Informed Consent

Does Anyone Really Understand What Is Contained In The Medical Record?

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Medical records, informed consent, information management

Summary

Background: Despite efforts to provide standard definitions of terms such as "medical record", "computer-based patient record", "electronic medical record" and "electronic health record", the terms are still used interchangeably. Initiatives like data and information governance, research biorepositories, and learning health systems require availability and reuse of data, as well as common understandings of the scope for specific purposes. Lacking widely shared definitions, utilization of the afore-mentioned terms in research informed consent documents calls to question whether all participants in the research process — patients, information technology and regulatory staff, and the investigative team — fully understand what data and information they are asking to obtain and agreeing to share.

Objectives: This descriptive study explored the terminology used in research informed consent documents when describing patient data and information, asking the question "Does the use of the term "medical record" in the context of a research informed consent document accurately represent the scope of the data involved?"

Methods: Informed consent document templates found on 17 Institutional Review Board (IRB) websites with Clinical and Translational Science Awards (CTSA) were searched for terms that appeared to be describing the data resources to be accessed. The National Library of Medicine's (NLM) Terminology Services was searched for definitions provided by key standards groups that deposit terminologies with the NLM.

Discussion: The results suggest research consent documents are using outdated terms to describe patient information, health care terminology systems need to consider the context of research for use cases, and that there is significant work to be done to assure the HIPAA Omnibus Rule is applied to contemporary activities such as biorepositories and learning health systems.

Conclusions: "Medical record", a term used extensively in research informed consent documents, is ambiguous and does not serve us well in the context of contemporary information management and governance.

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1.Introduction (including Objectives)

Historically, health information management (HIM) departments and professionals controlled access to medical records and the physical storage of the documents within medical records. In that environment, the medical record was commonly understood to be the collection of paper documents embodied within the "chart", although the term "legal medical record" was applied to identify specific documents that were discoverable and sharable from a regulatory perspective. In the two decades since the Institute of Medicine (IOM) published Computer-Based Patient Record (CPR) report [1], there has been an evolution of terms applied to name the electronic capture, storage, and viewing of data that was previously only available in paper format and organized as a chart or medical record. Despite efforts to provide standard definitions of terms such as "medical record", "computer-based patient record", "electronic medical record" and "electronic health record", the terms are still used interchangeably.

In part, the evolving use of terms reflects the expanding scope of stored clinical data and our enhanced ability to link source systems. Three contemporary efforts highlight the need to examine the use of the term "medical record" in research consent forms: data and information governance, the prospective collection of specimens in biorepositories, and the emergence of learning health systems (LHSs). Across these efforts, the availability and reuse of electronic data is assumed. Authors of this paper, involved in research projects underway in the context of these efforts, were surprised to note the use of the term "medical record" in research consent forms. We began to question how broadly the term was used in research consents and what types of data access were suggested. In this paper we explore the term "medical record" (in both its singular and plural form) in a set of informed consent research templates, terminology systems, and the implications for health information management and governance.

2.Background

With the pervasiveness of databases containing clinical and patient-specific data, researchers now have the ability to access the primary sources of data as well as the aggregations presented in the electronic health records. The emergence of robust federated approaches to data that reside in different systems thus challenges the use of the term "medical record" in informed consent documents. The importance of this topic is that a shared understanding of the terms used in the informed consent documents dictates what the scope of information release of clinical data should be. For example, do persons who consent to the use of their "medical record" in the context of a research study comprehend the potential scope of the data involved? How do health information management professionals and their colleagues in the regulatory and information technology space interpret these definitions and relate them to the risk of release of data from various sources that are accessed in a contemporary electronic medical record (e.g., blood bank systems, medication administrative management systems, etc.)? As healthcare organizations expand their data and information governance activities, how will the use of data and information for research be affected?

