply.

 Recommendation 2.4

As far as possible and depending on the relevance to the objective, epidemiologists should design and implement their studies and work in conjunction with other disciplines (ecology, sociology, psychology, environmental sciences, urban planning, animal health, plant health, etc.) in a transdisciplinary approach that includes all relevant compartments from the holistic perspective of One Health and Planetary Health.

33. See recommendation 7.1 in the chapter entitled "Interpretation of study results".

Epidemiologists must also take into account social (social determinants), socio-economic (including livestock health), perceived health, quality of life, well-being³⁴, and mental health dimensions³⁵.

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Recommendation 2.5

In describing the research or study questions, a distinction must be made between the main question, for which the study was specifically designed and statistically optimised, and secondary questions.

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Usually, a study can only adequately answer one question (the primary objective) and must be organised around that question. When several questions need to be addressed in the same context, the main question must be given priority. Secondary questions may help to refine the answer to the main question or be useful later for a complementary study. However, this principle must be relativised in certain cases, particularly for generalist cohorts and in surveillance systems.

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Recommendation 2.6

For any epidemiological investigation, the hypotheses to be validated or refuted and the methods for doing so must be formulated a priori, at the design stage of the study.

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This avoids results being selected because they are significant among a large number of analyses, with a greatly increased risk of type I error (α). In some cases, an exploratory approach (development of hypotheses) is possible, but the results obtained must be presented as such and require confirmation by a specific study.



34. HCSP, Uses and Proper Use of Perceived Health and Quality of Life Measurement in France, Paris, High Council for Public Health, 2022.

35. According to the World Health Organisation (WHO), health is defined as "a state of complete physical, mental and social well-being, [which] is not merely the absence of disease or infirmity", Constitution, <https://www.who.int/fr/about/governance/constitution>, (accessed on 21 April 2025).

Special cases

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Recommendation 2.7

When the objective is to produce indicators to describe and characterise a health phenomenon in a population, the justification must be based on public health needs.

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The data source to be considered must take into account its internal validity, availability and sustainability, representativeness (external validity), the metrological quality of the indicators that can be constructed from the available data, feasibility and cost.

If secondary big data is used, the indicators constructed from the source(s) should be evaluated and validated against a reference before being put into production.

If AI is used to construct the databases from which the indicators are derived, the type of AI and the sources must be mentioned.

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Recommendation 2.8

When investigating an epidemic or assessing a spatio-temporal aggregate of non-infectious syndromes or diseases, specific reference frameworks should be consulted (see footnotes for a non-exhaustive list)^{36,37,38}.

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Recommendation 2.9

If the purpose of the work is to formulate an opinion or recommendations to the public authority in the context of a health assessment (particularly in the context of a referral), epidemiologists must take into account the principles of conducting a collective public health expert advice.

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36. F. Dabis and J.-C. Desenclos, Chapter 25: Investigating an epidemic episode. Descriptive phase, and Chapter 39: Investigating an epidemic episode. Analytical phase, in *Field Epidemiology* (2nd edition), op. cit.

37. SPF, Methodological guide for the evaluation of spatio-temporal clusters of non-infectious diseases, <https://www.santepubliquefrance.fr/import/guide-methodologique-pour-l-evaluation-des-agregats-spatio-temporels-de-maladies-non-infectieuses>, (accessed 21 August 2024).

38. INSPQ, Assessment of a report of disease clusters suspected to have an environmental origin, <https://www.inspq.qc.ca/publications/2357>, 6 March 2018, (accessed 8 April 2025).

In France, these principles are set out in the Expertise Charter³⁹; for other countries, reference should be made to equivalent standards. In this case, the health authority must formally specify the question(s) to be addressed. If the question is not sufficiently clear, it is the responsibility of the epidemiologist and their institution to review and renegotiate the question to be addressed.

Recommendation 2.10

In the context of an expert advice in response to a referral, the definition of objectives must include an evaluation of the quality of the studies identified during the literature review.

Recommendation 2.11

It is necessary to evaluate the surveillance systems in place regularly on the basis of specifications established a priori.

When a surveillance system has been in operation for several years, it is appropriate to examine whether it has achieved its objectives (exhaustivity, representativeness, notification time, validity, etc.), how it functions (coordination, management, workload for information sources and producers), and its usefulness for public health needs. The evaluation will attempt to answer these questions and thus ensure that the resources allocated are used to best effect. Ideally conducted by an external team, it can also be carried out by the epidemiologists responsible for the system themselves (self-evaluation).

The evaluation should be a flexible process. The first step is to draw up a list of questions that an evaluation should attempt to answer. However, it should be borne in mind that a standardised evaluation process of this type is rarely implemented in its entirety. Certain quantitative and qualitative criteria (sensitivity, timeliness, specificity, representativeness, etc.) are most often evaluated. A standardised evaluation approach has also been proposed for human epidemiological surveillance⁴⁰. Recommendations also exist for animal epidemiological surveillance⁴¹. It is advisable to refer to any recommendations⁴² issued by the surveillance bodies of the country where such an evaluation is planned.

39. Decree No. 2013-413 of 21 May 2013 approving the charter of health expertise provided for in Article L. 1452-2 of the Public Health Code - Légifrance, <https://www.legifrance.gouv.fr/loda/id/LEGISCTA000027435246> (Health and Public Health), art. cit.

40. M. Herida and J.C. Desenclos, "Evaluation of different surveillance systems (for infectious diseases) based on a generic protocol," *Revue d'Épidémiologie et de Santé Publique*, 1 February 2015, vol. 63, no. 1, pp. 35-42.

41. OASIS | ESA PLATFORM, <https://www.plateforme-esa.fr/fr/oasis>, (accessed 8 April 2025).

42. European Centre for Disease Prevention and Control., Core competencies for EU public health epidemiologists in communicable disease surveillance and response., LU, Publications Office, 2010. https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/0801_TED_Core_Competencies_for_Public_Health_Epidemiologists.pdf

03.

Study protocol



One of the first steps in any epidemiological study, after determining the research questions and defining the objectives, is to draft a detailed, clear and precise study protocol describing the main characteristics of the study. The protocol is a document drafted by the study investigator and approved by his or her collaborators. The protocol justifies the study, specifies its objectives, methodology and target population, and describes its various phases and relationships with the institutions promoting and funding it. The information collected must be relevant, useful, adequate, non-redundant, not excessive in quantity in relation to the objectives, and acceptable to the participants.

The development of a protocol is essential to ensure the scientific quality of the study. The protocol is used to justify the project in order to obtain the necessary grants and authorisations. At all stages of the protocol, it is important to be transparent about the choices made, the biases and difficulties that may be encountered, and how they will be addressed. Administrative, legal and ethical issues, feasibility, and alternative options in the event of major difficulties must be anticipated. The protocol also addresses any adverse effects, limitations, completion deadlines, methods of communicating results, and any procedures for modification and revision. Any revisions to the protocol during the study must be formally justified and tracked, and must be subject to ethical re-evaluation. Participants must then be informed of these revisions in a transparent manner.

The main objectives of the protocol are to:

- justify the need for the study, i.e., explain, based on current knowledge and scientific or operational needs, why the study should be undertaken;
- define the general and specific (primary and secondary) objectives of the study and show that they correspond to the needs identified in the justification;
- demonstrate that the methods proposed to achieve the objectives are appropriate;
- demonstrate the feasibility of the proposed study, i.e., that the study can be successfully completed within a specified time frame and with the available resources, and that the investigator and his or her team have the necessary skills and capacity to conduct the proposed study;
- demonstrate that provisions to protect participants' personal data are in place and comply with the professional standards, ethics and regulations in force in the territory where the study is being conducted.



Epidemiological studies can take various forms, so it is not possible to present a standard model that is suitable for all studies. Nevertheless, the protocol must explicitly contain the following key points:

- the rationale for the study and a summary of the literature review;
- the research or study context;
- the hypotheses and research or study questions;
- the objectives;
- the study design;
- the study population and sampling;
- the inclusion and exclusion criteria for participants;
- the data collected and their format;
- adverse effects for interventional studies;
- endpoints, case definitions, and variables of interest;
- potential biases and their control;
- the data analysis plan (a priori statistical estimates and tests, software);
- assessment of the feasibility of the study;
- the limitations of the study;
- planned procedures for writing, publishing, and disseminating the results;
- where relevant, the benefit/cost balance of the study, taking into account financial, human and environmental costs.

An important point is the link and consistency between the parts of the protocol with judgement criteria, where the variables of interest must be able to answer the research questions in line with the data collected and the analysis plan.

Recommendation 3.1

When developing the protocol, reference should be made to guidelines, i.e., published and internationally recognised recommendation documents.

The protocol design should be based on reference documents containing recommendations for the publication of study results, which can also be used upstream to verify the quality and completeness of the proposed method. In this regard, the EQUATOR platform⁴³, which lists the main guidelines according to the proposed study design (observational study, randomised trial, cohort study, case-control study, clinical study, etc.) and field of application (human health, animal health, etc.), is a useful resource to consult.

