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Ethics of Implementing Electronic Health Records in Developing Countries: Points to Consider

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ABSTRACT

Electronic Health Record systems (EHRs) are increasingly being used in many developing countries, several of which have moved beyond isolated pilot projects to active large-scale implementation as part of their national health strategies. Despite growing enthusiasm for adopting EHRs in resource poor settings, almost no attention has been paid to the ethical issues that might arise. In this article we argue that these ethical issues should be addressed now if EHRs are to be appropriately implemented in these settings. We take a systematic approach guided by a widely accepted ethical framework currently in use for developing countries to first describe the ethical issues, and then propose a set of 'Points to Consider' to guide further thinking and decision-making.

INTRODUCTION

Electronic Health Record systems (EHRs) are increasingly being implemented in resource poor countries,¹ with systems like OpenMRS currently being used in over 15 different African countries.²⁻³ Several of these countries have moved beyond isolated pilot projects and are actively implementing EHRs as part of their national health strategies.⁴ By nature, such strategies require that a larger portion of the healthcare funds in these countries be channeled towards implementing and sustaining these systems, often at the expense of other healthcare priorities. Already, hundreds of millions of dollars have been spent by federal governments and organizations to support implementation of EHR strategies and in resource poor settings. In the coming years, the resources dedicated to EHRs implementation in these settings is only likely to increase.

Despite growing enthusiasm for adopting EHRs in resource poor settings, almost no attention has been paid to the ethical issues that surround their use. In developed countries, discussions about ethical issues and EHRs have largely focused on privacy, confidentiality, data security, informed consent, data ownership, and secondary use of data.⁵⁻⁹ While most of these same considerations exist within resource poor settings, their application and relevance vary in many ways, primarily because of differences in culture, literacy rates, patient-provider relationships, infrastructure level, and body of evidence surrounding the use of these technologies. Indeed, while benefits appear obvious few have stopped to ask whether EHRs should be used in these settings at all or how this determination should be made. If these systems should be used, what constraints, if any, need to be in place to ensure appropriate implementation? In addition, little research has been done to identify unique conflicts in ethical principles that exist when EHRs are implemented in resource poor settings. These and other relevant ethical questions should be addressed now if EHRs are to be appropriately implemented in resource poor settings.

In this article, we examine a range of ethical issues that arise from the development and use of EHRs in developing countries. We take a systematic approach guided by a widely accepted ethical framework currently in use for developing countries and propose a set of 'Points to Consider' to guide further thinking and decision-making.

APPROACH

A rigorous evaluation of ethical issues surrounding implementation of EHRs in developing countries requires a systematic approach. Such an approach could be derived empirically, but given that many ethical frameworks already exist, it makes sense to adapt one of these for the current use case. It would be ideal if we could apply an ethical framework specific to EHR systems, especially if the framework was already in use in the developed world. Unfortunately, such a framework does not exist. In fact, publications on ethics and EHRs in the developed world have largely focused on a limited number of issues,⁵⁻¹⁰ with a dearth of comprehensive reviews, perspectives, or overarching guiding principles and benchmarks. The ethical frameworks that do exist have generally focused on issues related to research ethics. For example, one such framework, proposed by Emanuel et al¹¹ has been used to

provide ethical guidance on evaluating clinical research in developing countries. Given this framework's relevance to economically developing countries, we used it as an initial guide to better understand the ethical issues around implementation of EHRs. Rather than developing benchmarks, as Emanuel does, we develop a set of Points to Consider (PtC), a strategy used in many deliberations on controversial topics.^{12 13} Unlike formal guidelines, a PtC is intended to be a more user-engaged approach to obtaining ethics input. Framed as questions, the answers to which are not predetermined,¹⁴ a PtC is intended as an approach to ensure that ethical issues are understood and considered, and not as a set of guidelines.