The 2013 Health Insurance Portability and Accountability Act (HIPAA) Omnibus Rule introduced "sweeping changes" to the HIPAA Privacy and Security Rule, including individuals' ability to authorize the use of their health information for research purposes. (www.hhs.gov/news/press/2013pres/01/20130117b.html) Many believe these changes better align with the Common Rule, including the notions of "compound authorizations" and "future use authorizations". A compound authorization allows an authorization for research to be combined with informed consent for the same research study. A future use authorization describes for persons whether his or her personal health information (PHI) could be used or disclosed for research. (www.hhs.gov/ocr/privacy/) Interestingly, while the Omnibus Rule was motivated in large part by the pervasiveness of electronic health records and other electronic sources of patient-specific clinical data, the government's website for consumer information on health information privacy is firmly grounded in the notion of a paper based medical record. For example, at the time of preparing this paper, the web page was titled "Your Medical Records" and includes a photo of a health care provider standing in stacks of paper medical records. (www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/medicalrecords.html) A cen-

tral concern is aligning the principles and values embedded in research to preserve consumer and provider trust with the reality of contemporary health information management practices.

2.1 Information governance

A current trend in health informatics and information management is the implementation of data and information governance programs. Organizations have found these programs to be essential for the effective management of proliferating databases, software applications, and data sources. Within the context of informed consent, data and information governance could assist organizations with defining exactly what is meant by the term "medical record" or other synonymous forms.

The American Health Information Management Association recently published the results of a research study on information governance (IG) where 65% of respondents in healthcare organizations recognized the usefulness of information governance for managing information across functional areas, i.e. across clinical and research areas [2]. However, only 43% of respondents had initiated formal data and information governance programs. Eleven percent (11%) of the respondents characterized their IG programs as mature, meaning they had "multidisciplinary direction and oversight; sponsorship for resources and funding; and leadership to engender organizational solidarity." Interestingly, regulatory compliance was cited by 80% of the respondents as a driver for information governance, ahead of patient safety and patient care cited by 73% [2].

Human subjects research that includes the use of patient data is highly regulated by the Department of Health and Human Services Office of Human Research Protections (OHRP). Failure to comply with OHRP regulations can result in the loss of all federal research funding. Among the recommendations in the AHIMA white paper was the creation of a policy infrastructure that addressed all of the organizational data and information in both electronic and paper formats [2]. This is the essence of the primary issue faced when contemplating truly informed consent for data and information use today. How do we develop a policy infrastructure that can be automated or operationalized to ensure patients understand what they are consenting to while allowing researchers access to the data and information they need? This becomes a particularly important question in two contemporary contexts: biorepositories and a learning health system.

2.2 Biorepositories

Collections of biospecimens from multiple sources are a fundamental resource that enables a variety of research and translational endeavors including, for example, the identification of targeted therapies in precision medicine. Fifteen years ago the RAND Corporation reported there were approximately 300 million tissue specimens in use, with the number increasing by approximately 20 million specimens a year [3]. Today, large scale, high quality biorepositories such as The Cancer Genome Atlas (TCGA) [4] have resulted in discovery of new diagnostic biomarkers and new driver mutations in specific types of human cancer, some of that in turn have been shown to have clinical significance [5]. The scientific value of biospecimens generally increases as the amount of clinical data electronically linked to specimens increases [6]. Consequently, the need to precisely and consistently represent obligations and access rights in consent forms is crucial, particularly as technology advances allow for more distributed research collaborations. While a number of ontologies and prototype electronic systems exist that attempt to manage access rights and permissions, these systems depend on shared understanding of the underlying concepts that can only be accomplished with precise definitions. This is not unique to biorepositories; in general the effective use of terminology systems, ontologies, and knowledge bases will depend on precise, shared definition of terms and concepts.

