Ethical Issues Arising From the Use
Of Electronic Health Records

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Ethical Issues Related to Electronic Health Records

**Rationale**

Many Americans are accustomed to seeing their health care provider(s) entering notes into a paper medical chart, whether in the physician’s office or hospital. That is rapidly changing. More and more, clinicians are entering notes and vitals into an electronic device, such as a laptop computer or tablet. The number of hospitals and medical practices implementing Electronic Health Records (EHR) is rapidly increasing.

In 2010 the percentage of US hospitals with at least a basic EHR system was 15.1 percent, and rose to 26.6 percent in 2011. Meaningful use also increased from a meager 4.1 percent to 18.4 percent for the same time period (DesRoches, Worzala, Joshi, Kralovec, Jha, 2012). EHR adoption rates for office-based physician practices are also increasing at an annual rate of three to four percent every year. In 2010, nearly 25 percent of all practices had at least a basic EHR system (Jsiao, Hing, Socey, Cai, 2010).

The move toward EHRs had been slowly growing through the late 1990’s and early 2000’s, but the pace rapidly increased with the passage of the American Recovery and Reinvestment Act of 2009 (ARRA, commonly referred to as the “Stimulus” or “The Recovery Act”). The Health Information Technology for Economic and Clinical Health Act (HITECH) is a provision of ARRA that provides $27 billion in incentives over ten years to health care providers who achieve improvements and advancement in processes and outcomes through the
widespread implementation EHR within specified timeframes (Blumenthal & Tavvenner, 2010). In order to qualify for these incentives, Medicaid and Medicare payees must have “meaningful use of certified EHR technology by 2014 or face Medicare payment reductions” (Miller, Bronston, Cole, Morelli, & Kraus, 2012).

Mark Rothstein (2010) argues that the Hippocratic oath, which was once a promise between physician and patient, has instead become “The Hippocratic Bargain”; as the patient-physician relationship has expanded to the point that private patient information passes through countless hands from treatment to billing to insurance filing. EHR promises to revolutionize the Hippocratic Bargain once again in ways that have yet to be identified. These changes prompt the exploration of the following research question:

RQ 1: What are the ethical issues regarding EHR in the current practice of medicine?

Because meaningful use of EHR in the U.S. is still in its initial stages, available research is sparse. However, many experts have raised concerns about privacy, the use of EHR in research, and other aspects of patient care related to EHR. For this reason, the theoretical approach to this research question will incorporate grounded theory. Glaser and Strauss (1999) describe grounded theory as “a general method of comparative analysis” (p. 1). This methodology is useful in discovering patterns, trends or themes within a body of research, which can subsequently be used to identify or apply other social theories (Scott, 2009).
Much of the discussion around ethical issues in healthcare is framed around the “four principles plus scope” approach outlined by Gillon (1994). The four prima facie moral principles are autonomy, beneficence, non-maleficence, and justice. It is not uncommon in health care for these moral principles to come into conflict. Prima facie refers to the idea that no one principle is greater than any other and, in some situations, we may have to choose between competing. Gillon (1994) argues that while we may agree on these principles, it does not answer the question of scope; “to what or to whom we owe these moral obligations” (p. 309).

Because the very nature of health care is rooted in ethical principles, there is little doubt that widespread use of EHR will impact health care ethics. A comparative analysis of existing literature on the subject will help identify the areas that are most concerning and enable health care providers to consider the issues, weigh competing values, and develop consensus on how they should be resolved.

**Literature Review**

Electronic Health Record (EHR) is the more prevalent term in the U.S. for a computer application that stores individually identifiable health data. Health care providers can link multiple sites or integrated providers into a single system to provide ready access to a patient’s record from the doctor’s office to the operating room. In some cases, patients can also access their own health records from their home computers.
To examine the ethical implications of EHR in healthcare, it is helpful to understand its purpose and capabilities. The primary uses of EHR relate to patient care, but there are secondary uses as well. Identifying the functions and capabilities of EHR helps to highlight the powerful benefits that EHR can provide, but also how those benefits could be misused or abused.