Recommendation 3.2

It is recommended that a risk analysis be carried out, i.e., that problems that could compromise the smooth running of the project be identified and solutions be anticipated that can be implemented in advance or in response to their occurrence.

This risk analysis is often required for calls for projects.

If necessary, a feasibility and acceptability assessment may be carried out, or even required. Feasibility refers to producing objective facts and elements in favour of the smooth running of the study, in particular the experience of the teams involved in the study, the logistical channels, the availability of equipment, recruitment capacities, etc. Acceptability refers to acceptability by participants, the study population, health decision-makers, etc. For ambitious and costly projects, this assessment may require a pilot study.

Recommendation 3.3

All choices made (type of study, source population, participants, endpoints, case definition, treatment, nature of the analysis, etc.) must be described precisely and justified adequately, particularly in relation to the study objectives, regardless of the study design and the nature of the data used.

When investigating epidemics, clusters of cases or temporal-spatial aggregates, it is important to define the case definition at a very early stage. In animal health, the term “epidemic foci” is used. A case definition must be operational and, in addition to clinical and biological diagnostic criteria, include temporal and geographical boundaries of the affected population. At the start of the investigation, the validity of these criteria must be verified in consultation with the practitioners concerned and microbiology, medical biology or toxicology laboratories. It is often necessary to obtain the opinion and specialist expertise of a reference laboratory. An epidemic case is defined from an epidemiological and public health perspective based on standardised data collection, which may differ from the medical definition or diagnosis of the disease. While the sensitivity and specificity of the case definition are two important elements, the definition must above all remain usable and applicable by the largest number of health professionals and other key players who will be involved in case finding and the implementation of control measures. A case definition may evolve during the investigation, from more sensitive to less sensitive and more specific, as knowledge about the disease improves.



The same applies to epidemiological or biomathematical modelling and its specific parameters. This study design is based on a simplification, in its essential parts, of the biological, epidemiological or social reality of a complex health phenomenon. The aim is to be able to reproduce it theoretically and, by altering some of the essential parameters to mimic management measures, to evaluate action strategies a priori and in situations of uncertainty. The construction of the protocol will involve close collaboration between epidemiologists, biomathematicians and specialists in the necessary or useful disciplines, which, depending on the subject, may include entomology, ecology, environmental sciences, behavioural sciences, or even social sciences, particularly for defining the structure of the model, documenting the parameters, calibrating and validating the model, and performing sensitivity analyses. These different dimensions must be defined at the protocol stage.

Recommendation 3.4

The sample size must be appropriate for the study objective and justified quantitatively.

The calculation of the number of participants required must be tailored to the main objective of the study and its design. Calculating the number of participants required makes it possible to assess the costs of the study (financial resources, time required, etc.) and further guarantees its ability to answer the question posed and the quality of the study. It is therefore necessary to find an optimal balance between these two requirements, cost and quality. The assumptions required to calculate the sample size, based on the main variable of interest or endpoint. The level of precision or statistical power, must be based on the literature and be explicitly mentioned in the protocol. The management of refusals, lost to follow-up and missing data must be anticipated. In some cases, it may not be possible or relevant to calculate the number of participants required (e.g., surveillance systems or “generalist” cohorts), in which case this must be explicitly justified.

Recommendation 3.5

The manner in which data will be managed during and after the study must be described in the analysis protocol or in a dedicated data management plan, which must be designed at the protocol and study implementation stage.

This concerns in particular the methods of collection, traceability, storage, archiving and possible publication of data and their metadata.

With this in mind, it is recommended that the FAIR principles (Findable, Accessible, Interoperable, Reusable) be applied from the study protocol stage⁴⁴. Where applicable, the data must meet the data sharing requirements of the country where the study is conducted.

Recommendation 3.6

As far as possible, valid, reliable and standardised tools and classifications should be used, and their choice should be justified.

This recommendation applies to measurement and data collection instruments, but also to variables/outcomes of interest. Diseases and their diagnostic methods, causes of death, classifications of diagnoses, medical procedures and degrees of severity must be defined and coded using internationally recognised and updated standards (e.g., the International Classification of Diseases [ICD]⁴⁵, tumours, nodules and metastases [TNM]⁴⁶ for human data and AGROVOC⁴⁷ or ICAR⁴⁸ for animal health and One Health data). These may also include classifications of hazards, exposures, risks or occupations and sectors of activity. Where such standards are not available or appropriate, it is imperative to describe the vocabulary used in the dataset.

Recommendation 3.7

The statistical methods used to test the study hypotheses must be valid and presented in an intelligible manner. They shall be consistent with the study design (or protocol), the primary and secondary objectives, the method of participant selection, the nature of the data and the endpoints. Where possible, it is recommended that a biostatistician be included in the team or, at a minimum, consulted.

44. INRAE, Producing FAIR data | Open science at INRAE, <https://science-ouverte.inrae.fr/fr/le-numerique-pour-la-science-et-les-donnees-scientifiques/produire-des-donnees-fair>, (accessed on 20 February 2025)

45. International Classification of Diseases: Publication of ICD-11 2022, <https://www.who.int/fr/news/item/11-02-2022-icd-11-2022-release>, (accessed 31 March 2025).

46. Tumour, Nodes, Metastases: TNM Classification of Malignant Tumours | UICC, <https://www.uicc.org/what-we-do/sharing-knowledge/tnm>, (accessed 31 March 2025).

47. https://data.apps.fao.org/catalog/organization/agrovoc?q=&sort=title_string+desc

48. <https://www.icar.org/>

 Recommendation 3.8

The biases and limitations of the study must be described and anticipated at all stages of the study. Measures to reduce these biases and limitations must also be documented.



When planning a study, care should be taken to search the scientific literature for documented or potential biases and confounding factors. Appropriate measures should be taken to prevent them, as much as possible.

To estimate the effect of potential biases and confounding factors on study results, it may be necessary to collect additional data, for example to verify the validity of measurement procedures, their validation and calibration, and to compare study participants according to characteristics other than those of interest. Additional sensitivity analyses may also be planned to assess the impact of biases.

 Recommendation 3.9

The protocol should detail strategies for publishing and communicating the results as well as the data and metadata associated with the study.



While it is not always possible to publish data, it is generally always feasible to publish metadata (consult the DPD to ensure this). Publishing metadata, even without the associated data, contributes to the transparency and reproducibility of the study. This publication can be done independently of the publication of the study results.

 Recommendation 3.10

It is necessary for representatives of the population being studied (or their owners in the case of animals) to review the information sheet, consent form and protocol, and for these documents to be adapted accordingly⁴⁹.



49. This approach is in line with good practices in participatory science, see recommendation 1.9 in the chapter on “Law, ethics and ethics”.

 Recommendation 3.11

To ensure the quality of the study to be conducted, the protocol should be reviewed by peers.

The protocol is usually only reviewed by a scientific committee in the case of a response to a call for proposals, which is why in other cases, an opinion from outside the study leaders is desirable. As with the evaluation of study proposals during a call for proposals, care should be taken to ensure that the persons reviewing it have no conflict of interest with the project or the team⁵⁰.

The protocol must therefore be treated as a confidential document by those who read or evaluate it.

 Recommendation 3.12

The protocol must be accessible in a form that is understandable to all those involved in the study, particularly those who will be included in it. If possible, it should be published in open access⁵¹.

It is recommended that the protocol be made public in an appropriate form before the study begins, to allow for greater transparency and to avoid publication bias. Revisions should also be published.

However, for certain epidemiological studies, it may not be desirable to specify all elements of the study in the document made available to participants, as revealing all hypotheses may bias the investigation when exposure and health events are known to respondents. In such circumstances, the personal data protection authority should be consulted.

 Recommendation 3.13

Epidemiologists may refuse to undertake an epidemiological study proposed to them if they consider that the probability of it producing valid results is too low or if the resources allocated are insufficient.

50. See recommendation 1.6 in the chapter entitled "Law, ethics and professional conduct".

51. Platforms such as ClinicalTrials.gov, Prospero and OSF (non-exhaustive list) allow protocols to be submitted for open access.

This decision must then be explicitly justified (e.g., unjustified assumptions, lack of power or difficulty in assessing exposures). If they nevertheless decide to undertake such a study, its value must be justified.

Special case of collaboration between human and animal epidemiology

Animal epidemiology and human epidemiology share many similarities, both in terms of methods (surveillance, sampling, modelling and field epidemiology, etc.) and legal and ethical aspects⁵². However, it is important to highlight a specific feature of animal epidemiology in studies conducted on farm animals (livestock): the unit of analysis is very often the herd rather than each individual animal⁵³.