2.3 Learning Health System

The Institute of Medicine (IOM) characterizes a LHS as a system where we are "drawing research closer to clinical practice by building knowledge development and application into each stage of the healthcare delivery process."[7] Among the IOM publications addressing an LHS is a 2011 report that focuses on the need for a digital infrastructure that enables the capture of clinical, delivery pro-

cess, and financial data for better care, system improvement, and creating new knowledge.[8] A key potential benefit of a digital health infrastructure for an LHS is when technical advances and innovative research methods bring research and practice closer together [8]. More recently, a 2013 report from the President's Council of Advisors on Science and Technology (PCAST) described the impact of networking and information technology (NIT) as "stunning" [9]. The potential of NIT to accelerate progress in health and well-being was emphasized, including capabilities to "use data mining and machine learning on health and healthcare information about millions or even billions of people while protecting their privacy" [9]. Within the IOM 2011 document one observes the term "medical record" used primarily in relationship to the privacy and security of data, although the term was not used in the PCAST document [9].

Biomedical ethicists, examining the moral imperative of learning within a LHS, are specifically reflecting on the tension between the existing human subjects protection framework in the U.S. and the new and expanded types of linked data that will increasingly be available to LHSs [10]. U.S. regulations and research ethics codified in the Common Rule were developed in the 1970s when health care delivery research was uncommon and medical records were all paper based. A framework addressing seven obligations that constitute necessary conditions of an adequate ethics framework for a LHS was proposed by Faden and colleagues, and includes a list of parties who bear responsibility for meeting those obligations [10]. The need to specify implications for oversight policies and practices, including informed consent, was highlighted although the focus was on the accountability of persons [10]. While the notion of linked, electronic data is clearly evident in this literature, the term "medical record" is not consistently differentiated from terms such as "electronic health record" or other synonyms.

The convergence of data and information governance, biorepositories linked to clinical data, and a learning health system present challenges to the use of the term "medical record" in the context of research informed consent documents.

3.Methods

To determine how pervasive the use of the term "medical record" was in informed consent documents, we compiled a convenience sample of organizations that have received Clinical and Translational Science Award (CTSA) grants from the National Institutes of Health (NIH) as of September 1, 2014. The assumption was that CTSA organizations were likely to have efforts in place related to data and information governance, biorepositories and learning health systems. Each CTSA's website was visited and searched for templates for informed consent. If no consent templates were located, the organization's Institutional Review Board (IRB) page was located and searched for templates. While a general web search identified consent document templates for most of the CTSAs, we limited our final sample to the 17 organizations with informed consent templates clearly posted on an organization's official web postings. In this way, we hoped to retrieve the most current and document templates, vetted by some level of governance within the organization. The documents were downloaded to a shared drive for analysis.

The analysis consisted of descriptive statistics such as the number and types of consent forms for each organization. In addition, each form was searched using the "find" function in Microsoft Word and Adobe Reader. Below is the final list of terms were used, based on our interpretation of the intent of the language in each template to provide a description of the types of data resources that may be accessed.

- Record(s),
- Medical record(s),
- Health record(s),
- Research record(s),
- Study record(s),
- Source record(s),
- Clinical record(s),
- Data,
- Research information,

- Genetic information,
- Electronic medical record(s).

Each informed consent document was tested for readability by entering the text into the website https://readability-score.com/.

In addition, we searched the National Library of Medicine's Unified Medical Language System Terminology Services (UTS release 2014AA) to determine (a) the extent that each of these terms was included in three of the clinical terminologies designated by the Consolidated Health Informatics (CHI) initiative as likely U.S. standards (LOINC, SNOMEDCT_US, HL7) and (b) terms and definitions that were relevant to the terms we identified. Each of our terms was separately entered into the UTS Metathesaurus Browser, first searching across all sources in order to identify definitions and then separately searching LOINC, SNOMEDCT_US, and HL7.

