Available online at
ScienceDirect
www.sciencedirect.com
Elsevier Masson France
EM|consulte
www.em-consulte.com
Revue d'Épidémiologie et de Santé Publique
Epidemiology and Public Health
Revue d'Épidémiologie et de Santé Publique 62 (2014) 207–214

Recommendations

Guide to good practices to ensure privacy protection in secondary use of medical records

C. Riou [a,*], J. Fresson [b], J.L. Serre [c], P. Avillach [d,e], L. Leneveut [d], C. Quantin [f] pour le groupe de travail CIMES, CUESP, CNIM, CCTIRS, CNIL [1]

[a] *Département d'information médicale, CHU de Rennes, rue Henri-Le-Guilloux, 35033 Rennes cedex 9, France*
[b] *Département d'information médicale, maternité régionale universitaire de Nancy, 54042 Nancy cedex, France*
[c] *Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé, 75231 Paris cedex 05, France*
[d] *Département informatique et santé publique, hôpital européen Georges-Pompidou, AP–HP, 75015 Paris, France*
[e] *Inserm UMR_S 872 eq22, faculté de médecine René-Descartes, université Paris 5, 75006 Paris, France*
[f] *Service de biostatistiques et informatique médicale, CHU de Dijon, 21079 Dijon cedex, France*

Received 27 February 2014; accepted 14 March 2014

The present provisional version was submitted to the CNIL and the CNOM for review. A few modifications may be made for the final version. The rules of good practices may also be updated so as to take into account any changes in regulations as well as working group conclusions on access to nominative medical records to be composed at the request of the French Hospital Federation (fédération hospitalière de France), to which the French Language Medical Information Society (Société francophone d'information médicale [SOFIME], President Gabriel Nisand) has requested to be included. Further work seems necessary to draw up a guide to good practices on the production of medical information in healthcare institutions to take into account specific characteristics of the different institutions (e.g., public versus private sectors) and changes in regulations.

Preface

This document is the result of the reflection of a working group whose participants included members of the colleges of professors of biostatistics, medical informatics, and public health (CIMES and CUESP), the National College of Medical Information (Collège national de l'information médicale [CNIM]), the Advisory Board on Medical Research Data Processing (Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé [CCTIRS]), and the French Personal Data Protection Authority (Commission nationale informatique et libertés [CNIL]).

This group was created in response to the growing demand for secondary use of medical records, notably with the Medical Information Departments (départements d'information médicale [DIM]), which occupy a strategic position as directors of medical data analysis and guarantors of the privacy of medical records in healthcare institutions.

The group's objective was to propose rules of good practice for the secondary use of patient medical records aimed at DIMs, researchers, and healthcare institutions.

The rules drawn up concern studies using heath data collected previously during healthcare procedures or for medical-economic purposes. They include data access conditions, regulatory procedures, the healthcare providers authorized to have access, and procedures for informing the patient.

These rules have no binding legal value. They comprise a review of the procedure so that medical records collected within healthcare institutions can be used with full respect of the regulations.

Abbreviations: ARC, attaché de recherche clinique (clinical research associate); CIL, correspondant informatique et libertés (data and liberties correspondent); CNIL, Commission nationale informatique et libertés (French Personal Data Protection Authority); CCTIRS, Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé (Advisory Board on Medical Research Data Processing); CNOM, Conseil national de l'ordre des médecins (French medical council); DIM, département d'information médicale (Medical Information Department); IPAQSS, Indicateurs pour l'amélioration de la qualité et de la sécurité des soins (indicators for improving quality and safety); PMSI, Programme de médicalisation du système d'information (Patient Care Classification System); RHA, résumé hebdomadaire anonyme (weekly anonymous summary); RSA, résumé de sortie anonyme (anonymous discharge summary); RSS, résumé standardisé de sortie (standardized discharge summary); TEC, technicien d'étude clinique (clinical study technician); TIM, technicien d'information médicale (medical information technician).

* Corresponding author.
E-mail address: christine.riou@chu-rennes.fr (C. Riou).