While collaboration between human and animal epidemiology is essential, the One Health concept implies transdisciplinary collaboration that goes far beyond this. The One Health principle⁵⁴ consists of an integrated and unifying approach that aims to balance and optimise the health of people, animals and ecosystems in a sustainable manner. It recognises that the health of humans, domestic and wild animals, plants and the environment in general (including ecosystems) is closely linked and interdependent. The approach mobilises multiple sectors, disciplines and communities at different levels of society to work together to promote wellbeing and combat threats to health and ecosystems. It also addresses the collective need for safe drinking water, clean energy, clean air, and safe and nutritious food, takes action against climate change and contributes to sustainable development.



52. See Chapter 1, “Law, Professional Conduct and Ethics”.

53. Bernard Toma et al., *Épidémiologie appliquée à la lutte collective contre les maladies animales transmissibles majeures* (Epidemiology applied to the collective fight against major transmissible animal diseases), 3rd ed., Maisons-Alfort, Association pour l'étude de l'épidémiologie des maladies animales (Association for the Study of Animal Disease Epidemiology), 2010.

54. The Tripartite Group and UNEP endorse the definition of the “One Health” principle formulated by OHHLEP, <https://www.who.int/fr/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health>, (accessed on 27 May 2025).



04.

Conducting the study



Once the legal, ethical and financial framework has been defined by written agreements between the collaborators⁵⁵ and their affiliated organisations, as well as with the funders and promoters, and once the protocol has been drafted, validated and registered, the epidemiological study can begin. It is conducted in accordance with the protocol, often by a team led by a principal investigator.

Recommendation 4.1

Before the study begins, it is essential to ensure that all the necessary authorisations have been obtained in the countries, provinces, territories or states where the study will be conducted, that the appropriate resources (human, material and time) have been allocated to conduct the study, and that the necessary funding and liability insurance have been obtained.

Epidemiologists must ensure that study personnel are trained, that the necessary resources are available to each member of staff, and that the data collection tools are of high quality⁵⁶. It is essential that all these elements, determined prior to the start of the study, are rigorously and regularly checked throughout the study.

Recommendation 4.2

It is recommended that the need for a feasibility study, in the form of a pilot study or risk analysis, be assessed.⁵⁷



55. See Chapter 1, 'Law, ethics and professional conduct'.

56. See Chapter 5, "Data collection, acquisition, management, storage, archiving and sharing".

57. See recommendation 3.2 in the chapter entitled "Study protocol".

The pilot study allows for testing the understanding of the tools, the administration time, and the logistical feasibility and acceptability. It is recommended if the study involves unfamiliar populations, little-studied phenomena, studies with innovative designs or tools, due to its size, the type of data collected, the number of sites, complex logistics or the recruitment of controls in a case-control study. The results of these preliminary studies are used to optimise the main study: updating the protocol, data collection tools, questionnaire, etc.

The pilot study may be an independent study or included in the main study as a preliminary stage with an interim data analysis which, depending on the results, would validate the continuation of the study with possible adaptation of the protocol. It is therefore important to anticipate an administrative delay in submitting the updated protocol to the ethics committees. In all cases, the pilot study must be documented and scheduled before the start of the main study.

Pilot studies are also relevant prior to the deployment of a surveillance system, over a defined period of time, target or spatial scale.

Recommendation 4.3

Conducting an epidemiological study requires cross-disciplinary and multidisciplinary collaboration with professionals from other fields (clinical, biostatistics, biology, sociology, environment, etc.) and necessitates coordination between these actors beforehand, during the study, and when interpreting and disseminating the results.

The One Health approach, for example, aims to balance and optimise the health of people, animals and ecosystems, particularly biodiversity, in a sustainable manner through a multidisciplinary and comprehensive concept of health issues.

Recommendation 4.4

The management of any subcontractors involved in a study requires specific preparation with specifications that are tailored to the operational objectives, feasible and compliant with laws and regulations, with appropriate and transparent monitoring and management by the investigators.

For certain studies or epidemiological work, it is necessary to call on one or more subcontractors for data collection or retrieval, the information system, database creation, etc. Rigorous planning with appropriate human resources in project management is crucial in order to comply with the legal rules of the country, province, territory or state where the study is being conducted (public procurement, GDPR, etc.). Subcontractors must provide sufficient guarantees to ensure the implementation of security and confidentiality measures.

Recommendation 4.5

It is recommended that all stages of what is done or modified be recorded and kept in a logbook.

The logbook is an essential tool, maintained and updated by team members, which ensures the traceability and comprehensive documentation of events and processes occurring both in the environment and during the study, relating to the protection and monitoring of participants, data management, sample management, etc.

Recommendation 4.6

All epidemiological studies must be accompanied by a quality assurance process⁵⁸.

This process encompasses all operational and accreditation practices that ensure that the study and data collection are conducted in accordance with the protocol, good practices, and applicable laws and regulations. These quality assurance procedures must be defined in advance, before the study begins, and recorded in the logbook.

These quality assurance checks, whether external or internal to the study, must be carried out by persons other than those collecting the data.

Depending on the type of study, it is necessary to assess whether monitoring and follow-up activities are required, as well as their methods and intensity, identifying the key stages at which checks should be carried out. Monitoring by a monitor, who may be a clinical research associate (CRA) or epidemiological research associate (ERA), for example, is the responsibility of the study promotor.

58. The ISO 9000:2015 standards set a number of benchmarks for ensuring quality: <https://www.iso.org/fr/standard/45481.html>.

An incident monitoring system, including the reporting and handling of protocol deviations, data collection errors or adverse events, must be put in place.

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Recommendation 4.7

If a scientific monitoring committee, composed of experts independent of the research team, has been provided for in the protocol, its meetings must be scheduled on a regular basis in accordance with the objectives and key stages of the study's implementation.

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Minutes of meetings must be written and recorded with the study-related documents.

”

Recommendation 4.8

At the end of the study, the investigator must implement the storage, sharing and archiving of all documents related to the study.

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These elements may be analysed, evaluated, commented on or reused at a later date, including in other studies or meta-analyses. They must be available to be shared with any interested natural or legal person, after verification of the scientific quality, objectives and methods of the new study by the promotor and the person responsible for the initial study. Any sharing must be governed by a written agreement between the parties, guaranteeing the protection of sensitive data in accordance with the regulations in force.

If the study is halted during its implementation independently of the study investigator (inability to continue the study, decision by the funder or promotor, etc.), the opinion of any scientific committee involved in the study must be sought on its future (possibility of continuing or archiving all documents related to the study). The personal data protection authority that gave the initial authorisation for the study must be consulted in accordance with the legal procedures in force to agree on the proposed conditions for continuation the study and of archiving of data and documents.





05.

Collection, obtaining, management, storage, archiving and sharing of data



Data is raw information, or a set of information, or even documents (collection notebooks, etc.) that can be stored and processed. Data can be structured, i.e., organised in a specific format such as a database, or unstructured, such as text, images, genomic sequences, audio data, etc. Data can characterise an individual (demographic, epidemiological, medical, socio-economic, behavioural, biological, phenotypic, genetic, etc.), or the environment and living conditions, particularly social, geographical and climatic conditions of groups of individuals (ecological data).

The quality of an epidemiological study depends largely on the origin of the data used. There are two ways of obtaining data: 1) directly, i.e. by collecting it from participants, including results from the biological analysis of clinical samples taken in accordance with the study protocol (primary data), or 2) indirectly, i.e. the secondary use of data initially collected or generated for another purpose, such as data from another study with a new objective, the use of biobanks, the use of surveillance data or big data from large databases, particularly medical-administrative databases, the matching of several databases (secondary data) or data warehouses. In both situations, it is essential to develop a detailed data management plan, ideally prior to collection or acquisition. This plan must specify the conditions and procedures for recording, storing, consistency checking, coding, archiving, confidentiality, integrity and availability of data. Where applicable, the methods for merging (e.g., matching) multiple data sources or extraction in the case of secondary use must be detailed. If AI has been used, this must be mentioned. This will ensure the quality and validity of the data files, respect for anonymity, and facilitate their traceability and availability for other research projects. In the event of merging data from multiple sources, the consistency of the initial collection protocols must be verified, as well as the absence of major discrepancies between the different samples or target populations of the original studies.

Recommendation 5.1

Before beginning to collect or obtain data, it is important to consult with data management experts, such as a DPO⁵⁹ and a data manager or data steward, on regulatory issues as well as data format, security and integrity.

59. CNIL, The Data Protection Officer (DPO), <https://www.cnil.fr/fr/passer-l'action/le-delegue-la-protection-des-donnees-dpo>, (accessed on 24 February 2025).

It is important to strictly comply with the regulations in force in the country, province, territory or state(s) where the study is being conducted⁶⁰.

If the study involves qualitative methods, it is important to work with an expert in this field.

Recommendation 5.2

Before undertaking primary data collection, it is advisable to assess whether existing data that has already been collected and is accessible and shareable can be used to (partially) achieve the study objectives.

This strategy will save time and money and reduce the environmental impact of the study.

Recommendation 5.3

For data collection, valid and reliable collection tools and reproducible methods should be developed or used, and the staff responsible for collection should be trained, while ensuring that the collection procedures are culturally appropriate to the local context.