<table>
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<th>Uses of Electronic Health Records</th>
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<tr>
<td><strong>Primary</strong></td>
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<td>Patient Care Delivery</td>
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<td>Patient Care Management</td>
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<td>Patient Care Support</td>
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<td>Financial and Administrative Processes</td>
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<td>Patient Self Management</td>
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<td>(Layman, 2008, p. 166)</td>
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<th>8 Core Functionalities</th>
<th>6 Key Capabilities</th>
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<td>Health information and data</td>
<td>Longitudinal collection of individual health information</td>
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<td>Results management</td>
<td>Interoperability among providers</td>
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<td>Order entry and management</td>
<td>Security access to only authorized users</td>
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<td>Decision support</td>
<td>Immediate access to individual and aggregate health information by authorized users</td>
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<td>Electronic communication</td>
<td>Connections to external medical and health knowledge decision supports and alerts</td>
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<td>Patient support</td>
<td>Support of processes that enhance quality, safety and efficiency</td>
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<td>Administrative processes</td>
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<td>Reporting and population health management</td>
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Users and beneficiaries of this information include patients, clinicians, managers, hospitals, clinics, insurance companies, government health organizations and universities. Broad access and the capacity for linking records, unauthorized access, data mining, and secondary research gives rise to what Stanberry (2000) broadly termed, “info-ethics” (Layman, 2008).

**Beneficence and non-maleficence**

The principles of beneficence and non-maleficence, requiring that those in health care act in ways that promotes the welfare of others while doing no harm, are often considered together. These principles apply not only to individual medical treatments, but also to the allocation of social resources (Gillon, 1994; Munson, 2004). Applying these ideologies to social resources means ‘doing the most good with the least harm,’ a fundamental challenge in this “info-ethics” age.

EHRs have the potential to improve productivity and reduce costs. One recent survey of primary care physicians found that 75 percent believed EHR could reduce errors; 70 percent perceived a potential increase in productivity; and 60 percent believed it could reduce administrative costs (Anderson, 2007). A recent Veteran’s Administration study verified this potential. The number of veterans treated annually between 1996 and 2003 increased by 75 percent while cost of care per patient was reduced by 25 percent (Layman, 2008).
The potential for EHR to provide both social and individual good was demonstrated in 2005 in the aftermath of Hurricane Katrina. The Veteran’s Health Administration electronically transferred 50,000 patient records from Louisiana to Texas and the National Coordinator for Health Information Technology worked with pharmacies, creating a database for 800,000 people, enabling continuity and access to care following that disaster (Layman, 2008).

EHR databases offer substantial benefits and opportunities for access to new information and research methods. Aggregated data for research, quality and outcome measurements, public health and decision-making offers considerable benefits. According to Hoffman (2010), EHR databases enable researchers to conduct comprehensive observational studies on virtually millions of demographically diverse patients, using actual clinical data.

Gene mutation and the genetics of disease can be gleaned by personal and familial medical data, as well as population data. The first breast cancer mutation, the BRCA1 gene, and inherited rheumatoid arthritis are just two examples in which the information contained in EHRs provided significant research findings (Wylie, Mineau, 2003). Another study demonstrated a pattern of gender disparities in the treatment of coronary heart disease, providing detailed information about the health characteristics of that population segment. Those findings enabled changes in public health policy and treatment recommendations (Layman, 2008).
The balance between beneficence and non-maleficence is an example of the prima facie dilemmas in which competing ethical principles must be weighed. Along with the benefits of EHR, the potential harms must also be considered. Concerns about patient privacy and the right to control one’s personal health information is frequently cited, and is also a factor in the principle of autonomy.

One of the tenets of research with EHR data is the “de-identification” of patient data. Elements of a data record that might identify the individual are deleted or altered. Currently, research projects that use de-identified health records are exempt from U.S. regulations governing research with human subjects and are not considered “protected health information,” thus exempting them from federal privacy protections (Rothstein, 2010). However, de-identified datasets constrain certain types of research in which familial or genetic information is necessary (Wylie, Mineau, 2003). Additionally, publicly available external data sources have been used to successfully re-identify data sets (Sittig, Singh, 2011; Hoffman, 2010), raising concerns about the reliability of de-identification.

Increased access to patient information through EHRs can improve clinical care and decision making; but the opposite is also true. Information “overload” can potentially lead clinicians to miss key pieces of information. With paper records, even if key information was in the record, it may not have been accessible within a reasonable timeframe for decision-making,
but with EHR, that same information may only be a keyboard click away, creating new liabilities for negligence among practitioners, if readily available information is not accessed or considered in decision making (Sittig, Singh, 2011).