[1] Working group composed of: F.A. Allaert, H. Aubé, P. Avillach, J.M. Cauvin, C. Colin, G. Chatellier, M. Cuggia, C. Daniel, J. Fresson, B. Garrigues, M. Goldberg, A. Lang, J.F. Laurent, L. Leneveut, C. Quantin, D. Rahal-Löfskog, C. Riou, E. Rial Sebagg, J.L. Serre, F. Séguret, M. Zins.

http://dx.doi.org/10.1016/j.respe.2014.03.005
0398-7620/© 2014 Elsevier Masson SAS. Open access under CC BY-NC-ND license.

Group members

Group coordination	Christine Riou, hospital practitioner, DIM, Rennes University Hospital, France
François André Allaert	Dijon University Hospital, CENBIOTECH, France
Hervé Aubé	DIM, Dijon University Hospital, France
Paul Avillach	Service informatique hospitalière et santé publique, hôpital européen Georges-Pompidou, AP–HP, Paris, France Inserm UMR_S 872 équipe 22, University Paris Descartes, France
Jean-Michel Cauvin	DIM, Brest University Hospital, France
Cyrille Colin	Pôle information médicale, évaluation, recherche, hospices civils de Lyon, France
Gilles Chatellier	Service informatique hospitalière et santé publique, hôpital européen Georges-Pompidou, AP–HP, Paris, France
Marc Cuggia	Inserm UMR 1099 LTSI, faculté de médecine, University Rennes 1, France
Christel Daniel	Centre de compétences et services du système d'information patient, AP–HP, Paris, France Inserm UMRS 872, équipe 20, University Paris Descartes, France
Jeanne Fresson	Maternité régionale universitaire de Nancy, CCTIRS France
Bernard Garrigues	DIM, CH Aix-en-Provence (president of the CNIM) France
Marcel Goldberg	Inserm U1018, University Versailles – Saint-Quentin, France
Astrid Lang	Centre de compétences et services du système d'information patient, AP–HP, Paris, France
Jean-François Laurent	Coordination 3C, centre Catherine-de-Sienne, Nantes, France
Laurence Leneveut	Service informatique hospitalière et santé publique, hôpital européen Georges-Pompidou, AP–HP, Paris, France
Catherine Quantin	Service de biostatistiques et informatique médicale, Dijon University Hospital (former president of the CIMES), France
Délia Rahal-Löfskog	CNIL, service des affaires juridiques, Paris, France
Emmanuelle Rial Sebagg	Inserm U1027, Toulouse, France
Jean-Louis Serre	President of the CCTIRS, France
Fabienne Séguret	DIM, Montpellier University Hospital, France
Marie Zins	Inserm U1018, University Versailles–Saint-Quentin, France

1. Introduction

Today it is emerging that the data collected in healthcare institutions for patient care or in medical-economic databases (Patient care classification system; programme de médicalisation des systèmes d'informationé [PMSI]) hold major potential for clinical and epidemiological research, vigilance programs, care quality and medical practices assessment, and public health in general. Crossing clinical and genomic databases is becoming imperative in biomedical research.

The patients' electronic medical records are being extended to healthcare institutions, facilitating data access by making data more readily available and easier to use directly.

Biomedical data warehouses are being set up, as are warehouses of medical-economic data, supplied from hospital information systems. They make it possible, for example, to examine the feasibility of a study, to create patient cohorts, and they can be the basis for production of health indicators or for the institution's management indicators.

The requests for access to healthcare institutions' medical files are growing, by both internal and external organizations. We can cite the IPAQSS (Indicateurs pour l'amélioration de la qualité et de la sécurité, indicators for improving quality and safety) audits, the evaluation of care within a network, the surveys of institutions by external companies, the prescreening phases in clinical research, the multicenter evaluation of healthcare practices, and the validation of data collection by researchers external to the institution. Similarly, DIMs are increasingly solicited to transmit PMSI data (audits, registries, assessment studies, indicator production).

