

Consent-Related Issues/Questions for Health Information Exchange in a Peer-to-Peer Exchange with Centralized Administration

Information Flows and Potential Points for Consent

Figure 1 shows a simplified model of a Health Information Network. The purpose of the picture is to provide a simplified version of the flow of a patient's information and the potential points where patient consent could be utilized. The picture allows us to examine the issues, concerns and legality of disclosing/accessing/exchanging information in various parts of the Health Information Network.

Key Elements of Figure 1:

Patient X – Patient X is being admitted to the Good Hospital for non-emergency treatment. Patient X has a number of chronic conditions and regularly takes a number of medications for his conditions. Patient X receives his primary care at Fine Clinic, which has the majority of his health records. Patient X would like to be able to share his health records with all medical organizations and physicians treating him.

Good Hospital – Is a hospital that participates in the Health Information Network and has the capacity to electronically exchange health information. Good Hospital would like to receive health information (e.g., medical history, medication history, etc.) about Patient X from Fine Clinic. Good Hospital and Fine Clinic are not affiliated or related through any common ownership.

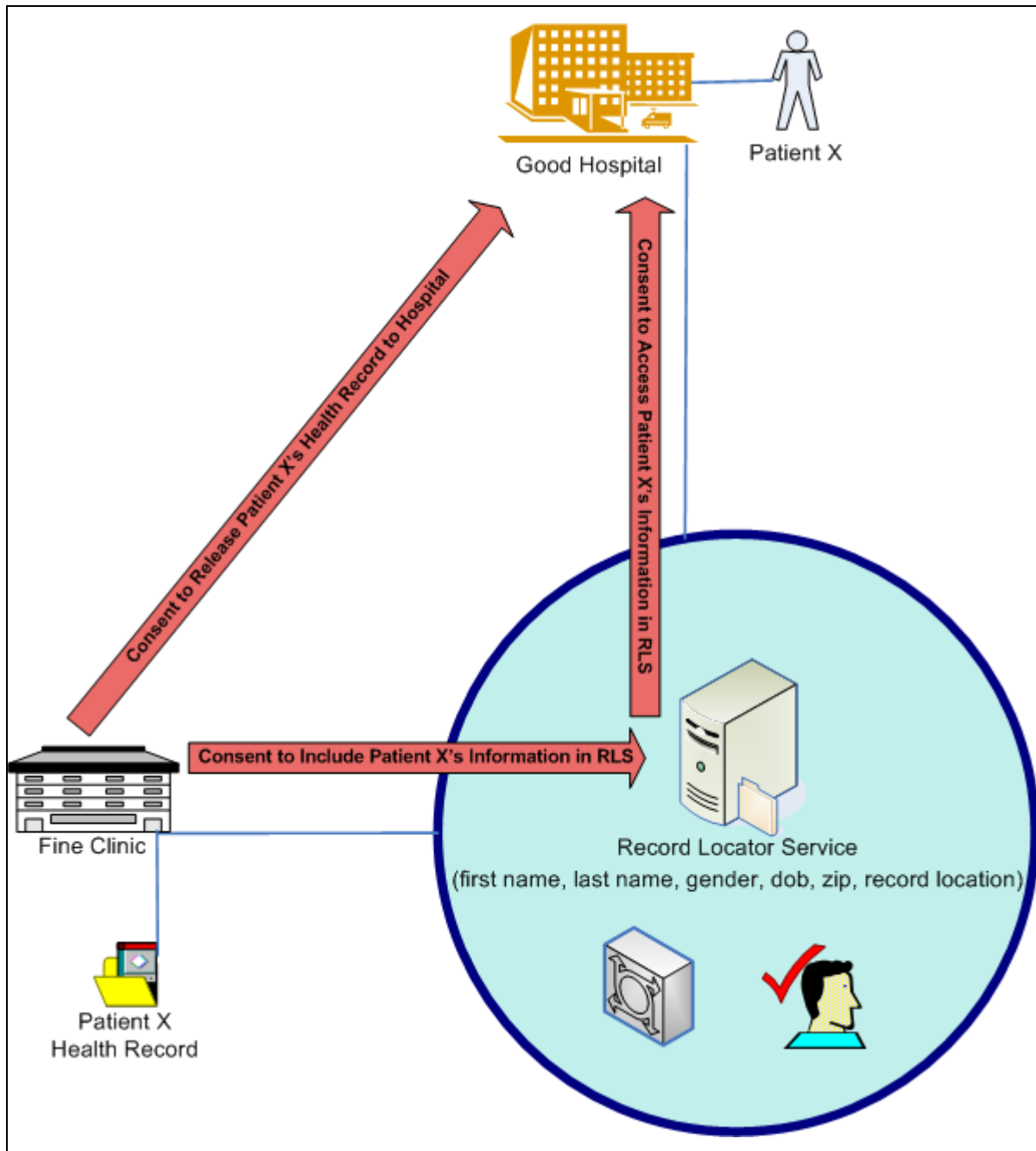
Fine Clinic – Is a clinic that participates in the Health Information Network and has the capacity to electronically exchange health information. Fine Clinic has served as Patient X's primary care clinic for a number of years and has a reasonably complete health record for Patient X. Fine Clinic and Good Hospital are not affiliated or related through any common ownership.

