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Recommendations

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

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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).

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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.

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