It should be emphasized that the secondary use of medical records outside the care setting changes the finality of the data analysis compared to the context in which these data were collected: they were initially collected for the medical management of individuals. Setting up electronic medical records in a healthcare institution requires a declaration with the French Personal Data Protection Authority (Commission nationale informatique et libertés [CNIL]). From that moment on, any use for purposes other than the care and follow-up of these individuals requires a new procedure within the CNIL aimed at declaring this new purpose. Although for biomedical research[2] or prospective epidemiological research, the procedures seem to be well known[3], guidance for other uses deserves to be specified more clearly.

The guide does not include the situations covered by regulations such as external inspection or accreditation visits.

Two cases are differentiated:

- access to personal medical records within the institution by the institution's health professionals without these data being communicated outside the institution;
- access to personal medical records within the institution by health professionals outside the institution or communication of these data outside the institution.

In each case, the health professionals who may make a request for access to data are specified, as are examples of practical situations encountered, the rules for good practice, a review on informing the patient, and the formal procedures to carry out with the CNIL by those requesting data.

Decisional trees are provided in the appendix.

2. Case 1 – Access to personal medical records within the institution by the institution's health professionals with no communication of data outside the institution

2.1. Professionals concerned

- Member of the senior healthcare team[4] or in training, notably physician, intern, midwife, midwife student, head nurse, nurse, or nursing student;

[2] Reference methodology MR-001adopted by the CNIL, 5 January 2006.

[3] See information technology and civil liberties law (Loi Informatique et libertés), 6 January 1978, modified (notably chapter IX).

[4] This means professionals belonging to a healthcare team, not necessarily the team that participated in the patient's care.

- interns and students are under the responsibility of a senior supervisor from the institution, for example, an MD, midwife, or head nurse;
- non-members of the healthcare team within the framework of their missions, e.g., DIM physician, clinical research associate (ARC), clinical study technician (TEC), medical information technician (TIM), quality engineers, and risk-management engineer under the responsibility of a physician with authorized access to medical records.

2.2. Practical situations

- Healthcare safety audit (e.g., verification of the operating room check-list in the patient file, identification of surgical site infections);
- doctoral and master's theses;
- single-center research project on previously collected data (same group of institutions);
- evaluation of practices;
- pharmacoepidemiology (it may be necessary to contact the patient at a later date);
- feasibility study (before setting up a project, the researcher wishes to verify that a sufficient number of patients is available);
- setting up a cohort: data-based retrospective research;
- prescreening: for therapeutic trials or setting up a cohort or identifying cases may involve contacting the patient at a later date;
- development of decision-support systems (e.g., identification of adverse effects of medications, surgical site infections).

2.3. Good practice rules

Access to personal medical records should only be granted under the responsibility of a physician of the institution authorized to provide such access to patient files, either professionally through his or her caregiver relation with the patient or institutionally through the mission entrusted him or her by the institution. An agreement to respect professional secrecy should be signed if access is granted to a non-health professional.

A personal data access and proper use charter should be drawn up by the institution and is brought to the attention of health professionals (see a model in Appendix D).

A validation commission for access to personal medical records can be created in the institution (from the medical board, for example).

The nominative list of patients whose medical records will be used cannot leave the institution. This list can be used as a table of correspondence (patient identity and study number). Depending on the local organizations, this list should be preserved by the DIM physician, the archives, or the supervising physician in his or her department. This list should only be circulated in accordance with article 34 of the information technology and civil liberties law.

The DIM physician must be notified of how the PMSI hospitalization data will be used and how the PMSI databases will be searched.

The responsibility of cross-searching the institution's medical databases lies with the DIM physician, who delivers the authorizations to those concerned.

The traceability of requests for access to patient files is guaranteed.

Access to data is accorded for the time of the study.

Whenever possible, it is recommended to only give access to anonymous or deidentified data.

Access to or communication of anonymous data does not require the patient's agreement, but the research project must be validated.

Patients' refusals to use their medical records are recorded in the medical file and when the file is computerized in the institution's data system. A separate refusal file should not be created.

If it is necessary to contact patients, only those who have not refused will be contacted.

The patient will be contacted by the clinician responsible for the department that cared for the patient or a member of the team under the responsibility of said clinician.