Record Locator System – The Record Locator System (RLS) is the mechanism used by the Health Information Network to identify the location of patients' health records at health care organizations participating in the Health Information Network. The RLS does not contain the patients' health records, but rather sufficient demographic information to identify patients and a pointer to the organizations with records.

Three Points of Information Flow:

1. **Demographic information** about Patient X is exchanged **from Fine Clinic to the RLS** in the Health Information Network, allowing other organizations in the network to know that Fine Clinic has records for Patient X.
2. **Demographic information** about Patient X is exchanged **from the RLS to Good Hospital** to find the location of Patient X's records to assist in treating Patient X.
3. **Portions of Patient X's Health Record** are exchanged **from Fine Clinic to Good Hospital** after Good Hospital requests relevant portions of the health record.

Figure 1: Information Flows and Potential Points for Consent in Health Information Network



Notes to Figure 1: The **three red arrows** represent the information flow within the picture. For example, the red arrow between Fine Clinic and the Record Locator Service represents the flow of Patient X's demographic information between Fine Clinic and the Record Locator Service. The **words on the arrows** indicate that it would be possible to get patient consent prior to the exchange of information. The words are intended to aid in understanding what would be covered by the patient consent, the words do not indicate who needs to be provided documentation of the consent.

Within Figure 1, there are three points of information flow that provide three potential points where patient consent could be obtained; that is, consent could be obtained at any, or all of the points. Additionally, the consent could be for any or all of the exchanges. Hence, the

possibilities for consent are contained in Table 1: Possible Points of Consent in Health Information Network. As Table 1 shows, there are eight possible options for how consent could be used within this model of a Health Information Network.

Investigating the Issues, Concerns and Legality of Consent Options

The eight possible options for consenting to the exchange of information in a health information network have different advantages and disadvantages for patient care, patient choice, and patient privacy. An example of the different advantages/disadvantages between Options in Table 1 can be highlighted with Options 1-4 and Options 5-8. In Options 1-4, a patient must consent in order for any of their information to be sent to the record locator system. While this consent enhances the patient’s control over his/her data, it limits providers and emergency departments’ ability to find and access his/her health records in an emergency. In contrast, Options 5-8 allow a patient’s demographic information to be included without patient consent. These options allow the patient’s health information to be found in an emergency, but rely on consent at some other points in the process to provide privacy protections.

Because all eight of the options have different advantages and disadvantages for patient care, patient choice and patient privacy, the desirability of the options will vary for those evaluating the options. At this stage of the project, our goal is not to evaluate the desirability of the options. Rather, we want to identify the issues, concerns and legality (under current Minnesota law) of the options. Issues and concerns may include:

- Patient control over their information
- Liability concerns
- Consistency with current State and Federal law
- The capacity to operationally implement the requirements
- Other

Table 1 – Possible Points of Consent in Health Information Network

	Provider Including Patient Locator Information in RLS	Provider Accessing Patient Locator Information in RLS	Providers Exchanging Patient’s Health Record
Option 1	Consent	Consent	Consent
Option 2	Consent	Consent	Consent Not Required
Option 3	Consent	Consent Not Required	Consent
Option 4	Consent	Consent Not Required	Consent Not Required
Option 5	Consent Not Required	Consent	Consent
Option 6	Consent Not Required	Consent	Consent Not Required
Option 7	Consent Not Required	Consent Not Required	Consent
Option 8	Consent Not Required	Consent Not Required	Consent Not Required

