

The Role of Consumer Consent in Health Information Exchange (HIE)

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Abstract

The traditional one-way information transfer considered the healthcare provider as the expert communicator and the patient as passive receiver of information. Patient-centered care operates based on patients' preferences to improve patient safety and increase patient satisfaction and participation. A mutual exchange of information ensures that both patients and healthcare professionals form a partnership. Greater patients' participation in Health Information Exchange can lead to higher degree of trust among all types of demographic groups. Patients need to be more engaged in decisions about data exchange through HIE in order to trust the technology and the healthcare system. The right of informed choice and consent is a meaningful means to achieve the support of consumers regarding HIE. However, the process of handling informed consent has caused variety of concerns such as security and privacy risks for patients. In this study, the role of consumer consent is discussed using the literature review method.

Keywords

HIE, consumer consent, patient engagement.

Introduction

The Health Information Exchange (HIE) is an important component of the Health Information Technology (HIT) infrastructure that is designed to facilitate electronic movement of patients' health information among healthcare organizations during the care process (Vest and Gamm 2010). HIE promises several potential benefits through improved quality, safety and efficacy of healthcare services (Adler-Milstein et al. 2008). Ancker et al. (2012) indicated three possible architectures designed for HIE. The first model is called Direct Project that enables exchanging patients' health information directly from one physician to another one through a secure network. The sender should be aware of recipient's identity. The second model is called patient-controlled exchange and it engages patients in the process of data exchange by considering a mediating role for patients so that patients can receive data from a physician and send it to other physicians as required. In the last option which is called non-directed exchange, physicians can release patients' information to a central organization where other physicians can get access to it through a lookup process (Ancker et al. 2012).

Health providers can produce and use health information but some other stakeholders such as health insurers, regulators and policy makers mostly use these information. Obtaining coordination among all the stakeholders can be very challenging due to legal, safety, security, and operational issues (Park et al. 2013). One of the most critical stakeholders is healthcare consumers because their consent is required for sharing their health information. The patients' attitude towards sharing their personal health information can affect the design of future health information systems (Whiddett et al. 2006). Therefore, studying patient attitude toward the system and addressing potential disparities in HIE implementation is very significant (O'Donnell et al. 2011). Literature shows that consent and permission of viewing medical records are important to patients and can form their attitudes. For instance, Patel et al. (2012) indicated that the majority of consumers allowed the doctors and providers who are involved in their healthcare to view their records electronically via HIE with their permission except in medical emergency conditions. The right of informed choice and consent is violated when many healthcare providers assume that patients have implicitly given consent to distribute their health information by seeking their services (Sankar et al. 2003). In this case, healthcare providers will rarely get further clarification when they share

patients' health-related information with other providers (Whiddett et al. 2006). However, the process of dealing with informed consent and consultation for access to patient information should be handled carefully to avoid increasing the workload of healthcare professionals. Dimitropoulos and Rizk (2009) specified that consent is a vital factor affecting the implementation of HIE systems. The first form of consent is defined for any types of data to be shared through HIE among healthcare providers. In the second form, consent is needed depending on types of situations, senders, recipients, or sensitive data. Since the process of obtaining consent vastly depends on type of HIE infrastructures, security issues and policy of healthcare providers, there are a great deal of confusion around it. In this study, current literature has been reviewed to give us a better understanding of consent, different types of it, and how it operates.

Methods

The main objective of this study was to undertake a literature review of existing studies regarding the role of consumer consent in HIE. To identify the right set of key words and databases, the authors used the help of a health librarian. To meet the objective, the studies were mainly searched in five electronic research databases of ScienceDirect, PubMed, Web of Science, CINAHL, and Academic Search Premiere. The main keywords used for searching articles were "Health Information Exchange", "HIE" and patients participation", "Consumer consent", "Role of consent in HIE", "Types of consumer consent", "Patients' concerns related to consent", and "Benefits of consumer consent in HIE". Through database searching, 196 articles published during and after 2005 were retrieved. There were 41 duplicates and non-English articles that were removed resulting in 155 articles. The titles and abstracts of these 155 papers were screened and 76 papers were excluded based on the initial exclusion criteria (no or not relevant abstracts and not relevant settings). The selected papers (79 studies) were reviewed in full and assessed for eligibility. To obtain the final set of papers, 43 papers were further excluded with reasons such as having irrelevant focus of study, lack of relevant research results, or offering too general discussions with no clear theoretical and practical contributions. Finally, 36 papers were used in a qualitative synthesis and a summary of included papers are indicated in next section.