2.4. Informing the patient

Patients should be provided clear and honest information by their caregivers. A notice included in the patient handbook or given to patients during a consultation informs them of the secondary use of their medical records and access to their medical records (see model, Appendix C).

Information will also be posted in waiting rooms as well as on the institution's web site.

With the exception of mandatory studies, determined by legislative or regulatory provision, patients are entitled to discretionary refusal concerning access to their individual medical records.

A form is provided for patients refusing to be contacted.

When contacted, patients are informed of the data that may already have been collected from their medical records.

Use of institutions' medical and medical-administrative databases resulting in the production of aggregated indicators (with at least 10 subjects) is not subjected to patient agreement.

Access to anonymous data by the institution's health professionals is not subjected to patient agreement.

The list of the studies for which personal medical records are used will be available on the institution's web site.

Crossing clinical data with data from the Biological Resources Center (Centre de ressources biologiques) should respect the regulations as regards collection of biological materials, which assumes written consent by the patient for secondary use of samples for research purposes. This regulation also applies to genetic data and genetic samples linked to identifying information.

2.5. CNIL formalities

See Appendix B for details of specific situations.

The statistical use of computerized patient records by the institution in possession of data must be declared to the CNIL

under the hypothesis that this secondary use is ''monocentric''[5]. This is done through the data and liberties correspondent (correspondant informatique et libertés [CIL]) for the institutions where this is in place.

If the party requesting access is creating a personal data file, this party will initialize the CNIL declaration, with the person responsible for data analysis being the representative of the organization (e.g., director of the healthcare institution).

A declaration is made for every end-use of a file created. Implementation of new analysis on this file with the same end-use on the same data categories does not require a new declaration. However, any modifications should be declared to the CNIL (notably recipients, new categories of data).

Statistical analysis based on databases of PMSI hospitalization summaries that are internal to the institution must be declared to the CNIL either during the initial declaration of PMSI analysis or by an amendment letter.

Authorization for use of regional or national PMSI databases (RSA, RHA, etc.) by institutions must be requested, as stipulated in the relevant texts of chapter X[6], with the CNIL. If the institution is conducting several studies responding to the same end-use on identical data with identical recipients, the institution can request a single authorization from the CNIL. It should detail the list of projected analyses.

Studies leading to production of aggregated results (e.g., feasibility study) with no access to individual data do not require a declaration with the CNIL. It is nevertheless advisable to ensure the absence of patient identification, most particularly when rare diseases are concerned.

3. Case 2 – Access to personal medical records within the institution by health professionals not within the institution or communication of individual medical records outside the institution

3.1. Professionals concerned

Within their missions:
- health professionals;
- non-health professionals, e.g., clinical research associate (attaché de recherche clinique [ARC]), clinical study technician (technicien d'étude clinique [TEC]), quality engineer, risk-management engineer under the responsibility of a physician with authorized access to medical records.

3.2. Recipients of the data

- Research organization;
- health authority;
- healthcare network;
- structure with a public health mission;
- promoter of clinical trial or other health study (observational, epidemiological, etc.);
- consulting firm.

3.3. Practical situations

- Multicenter research projects or projects designed to assess practices;
- assessment of practices within the healthcare network context, by an organization with a public health mission or by an external firm:
  - data collection by the institution's professionals, transmission of questionnaires to the project head,
  - data collection by external TECs,
  - communication of data extracted from the institution's PMSI file,
  - access to the medical records through external ARCs or TECs to verify data transmitted (quality control of assessment or epidemiological studies),
  - communication of parts of medical records;
- research survey requiring contacting patients:
  - patient satisfaction survey,
  - prescreening to establish a multicenter cohort,
  - audit to optimize coding of PMSI hospitalization reports by an external firm,
  - development of decision-support system.

3.4. Good practice rules

Access to personal medical data or their communication is only possible if the analysis has received prior authorization by the CNIL (see Appendix B).

The institution will set up a validation committee for access to personal medical records.