ETHICAL ISSUES

The innovation proposed by Emanuel et al in which ethical requirements could be framed as normative benchmarks for assessing research¹¹ has much to recommend; indeed, it was explained in some detail during a recent meeting of the Presidential Commission for the Study of Bioethical Issues (<http://bioethics.gov/transcripts/human-subjects-protection/030111/social-justice-and-ethics-issues.html>). We too found this framework to be useful in explaining ethical issues, but as we show below there are good reasons for modifying and adapting them. We outline the ethical principles below.

Collaborative partnership

Implementation of EHRs in developing countries usually involves multiple stakeholders. Patients have a stake primarily because their records are stored within the system. The patients' communities also have a stake and often guide decisions made by the patients. Other stakeholders include care providers, funding and governmental bodies, and the EHRs developer and technical support organizations. These stakeholders typically have varying levels of understanding of the systems being implemented, and also different (and sometimes conflicting) interests in their implementation. The risks and potential benefits borne by each group are often uneven, as is the power of each stakeholder group to have their interests protected.

Collaborative partnership calls for stakeholders to work as a team before, during, and after implementation of the system to help maximize the value of the system and discover any shortcomings. Oftentimes, the key decision on whether and how to implement the EHRs is reached without input by all relevant stakeholders. At the very least, all stakeholders should have input on who will provide or deny permission for the implementation, including whether the decision to implement will be made unanimously or through other means. In developing countries, selected individuals from within the community can act as patient and community representatives. Ensuring that each stakeholder is involved can be achieved if there is mutual respect between the various partners. As such, concerns by patients, providers and the community need to be given equal consideration as those by the funding organization or the government.

Collaborative partnership also demands that efforts be made to understand cultural differences and sensitivities. It greatly helps an implementation if perceptions toward technology and data storage are clarified in advance. For example, it might be unwise to store demographic information about a patient's ethnic group in places with a history of violent ethnic conflicts. Furthermore, efforts should be made to build the community's capacity so as to increase their ownership-stake in the system. Examples of capacity building to projects to sustain EHRs implementations can be found in Kenya and Rwanda, but are typically lacking in many settings. Implementer communities, like one seen with OpenMRS EHRs, can also play a role in improving the level of community involvement.² Lastly, a collaborative partnership should strive to optimize mutual benefits and minimize disproportionate risk to particular groups at all stages of the implementation process.

Favorable Risk-Benefit Ratio and Social Value

It would be difficult to argue against broad implementation EHRs in an economically developing country if the benefits of their use far outweighed the potential risks and costs. Unfortunately, the evidence of the benefits, risks, and costs of EHRs in developing countries is scant. We see examples of improvements in care processes and positive attitudes towards these systems in isolated cases.¹⁵⁻¹⁶ However, there are few evaluations of the impact of these systems on quality of care and patient outcomes, or cost-benefit analyses of these systems. Even in the developed world, evidence of the benefits of these systems is often conflicting. As an example, a recent comprehensive systematic review of eHealth systems found a paucity of evidence that EHRs improve patient outcomes beyond a few isolated cases. This review concluded that 'there is a lack of robust research on the risks of implementing these technologies and their cost-effectiveness has yet to be demonstrated, despite being frequently promoted by policymakers and "techno-enthusiasts" as if this was a given'.¹⁷

Given a lack of good evidence of the benefits and social value of EHRs in developing countries, it is appropriate to ask whether there is a defensible position to advocate for large-scale EHRs implementation in these settings. At the very least, greater emphasis should be placed on generating the relevant evidence on the role of these systems in developing countries. It could be argued that EHRs implementation should 'only be justified if there is a reasonable likelihood that the populations in which the *EHRs is being implemented* stand to benefit' from the use of the system.¹⁸ But even when there is a reasonable likelihood of benefit, EHR-based interventions need to also be evaluated against the many other proven healthcare interventions (e.g. safe water and immunizations) to identify the intervention that best addresses the health needs and priorities of the community in question.