Results

Our findings show that there are four main forms of consent: 1. General consent: it is assumed that patients have given an inclusive consent for their information to be used and shared in all cases and instances. 2. General consent with specific denial: patients place some limitations and restrictions on using and distribution of their health information. It applies many restrictions in case of sharing patient information for the purpose other than provision of care such as research. Therefore, by using this form of consent, healthcare professionals can use and exchange patient information for purposes of care delivery within the clinical setting. This form of consent also allows patients to limit access to some sensitive health and medical information (Coiera and Clarke 2004) 3. General denial with specific consents: patients don't generally allow providers to access to their information except in some specific circumstances such as for care purposes. In general, healthcare providers are banned from using and exchanging the patient health information unless a permission granted by them for care provision purposes. In this case, since patients are aware of how their information is used, it requires obtaining a great deal of consents from patients on an ongoing basis. 4. General denial: Healthcare providers require consent from patients to use or share their information on each occasion. It enforces a very severe access control protocol to ensure privacy requirements. On the other hand, it also increases administrative burdens on healthcare providers (Whiddett et al. 2006). The following table (Table 1) illustrates the four types of consent.

Now, the key question is: which one is the best option? The hybrid model implies that there is no best access control protocol to achieve public acceptance. Different reasons for using patient information can define different forms of consent. Patients choose an HIE system with a robust consent feature as the most preferred sharing method among healthcare providers (Park et al. 2013). According to a phone survey of adults in the U.S., majorities supported the implementation of HIE among healthcare providers owing to improved quality of care and efficiency. The respondents endorsed use of HIE by healthcare providers even with no need to get patients' consent in case of emergencies (Ancker et al. 2012). The

following figure (Figure 1) shows the hybrid model of consent where type of data, senders, recipients and occasion of using and sharing patient health information affect choice of consent.

Type of consent process	Access protocol	Type of situation
General consent	Access to all types of medical data	All cases and instances
General consent with specific denial	Limited access to some sensitive medical information (such as sexually transmitted diseases and mental disorders)	Only for the purpose of care delivery within the clinical setting
General denial with specific consents	Limited access to all data (current health problems and past medical information)	Only in some specific circumstances such as medical emergency conditions
General denial	Very severe access control procedure applied to full current and past medical/health information	All occasions

Table 1. Summary of four consent forms

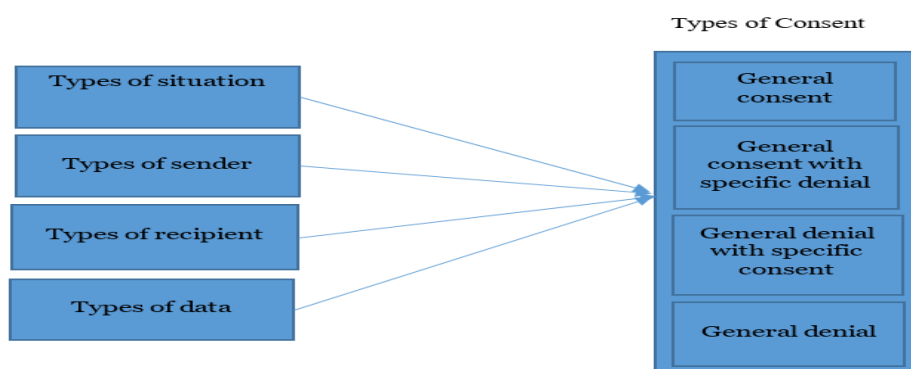


Figure1. Hybrid Model of Consent

The consent process can also be described in two forms: opt-in and opt-out systems. An opt-in system gives patients the ability to participate in HIE by providing explicit consent so that they can allow or avoid health information exchange. Patients believe that the process of opting in to the system for providing consent should include more information resources and a new organizational position should be dedicated to the consent process in order to manage consent procedures seamlessly (Simon et al. 2009). In opt-in policy, prior to uploading patient’s data from a physician office Electronic Health Record (EHR) system to the HIE community database, a signed patient consent form is required in all cases (Yasnoff et al. 2004). Opt-in consent approach allows other providers (other than the primary physicians) to access patients’ personal health information via HIE if it is along with patients’ permission (Patel et al. 2012). A specific type of Opt-in form is Opt-in with break the glass which allows access to data without agreement only in an emergency (Kim et al. 2015). An opt-out system assumes that there is no need to obtain explicit consent from patients for the purpose of information exchange. In opt-out model clinical data can be shared over the network unless a patient formally requested otherwise (Tripathi et al. 2009).