The requesting party should be able to explain its request and provide the authorization delivered by the CNIL. The institution can make use of a form letter listing the documents to be provided by the organization requesting data be transmitted. Formalizing the exchanges and commitments with the requesting party ensures a safer legal framework. The requesting party guarantees that the data transmitted are in accordance with the data declared with the CNIL for analysis and also guarantees having set up a procedure for informing patients and managing refusals or having obtained a special dispensation to the CNIL's information technology and civil liberties law.

Access to personal medical data by a person external to the institution or their communication to another organization is granted under the responsibility of a physician from the institution authorized to access the patient's file, either professionally through his or her caregiver relation with the patient or institutionally through the mission entrusted him or her by the institution.

Medical records are accessed within the institution. An agreement to respect professional secrecy should be signed by professionals outside the institution. A personal data access and proper use charter should be drawn up by the institution and is brought to the attention of health professionals (see a model in Appendix D).

Whenever possible, it is recommended to give access only to anonymous or deidentified data.

When data from the PMSI standardized discharge summary is requested, a DIM physician should be associated starting at

[5] See the Glossary.

[6] Personal health data analysis for purposes of evaluation or analysis of healthcare and preventive practices and procedures.

the conception of the research project so as to ensure the feasibility of its implementation in the institutions concerned. The request will be treated under the responsibility of the DIM physician of each institution.

The institution's medical databases will be searched by the DIM physician or under his or her responsibility.

Access to individual personal medical records under the responsibility of a physician of the institution is possible during quality control or case validation by the organization responsible for a medical research project in which the institution is collaborating.

The research organization will have specified the need to access personal medical records in its request for authorization with the CNIL.

The retrospective collection of data from the patient records by a professional external to the institution should be authorized by the CNIL. In this case, the authorization will be based on chapter IX of the modified law of 6 January. The request submitted to the CNIL should describe the data access modalities and explain the request for special dispensation to informing the individual patient; access by ARCs and TECs within the limits of their missions will be specified therein. The request for special dispensation to the obligation to inform the individual can be found in the authorization delivered by the CNIL.

The prescreening phase of clinical trials or epidemiological studies is carried out by the institution's ARCs and TECs under the responsibility of an accredited physician within the institution, with ARCs made available by the Cengeps subject to a contract with the institution.

Following the prescreening phase, if patients must be contacted, only those patients who have not previously refused can be contacted. The patient will be contacted by the clinician responsible for the department that cared for the patient or a member of the team under the responsibility of said clinician.

Except in cases of exceptional dispensation, identification data are removed or blinded at the time of data transmission.

Access to or communication of indirectly nominative data does not always require the patient's individual agreement; the research project must, however, be validated scientifically and the researcher commits to not attempting to reidentify the patient.

If the type of data used (whether or not it is indirectly nominative) is questioned, the opinion of the DIM or the data access validation commission may be solicited.

Aggregate health data will be communicated under the responsibility of a physician of the accredited institution. It must be ensured that patients cannot be identified (with at least 10 subjects in the study).

3.5. Exceptional cases

3.5.1. Communication of medical records to registries

In France, registries respond to a precise definition[7]. Healthcare institutions are authorized to transmit nominative data crossed with PMSI files that have CNIL authorization for this. Recommendations were issued by the CNIL in 2003[8] for the implementation of cancer registries. This could be reviewed and extended to all registries. Work is currently underway within the CNIL so that this recommendation is revised.

3.5.2. Access to RSS or RSA files by consulting firms

A priori, RSS (résumé standardisé de sortie, standardized discharge summaries) files cannot be communicated to persons who do not belong to the DIM. The institution can decide to relegate the coding or an audit of the coding to a DIM physician in another institution in conditions adhering to article L. 6113-7 of the Public Health Code within the framework of a contract.

If an external firm processes the RSA (résumé de sortie anonyme, anonymous discharge summary) file, an authorization from the CNIL must be obtained. A contract must be signed, the firm undertakes to destroy the file after data analysis or to return it to the institution. The DIM physician is advised of this contract.

3.6. Informing the patient

A notice included in the patient handbook or given to patients during a consultation informs them of the use of their medical record and their right to refuse.