The potential for good from the information in an EHR is only as good as the information that has been entered into it. Layman (2008) cited numerous studies in which incomplete or inaccurate data was found in EHRs:

- 22 percent of internal information was missing from the EHR in a pre-anesthetic clinic
- A primary care study on osteoporosis found major differences within individual practices:
  - How data was recorded
  - Treatment records exceeded diagnoses
  - Absent or different versions of diagnostic codes used
  - Manual searches of paper records were required to locate missing data
- For patients receiving hemodialysis, drug record discrepancies (60 percent)
- A 2004 Iowa VA report found only 5.3 percent of patient records for medications were completely accurate

Of course data entry by clinical personnel may account for only a part of these results. It is not uncommon for patients to censor their medical histories. They may doubt the privacy and
security of the system or may be embarrassed and fear that certain information might result in bias, stigma or discrimination (Layman, 2008).

Currently, integration of patient records from multiple sources fails to correctly match records five to ten percent of the time. As more providers implement EHR, the need to integrate data from disparate sources will increase, making data accuracy and consistency increasingly important (Sittig, Singh, 2011).

The potential benefits of EHR are great, but are yet to be fully realized. It is clear, however, that the possible harms must be managed and minimized in order for this technology to succeed in ways that promotes the welfare of others while doing no harm. These are not the only conflicts yet to be resolved. Concerns over how EHR systems affect the principles of autonomy and justice must also be resolved.

**Autonomy**

Autonomy is the principle that rational individuals should be permitted to be self-determining and there is a duty of others to respect the inherent worth of all. Self-determination involves action, options and decision-making. Autonomy involves the initiation of action through one’s own choices. Coercion restricts the freedom of individuals to act as they may choose and violates autonomy. Individuals must also have genuine options and the opportunity to make informed decisions. It is pointless to have options if we are not aware of them or do not
understand them (Munson, 2004). Concerns over privacy, control of one’s personal health information and participation in research are at the heart of the ethics of autonomy.

Patient records often contain detailed information about their family history (including violence, sexual or substance abuse, or mental illness), genetics, sexual habits, medications, mental health, test results (including HIV and sexually transmitted diseases), employment status, income, and marital information. They also contain clinician observations about a patient’s mental state or personality. Goldberg (2000) states that many Americans are unaware of the scope of information or even the number of people and organizations that have access to their personal information.

Patients provide information to health professionals for their own benefit, not to benefit others. Yet, demand for secondary use of personal health information is high. Secondary users include health insurance payers, public health organizations and researchers, but also government agencies, law enforcement, licensing organizations, credit bureaus and employers (Goldberg, 2000; Sittig & Singh, 2011).

A 1996 survey of Fortune 500 companies found that one-third had made job related decisions based on individual medical information. Insurance companies want to know health and genetics information. Pharmaceutical companies want health diagnosis and medication information to market drug products to patients and their physicians (Goldberg, 2000).
Individuals are often required to consent to disclose information as a condition for obtaining insurance or employment, yet information is often obtained without consent, and in some circumstances consent is not required (Goldberg, 2000). EHR vendors have also sold de-identified copies of EHR patient databases to pharmaceutical and medical device companies, and health service researchers, raising greater concerns about unauthorized disclosure of personal health information via EHR (Sittig, Singh, 2011).

This has led some experts and patient privacy advocacy groups to propose an “opt-out” feature, allowing patients to refuse to have their personal health information stored in an EHR, leading to a whole new ethical dilemma. Such an option would likely add to the cost of health care and further complicate an already complicated record keeping system. One potential problem is that clinicians might not offer care unless patients subscribe to EHR, in part because “meaningful use” of EHR will be required for full Medicare reimbursement (Sittig & Singh, 2011). Yet, one of the principles of autonomy is choice. Additional ethical questions then include, ‘must autonomy always offer choice?’ and ‘does lack of choice equate to coercion and violate autonomy?’

Privacy involves the right to be left alone and also implies control over intrusion (Davidson, 2009). Patients want access to their own records, to see and have an opportunity to correct information, and control who has access to their health records (Goldberg, 2000;
A 1983 study on privacy values, beliefs, and attitudes (Stone, Gardner, Guetal & McClure, 1983) found that the degree of control people believe they have over personal information correlates positively to their support of and participation with an organization, making them less likely to demand added legal protections. Likewise, those having bad experiences with privacy were more negative toward information control and participation in those organizations and often sought greater legal protection.