It is important to recruit data collection staff according to objective technical criteria, including cultural aspects where appropriate, to ensure that they have the necessary skills and qualifications, and to provide them with practical training and support throughout the collection process.

Recommendation 5.4

Before the actual collection of data and biological samples begins, if applicable, it is necessary to test the collection tools and the methods for obtaining, processing, transporting and storing biological samples under real conditions. These field tests must be defined in the protocol. When using diagnostic tests, for example, it is important to ensure that they are valid for the target populations of the study if they differ from the target populations for which the test was designed.

60. See Chapter 1, 'Law, Professional Conduct and Ethics'.

This makes it possible to identify and anticipate problems, particularly with interpretation, to adapt the tools and to ensure optimal, acceptable and respectful data collection.

While direct data collection on electronic media should be preferred whenever possible, paper-based collection may be necessary in difficult field conditions.

Recommendation 5.5

Before implementing data collection or obtaining data, a dictionary of variables should be established and adapted during the study if necessary.

The dictionary of variables provides a comprehensive description of the structure, meaning, relationships and use of the data used in the study. It must be updated with any variables that are modified or created. It will be supplemented by metadata describing the characteristics of the data for the purposes of organisation, search and management, in particular by providing information such as the source, producer, date, format or context.

Recommendation 5.6

Epidemiologists have an obligation to collect only data that is relevant, useful, adequate and not redundant in relation to the objectives of the study; data that is not related to any of the objectives should never be collected.

Recommendation 5.7

Quality and consistency checks must be put in place and carried out on raw data throughout the collection process (daily if possible) in order to identify errors as early as possible so that they can be corrected as close as possible to the point of collection, thereby minimising information and measurement bias.

It is important to have a good understanding of the operational protocol and the context of the study, as well as the characteristics of the data collected, in order to be able to detect anomalies.

Recommendation 5.8

Once data have been collected, they must be quickly entered or transferred (as appropriate) in a secure manner to a database suitable for the planned processing and analysis, and stored in anonymised form to ensure their security.

It is necessary to provide a reliable interface for the uniform entry of study data. Several software programmes, some of which are in the public domain, are designed to ensure the proper entry and editing of data in epidemiological studies, assessments and investigations of epidemics or outbreaks: names and formats of variable fields, codes and values, logical checks and jumps, description and management of metadata, etc. In some studies, data collection may be multimodal, so the possible effects of trends must be taken into account. The technical characteristics of the database must take into account the processing and analysis planned on a stable and shared medium (a relational database should be preferred).

Recommendation 5.9

All stages of cleaning and processing raw data prior to analysis must be documented in the programming code that is saved to ensure that all working files, even temporary ones, are traceable and reproducible.

This enables and facilitates the sharing and future use of data by other epidemiologists. Finally, it helps to ensure consistency from one study to another.

The original raw data files, any intermediate files and the final files after data processing should be kept in separate files.



Recommendation 5.10

Taking into account current data protection and ethical regulations, study data should be made available for reuse in other studies.

Collecting data requires time and resources. When large amounts of data are obtained, not all of it is necessarily analysed for purposes that were not initially planned by the investigators. It is therefore ethical – and sometimes mandatory, depending on the funding body – to make this data available for subsequent reuse in accordance with terms and conditions to be defined based on local recommendations and context (see, for example, Recherche Data Gouv in France⁶¹, the Health Data Hub⁶² or the Progedo-Quetelet repository⁶³). Access to data by other teams must be examined according to a clearly defined process, with transparent and secure conditions for the protection of participants, and with their consent or non-objection.

Under certain conditions (e.g., when there are few cases in a small geographical unit), there may be a risk of re-identification of participants from pseudonymised data. In such cases, the data should not be made accessible. This risk must be analysed on a case-by-case basis in conjunction with the DPO.

Recommendation 5.11

A protocol must accompany any request for secondary use of personal data and justify the quality (bias, accuracy, limitations, etc.) of the data and its relevance (purpose, benefit, efficiency, etc.) in relation to the objectives of the secondary study.

Recommendation 5.12

The use of big data must be tailored to the objective of the study and requires expertise and capacity in data science, bioinformatics and storage for its acquisition, extraction, storage, processing and analysis.

61. Recherche Data Gouv, <https://recherche.data.gouv.fr/>, (accessed on 22 May 2025).

62. Home page | Health Data Hub, <https://www.health-data-hub.fr/>, (accessed 28 February 2025).

63. Quetelet-Progedo – Progedo, <https://www.progedo.fr/donnees/quetelet-progedo/>, (accessed on 16 April 2025).

Big data (or massive data) in health refers to all available data on health, in the broadest sense of the term, collected from various sources. It is increasingly being used secondarily for epidemiological purposes. While the epidemiological use of this data has many benefits, its collection, extraction, use, storage and analysis pose numerous technical and methodological challenges, as well as ethical questions. This data is diverse in nature (omic, physiological, biological, clinical, social, environmental, medical-administrative, etc.), variable in format (text, numerical values, signals, 2D and 3D images, genomic sequences , etc.) and often scattered across multiple information systems. This data is not necessarily interoperable, structured or standardised within the source databases for direct use in an epidemiological study, which requires significant processing of the primary information prior to analysis, skills in bioinformatics and data science in particular, and sufficient computer storage capacity.

Recommendation 5.13

It is necessary to ensure the validity of the extracted data and the variables and indicators constructed from big data by evaluating their performance and metrological quality, as required by the study objectives.

This principle applies regardless of the method used to generate variables or indicators from big data: simple data extraction (e.g., medical procedure codes from a healthcare reimbursement database) or the use of algorithms, particularly AI algorithms.



Special case

Recommendation 5.14

When collecting biological samples, it is imperative that participants be informed of the methods of collection, storage and use (immediate or future), as well as the management of sample banks, and that they have given their consent or expressed their non-objection. Furthermore, the regulations in force on the storage of human body parts and products for scientific purposes must be complied with⁶⁴.

In many epidemiological studies, it is necessary to establish a bank of biological samples (cells, blood, body fluids, tissues, etc.) so that they can be stored and analysed at a later date. The type and quantity of biological material collected, and the immediate or future use of these samples, must be described in the protocol. The same applies to the procedures for accessing these biological samples, as well as the method, structure, location and duration of storage. The institution and persons responsible for managing the sample bank must also be clearly identified. Specific funding must be provided for this within the study. Procedures for the destruction of samples must be established. The informed consent or non-objection of participants on all these aspects must be obtained before the study begins.

Additional references

- **For omics data, refer to the document from the Belgian Superior Health Council⁶⁵.**
- For research data, refer to the French CNRS guide⁶⁶.

64. In France, see Presentation of regulations relating to the storage of human body parts and products for scientific purposes, <https://www.enseignementsup-recherche.gouv.fr/fr/presentation-reglementation-conservation-elements-produits-corps-humain-fins-scientifiques-86272>, (accessed on 27 May 2025).

65. Higher Health Council. The current state of 'omic' technologies and their clinical application. Brussels: CSS; 2021. Opinion No. 9477, <https://www.hgr-css.be/fr/avis/9477/technologies-omiques> (accessed 17 April 2025).

66. Alain Rivet et al., "Guide to best practices in research data management", Marseille, France, Renater, 2022.

06.

Data analysis



The analysis of epidemiological data allows to organise and describe the main variables according to time, place and person characteristics, to report on their quality (missing data, outliers, etc.), and to link the different variables using the statistical approaches defined in the protocol. This will enable conclusions to be drawn in relation to the study objectives and even aid decision-making. This analysis phase must be carried out as soon as possible after data collection, validation and cleaning, as the prevention, management or detection of a disease often depend on of the study results.

Recommendation 6.1

Data analysis must be carried out in accordance with the analysis plan developed in the study protocol⁶⁷.

The analysis plan (univariate, bivariate, stratified, multivariate analyses, etc.) specifies the data and variables to be included, the appropriate statistical models and methods to be used according to the data distribution, the treatment of missing or outlier values, and sensitivity analyses.

However, it is possible to perform an exploratory or post hoc analysis of the data to meet a different or complementary objective, or to test hypotheses that were not explicitly formulated in the analysis plan.

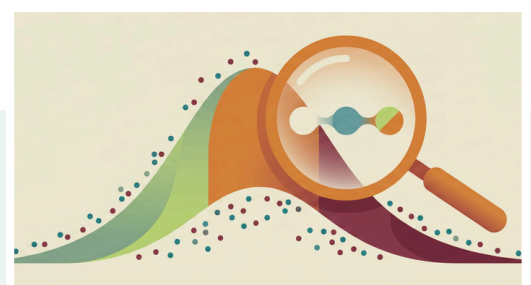
Any significant changes to the analysis plan set out in the protocol must be justified and described transparently in any publication or presentation of the study results. This information will also be useful for systematic reviews of scientific literature.