If the data for which access or communication are requested are directly nominative or coded with a table of correspondence, the patient must have been informed individually or a special dispensation from the CNIL information technology and civil liberties law is required, and the patient must not have indicated his or her right to refuse secondary use of his or her medical records.

In absence of a special dispensation from the information technology and civil liberties law, the project head or the investigators are required to set up the procedure for informing the patient. The notice to provide to the patient is therefore specific to each study.

The research organization can also provide the institution with an information notice.

In addition, assuming that the request involves access to personal data of patients present in the institution, the written forms must be accompanied by clear and honest verbal information allowing the patient to legitimately exercise his or her right to refuse.

For registries, general information on registries can be found in the institution's patient handbook, on the institution's web site, or is posted in the hospital departments.

In addition, the law on data and liberties stipulates that persons concerned should be informed individually. This is the case for all studies that come under chapter IX of the law (health research), also applicable to registries.

Patients are entitled to discretionary refusal of access to their medical records, except when this access is allowed by

[7] Decree of 6 November, modified, relative to the National Committee of Registries.

[8] Deliberation No. 03-053n, 27 November 2003 on the adoption of recommendations concerning personal data analysis implemented by cancer registries.

legislative or regulatory provision (e.g., national health insurance system validation).

Use of institutions' medical and medical-administrative databases resulting in the production of aggregated indicators is not subject to patient agreement (see CNIL formalities above).

Transmission of aggregated or anonymous data or access to anonymous data without access to the medical records is not subject to patient agreement. Particular precautions should nonetheless be taken so that the patient cannot be identified (e.g., rare diseases).

The list of the studies for which personal medical records are used will be available on the institution's web site.

Analysis of genetic data requires the express and prior consent of the persons involved.

3.7. CNIL formalities

The requesting party must show proof of its request with the CNIL (see Appendix B).

General principles:

- the requesting party responsible for a study requiring communication of personal medical records must have CNIL authorization:
  - chapter IX[9] (CCTIRS and CNIL) if there is access to the medical file or if the data communicated are identifying;
  - chapter X if the data communicated are indirectly nominative with no return to patient files. This is also the case if the study includes a request for access to the SNIIRAM[10] (with or without the PMSI database).

This also applies to communication of data from the institution's PMSI databases of hospitalization summaries. Transmission of RSA-type data or data that is indirectly nominative comes under chapter X. Failing this, the study comes under chapter IX.

Acknowledgements

We wish to thank Ms. Délia Rahal-Löfskog of the French Personal Data Protection Authority (Commission nationale informatique et libertés) for her availability and her assistance on the legal texts, most particularly on personal data protection, Dr. Jacques Lucas, Vice-President of the French Medical Council (Conseil national de l'Ordre des médecins), and Dr. Jean-Marie Faroudja, President of the Ethics and Deontology section, for their attentive reading and comments as well as the Privacy Commission of the SOFIME for its comments.