According to Simon et al. (2009), patients are more willing to participate in opt-in rather than opt-out HIE systems. There are three drivers for choosing an opt-in approach. The first one is due to strict privacy laws that lead to conservatism in the face of uncertainty. The second factor is the HIE architecture which is characterized by a centralized data repository for authorized users. In this architecture, patients feel more control over their health data and they can organize their clinical data before their data are stored in a central repository. The third driver is feedback from consumers. Increasing concern about privacy and security of clinical data requires new technologies to allow patients to be stewards of their own medical

information (Tripathi et al. 2009). The main question in a centralized repository structure and an opt-in model is what types of data patients desire to be shared? Patients might refuse to allow data sharing for privacy reasons even if the data exchange is legal. Data exchange would be clinically useful when it would not make large numbers of patients to refuse to opt in. A successful HIE initiative should balance the richness of clinical data that should be shared and coverage of patients. If shared information is not enough, opt-in would be high and more patients would allow exchange but little or incomplete information is available and physicians might not adopt HIE because they would not find the exchange valuable. On the other hand, if too much information is shared, the clinical information would be rich enough but fewer patients would opt in and again physicians are less likely to adopt HIE (Tripathi et al. 2009).

Paper-based consent may result in an additional work burden due to frequent human contact (Ancker et al. 2012). Therefore, e-consent is a solution to patient consent concern by which patients agree to share their medical information with other hospitals in case of clinical needs when their privacy is ensured (Galpottage and Norris 2005). Consent forms are written by the health care organizations seeking the data and are often termed in general or vague words that highlight potential uses of the data. Therefore, consumers may authorize access to their personal health information via a consent form or policy that they don't fully comprehend. A new mandate should describe the terms of HIE service and the privacy policies in a meaningful way not just with very general and unclear terms. Different consent forms should be obtained from patients for disclosing their personal data for health care, marketing or research purposes (McGraw et al. 2009). Most people do not read the details of consent forms and just assume that the presence of privacy terms and conditions means their data will not be shared at all (Good et al. 2005). Many consent forms are not very informative and written in a way to obtain patient consent for all potential uses of data (Goldman et al. 2000). People are usually asked for a consent when they are in hospitals waiting for a vital treatment or when they apply for insurance. Under these circumstances, it is not very likely that people say no to authorization if they perceive that the treatment or insurance coverage may be cancelled. Then, they authorize disclosure of information for all potential uses and purposes and third parties mine their sensitive data based on the initial authorization. This fact highlights deficiencies in current consent guidelines and serves as an evidence for a new policy approach to educate patients on consent forms and features.

Contributions

Patient engagement in the treatment process is vital to HIE efforts in determining how much information is shared and how it is shared. HIE will require a long-term connection between patient engagement and clinicians. Our results show that patients are not well informed about how their information is shared whereas they prefer to be consulted about the distribution of their information. Additional effort should be made toward education among all types of demographic groups to clearly articulate the potential advantages and risks associated with HIE. Patients prefer to share information if used for their health benefit otherwise they like to keep it private. Patients should be aware of the current information sharing practices between healthcare providers to convert an implied consent to an informed one. As mentioned, patients' consent preference is affected by four factors: 1) identity of recipient, 2) identity of sender and 3) type of information and 4) type of situation and purpose of sharing. We also argue that consent provision can enhance perception of benefits and mitigate perceived concerns associated with HIE.

Policy makers should devise new strategies to ensure patient right to informed consent by articulating and addressing the perceived privacy and security risks of HIE. By removing the potential risks, patients would be more likely to endorse HIE when they believe that the potential benefits far outweigh the possible risks. Potential benefits of HIE such as improved quality and safety of health care can encourage patients to provide consent for participation. New regulatory standards need to prevent certain uses of patient genetic information for some nonmedical purposes such as employment, credit, or insurance even with consent. Additional policies are required to better explain how and when consent is obtained and how the information will be used. New policies should give more weight to individual's right to limit access to some sensitive data.

Conclusion

HIE is successful only when patients are willing to share their medical data. Consumers may conceptually support the development of HIT and infrastructures which enable HIE but it is not guaranteed that they

will exchange their personal health information. Patients are willing to support HIE but they also value elements of transparency, privacy and security issues such as individual control, who can access their data, and the purpose of using their health data. The vulnerable health status of patients makes them seek more privacy and confidentiality protection through informed consent. This study shows that different types of consent are being used in hospitals to accomplish HIE. Policy makers can streamline the consent process through better electronic communication strategies.

