COLLEGE GENETICS

Belgian College for Human Genetics and Rare Diseases

Proposal national policy concerning the disclosure of genetic information in electronic health records

Prepared by the ELSI WG of the College for Genetics & Rare Diseases and endorsed by the College on October 6th, 2023.

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1. Introduction

In accordance with hospital law[1], a file or health record (HR) is created for each patient. This HR contains the necessary administrative, nursing and medical data to guarantee optimal care and treatment and to enable correct administrative handling. To date, these HRs should be available electronically (eHR).

The eHR allows more efficient sharing of data between health care providers directly involved in the care for a particular patient within an institution, hub[2] or with a patient's general practitioner, which benefits the continuity of care and medical management of the patient. In addition, it also facilitates the patient's right to access their medical data (cfr. art.9 of the law concerning patient rights – August 22 2002[3]) and govern their own health care decisions.

In comparison to some types of medical data, genetic data are both complex and sensitive and require a degree of "genetic literacy" to fully understand the implications of test results. An incomplete understanding of the test results may cause harm to the patient. Currently, national guidelines concerning the disclosure of sensitive genetic data in electronic health records is lacking. The College for Genetics and Rare Diseases therefore prepared this proposal to help establish a national policy concerning this matter.

[1] 10 JULI 2008. - Gecoördineerde wet op de ziekenhuizen en andere verzorgingsinrichtingen

[2] Hubs centralize medical data and serve as exchange platforms between a network of health care providers from different health care institutions (academic hospitals, general hospitals, etc) and general practitioners. Existing hubs in Belgium: Collaboratief Zorgplatform including the Antwerpse Regionale Hub, Vlaams Ziekenhuisnetwerk KU Leuven, Brusselse Gezondheidsnetwerk, Le Réseau Santé Wallon.

[3] 22 AUGUSTUS 2002. - Wet betreffende de rechten van de patiënt.

2. Legislative framework

Relevant legislative framework related to the proposal:

8 DECEMBER 1992. - Wet tot bescherming van de persoonlijke levensfeer ten opzichte van de verwerking van persoonsgegevens. Loi relative à la protection de la vie privée à l'égard des traitements de données à caractère personnel.

22 AUGUST 2002. - Wet betreffende de rechten van de patiënt. Loi relative aux droits du patient.

25 APRIL 2014. - Decreet betreffende de organisatie van het netwerk voor de gegevensdeling tussen de actoren in de zorg.

16 OKTOBER 2015. - Décret insérant certaines dispositions dans le Code wallon de l'Action sociale et de la Santé, relatives à la reconnaissance d'une plate-forme d'échange électronique des données de santé

Currently, there are no specific national guidelines concerning the availability and sharing of genetic information in electronic health records.

3. Proposal national policy

Genetic data should not be disclosed freely in eHRs without the necessary context. Different types of genetic data warrant a different approach with regards to reporting in eHRs for (non-geneticist) health care providers and patients to consult. This is also true for the type of report. A distinction must be made between reports containing laboratory test results and clinical reports. The College of Genetics and Rare Diseases strongly advices that laboratory test results are not disclosed to patients in eHRs without an accompanying interpretation (clinical report or consultation) of a clinical geneticist or genetic counselor. Laboratory reports can be shared with referring physicians. The disclosure of genetic data to referring physicians, however, must be done by publishing it on secure digital platforms or hard copy letters. Exceptionally, the data can be shared via email but only when multifactor authentication measures are applied and only to verified email addresses. Depending on the type of genetic data, clinical reports can be shared with referring physicians and/or patients in eHRs. Recommendations per type of genetic data are formulated in Table 1.

Importantly, all results reported in a clinical letter should be clinically valid now and/or in the future, meaning that these results have value for medical management of the disease and are not merely biological variations or genetic variants of uncertain clinical significance.

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Table 1. *Recommendations with respect to the disclosure of genetic data in the form of a clinical report in eHRs depending on the type of genetic data.*

Types of genetic data	Disclosure in eHR				Sensitivity code
	Health care providers		Patients		
	Clinical report	Lab report	Clinical report	Lab report	
Postnatal diagnostic testing	Open access for the involved health care providers	Open access for the involved health care providers	Open access	No disclosure in eHR	Normal
Pre-symptomatic carrier testing - Late-onset neurodegenerative disorders - Other disorders	Access strictly limited to involved clinical geneticists/counselors Open access for the involved health care providers	Access strictly limited to involved clinical geneticists/counselors Open access for the involved health care providers	No disclosure in eHR (hard copy available post counseling) Open access	No disclosure in eHR	High Normal
Prenatal testing	Open access for the involved health care providers	Open access for the involved health care providers	Open access	No disclosure in eHR	Normal
Pre-implantation genetic testing	Open access for the involved health care providers	Open access for the involved health care providers	Open access	No disclosure in eHR	Normal
Non-invasive prenatal test (NIPT)	Open access for the involved health care providers	Open access for the involved health care providers	Open access	No disclosure in eHR	Normal
Population-based variant screening (BEGECS)	Open access for the involved health care providers	Open access for the involved health care providers	Open access	No disclosure in eHR	Normal

In addition to different types of genetic data, several technologies can be used to obtain the data (copy number variation sequencing, whole exome sequencing, whole genome sequencing, multigene panels, microarrays, (molecular) karyotyping, etc...). Some of these methods, e.g. untargeted whole exome or genome sequencing, may result in the discovery of secondary and/or incidental findings[4]. Whether or not these data will be reported is discussed with the patient and/or family members prior to the analysis. If informed consent is obtained, secondary and/or incidental findings can be disclosed in the clinical report and made available in eHRs.

Important points to consider

(1) All reports should be clearly time stamped. The patient's phenotype and the interpretation of the laboratory test results may evolve over time warranting re-classification of genetic variants or a new diagnosis. Hence, the most recent report should unequivocally state that it supersedes all prior reports on this particular analysis and why it does so.

(2) Be aware of disclosure of third party information in clinical reports to family members in case of pre-symptomatic carrier testing.

[4] Secondary findings refer to intentionally and deliberately pursued findings. Incidental findings refer to unintentionally discovered results. Both are unrelated to the initial diagnostic question. (To: Presidential Commission for the Study of Bioethical Issues. Anticipate and communicate: ethical management of incidental and secondary findings in the clinical, research, and direct-to-consumer contexts. 2013. http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf.)