A more recent study by Angst and Agarwal (2009) suggests that the Elaboration Likelihood Model (Petty & Cacioppo, 1986), a model in which individuals’ attitudes evolve as new information is processed, could help frame messages about EHR and privacy. People often weigh the costs and benefits of potentially compromising some degree of privacy in exchange for greater benefits. Angst and Agarwal (2009) found that attitudes could be positively shifted in favor of EHR, despite privacy concerns.

Medical research using EHR databases also raises significant concerns about privacy and control. Abuse of research subjects around the world has resulted in great distrust of the biomedical research process (Macardle, Stanley 2009). Failure to obtain informed consent is strongly condemned by most in the research community. Internal review boards (IRB) and research ethics boards (REB) generally ensure compliance with federal regulations on human subject research, set policy, approve and oversee research involving human subjects.
Despite these policies and practices, clear guidelines for the use of personal health information contained in electronic health record databases have yet to be established. A 2006 study of research ethics boards around the U.S. found significant variation in their requirements of consent for research using medical records. One of the reasons is that there are a varied methods and safeguards for the use of de-identified records. The study also found that, among the REBs interviewed, there were substantial differences of interpretation and understanding about patient protections using de-identified records (Willison, Emerson, Szala-Meneok, Gibson, Schwartz, Weisbaum, Fournier, Brazil, Coughlin; 2006).

EHR databases hold tremendous promise for contributions to scientific medical research. Kaiser Permanente has received a grant in excess of $3 million from stimulus funds to create a national database of 30,000,000 de-identified patient records from eight regions of the country. The Federal Drug Administration has also authorized creation of a database of 100,000,000 records. However, it is vital that these databases be representative of the U.S. population if they are to be valid and useful. Exclusion of certain minority populations or those with stigmatized diseases could very likely cause disproportionate populations to be underrepresented. This is one of the concerns with the opt-out option that some propose (Hoffman, 2010).

In a 2003 Canadian study, patients were surveyed and interviewed regarding attitudes toward consent. Most were willing to allow use of their information for research, although 74
percent preferred prior consent. Patients cited respect as an important element in seeking prior consent. Interestingly, participants made little distinction between identifiable and de-identified data. One study participant commented on control and privacy surrounding consent (Willison, Keshavjee, Nair, Goldsmith, Holbrook, 2003).

> “I think you need to give conscious consent to having any data, any personal data used, whether you are identified or not. That’s certainly a right. That’s your information; it’s your medical history. Whether it’s identified or not, you should control it.” Patient 14

Challenges to reliably de-identifying information have been previously discussed. There are other considerable challenges to managing consent as well (Willison, et al. 2003).

- Size of the study population
- Sources of data – single source or multiple sources
- Difficulty in contacting participants, either directly or indirectly
- Risk to research bias
- Risk of breaching privacy or inflicting psychological, social or other harm by contacting the individual
- Undue hardship to the organization to provide resources for contacting

**Justice**

Equity and fairness lie at the heart of justice. Aristotle argued that people could be treated unjustly, even if they are being treated equally (Gillon, 1994). Fidelity is also
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fundamental to the patient/provider relationship and, as Rothstein (2010) argues, underpins the original Hippocratic oath. Communication that respects the dignity and rights of the patient must maintain confidentiality, honesty and trust.

There is great potential in the power of EHR to discern and address patterns of discrimination in health care. Analysis of aggregated data can, and has, lead to changes in treatment protocols and improved care, such as with gender disparities in the treatment of coronary heart disease (Layman, 2008), mentioned previously.

However, inequitable disclosure of public health information also has the potential for harm, especially to disadvantaged or marginalized populations. Increasing use of geographic information systems (GIS) for health research is so precise that house addresses can be identified with 79 percent accuracy (Layman, 2008). This, coupled with the database capabilities of EHR, makes re-identification of epidemiological data, highly likely. One study re-identified genomic data that had been de-identified and pseudonymized, resulting in 33 percent re-identification of patients with cystic fibrosis, Huntington’s disease, sickle cell anemia, and other stigmatizing conditions (Layman, 2008).

Breaches of security are inevitable. The Privacy Rights Clearinghouse tracks breaches of security, especially those that involve identifying information such as social security numbers. In 2006, from January to November, there were 27 security breaches of health information
affecting more than 900,000 persons. One-third involved EHR, and were the result of either flawed or weak software security, or theft of electronic devices used to access EHR data (Layman, 2008).