For these reasons, there should be a clear determination of who is expected to benefit from the implementation, and who will bear the risks, and they should as much as possible be based on explicit and transparent evaluations. There should be a reasonable probability of a favorable risk-benefit analysis for the individual and greater social value to the community, and these should be sustainable over time. But risk and benefit have substantial subjective components, mediated by social and political values. Therefore, while EHRs could rank high in the list of priorities for the community, especially in relation to other proven health interventions, care should be taken to ensure that the implementation does not adversely affect or disrupt existing care services and workflows. Moreover, there should be continuing re-evaluation of the risk-benefit and social value of the implemented EHRs.

System and Implementation Validity

EHRs need to be evaluated to determine suitability for the intended implementation settings. Do these systems meet the country's and/or implementing institution's requirements for security, costs, usability, and interoperability? In countries that lack EHRs standards and guidelines, is it even justifiable to advocate for extensive implementation? It would seem that these standards and guidelines need to be in place prior to widespread implementation.

EHRs can be invalid if they stifle comprehensive care for the individual. Several systems in current use in developing countries only capture information for particular diseases, e.g. HIV or TB, with little flexibility to record other clinical information. While such systems work well for reporting purposes and for the specific condition, they can serve patients poorly because they omit critical information relevant to the patient's comprehensive care. Other systems risk being invalid simply because they are too sophisticated or impractical for the setting. While it might make a for-profit implementing company more money by having a 'computer at every desk', requiring providers to enter data directly into a computer often proves impossible and impractical in some developing country settings. In addition, systems that depend on real-time internet connectivity typically fail simply because this infrastructure might not be in place in developing countries.

It is an ethical requirement that sustainability issues be addressed prior to any EHRs implementation. Implementations that require full-time availability of highly skilled technical personnel, frequent input by expatriates, high licensing fees, and expensive hardware and software, are often unsustainable in publicly-funded health care systems and institutions in the developing world. The optimal implementation strategies have also not been well defined, and more research is needed to determine what strategies offer the best chance of long-term sustainability in these settings.¹⁹ From this we suggest that the systems must be appropriately designed for the context in which they will be implemented – from a technical, cost, usability and workflow standpoint. They should conform to core standards within the setting; they should primarily be used to promote care feasibility; and sustainability strategies should be explicitly addressed. Where standards and operating procedures do not exist, these should be implemented prior to or along with the EHRs.

Justice, Equity & Access

It is reasonable to expect that access to resources intended to provide health benefits should be unfettered by limitations that discriminate against an individual, group or community. For example, it is wrong to deny access to necessary medical treatment for reasons of race, ethnicity, gender or other morally irrelevant criteria.²⁰⁻²¹ Similarly, while society places certain restrictions on access to *technology* resources such as ventilators or dialysis machines on the basis of complicated criteria – these are properly based on need, severity, likelihood of benefit -- the same argument crumbles when it comes to health information technology resources such as EHRs which are designed to benefit populations (whether healthy or sick). Can a hospital, region, or country's implementation and adoption of EHR systems ever be considered unfair or unjust? While we hesitate to draw such a stark conclusion, we suggest that the answer is not always obvious, for three reasons.

First, it is self evident that any effort to implement a new technology should not undermine existing health-care services.²² If an EHR system is introduced that is unreliable, unstable, and vulnerable to hacking or privacy breaches, it would be difficult to justify its adoption. Similarly, if the new system was not a substantial improvement over the existing system, e.g. replacing an outmoded multi-registration paper-based system with an equally outmoded *electronic* multiple registration system that would not only waste money and other resources, it would run the risk of unfairly including or excluding patients in databases.²³ Worse, it would waste precious resources that could have been used more effectively to advance health.