Recommendation 6.2

Before beginning the analysis of the data according to the analysis plan described in the protocol, it is recommended that a descriptive analysis of the data be performed to familiarise oneself with the data and identify any inconsistencies.

These elements must be documented in the logbook.

67. See recommendation 3.7 in the chapter entitled "Study protocol".



 Recommendation 6.3

Unless explicitly stated in the protocol, no statistical analysis should be performed before data collection is complete or the sample size specified in the protocol has been reached.

Interim analyses may be performed in certain situations, particularly in clinical epidemiology or community intervention trials, if there are concerns about adverse effects of the intervention, uncertainty about the ability to achieve the planned sample size or statistical power, or in emergency situations. This also applies to prolonged or ongoing studies (prospective generalist cohorts and surveillance systems) in order to adapt the data collection protocol or analysis plan in the event of problems not initially identified. Interim descriptive analyses allow for feedback to data sources and collectors (for example, annual analyses of multi-year studies maintain the motivation of collectors). Ideally, these interim analyses should be planned and justified in the protocol after consultation with an independent committee to assess their scientific relevance. Otherwise, the unplanned nature of the analyses must be mentioned when the results are reported.

 Recommendation 6.4

In the case of an emergency epidemiological investigation due to a threat to public health (epidemic, environmental exposure, industrial disaster or climate- , etc.), the analysis must be able to guide the response of public authorities and decision-makers as effectively as possible through repeated analysis over time and space.

In the event of an epidemic or any other threat to health, and in order to manage it more effectively, it is useful to carry out repeated descriptive analyses (according to time, place and person), depending on the situation, on a weekly, bi-weekly or monthly basis, in order to monitor trends as closely as possible and assess the effect of the measures put in place. The results of these repeated analyses must be interpreted with caution. They will be shared with local, national or international public health authorities with a clear mention of all identified limitations and biases to enable informed decision-making. Particular attention will be paid to ensuring that the data is not identifiable, even indirectly⁶⁸.

68. See Chapter 1, "Law, Professional Conduct and Ethics".

In an epidemic situation, mathematical modelling may be useful, or even necessary, to assess the dynamics and effect of the management measures to be recommended. This will require the mobilisation of expertise beyond that of epidemiologists⁶⁹.

Recommendation 6.5

When developing the analysis programme, all stages of the analysis must be commented on and organised according to the analysis plan and in line with the study objectives, in order to ensure transparency and enable understanding and reproducibility.

Recommendation 6.6

It is always preferable to report the parameters that answer the question (incidence or prevalence measure, association measure, effectiveness of an intervention, etc.) with a confidence interval rather than reporting only the statistical test.

For example, the association between two variables should be estimated by a measure of association and not just by a degree of significance (p). Calculating a relative risk (RR) or odds ratio (OR) and its confidence interval allows the direction and strength of the relationship (effect size) to be quantified, whereas the degree of significance (p) depends mainly on the sample size.

Recommendation 6.7

The statistical analysis programmes underlying the results must be documented, annotated and stored in a fully reproducible form after the end of the study, for an extended period of time before being transferred to the archives of the institution to which the epidemiologist responsible for the study belongs.



⁶⁹. See recommendations 3.3 in the chapter entitled "Study Protocol" and 6.9 in this chapter entitled "Analysis".

Recommendation 6.8

If the issue requires it, crucial parts of the statistical analyses should be validated by double programming by an independent epidemiologist, or even by an external audit, before the results are published.

Recommendation 6.9

If mathematical modelling is considered for analysis, it is recommended to follow good practices and work with a biomathematician, biostatistician, econometrician or other modelling specialist.

Mathematical models are increasingly used in data and risk analysis, particularly for infectious diseases. The application of mathematical models to data sets is particularly useful for evaluating management options and even predicting the dynamics of a health phenomenon. The results of such analyses are highly sensitive to the assumptions, data and models used. The calibration and validation of the mathematical model applied to the data are essential issues: the predictive performance of the model will be evaluated by comparison with empirical data, and their uncertainties must be explicitly assessed through sensitivity analyses.

It is therefore necessary to refer to good scientific and ethical practices specific to modelling (see articles in footnotes)^{70,71,72}.

Recommendation 6.10

If AI is used in the analysis, it is essential that the algorithms developed are tested on a dataset that is independent of those used to train the algorithm. It is necessary to comply with good practices in this area and, in particular, with the European law on AI⁷³ or the law of the country concerned if outside the European Union.

70. Chelsea S. Lutz et al., "Applying infectious disease forecasting to public health: a path forward using influenza forecasting examples," *BMC Public Health*, 10 December 2019, vol. 19, no. 1, p. 1659.

71. Hans Heesterbeek et al., "Modelling infectious disease dynamics in the complex landscape of global health," *Science* (New York, N.Y.), 13 March 2015, vol. 347, no. 6227, p. aaa4339.

72. Lisa A. Boden and Iain J. McKendrick, "Model-Based Policymaking: A Framework to Promote Ethical 'Good Practice' in Mathematical Modelling for Public Health Policymaking," *Frontiers in Public Health*, 5 April 2017, vol. 5.

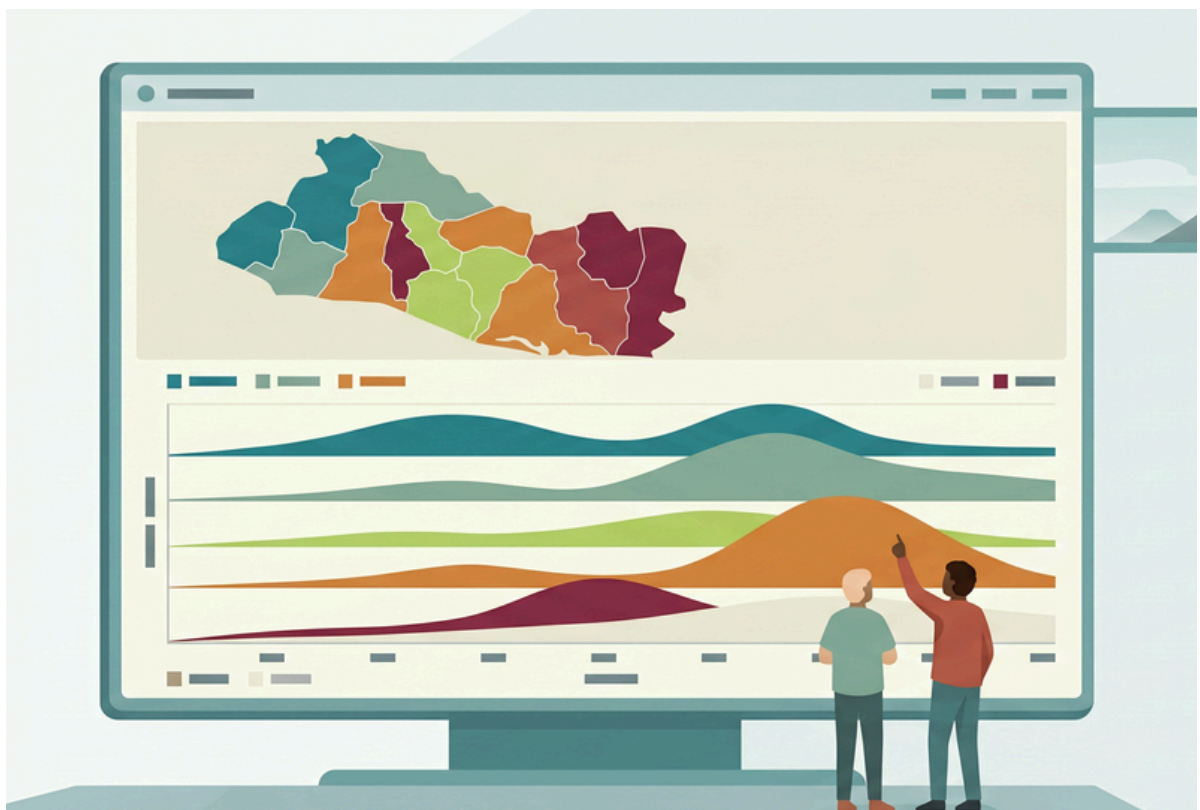
73. See recommendation 1.13 in the chapter entitled "Law, Professional Conduct, Ethics."

Special case

Recommendation 6.11

During systematic reviews and meta-analyses, it is necessary to check whether any articles selected during the literature search have been retracted by the publisher and to explicitly exclude them from the analysis.

Retraction may occur after the literature review or meta-analysis has been completed or even published. In this case, it is the responsibility of the investigators to redo the analysis without the retracted studies and, if the study has been published, to transparently inform the journal editor by modifying the results without the retracted studies⁷⁴.



74. Cary P. Gross et al., "Mitigating the Impact of Retracted Studies in the Medical Literature," JAMA Internal Medicine, 31 March 2025.

07.