How security breaches should be, and will be addressed must be part of the discussion of justice ethics. Kim and colleagues (2010) suggest that prompt, voluntary disclosures of security breaches are necessary in order to preserve the trusted relationship. Communicating breaches of security will likely be a new kind of “bad news” that practitioners must learn and be prepared to share (Satkoske, Parker, 2010). Kim, et al. (2010) note that there is sufficient evidence that practitioners often have difficulty taking responsibility for and telling patients about medical errors, yet it is the most ethical approach. There is also evidence that, when errors are promptly disclosed, litigation is decreased and related costs are also lower. In June 2009, the American Medical Association adopted recommendations for prompt disclosure of breaches of security information. Those recommendations have now been adopted as official policy and are in the process of being incorporated into future editions of the Code of Medical Ethics (Kim, et al. 2010).

**Scope**

Gillon’s (1994) Four Principles Plus Scope approach to medical ethics discussions, asks, “to what or to whom we owe these moral obligations” (p. 309). Currently, health care providers
(or their employers) have ownership of the notes and information amassed of a patient. EHR does not change this, since the form of the information will now be digitized. But there is a question of ownership of aggregated data when many professional and clinicians contribute to the body of information that makes up a patient’s record. That question expands exponentially when records are combined into a centralized database (Davidson, 2009).

Kluge, (1999) elaborates on that question by suggesting that a new set of ethical challenges centers on the professionals that that contribute to the construction of the record. Kluge argues that it constitutes data-space, “relative to a particular specialty as well as phenomenologically unique to the specific professional who constructs the profile” (p. 253), suggesting that the diagnosis and treatment plan can be interpreted as a professional path taken by the clinician. Those who devise and develop the database methods and algorithms have interests distinct from the patient and clinicians. This way of thinking constructs artificial intelligence and competence algorithms, essentially constituting intellectual property. This logic also creates new ways of looking at the patient record. One represents the professional and patient relationship with a quality assurance orientation. The second focus is on the ethical treatment of the patient record itself and is security oriented. The third relates to ownership and is proprietary. Kluge suggests that the new technology associated with the patient record creates a new ethical challenge to develop and articulate a theory that will lead to recognition of the
collaborative contribution of the record.

Hall, (2010) provides yet another perspective on ownership and control of health records. Hall uses a network economics perspective to argue that conferring property rights on information limits is beneficence, suggesting that patients be allowed to monetize their access and control rights by assigning a regulated intermediary with authority to place the records in a commercial market that will set their value and use.

**Conclusion**

When Stanberry referred to “info-ethics” in 2000, there was not an abundance of literature on privacy ethics related to health care. That is no longer the case (Layman, 2008). For this research, a number of articles were accessed and reviewed beyond those cited here. Following the grounded theory approach, open coding of the articles was used to identify areas of ethical concerns for EHR in healthcare. Additionally, Gillon’s (1994) four principles plus scope approach provided a useful framework for outlining the ethical issues related to EHR privacy and research.

Open coding identified privacy and research as two broad areas of ethical concern and each of these areas often overlapped with the other and with multiple ethical principles. The available literature raised many more questions than were answered. In fact very few viable solutions to the ethical dilemmas are proposed in reviewed literature.
Kluge (1999) and Hall (2010) raise unique questions of scope not seen elsewhere in the literature. As technology evolves, questions of scope, “to what or to whom we owe these moral obligations” (Gillon, 1994. p. 309) will continue to be raised. Just as Rothstein’s (2010) ‘Hippocratic Bargain’ has expanded the parties who have an interest in health information, so will those to whom “we” owe moral obligations.

In the early stages of any organized inquiry, the establishment of a common language or understanding of terms is essential. It seems that this is where the literature about EHR ethics is today. Frequent in the literature were suggestions about possible agreement in standards and definitions.

Opportunities for further investigation include:

• Cataloging proposed standards for de-identification methods and levels of de-identification

• Expanded research on various IRB and REB practices, policies and definitions for human subject research using EHR databases and de-identified data

• New definitions for “protected health data”

• Institutional policies for consent for secondary use of health data

Technology, especially information technology, is advancing at a pace far ahead of the ability of ethics, policy and law to resolve the questions and dilemmas it poses. Acceptable
standards in ethics and legality develop in time as a result, or in reaction to new technologies. As use of EHR systems increases, obstacles will become clearer and policy will be naturally determined in response to these core ethical dilemmas. We can be assured that, as these questions are resolved, new ones will always need to be balanced against changing values and medical technology and assures that these issues will always be debated and resolved in new and innovative ways.
References