Appendix A. Supplementary data

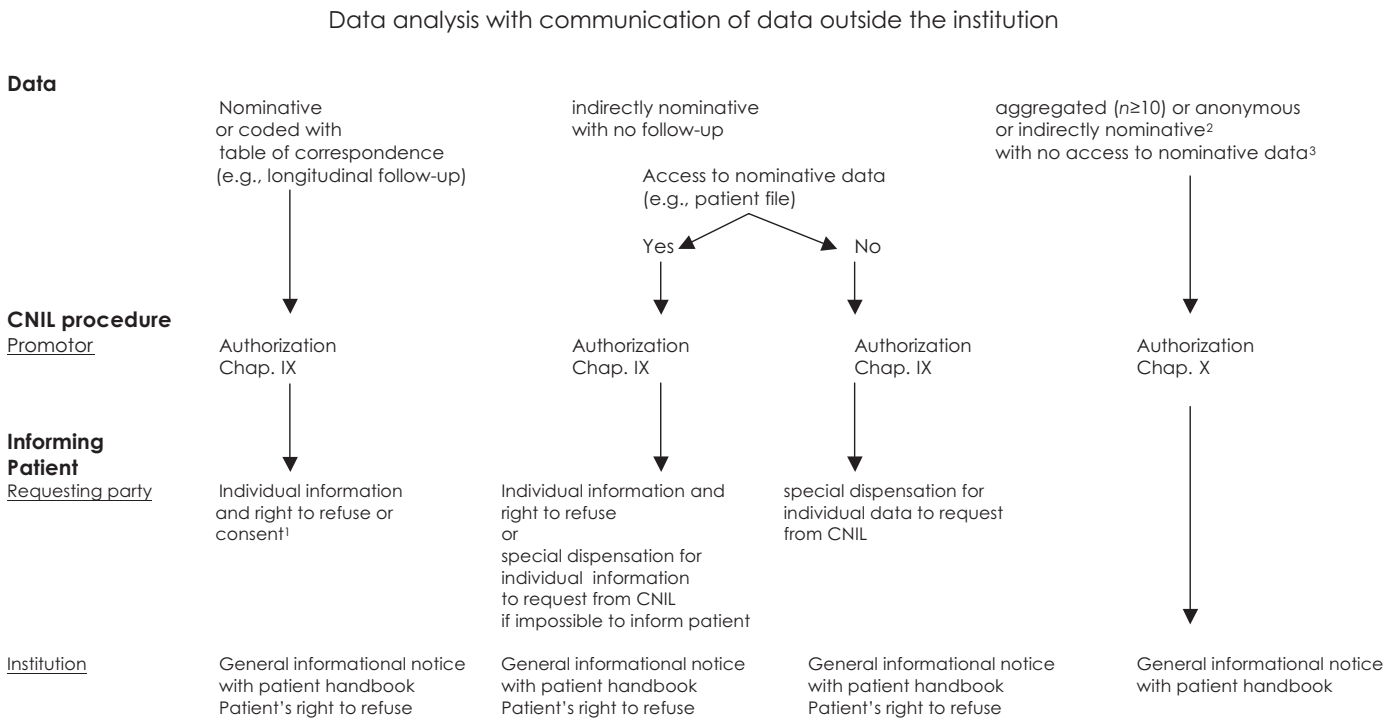
Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.respe.2014.03.005.

Appendix B. Procedure for implementation of personal health data analysis requiring secondary use of previously collected data for healthcare or medical-economic purposes

Data analysis internal to the institution with no external communication		
Data	Nominative or indirectly nominative	Aggregated ($n \geq 10$) or anonymous (data analyzed by DIM)
CNIL procedures	Normal declaration	No declaration subject to declaration of statistical analysis in declaration of initial analysis If not, amending letter
Informing the patient	Information note included with patient handbook Patient right to refusal	Information note included with patient handbook

[9] Analysis of personal data for research purposes in the healthcare sector.

[10] Under this assumption, notification of the l'Institut des données de santé (Institute of Health Data) is also required.



[1] *if data shared between institutions, the patient's written consent is required*
[2] *probability of identifying the patient is low*
[3] *the case of access to nominative data remains to be clarified, notably in terms of of the data and the patient's right to refuse*

Appendix C. Patient information notice for healthcare institutions' secondary use of medical records

The data in your medical records may be used for research purposes. In all circumstances, only those individuals subject to professional secrecy can access these data under the responsibility of a physician from the institution.

In accordance with the provisions of the information technology and civil liberties law, these studies are declared with the CNIL, only coded data respecting patient privacy are analyzed, with no mention of patient family or given names, and the results are produced in an aggregated form making it impossible to identify you.

You may also be contacted by the department responsible for your care should they wish you to participate in a new study.

In all circumstances and in accordance with the information technology and civil liberties law (law of 6 January 1978, modified), you have the right to access and rectify your data. At any time you can refuse to have the data in your medical records used or to be contacted, as long as the data analysis is not subject to a legal obligation, without having to justify your refusal. Exercising your right to refuse will have no consequence on your care or the quality of your relation with the medical teams. You can also refuse to be contacted to participate in a new study.

To exercise your rights you can contact . . . . . .