Interpreting study results



Interpreting the results of an epidemiological study means giving them meaning based on the question(s) asked in the protocol, arguing the strengths and weaknesses of the study. This step should not be left to the study promoters, the administration, social decision-makers, politicians or the media. It is one of the essential tasks of the epidemiologists who conducted the study and falls directly under their scientific responsibility. The interpretation may require the involvement of the population concerned or its representatives.

Recommendation 7.1

The interpretation of the results must be presented in a transparent and comprehensible discussion, based on an up-to-date scientific bibliography in the field of epidemiology and other relevant disciplines (e.g., clinical, biological, environmental, One Health or social).

When a statistical association is identified, the following possibilities that may explain it should be analysed before drawing conclusions⁷⁵: chance, selection bias, information bias, confounding and limitations of the study design. The issue of residual confounding once the analysis is complete is a recurring one in the interpretation of analytical observational studies. It can be assessed by calculating the E value proposed in 2017, which estimates the minimum strength of association (and its confidence interval) that an unmeasured confounding factor would need to have in order to explain the observed association, thereby helping to interpret any unmeasured confounding factors⁷⁶.

The results must be put into perspective and compared with an up-to-date scientific bibliography in order to make them understandable, relevant and meaningful. Indeed, demonstrating a causal link between two variables and/or events is often the ultimate goal of investigating an epidemiological question. It is necessary to present and discuss the evidence provided by a study, in addition to that found in the scientific literature. For this, one can refer to Hill's article⁷⁷, which proposes nine points of view to discuss, commonly referred to as "criteria for causality". These points have been the subject of much discussion in the scientific literature^{78,79} and, with hindsight, some appear more relevant than others. While there is no consensus on this subject,

75. Dicker RC. Analyzing and Interpreting Data, <https://www.cdc.gov/field-epi-manual/php/chapters/analyze-interpret-data.html>, 6 January 2025 (accessed 20 April 2025).

76. VanderWeele TJ, Ding P. Sensitivity Analysis in Observational Research: Introducing the E-Value. *Ann Intern Med*. 15 August 2017;167(4):268-274. doi: 10.7326/M16-2607. Epub 11 July 2017. PMID: 28693043.

77. Austin Bradford Hill, "The Environment and Disease: Association or Causation?", *Proceedings of the Royal Society of Medicine*, May 1965, vol. 58, no. 5, pp. 295-300.

78. Shimonovich M et al. Assessing causality in epidemiology: revisiting Bradford Hill to incorporate developments in causal thinking. *Eur J Epidemiol*. 2020 Dec 16;36(9):873-887. doi: 10.1007/s10654-020-00703-7. PMID: 33324996.

79. Dumas O, Siroux V, Le Moual N, Varraso R. Approaches to causal analysis in epidemiology. *Rev Epidemiol Sante Publique*. 2014 Feb;62(1):53-63. French. doi: 10.1016/j.respe.2013.09.002. Epub 2014 Jan 1. PMID: 24388738

when interpreting causality, it is better to refer to theoretical models of causality and use an analysis based on a causal diagram (particularly DAGs). DAGs, which represent the links between variables, allow to visualise the causal relationship between different variables. This representation provides a model of the relationship between the exposure and the variable to be explained and the other variables that may be involved in the relationship. DAGs are therefore very useful in the design (study protocol) to structure the analysis, interpret observational studies and help to better identify the mechanisms of the various biases that may affect their validity^{80,81,82}.

Recommendation 7.2

Important results should be highlighted in the discussion, whether they are new or not, especially if they have implications for the health of the individuals and populations studied.

Epidemiological studies, particularly descriptive ones, regularly highlight the importance of public health issues that are not sufficiently addressed. The interpretation and promotion of these results from a public health advocacy perspective are essential.

Recommendation 7.3

Insights from other scientific disciplines (medicine, physiopathology, biology, genomics, ecology, environmental sciences, One Health, humanities and social sciences, ethics, etc.) are useful, even necessary, for interpreting the results, distinguishing in the discussion between the study's own results and the contributions of other disciplines. However, it should take into account the authors' expertise.

Recommendation 7.4

The discussion of the results should also present the strengths and limitations of the study.

80. Greenland S, Pearl J, Robins JM. Causal diagrams for epidemiological research. *Epidemiology*. 1999 Jan;10(1):37-48. PMID: 9888278.

81. Tennant PWG, Murray EJ, Arnold KF et al. Use of directed acyclic graphs (DAGs) to identify confounders in applied health research: review and recommendations. *Int J Epidemiol*. 2021 May 17;50(2):620-632. doi: 10.1093/ije/dyaa213. PMID: 33330936; PMCID: PMC8128477.

82. DAGitty — draw and analyse causal diagrams. <https://www.dagitty.net/>

The limitations of a study refer to constraints (in particular any specific characteristics of the sample), flaws and biases that may arise at each stage. It is important to be transparent about these limitations, to describe their impact on the interpretation of the results and to be cautious about generalising them to other populations or contexts (external validity). The strategies and means put in place to overcome these limitations must also be explained. This description may include sensitivity analyses. Conversely, the strengths must be mentioned to support the quality and validity of the results.



Recommendation 7.5

The statistical power of the study must be taken into account.

Statistically non-significant results are of real interest if they are obtained with good statistical power. These non-statistically significant results are informative of the absence of an association (with, of course, an *a priori* risk of error).

Conversely, statistically significant results obtained from very large samples should be interpreted with caution. They may correspond to a very small difference between the groups compared, and the "effect size" is then very limited and its practical value must be discussed in terms of its public health or clinical impact.



08.

Scientific communication



Initially, communication of the work carried out by epidemiologists should target the scientific community before being extended to the social and professional fields, the general public and public decision-makers. However, in the event of a public health emergency, priority should be given to presenting the findings to the relevant decision-makers.

Publication and scientific communication enable the results of an epidemiological study to be disseminated and should, ideally, be synchronised. They include the key elements of the protocol, in particular the justification, the objectives of the study and the methodological elements, as well as the analysis of the data collected, the results, their interpretation, discussion and conclusion.



Recommendation 8.1

Results should always be made public, even if they are not what was expected.



The results of a well-conducted study are equally important whether they show a statistically significant association validating the initial hypotheses or whether they show no statistically significant association (if the study has sufficient power). Thus, if the number of participants required by the protocol has been reached, refusal to disclose or publish results should not be justified by the fact that these results do not confirm the initial hypotheses. The risk is that this could lead to harmful publication bias.

If the results show a statistically significant association that contradicts the initial hypotheses and differs from the scientific literature, they must also be made public after verifying that they are not the result of an error or unanticipated bias.

Withholding information or refusing to disclose results can only be justified in exceptional circumstances, for example, when methodological problems encountered during the study render the results meaningless.

All study results, whether publicly or privately funded, are under the scientific responsibility of the study investigators, not the funder, promotor or organisation to which the epidemiologists belong. Any request not to disclose certain results, to change or tone down the content of a publication, or to delay the publication of results is unethical, unprofessional and dishonest, and must be rejected.

Recommendation 8.2

Scientific publications must follow relevant and validated editorial standards.

There are numerous guidelines for academic reporting depending on the type of study conducted and the populations studied, for example STROBE for observational studies, PRISMA for systematic literature reviews, and STROBE-Vet for animal epidemiological studies. The EQUATOR (Enhancing the QUALity and Transparency Of health Research) network lists more than 660 guidelines and offers a decision tree to facilitate the choice of procedures to follow⁸³. These guidelines make it easier for published manuscripts to be understood, reproduced, used for clinical or public health decision-making, and possibly included in a systematic review of the literature⁸⁴.

Recommendation 8.3

Scientific publications should contain a critical discussion of the data collected, methods and results, based on up-to-date bibliographic research⁸⁵.

Recommendation 8.4

The publication should describe all aspects of the study in a reasonable and balanced manner, without taking into account other interests, particularly non-scientific ones. Any links or conflicts of interest and sources of funding, as well as the context in which the study was conducted, should be explicitly mentioned.

83. Daniel R. Shanahan, Ines Lopes De Sousa, and Diana M. Marshall, "Simple decision-tree tool to facilitate author identification of reporting guidelines during submission: a before–after study," *Research Integrity and Peer Review*, December 2017, vol. 2, no. 1, p. 20.

84. What is a reporting guideline? | EQUATOR Network, <https://www.equator-network.org/about-us/what-is-a-reporting-guideline/> (accessed 27 January 2025).

85. See Chapter 7, 'Interpretation of results'.

Epidemiologists should not exaggerate their conclusions in order to increase their chances of obtaining more funding for future research or to make their articles more attractive to a journal's editorial board. The results of a published study generally constitute only a small part of the scientific information available, and any bias in the choice of published data by selecting results that converge with the research hypothesis and, even more so, with the epidemiologist's point of view, or by ignoring contradictory results, is to be avoided and goes against the principles of scientific integrity⁸⁶.

Recommendation 8.5

A scientific publication must be signed by all the actual authors of the study, and only by them, thereby publicly committing their personal responsibility.