REFERENCES

- Adler-Milstein, J., McAfee, A. P., Bates, D. W., and Jha, A. K. 2008. "The State of Regional Health Information Organizations: Current Activities and Financing," *Health Affairs* (27:1), pp. w60-w69.
- Ancker, J. S., Edwards, A. M., Miller, M. C., and Kaushal, R. 2012. "Consumer Perceptions of Electronic Health Information Exchange," *American journal of preventive medicine* (43:1), pp. 76-80.
- Coiera, E., and Clarke, R. 2004. "E-Consent: The Design and Implementation of Consumer Consent Mechanisms in an Electronic Environment," *Journal of the American Medical Informatics Association* (11:2), pp. 129-140.
- Dimitropoulos, L., and Rizk, S. 2009. "A State-Based Approach to Privacy and Security for Interoperable Health Information Exchange," *Health Affairs* (28:2), pp. 428-434.
- Galpottage, P., and Norris, A. 2005. "Patient Consent Principles and Guidelines for E-Consent: A New Zealand Perspective," *Health Informatics Journal* (11:1), pp. 5-18.
- Goldman, J., Hudson, Z., and Smith, R. M. 2000. *Privacy: Report on the Privacy Policies and Practices of Health Web Sites*. California HealthCare Foundation Oakland (CA).
- Good, N., Dhamija, R., Grossklags, J., Thaw, D., Aronowitz, S., Mulligan, D., and Konstan, J. 2005. "Stopping Spyware at the Gate: A User Study of Privacy, Notice and Spyware," *Proceedings of the 2005 symposium on Usable privacy and security*: ACM, pp. 43-52.
- Kim, K. K., Joseph, J. G., and Ohno-Machado, L. 2015. "Comparison of Consumers' Views on Electronic Data Sharing for Healthcare and Research," *Journal of the American Medical Informatics Association*, p. ocv014.
- McGraw, D., Dempsey, J. X., Harris, L., and Goldman, J. 2009. "Privacy as an Enabler, Not an Impediment: Building Trust into Health Information Exchange," *Health Affairs* (28:2), pp. 416-427.
- O'Donnell, H. C., Patel, V., Kern, L. M., Barrón, Y., Teixeira, P., Dhopeswarkar, R., and Kaushal, R. 2011. "Healthcare Consumers' Attitudes Towards Physician and Personal Use of Health Information Exchange," *Journal of general internal medicine* (26:9), p. 1019.
- Park, H., Lee, S.-i., Kim, Y., Heo, E.-Y., Lee, J., Park, J. H., and Ha, K. 2013. "Patients' Perceptions of a Health Information Exchange: A Pilot Program in South Korea," *International journal of medical informatics* (82:2), pp. 98-107.
- Patel, V. N., Dhopeswarkar, R. V., Edwards, A., Barrón, Y., Sparenborg, J., and Kaushal, R. 2012. "Consumer Support for Health Information Exchange and Personal Health Records: A Regional Health Information Organization Survey," *Journal of medical systems* (36:3), pp. 1043-1052.
- Sankar, P., Mora, S., Merz, J. F., and Jones, N. L. 2003. "Patient Perspectives of Medical Confidentiality," *Journal of general internal medicine* (18:8), pp. 659-669.
- Simon, S., Evans, J. S., Benjamin, A., Delano, D., and Bates, D. 2009. "Patients' Attitudes toward Electronic Health Information Exchange: Qualitative Study," *Journal of medical Internet research* (11:3), p. e30.
- Tripathi, M., Delano, D., Lund, B., and Rudolph, L. 2009. "Engaging Patients for Health Information Exchange," *Health Affairs* (28:2), pp. 435-443.
- Vest, J. R., and Gamm, L. D. 2010. "Health Information Exchange: Persistent Challenges and New Strategies," *Journal of the American Medical Informatics Association* (17:3), pp. 288-294.
- Whiddett, R., Hunter, I., Engelbrecht, J., and Handy, J. 2006. "Patients' Attitudes Towards Sharing Their Health Information," *International journal of medical informatics* (75:7), pp. 530-541.
- Yasnoff, W. A., Humphreys, B. L., Overhage, J. M., Detmer, D. E., Brennan, P. F., Morris, R. W., Middleton, B., Bates, D. W., and Fanning, J. P. 2004. "A Consensus Action Agenda for Achieving the National Health Information Infrastructure," *Journal of the American Medical Informatics Association* (11:4), pp. 332-338.