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Giving patients granular control of personal health information: Using an ethics 'Points to Consider' to inform informatics system designers☆

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ABSTRACT

Objective: There are benefits and risks of giving patients more granular control of their personal health information in electronic health record (EHR) systems. When designing EHR systems and policies, informaticists and system developers must balance these benefits and risks. Ethical considerations should be an explicit part of this balancing. Our objective was to develop a structured ethics framework to accomplish this.

Methods: We reviewed existing literature on the ethical and policy issues, developed an ethics framework called a "Points to Consider" (P2C) document, and convened a national expert panel to review and critique the P2C.

Results: We developed the P2C to aid informaticists designing an advanced query tool for an electronic health record (EHR) system in Indianapolis. The P2C consists of six questions ("Points") that frame important ethical issues, apply accepted principles of bioethics and Fair Information Practices, comment on how questions might be answered, and address implications for patient care.

Discussion: The P2C is intended to clarify what is at stake when designers try to accommodate potentially competing ethical commitments and logistical realities. The P2C was developed to guide informaticists who were designing a query tool in an existing EHR that would permit patient granular control. While consideration of ethical issues is coming to the forefront of medical informatics design and development practices, more reflection is needed to facilitate optimal collaboration between designers and ethicists. This report contributes to that discussion.

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1. Introduction

1.1. Access to and control of health information by patients

Determining how much information to give to patients about their medical care has been the subject of discussion for as long as there have been physicians, patients, and medical information. For close to three decades, bioethics scholarship and case law reflect a deliberate trend toward giving patients more information and more control over health decision making [1]. How much information to give, in what format, and by who remains a source of continuing interest, though [2].

With the advent of electronic health records (EHRs), in which data are stored electronically, transmitted via regional health information exchanges (HIEs) and accessed by many providers and insurers, the idea that within certain limitations patients should be able to control what information is made available to physicians has taken on greater urgency and complexity. More data and information about patients – which includes test results, genome analyses, prognoses, diagnoses, prescription patterns, admission or discharge plans – can be collected, stored, and accessed by more people than ever before [3,4].

This potential "tsunami of data" [5] may create several ethical and legal barriers [6], complicated by the different perspectives of physicians [7], patients [8], and consumers [9] about the proper scope of such control. Indeed, privacy issues alone are responsible for considerable commentary and reflection [10,11]. For instance, the Health Insurance Portability and Accountability Act (HIPAA) stipulates numerous uses and disclosures of health information that do not require patient authorization (e.g., for treatment, payment, and health care operations) that could result in the disclosure of information to dozens of recipients [12].

Asking patients to consider disclosure of information for all potential recipients/uses could prove overwhelming to them and detrimental to the health care system. For example, a patient might wish to restrict her cardiologist from seeing information regarding prior psychiatric treatment, or an individual who abuses pain killers might wish to block access by his family doctor to information about previous drug abuse or concurrently prescribed controlled medications. Patients might believe they have good reasons for exercising control given the selective history of discrimination in health care [13–15]. Whether the reasons are defensible or not, there are consequences, particularly for physicians to safely prescribe medications.

1.2. Ethical issues in the use of health information technology

The purported benefits to patients and society from the use of health information technology have been well documented [16,17] though these benefits come with profound logistical, policy, and ethical challenges [18,19]. While some ethical guidance exists for using these new tools, gray areas remain, particularly at the intersection of personal health information and decision making [20]. Indeed, while it has recently been argued that it might be as ethically blameworthy not to apply such tools as it would be to apply them inappropriately [21], the available policy tools are not yet nuanced enough to guide ethical decision making. For example, the Health Information Technology for Economic and Clinical Health (HITECH) Act [22] includes additional privacy and security requirements over those mandated by HIPAA [23], but does not specify the scope of patient control. The President's Council of Advisors on Science and Technology (PCAST) 2010 report raised this point when it discussed, among other things, the need for "innate, strong, privacy protection on all data, both at rest and in transit, with persistent patient-controlled privacy preferences…" [24]. PCAST also recognized that there are risks of patients' exercising unbridled granular control of the information in the EHR.

Developers of EHR systems and policies, therefore, must balance the benefits of granular control *by* patients with the risks of clinical harm *to* patients. Support for the idea of giving patients "granular" control also emerged from the U.S. Office of the National Coordinator for Health Information Technology (ONC), which indicated that patients should have a "greater degree of choice to determine, at a granular level, which personal health information should be shared with whom, and for what purpose" [25].

1.3. Bioethics principles and fair information practices

The idea of granular control is a logical application of many well-accepted ethical principles including respect for autonomy, beneficence, non-maleficence and justice [26]. For example, the argument for giving patients greater autonomy in decision making about medical treatment and research builds on developments over the past three decades aimed at supporting patient empowerment and informed choice [27–29]. At the same time, the argument for restricting the scope of control follows from a long tradition of benevolent paternalism in medicine [30]. Thus, granular control fits within the fundamental interest that individuals have in informational privacy, which is generally exercised, at least in part, through the ability to limit access by others to personal information [3]. Providing this type of control may be seen to re-balance the relationship between clinician and patient, to promote trust, and to enhance overall quality of care [31–33].

Similarly, granular control is a logical application of Fair Information Practices (FIPs), described originally in a 1973 report of the Department of Health, Education and Welfare's Secretary's Advisory Committee on Automated Personal Data Systems [34], and which have evolved over time [35]. The nine FIPs as described by the ONC are: individual access, correction, openness and transparency, individual choice, collection, use and disclosure limitation, data quality and integrity, safeguards, and accountability. Indeed, many versions of FIPs exist in the US (e.g., the Federal Trade Commission's FIPs, the ONC HIT FIPs), in countries other than the US (e.g., Canada's FIPs), and in non-national organizations (e.g., the Madrid Privacy Declaration [36]).