For the definition of authorship, please refer to the rules for scientific publication adopted by the International Committee of Medical Journal Editors (ICMJE)⁸⁷. All signatories to the publication must have made a substantial contribution 1) to the design of the work or to the acquisition, analysis or interpretation of data; 2) the writing or critical revision of important intellectual content; 3) formally approved, in writing, the final version to be published; and 4) agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Signing as a co-author to acknowledge someone should be prohibited. All individuals who contributed to the study but do not fully meet the four conditions recommended by the ICMJE should be cited in the acknowledgements of the article. The role of those acknowledged must be specified and their agreement to such acknowledgement must be obtained. The acquisition of funding, the provision of facilities, and laboratory supervision do not in themselves justify authorship.

Regarding the order of authors, while there are no universally recognised rules, principles are proposed by research organisations, among others, but these may vary slightly depending on the discipline and country. For example, a French document from Aviesan Sciences de la vie⁸⁸ proposes principles that apply in the field of health. But the decision is ultimately a matter for prior discussion between the authors of the study.

86. See Chapter 1, "Law, Professional Conduct, Ethics".

87. ICMJE | Recommendations, <https://www.icmje.org/recommendations/> (accessed 21 August 2024).

88. https://pro.inserm.fr/wp-content/uploads/2020/08/recommandationssignature_article_-Aviesan_2019.pdf

Recommendation 8.6

Epidemiologists who author scientific publications should exercise restraint when citing their own work or articles by colleagues from the same research or educational institution. Bibliographic references should be directly related to the content of the study being published.

Recommendation 8.7

Scientific publications must be peer-reviewed.

This review is organised independently by the editors of scientific journals. This principle must also be applied to the review of study reports published by the institution to which the study investigators belong or are affiliated, and which have not yet been accepted by a scientific journal. This principle, which implies the responsibility of the epidemiologist, must be guaranteed by the institution to which they belong or are affiliated.

However, it is increasingly common for scientific articles to be made available as preprints at the time of submission and before acceptance. This may be on an open archive site such as HAL⁸⁹, on scientific journal preprint sites, or on preprint sites such as medRxiv⁹⁰. Given the time required for publication, this approach allows to make work and results that have not yet been formally evaluated, and therefore cannot and should not be considered scientific publications, available to the scientific community more quickly. This approach also allows authors who submit their manuscripts to establish a date and protect the priority of their discoveries. Some preprint sites have a discussion forum which, when active, provides critical analysis of the study and gives an idea of the quality of the articles submitted. Furthermore, the submission of a document for pre-publication does not prevent epidemiologist readers from reviewing the article with the same care as if they were reviewers for a journal. The guide "Preprints: a practical guide"⁹¹ is a useful guide to information, use and good practices in this area. Reference can also be made to the good practices formulated by the Centre for International Cooperation in Agricultural Research for Development (CIRAD)⁹².

89. <https://hal.science/>

90. medRxiv.org - the preprint server for Health Sciences, <https://www.medrxiv.org/> (accessed 10 March 2025).

91. Kristina Hettne et al., "Preprints: a practical guide," 2021. Kristina Hettne et al., « Les préprints : guide pratique », 2021. <https://shs.hal.science/halshs-03470613v1/document>

92. Deboin Marie-Claude, Making your draft article public on a preprint site, s.l., CIRAD.

Recommendation 8.8

Peer review of scientific articles or reports must be impartial and independent.

Epidemiologists acting as peers for the peer review of scientific articles or reports must avoid any bias. This impartiality and independence are important for maintaining scientific quality and public confidence in epidemiological results. Reviewers assess the originality, scientific quality, clinical or public health relevance, and interpretation of the article, and evaluate the article as a whole, including its suitability for publication.

A peer reviewer should not accept to review an article if this puts them in a position of bias or conflict of interest, because they work too closely with one of the authors or are competitors in the same field. The reviewer must respect the confidentiality of the hypotheses, methods and research results of the studies they review and must complete this work within a reasonable time frame. They must not attempt to influence a publication project for personal gain.

Recommendation 8.9

While an epidemiological study may legitimately give rise to several scientific publications reporting original and complementary results, under no circumstances should the same results be published multiple times, as this is contrary to the principles of scientific integrity and ethics⁹³.

There is a limitation to this recommendation when republishing in a journal in a language other than that of the original publication. However, this cannot be done without the prior consent of the original journal.



93. See Chapter 1, "Law, Professional Conduct, Ethics."

Recommendation 8.10

As far as possible, research results should be published in open access and free of charge, guarding against predatory journals, or deposited after publication on an open archive site such as HAL.

Diamond Open Access allows completely free access to scientific information, from authors to readers, which promotes the dissemination of knowledge. This is not always possible due to embargoes imposed by certain journals. The European Union and countries such as Belgium⁹⁴ and France⁹⁵ require or allow any work that is at least half funded by public funds to be made accessible, regardless of the contract signed with the publisher. In addition, to facilitate the dissemination of scientific articles, a recognised free and open access publication system can be used (Peer Community In)⁹⁶.

It is also important to avoid publishing in predatory journals, which often promote their open access for readers and the speed with which articles are accepted and published. These factors in no way guarantee the quality of the results and conclusions, since the peer review process is either bypassed or biased. It is therefore the responsibility of epidemiologists, with the help of their institutions, to avoid contributing to predatory journals and to evaluate the journals to which they intend to submit their work before doing so. To do so, they can consult the recommendations of the French Office for Scientific Integrity (OFIS)⁹⁷ or the recommendations made on the websites of universities or academic organisations (e.g., those of Sorbonne University)⁹⁸, which are regularly updated. The University of Liège library offers an online test to assess the status of predatory publishers or predatory journals⁹⁹.

Recommendation 8.11

In the field of human health, scientific manuscripts submitted for publication must meet the requirements of the International Committee of Medical Journal Editors (ICMJE)¹⁰⁰. The principles set out in this reference document are applicable to epidemiological studies carried out in animal health or within the framework of One Health.

94. ULB, Sharing and preserving your scientific work – Open Access, <https://bib.ulb.be/fr/support/chercheurs/partager-et-preserver-vos-travaux-scientifiques> (accessed on 4 April 2025).

95. Law for a Digital Republic, <https://www.vie-publique.fr/loi/20755-loi-pour-une-republique-numerique> (accessed on 27 May 2025).

96. Peer Community In - free peer review & validation of preprints of articles, <https://peercommunityin.org/> (accessed on 16 April 2025).

97. Predatory journals, <https://www.ofis-france.fr/espaces-thematiques/revues-predatrices/> (accessed 10 March 2025).

98. List of journals recommended by the Conference of Deans, <https://sante.sorbonne-universite.fr/recherche/liste-des-revues-presumees-non-predatrices> (accessed 10 March 2025).

99. <https://services.lib.uliege.be/compass-to-publish/test>

100. ICMJE | Recommendations, <https://www.icmje.org/recommendations/>, art cit.

Recommendation 8.12

Epidemiologists should also disseminate the results of their studies through other means of scientific communication (symposiums, seminars, conferences, public information notes, etc.).

Participation in these events allows them to share their results with the wider scientific community and open them up to scientific discussion. Nevertheless, it is important to be aware of the variability in the quality of these events, given that selection is based on the analysis of abstracts and that the issue of funding and private interests may arise (unless a declaration of interests is required).

Recommendation 8.13

The procedures for accessing data and the steps to be taken to carry out any other analysis/work that other teams may wish to undertake shall be communicated in an appropriate manner, in particular via the institutional website of the referent epidemiologist's organisation, after consultation with the DPO (refer to the rules and good practices in force in the country concerned).



09.

Public and social promotion



Beyond the scientific and public health community, the results of epidemiological studies must be communicated and promoted to society, its representatives, stakeholders and public decision-makers.



Recommendation 9.1

Public communication must await scientific peer review.



Epidemiologists should only make the results of a study public or inform the mainstream media when they are based on a publication or report that is accessible, has been peer-reviewed, or has been presented and discussed at a scientific conference in the presence of peers, and when the study participants have been informed in advance¹⁰¹.

Exceptions to this principle can only be made in certain specific situations (health emergencies, epidemics, etc.). For example, epidemiologists may discover a health risk requiring rapid or even immediate control measures (withdrawing a contaminated food product identified by an epidemiological investigation, etc.). Their recommendations to public authorities or managers must be based solely on objective and scientific data. However, in situations where the public health interest of the results prevents the usual peer review process from taking place, it is highly desirable that an independent expert recognised by peers be asked to carry out a critical analysis of the study as soon as possible before it is made public. Those affected by the study must be informed of this prior to the public release of the results.



Recommendation 9.2

Epidemiologists should plan to communicate the results of their studies to the population concerned, but also to the general public, social and business actors, public decision-makers, particularly those involved in health policy, and more broadly to the relevant stakeholders.