4.Results

We identified a total of 68 research consent form templates (▶Table 1). The number of templates ranged from a low of 1 for both Georgetown and The Medical University of South Carolina to a high of 8 for Johns Hopkins University. Those with more than one document might have separate consent forms for adults (competent and incapacitated) and children, or have one for expedited approval versus regular, or have a short-form version versus the long consent form. Two organizations had documents for "great risk" as opposed to "minimal risk," while one had a special informed consent for videos. Only three of the 17 organizations had a document specifically for genetic testing. Biobanking was included in many of the document templates as optional paragraphs that could be included or not, as appropriate.

The frequency that terms were used to describe patient information in the informed consent documents can be seen in ▶Table 2. The term "medical record" was used by 10 (or 58.8 %) of the 17 organizations, with "research record" being the next most common at 7 of the 17 organizations. "Study record" and "source record" were used 3 and 2 times respectively, with "record," "health record," and "clinical record" each used one time. Interestingly, none of the informed consent documents used the terms "research information," "electronic medical record," or "genetic information".

The average readability score for the informed consents from the 17 organizations was a 10.6. Two of the organizations (Mount Sinai and Case Western Reserve University) had readability scores above that of a high-school graduate. Children's National Medical Center had the lowest readability score at 8.8.

▶Table 3 summarizes our findings from the UTS search of SNOMEDCT-US, HL7 V3.0, and LOINC, using the same list of terms searched across the consent document templates. As an example of the findings, the term "medical record" retrieved 8 terms in SNOMEDCT-US, 0 terms in HL7 V3.0, and 4 terms in LOINC. As we reviewed the results, across the twelve terms "medical records", "medical problem oriented", "medical record number", and "patient medical record not available" were examples of terms that appear to be particularly relevant to our use of the term in research informed consent documents.

▶Table 4 presents examples of search results across all UTS terminologies, the concept unique identifier (CUI) for examples we present, and textual definitions. As an example of the findings, when we reviewed the term "medical record" concepts the query returned 58 search results. The term "medical record" was just one of the 58 terms returned. The CUI associated with the term "medical record" was C002512, and three definitions from three different sources were associated with that CUI. A complete listing and detailed analysis of the searches reported in ▶Table 3 and ▶Table 4 is beyond the scope of this paper; our intent here is limited to illustrating the diversity in terms and definitions.

5.Discussion

The results of this review of informed consent document templates and related terms from select terminology systems suggest that the terminology used in research consent documents has not kept pace with development of the electronic "medical record". The terminology systems likely to be used as standards in electronic health care applications need a focused review to ensure that the underlying definitions of terms contained in those systems are appropriate for use in the context of research. There is significant work to be done to assure that, as the HIPAA Omnibus Rule is applied to contemporary activities such as biorepositories and learning health systems, the intent of the person donating biospecimens and data is "known" to our automated information systems.

The readability scores are, in and of themselves, cause for concern. However, it must be pointed out that readability is not equivalent to comprehension. What is the intent of the words? Does everyone understand what is meant by medical record and the scope of the data to be shared? Only two of the organizations (Albert Einstein and Duke) included glossaries with their informed consents to assist with definitional understanding.

Electronic informed consents may offer new opportunities to more effectively represent the nature and scope of data under consideration for research studies. For example, a research permissions management system (RPMS), designed to electronically capture patients' potential interest in current or future research studies and distribute that consenting information across a distributed network of participating organizations, is currently under development [11]. Evaluations indicate that, when compared to paper based systems, the RPMS may provide better comprehension and awareness of the intent of the consent form because of options for expanded access to information using embedded media (e.g., audio-video, weblinks) [12]. Such a system addresses patient needs for more usable and understandable consent documents; as well as a platform for the essential discussions around the scope of data that may be specifically retrieved across participating organizations if the term "medical record" is included in a specific study context. The need is not only for patients to understand the term, but also for the increasing numbers of programmers, analysts, and investigators who are increasingly removed from the electronic data storage to understand the scope of data that is appropriate for retrieval and reuse if the term "medical record" is used. Informed consents need to more explicitly define data sources likely to be used in a study, and assure that all those involved in the research data understand the appropriate use and precautions.