Second, whereas EHRs purport to be cost-saving for a hospital or a country, they still cost money to develop, build, implement and maintain. As such, EHRs and eHealth systems in general must be considered in the context of other institutional and domestic spending. Hospitals in resource rich countries regularly face budget-balancing decisions that can easily be seen from this justice perspective: if care is rationed because money is not available to support programs it is inevitable that this will be seen as unfair.^{20, 24} Resource poor countries are no different, especially when hard choices about domestic spending priorities result in the limitation or removal of some programs in favor of others. EHRs are more challenging, since infrastructure spending with its promise of benefits over the long term are always less popular than immediate spending to respond to a specific need such as immunization or safe water. Arguments about why EHRs ought to be implemented as a matter of justice and equity look somewhat different when compared to arguments about other basic needs.

Third, if as we believe, the right to health care includes a right to care of acceptable *quality*;²⁵ and if EHRs are lauded as mechanisms for providing at least equivalent and possibly superior care, then it might follow that all individuals have a right to receive care mediated through an EHRs. But does it follow? What if overall benefits to individuals from EHRs are only equivalent to but not superior to traditional systems?

Governance, Conflict of Interest, and Oversight

Just as no EHRs should be implemented without the scientific merit of the technology being beyond reproach, neither should EHRs be implemented without attention to the integrity of those implementing the systems and the potential for conflict of interest.²⁶⁻²⁷ This is not unique to a particular technology or location. If there is an opportunity to make money, the potential for conflicts is real.¹⁴ And EHRs are not inexpensive. In economically developing countries the potential for conflict of interest may be heightened by other economic and political pressures. Whether there are cultural or country-specific norms about the exchange of money or favors for contracts is not the point; rather the issue is whether the development and implementation of large institutionally-based eHealth systems can be adequately monitored by regulatory bodies and other oversight systems to ensure that both real and perceived conflicts of interest are avoided.

Managing Patient and Public Expectations: Informed Consent, Confidentiality and Trust

Central to the ethical implementation of any system in which personal health information is collected, stored, analyzed and distributed to others is the degree to which patients and the public trust those charged with these functions.²⁸⁻²⁹ But trust alone is unlikely to satisfy ethical and legal requirements for using these data responsibly, especially for research purposes. Among the more unique challenges in many resource poor countries is the need to provide individuals with information in a culturally and linguistically appropriate format.³⁰⁻³¹ Informing people of methods to protect confidentiality and what will happen if there are data breaches may be a very different task in cultures that do not ascribe to a more western notion of individual privacy and personal autonomy. The same is true of any disclosures about research use, secondary use, data ownership, or any contemplated data sharing agreements and legal accountability.^{22, 32}

It is unrealistic, however, to expect that every individual can provide sufficiently detailed consent for the collection, storage and use of all data held in EHRs, particularly when much of the data is of an administrative nature, and not limited to research protocol-specific activities. The lessons from biobanking may be instructive as there are ethical arguments for and against broad consent to biobank research (which increasingly combines biological specimens and phenotype health information) in which the burden is placed on research subjects to consider carefully the fact that samples donated now may be used for unspecified future research.³³⁻³⁴ Managing the technical implementation of EHRs therefore becomes a matter of managing patient and public expectations.

POINTS TO CONSIDER

From the discussion above, it is clear that many ethical issues need to be addressed carefully when implementing EHRs in resource-limited settings. For most individuals and organizations, some guidance on how to navigate through these ethical issues can be valuable. Below, we present a set of Points to Consider to help in the ethical decision-making process around EHRs implementations in developing countries. These points are framed as questions whose answers are not pre-determined: the answers should depend largely on the context and circumstances surrounding the particular implementation. As stated by Fife et al.: “The points are neither a set of decision rules that mechanistically resolve issues at stake, nor a set of principles the interpretation of which can be manipulated by various parties to support their particular points of view.”¹⁴ They should be used to help reach sound and principled ethical judgments. We propose the following Points to Consider as an initial step in beginning a conversation about ethically defensible approaches to implementing EHRs in resource poor settings:

Initial and Long Term Costs and Benefits of the EHRs

Too often, institutions in developing countries embark on EHRs implementations without rigorous considerations of what the costs and benefits of these systems are. In any implementation, the following questions should be asked of institutions:

- What are the accurate financial and social costs of the implementations, and how do these change over time?
- What alternative interventions have been considered?
- How does the cost versus benefit of the EHRs compare with those of alternative interventions?
- Who will bear the cost over time and what is the strategy for long-term support?