The following questions are designed to aid in evaluating the eight options for consent and address other consent-related issues that might impact the ability to share health records in accordance with patients’ desires:

Questions Related to Providing Data to RLS

1. Under current Minnesota law, would it be legal for Fine Clinic to provide Patient X's demographic information to the RLS without Patient X's consent?
2. Under current Minnesota law, would it be legal for Fine Clinic to provide Patient X's demographic information to the RLS without Patient X's consent, if no one other than Fine Clinic were able to access the data without Patient X's consent? That is, all organizations load demographic information into the RLS, but accessing a particular patient's information requires the patient's consent.
3. Under current Minnesota law, if Fine Clinic obtained Patient X's consent to include his data in the RLS, would that consent expire after one year?
4. What changes would be needed to allow patients to consent to include their data in the RLS until they revoke the consent?
5. What are your privacy-related concerns about including patient data in the RLS in general? With consent? Without consent, but with consent at other points in the process?
6. What are your liability-related concerns about including patient data in the RLS in general? With consent? Without consent, but with consent at other points in the process?

Questions Related to Accessing Data from RLS

7. If data from Fine Clinic were provided to the RLS with Patient X's consent, would there be any legal restrictions on Good Hospital accessing the data without consent for treatment purposes?
8. If data from Fine Clinic were provided to the RLS with Patient X's consent, are there legal restrictions on Good Hospital prohibiting it from accessing the data without consent for non-treatment purposes?
9. If there are not explicit legal restrictions in Question 8, do you anticipate that this would be an issue addressed in the policies and procedures of the health information network and integrated into the contractual arrangements for participating in the network? Do you have concerns about addressing these issues contractually?
10. Assume that it were possible to provide data to the RLS without Patient X's consent, but that Patient X's consent is required for Good Hospital to access the RLS and obtain patient data. What documentation would you expect Good Hospital to maintain? What documentation should they be required to provide the RLS? What stands in the way of providing the RLS any and all documentation electronically?
11. Assume that it were possible to provide data to the RLS without Patient X's consent, but that Patient X's consent is required for Good Hospital to access the RLS and obtain data. Under current Minnesota law, in the event of an emergency, what type of documentation would you expect Good Hospital to maintain? What documentation should they be required to provide the RLS? What stands in the way of providing the RLS any and all documentation electronically?
12. What are your privacy-related concerns about accessing patient data in the RLS in general? With consent? Without consent, but with consent at other points in the process?

13. What are your liability-related concerns about accessing patient data in the RLS in general? With consent? Without consent, but with consent at other points in the process?

Questions Related to Exchanging Data between Providers

14. Assume Good Hospital uses the RLS to identify that Patient X has health records at Fine Clinic. Fine Clinic needs Patient X's consent to provide Good Hospital Patient X's health record. What are the barriers to:
- Patient X providing consent at Good Hospital;
 - The hospital sending Patient X's consent electronically to Fine Clinic; and
 - Good Hospital accessing the relevant portions of Patient X's records from Fine Clinic system?
15. What changes to current Minnesota law would be necessary to allow Patient X to consent to allow Fine Clinic to release his health records to any health care provider in the Health Information Network until the consent is revoked?
16. If Patient X is at Good Hospital and it is an emergency, what changes to current Minnesota law would be needed to require Fine Clinic to accept that the situation is an emergency and provide Good Hospital the relevant portions of Patient X's health record?
17. What liability concerns do you see for Fine Clinic in either Questions 15 or 16?
18. For the situation in Question 16, what documentation would you expect Good Hospital to maintain? What documentation should they be required to provide Fine Clinic? What stands in the way of providing Fine Clinic any and all documentation electronically?
19. The Variations Work Group has stated that the responsibility and liability for disclosing health information resides with the organization disclosing the health information and not the organization requesting the information. Does all of the potential liability reside with the disclosing organization (i.e., Fine Clinic, in our example)? What types of changes would be necessary to redistribute the potential liability to more fairly onto those who may disclose inappropriately and those that make inappropriate requests or access?
20. Assuming that Patient X wants to share his data with other providers (e.g., Good Hospital and others) for treatment, what changes to the current consent requirements would permit Patient X to give health care providers easier access to his information?
- What liability concerns do you envision with allowing Patient X to permit easier access to his data?
 - What privacy concerns do you envision with allowing Patient X to permit easier access to his data?
 - What operational concerns do you envision with allowing Patient X to permit easier access to his data?