The questions that prompted this review remain: Does the use of the term "medical record" in the context of a research study consent form accurately represent the potential scope of the data involved? How should health information management professionals and their colleagues in the regulatory and information technology space interpret these terms and relate them to the risk of release of data from various sources that are accessed as part of the contemporary electronic medical record (e.g., blood bank systems, medication administrative management systems, etc.)? As healthcare organizations expand their data and information governance activities how will the use of data and information for research be affected? The health information management professional has long had the role of an "honest broker" in releasing patient data for information, and now need to be active partners in information management and governance. Future research into the content of the patient data and information used for primary and secondary research is needed. A vast amount of EHR data, pulled from a wide variety of sources, is now used and reused for many different purposes, including studies that have great risk as well as those with minimal risk. The risks for subjects can include non-medical risks, such as family reactions for genetic testing or making tissue available for biobanking. The research community must come to agreement on the boundaries and definitions so that research subjects can be informed when they provide or withhold consent.

Limitations of this study are recognized and include the small convenience sample that we used to identify research informed consent document templates. Notably, the review did not address "sensitive" records such as those related to psychiatric or substance abuse care. A broader review of consent templates is needed to confirm these findings. Our analysis of terminology systems was limited to those in the UMLS. There is evidence of increasing efforts to address computable knowledge-bases to support decision-making around the research use and sharing of biospecimens and clinical data. For example, a workshop on the topic of ontologies for biorepository data sharing took place at the 2014 ICBO (International Conference on Biomedical Ontology) in October 2014.

6.Conclusions

"Medical record", a term used extensively in research informed consent documents, is ambiguous and does not serve us well in the context of contemporary information management and governance. Collaborative efforts are needed to ensure the definitions of current and future uses of "medical record" data are accurate and provide direction for patients, as well as all those who are involved in health care and research information life cycles.

Clinical Relevance Statement

Information governance from both informaticians and HIM professionals is essential for research informed consent as EHRs are implemented and technology continues to evolve. Without this patient consent cannot truly be informed.

Conflict of Interest

None of the authors have any conflicts to report.

Human Subjects Protections

This manuscript did not involve human subjects.

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None.

Table 1 Number of Informed Consent Documents by Organization

Organization Name	Number of Consent Forms
Albert Einstein College of medicine	2
Boston University	2
Case Western Reserve University	4
Children's National Medical Center	4
Columbia University	1
Dartmouth University	7
Duke University	5
Emory University	5
Georgetown	4
Harvard Catalyst	1
Indiana University	3
Johns Hopkins University	8
Mayo Clinic	1
Medical College of Wisconsin	2
The Medical University of South Carolina	1
Mount Sinai School of Medicine	7
Northwestern University	6
Oregon Health and Science University	5
N = 17	N = 68

Table 2 Frequency of Terms Used Across Organizations (n = 17)

Terms	# Organizations Using the Terms*	% of Organizations Using the Term*
medical record	10	58.8%
research record	7	41.2%
study record	3	1.8%
source record	2	1.2%
clinical record	1	0.6%
record	1	0.6%
health record	1	0.6%
research information	0	---
genetic information	0	---
electronic medical record	0	---

*Note: There may be more than one term in a single template, and more than one template in a single organization.

Table 3 UTS Term Search across SNOMEDCT_US, HL7 RIM, and LOINC

Search Term	Terms with Unique CUIs			Examples of Retrieved Terms Relevant to Informed Consent Documents
	SNOMEDCT_US#	HL7 V3.0#	LOINC #	
Medical record(s)	8	0	4	• Medical records • Medical records, problem-oriented • Medical record number • Patient medical record not available
Data	62	30	666	• Patient data • Child health data • Institution data source
Record(s)	352	13	75	• Records • Patient information system • Electronic health record • Patient record type (many specific types)
Electronic medical record(s)	0	0	0	
Electronic health record(s)	1	1	2	• Template entry
Health record(s)	0	1	0	• Patient information system
Source record(s)	0	0	0	
Research information	0	1	0	• Research information access
Research data	0	0	0	
Genetic information	0	0	0	
Research record(s)	1	0	0	
Study record(s)	0	0	0	
Clinical record(s)	10	0	5	• Clinical report • Clinical record verified by subject • Patient clinical record lost • Clinical record items