Level of Evidence

As organizations and institutions consider adopting EHRs systems, they have to evaluate the scientific validity of the evidence supporting the costs and benefits of the system. As such, institutions should be able to answer the following questions:

- What evidence exists of the benefits of the proposed system and how directly applicable is this evidence?
- What mechanisms have been put in place to gather rigorous evidence to prove the benefits and risks of the EHRs and of the planned or existing implementation?

Inclusion of Partners

Appropriate decision of whether and how to implement the EHRs should be reached if input from all stakeholders is heard, and if the community capacity is built to sustain the system. Implementers should be asked to answer these questions:

- Who is representing the patients and the community in EHRs-related decision-making processes?
- What are the different stakeholders’ interests and concerns, and how is each concern being handled and addressed?
- What is being done to increase the community’s capacity to self-manage the EHRs?

Quality of the System and the Implementation Strategy

Sub-standard systems and poor implementation plans can compromise patient care. Implementers of EHRs in resource poor countries should be asked to answer the following questions:

- What are the EHRs standards and implementation guidelines in the setting?
- How does the system rate against accepted EHRs standards (both local and international)?
- What cultural or societal issues will affect the types of data collected within the EHRs and how the system is implemented?
- What implementation strategies are being put in place to ensure that the system is sustainable?
- What back-up strategies are in place in case the system runs into problems?
- What are the standard operating procedures for all aspects of the implementation?

Oversight

A level of ownership is needed for specific functions in the implementation. At the same time, strict monitoring needs to be in place to ensure that the implementation operates smoothly. Questions that institutions should answer include:

- What are the important tasks and who is assigned responsibility for each?
- Who is in the independent body that will oversee the system and evaluate the appropriateness of the implementation?

- What are the potential conflicts of interest and how have they been addressed?

Informed consent

Patients and communities in resource poor settings might not be very familiar with particular technologies, and different approaches might be required to help them understand what it means to have their medical records stored electronically. Implementers and organizations should be asked:

- What is in place to educate the patients and community (in a culturally sensitive way) what it means to have records stored in the EHRs?
- What are the protocols for obtaining informed consent from patients, and what mechanisms are there to ensure that this actually happens?
- How are individuals and communities being made aware of the secondary uses of the information in the EHRs?
- Who will have the rights and ownership to the data stored electronically?

Data Security

Electronic equipments are very attractive targets for theft in resource limited settings. Furthermore, unauthorized data access puts patients at risk. Implementers should be asked:

- What security measures (both physical and technical) are in place to protect patient data?
- How can levels of data protection be justified if they are not similar to those in the West?

Equitable Access

Technology should not be discriminative. Implementers should be asked:

- How will the benefits or risks of the system be distributed between different groups in the community?
- What strategies are in place to ensure that one group is not favored over others with the EHRs implementation?

NEXT STEPS

Given the enthusiasm for developing and implementing EHRs, it may be unpopular to ask that a pause be taken to consider some of the ethical issues that arise from proposals to implement them, especially in the economically developing world where their potential to benefit so many appears so obvious. But we believe that careful assessment of these ethical issues should be undertaken at least at the same time. We agree that the potential is great, but believe that now is the time to evaluate how well current EHRs implementations have considered ethical issues, and to address these going forward.

ACKNOWLEDGEMENT

Support for E.M. Meslin is provided by 1 R25 TW008183-01 and 1S07TW008850-01 Fogarty International Center, NIH; UL1RR025761-01 NCCR/NIH; Richard M. Fairbanks Foundation program in Predictive Health Ethics Research.

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