It is contrary to the collective interest for the results obtained to be unavailable or unable to be taken into account by citizens, public decision-makers or representatives of the community or population where the study took place. This communication is part of the social and ethical responsibility of epidemiologists and their institutions.

101. See Chapter 8, 'Scientific Communication'.

The language, format and means of accessing information must be appropriate and tailored to the different target audiences, and adequately simplified (health literacy¹⁰²). In communication with the public, particularly via social media, while the form must be designed to be understandable to everyone, the content must remain faithful to the scientific approach by indicating limitations and uncertainties, particularly in the interests of the general public and public health action.

Experience has shown that certain results may be interpreted and disseminated in a partial, biased or even erroneous manner by the media, stakeholders with an interest in the study results, or political authorities. Epidemiologists must play an active role in communicating the results clearly, reliably and objectively, and putting them into perspective for society. It is advised to be factual and cautious about the implications of the results when uncertainties remain.

Recommendation 9.3

In all circumstances, epidemiologists appearing in the mainstream media or on social media must be educational, take care to remain within their field of expertise and stick to subjects for which they have reliable data. They should be accompanied by the communications departments of their institutions.

Epidemiologists must refuse to be drawn into areas that are not their own. While their advocacy role is essential, they must also refuse to go beyond reasonable scientific interpretation, for example by taking positions that could be interpreted as excessive or even militant. Live broadcasts are risky, recorded broadcasts are uncontrollable, and requests for corrections are not always taken into account.

Recommendation 9.4

If the results imply recommendations to the public health authority, it is up to epidemiologists to draft them, in conjunction with other types of expertise (biological, medical, socio-economic, environmental, etc.), taking the necessary distance and taking into account the principles set out in the charter for health expertise¹⁰³ or similar standards¹⁰⁴.

102. Stephan Van den Broucke, "Health literacy: a critical concept for public health", La Santé en Action, 2017, vol. 2017, p. 11.

103. Decree No. 2013-413 of 21 May 2013 approving the charter of health expertise provided for in Article L. 1452-2 of the Public Health Code - Légifrance, <https://www.legifrance.gouv.fr/loda/id/LEGISCTA000027435246>, art cit.

104. Afnor has published a standard on expertise (NF X50 110): <https://www.boutique.afnor.org/fr-fr/norme/nf-x50110/qualite-en-expertise-prescriptions-generales-de-competence-pour-une-experti/fa118385/21460>

Scientific publications may lead to a reconsideration of previously established clinical or public health recommendations. It will then be the responsibility of epidemiologists to contribute to updating recommendations within expert groups of public health organisations and agencies whose institutional and collegial mission is to put the epidemiological results generated into perspective. These organisations vary from country to country. Here are a few examples in France (HCSP¹⁰⁵, ANSES¹⁰⁶, HAS¹⁰⁷, INCA¹⁰⁸); Belgium (AFMPS¹⁰⁹); Canada (PHAC¹¹⁰, INSPQ¹¹¹ for the province of Quebec); and Africa (Africa-CDC¹¹²).



105. High Council for Public Health: <https://www.hcsp.fr/explore.cgi/Accueil>

106. National Agency for Food, Environmental and Occupational Health Safety: <https://www.anses.fr/fr>

107. High Authority for Health: <https://www.has-sante.fr/>

108. National Cancer Institute: <https://www.cancer.fr/>

109. Health Canada: <https://www.afmps.be/fr>

110. Public Health Agency of Canada: <https://www.canada.ca/fr/sante-publique.html>

111. Quebec National Institute of Public Health: <https://www.inspq.qc.ca/>

112. African Centre for Disease Control and Prevention: <https://africacdc.org/>



Discussion and perspective



Discussion

Initially, the revision of the GPE guidelines was based on a scoping literature review and a series of interviews with professionals covering all fields and practices of epidemiology in French-speaking countries and regions. This allowed to identify the changes needed compared to the 2007 edition and to propose new practices to be covered. It also involved a scientific committee, composed of 23 epidemiologists belonging to the four associations promoting the revision of the GPE, which contributed directly to their structuring and drafting. As a result, 92 good practice recommendations organised into 9 chapters (the number of recommendations varies from 4 to 14 depending on the chapter) are proposed in this new edition.

This document is a guide to good practices in epidemiology and not to good practices in public health, which would involve recommendations of a different and much broader nature. The GPE apply to all fields of epidemiological practice (research, studies, surveillance, urgent investigations, etc.) and are fairly universal, with few specific features, particularly in the areas of animal health and occupational health. Initially, the question arose as to whether a chapter should be dedicated to specific features, but in the end these were incorporated into the various chapters of the guide when deemed relevant.

The revised GPE address new issues that have emerged since 2007. They take into account the social dimension (particularly through health inequalities) and participatory aspects, and emphasise the importance of collaboration between fields of application (One Health, Planetary Health) and disciplines, particularly the humanities and social sciences. These topics are still evolving, and a very recent article highlights the importance of redefining human health to facilitate the effective implementation of One Health approaches¹¹³. Furthermore, the emergence of issues raised by big data and AI is real but was not materialised into a specific chapter, as the questions that arise for the practice of epidemiology can be integrated into more cross-cutting chapters.



113. Thierry Lefrançois et al., "A new definition of human health is needed to better implement One Health," *The Lancet*, 2025; 406:672-675. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(25\)01015-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)01015-3/fulltext)

Writing this guide required careful consideration of the level of detail in the recommendations. It was necessary to find a balance between providing too much detail, in an overly precise or even prescriptive manner, and being too general and insufficiently practical. The decision was also made to refer to existing and recognised standards where they existed, rather than attempting to formulate recommendations that were likely to be less precise or incomplete. This balance was achieved through exchanges between reviewers and discussions within the SMC, with the diversity of practices and contexts of exercise of its members contributing significantly to this.

Any explicit reference to national legislation or personal data protection or ethical bodies is given as an example according to the country, province, territory or state, and does not serve as a reference for all French-speaking countries. The references provided are not exhaustive or complete for all French-speaking countries to which this guide is addressed. It is always advisable to refer to the regulations in force in the country, province, territory or state where epidemiologists practise.

Recommendations based on the level of evidence from the literature review (GRADE¹¹⁴) for good clinical or public health practice recommendations are not applicable, as they relate to good practices in a discipline, epidemiology, and not good practices for the management of a specific disease or preventive intervention in public health. Good practices here are based more specifically on values and principles including scientific quality, integrity and ethical values. They are the result of collective and transdisciplinary work involving numerous discussions organised within the SMC, numerous reviews and external expert opinions. They can therefore be considered representative of the current consensus within the French-speaking epidemiological community. Nevertheless, the recommendations in the GPE guide are not exhaustive and concern only the most common practices. They provide a framework for the epidemiological approach to be followed and must be applied with discernment according to the situation and taking into account the context. Only epidemiological expertise based on peer review and, if necessary, a scientific or ethics committee can assess the justification for any deviations from these recommendations. Feedback should then be provided to the four promoting associations on the situation that required a deviation so that the guide can be updated if necessary.



Perspective

The recommendations proposed in this French-language GPE guide should not be understood as a rigid set of standards, given that epidemiology is a living discipline that is constantly evolving and undergoing constant innovation. Indeed, these recommendations have a limited validity period (3 to 5 years according to the HAS guide¹¹⁵) and it is important to start thinking about their next revision now. One option could be to make it a living, collaborative document, in which the recommendations are regularly updated by the relevant scientific community before being validated by the promoting institutions.

The evolution of the fields of application of epidemiology, data, particularly big data, the place and role of AI, concepts (One Health, Planetary Health), modes of publication and social promotion, and participant involvement (participatory science) means that we need to anticipate now the prospects for future revision and adaptation of the GPE in a form to be specified by the four promoting associations. This could involve maintaining regular monitoring and coordination within a dedicated working group or network of epidemiologists (shared email address, annual review during scientific conferences and meetings, case studies, etc.) to keep abreast of news, emerging topics and changing concepts.

Issues of integrity, professional conduct and ethics underpin many good practices. The population dimension specific to the discipline of epidemiology (and public health) can create tension between ethical values (the general interest versus individual autonomy or social justice versus economic interests, for example). With this in mind, it will be important to ensure fairness in countries with limited resources (particularly French-speaking Africa) when funders and promoters come from so-called rich countries.

These updated GPE target French-speaking countries and are, at the date of publication, the most recent to have been thoroughly updated. It will be important to establish a dialogue with international epidemiology associations and learned societies in order to implement GPE at the global level.

The four epidemiology associations that sponsored the revision of French-speaking GPE will promote them through a communication strategy targeting members of the epidemiological community and, more broadly, the public health community, public decision-makers and society as a whole. Promoting the GPE will also be essential for training in epidemiology (academic and professional training).

115. Update of good practice recommendations and care pathways, https://www.has-sante.fr/jcms/p_3312383/fr/actualisation-des-recommandations-de-bonne-pratique-et-des-parcours-de-soins, (accessed 17 June 2024).





Guide of good practices in epidemiology

2025 Revision

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