Appendix D. Model of a charter giving access to the institution's medical records when used outside the healthcare setting

1. Subject

   The present charter defines the rules to be observed during access to and analysis of medical records as well as the obligations beholden to users concerning data security.
2. Scope of application
   a. Access by professionals of the institution for studies conducted by the institution:
      i. Subject to the signature of a commitment to respecting professional secrecy for non-healthcare professionals.
   b. Access for multicenter studies under the following conditions:
      i. A copy of the authorization delivered by the CNIL provided;
      ii. Agreement to respect the CNIL authorization (data collected, personnel collecting data, recipients, informing patients);
      iii. Agreement to respect professional secrecy signed by the person accessing the data if said person is external

to the institution or a non-healthcare professional within the institution.

3. Responsibilities

Medical records are accessed by or under the responsibility of a physician authorized to access the patient records (indicate physician's name and position).

The professional agrees to:

- respect the confidentiality of the data;
- access only the data necessary for the study;
- make no copies of and not remove nominative data or documents from the institution, including tables of correspondence unless there is a specific arrangement with the CNIL: in this case the nominative data are preserved in a file separate from the medical records;
- protect the files created (indirectly nominative data) and destroy them after publication of the results.

4. Organization of access to data

The institution shall describe the procedure for collecting data or agreement of the physicians caring for the patients concerned by the study.

The institution can draw up a request form specifying:

- the study's project leader;
- the study's subject and protocol;
- the data that the requesting party wishes to access;
- the study's CNIL authorization number;
- the authorizations requested (CPP, Committee for the Protection of Persons; ethics committee; the department head or pole director);
- the nominative list of the professionals who can access data during the study;
- the access period.

It will specify the modalities of opening and closure of access.

5. Sanctions

The failure to respect the legal dispositions and the principles established or reviewed by the charter entails the personal responsibility of the user.

Unauthorized access to confidential data is punishable by 1 year imprisonment and a 15,000-euro fine (CSP article l110-4).

Breach of the information technology and civil liberties law is punishable by 5 years' imprisonment and a 300,000-euro fine (Penal Code, articles 226-16 to 226-21).

I, the undersigned, ..., hereby certify that I have read and understand the chart and agree to comply with it.

Date:

Signature:

Glossary

Personal or identifying data: Any data relative to a natural person, identified or identifiable, directly or indirectly, by reference to an identification number or one or several elements that are specific to him or her (article 2, information technology and civil liberties, CNIL glossary). Example of indirectly nominative data: file with no indication of individuals' identity replaced with a number allowing retrieval of identity through a table of correspondence. This guide concerns all medical records on patients collected in the healthcare institution, including standardized discharge summaries.

Analysis of personal data: Any operation or any group of operations involving such data, whatever process may be used (article 2, information technology and civil liberties law)

Single-center research: Study conducted by the institution within said institution and for its own account (the institution is the promoter of said study and is responsible for data analysis)

Making data anonymous: Process applied to data ensuring that the patient can no longer be identified directly or indirectly

Deidentification: Removal of identifiers (list of data categories defined as the patient identification numbers or hospitalization numbers, dates, family names, given names, addresses, patients' or institutions' telephone numbers, city or postal codes, etc.)

Anonymous data: Data that does not allow direct or indirect identification of a natural person even when grouped.

Feasibility study: First phase of clinical trial development, before submission of the CNIL file, the purpose of which is to determine the number of potential subjects for a study and to identify the populations of interest that may be included in the trial. This definition may be extended to the preparatory phase of a health research protocol in view of putting together a patient cohort.

Prescreening: During a declared clinical trial, the phase preceding patient contact, based on the institution's medical records and/or PMSI databases, consisting in searching for patients responding to the trial's criteria. This definition may be extended to drawing up a cohort for a health research project. This phase differs from the screening phase, which is conducted once the patient has been contacted and has granted consent to participate in said research; the inclusion criteria are verified and/or completed at this time.

Registry: A registry is defined as a continuous and exhaustive collection of nominative data involving one or several health events in a geographically defined population, for research or public health purposes, by a team possessing the appropriate skills.