Table 4 Examples of Relevant Terms, Definitions and CUIs across all UTS Terminology Systems

Term Searched	Search Result	Examples of Relevant UTS Concept(s)	UTS CUI(s)	Textual Definition(s)
Medica20,6 mml record(s)	58	Medical records	CO025102	Recording of pertinent information concerning patient's illness or illnesses. (Source CPS, MSH/MH)
			CO025102	A chronological written account of a patient's examination and treatment that includes the patient's medical history and complaints, the physician's physical findings, the results of diagnostic tests and procedures, and medications and therapeutic procedures. (Source NCI)
			CO025102	Represents the HL7 content "domain" that supports medical records – and is "supports clinical document management and document querying" (Source HL7V3.0)
Data	1524	Data	C1511726	A collection or single item of factual information, derived from measurement or research, from which conclusions may be drawn. (Source NCI)
Record(s)	144	Records	CO034869	The commitment in writing, as authentic evidence, of something having legal importance. The concept includes certificates of birth, death, etc., as well as hospital, medical, and other institutional records. (Source MSH)
			CO034869	Anything (e.g., a document) providing permanent evidence of or information about past events. (Source NCI)
Electronic health record(s)	7	Electronic health record system	C1707898	A computer-based clinical information system that is dedicated to collecting, storing, manipulating, and making available clinical information important to the delivery of patient care. The central focus of such systems is clinical data and not financial or billing information. (Source NCI)
		Electronic health records	C2362543	Media that facilitate transportability of pertinent information concerning patient's illness across varied providers and geographic locations. Some versions include direct linkages to online consumer health information that is relevant to the health conditions and treatments related to a specific patient. (Source MSH/MH)
			C2362543	An automated, on-line medical record containing clinical and demographic information about a patient that is available to providers, ancillary service departments, pharmacies, and others involved in patient treatment or care. (http://www.agencyinfo.net/iv/medical/health-glossary.htm) (Source: NCI)

Table 4 (Continued)

Term Searched	Search Result	Examples of Relevant UTS Concept(s)	UTS CUI(s)	Textual Definition(s)
Electronic health record(s)	7	Electronic health records	C2362543	A collection of a patient's medical information in a digital (electronic) form that can be viewed on a computer and easily shared by people taking care of the patient. (Source: NCI)
Health record(s)	8	Electronic health records	(See above)	(See above)
		Patient information systems	C0679919	NA
Source record(s)	1	Source of patient record was medical records	C2017831	NA
Research information	3	Research information access	C3244129	Consent to have healthcare information in an electronic health record accessed for research purposes. (Source HL7V3.0)
Research data	8	Study data	C0681873	NA
Genetic information	4	Genetic information, personal	C0950146	NA
		Databases, genetic	C0872179	Databases devoted to knowledge about specific genes and gene products (Source MSH/MH)
Research record	1	Report to drug safety research unit	CO588121	NA
Study record	6	Data linkage	CO242239	A study in which data from different sources are „linked". Usually used to compile epidemiological data. The logic of record linkage is that two or more items of information about a person recorded at different times, and perhaps in different places, may be of greater value when considered together than when either is considered alone.
Clinical record	21	Clinical report		NA
		Clinical document	CO1828480	A documentation of clinical observations and services with the following characteristics: persistence, stewardship, potential for authentication, wholeness, human readability (Source HL7)
		Clinical records items	C2735296	NA

*NA = Not available
CSP = CRISP Thesaurus , MSH = MeSH, NCI = National Cancer Institute Thesaurus , HL7V3.0 = Health Level 7 Version 3.0

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