

The Risks of Absent Interoperability: Medication-Induced Hemolysis in a Patient With a Known Allergy

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Case Objectives

- State the goals of the HITECH Act of 2009.
- Describe the "summary of care record" requirement that is part of the meaningful use criteria.
- List two key barriers to incorporation and reconciliation of information transmitted between institutions.
- Define interoperability.
- List barriers to rapid and seamless transmission of usable patient care data.

The Case

A 47-year-old man with paraplegia (secondary to a gunshot wound) and a history of polysubstance abuse presented to the emergency department (ED) of Hospital Y late in the evening with pain and fever. The patient reported he had been to four different hospitals in the past few weeks and recently left against medical advice from Hospital X that morning to celebrate his birthday. Outside records from Hospital X obtained by the ED were scanty but revealed that the patient had presented with sepsis and had received antibiotics and intravenous fluids for presumed infection prior to leaving.

He was diagnosed, again, with sepsis secondary to sacral decubitus ulcers. He was given intravenous fluids, started on vancomycin and piperacillin-tazobactam, and admitted to the hospital for further management. During the day, he appeared to be improving on antibiotics. At approximately 3 AM, the patient was found unresponsive by his nurse. A code blue was called, and he was noted to be in PEA [pulseless electrical activity] arrest. He achieved return of spontaneous circulation after 4 minutes of cardiopulmonary resuscitation. He was intubated and transferred to the intensive care unit (ICU).

Upon arrival to the ICU, his hemoglobin was undetectable, and clinicians determined that the arrest was secondary to massive intravascular hemolysis (acute rupturing of his red blood cells). Based on the clinical presentation, the hemolysis was presumed to have been caused by a reaction to the piperacillin-tazobactam.

The patient was transfused with 8 units of packed red blood cells and his hemoglobin improved. Unfortunately, his cardiac arrest led to an anoxic brain injury, and he remained in a vegetative state.

Later that day, previously requested records arrived from three hospitals where the patient had been cared for recently. One record revealed that he had experienced piperacillin-tazobactam-induced hemolysis last month, resulting in cardiac arrest and a 2-week ICU stay. This severe life-threatening allergic reaction was not known to any providers in the current hospital. On admission, the patient reported no allergies to medications, but he did state that he had "a reaction to a transfusion" where "my white cells were attacking my red cells and my heart stopped." In light of this answer (and the absence of data from the other hospitals), he was noted to have no medication allergies.

After 3 weeks in the hospital, the patient was transferred to a long-term care facility with a poor likelihood of recovery.

The Commentary

The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 created the Centers for Medicare & Medicaid Services (CMS) electronic health record (EHR) incentive programs (often referred to as "meaningful use") and the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program. Both were designed to not only facilitate the development and implementation of health information technology (IT), but ultimately to create systems that would enable care providers to share information instantly and seamlessly, just as we have come to expect from our banking, Internet searching, and social networking tools.⁽¹⁻³⁾ Why, we ask, can we withdraw \$50 from an ATM in Moscow and see Facebook updates from long-lost high school friends, yet we are unable to seamlessly move clinical information across town in an emergency?

However, cases like the one presented above, which we had hoped would become a distant memory, still occur with some regularity. The patient offered a vague description of a serious transfusion-related event. Some records were obtained, but clearly the care providers had inadequate knowledge of the specifics to prevent this serious adverse event. This case illustrates why interoperability is so important. It forces us to ask: How can cases like this be prevented? And, what are reasonable expectations of health IT systems to help avert such events?

First, it may be useful to review the policies and requirements (articulated in both the meaningful use objectives and certification criteria) in the HITECH Act that were intended to prevent cases like this one.

The EHR incentive programs in the HITECH Act require that hospitals and physicians, referred to as eligible professionals, meaningfully use certified health IT in order to receive incentive payments or avoid penalties. The programs specify IT-related activities that indeed meaningfully contribute to improved care quality and efficiency and require that such activities be performed. The rationale for meaningful use was

simple: policymakers were concerned from the outset that without the policy lever and financial incentives of meaningful use, there would be no compelling reason for care providers to use their newly purchased (with government subsidies) IT systems optimally in the service of improved care.

Among the many meaningful use criteria, one relevant to this case is the Clinical Decision Support Rule.⁽⁴⁾ This requirement states that the eligible hospital has "enabled the functionality for drug–drug and drug–allergy interaction checks for the entire EHR reporting period." Note that this requirement is focused on the providers (hospitals and doctors). But the ONC was well aware that such requirements could not be met unless the developers of IT systems built in the relevant functionality. So the ONC certification program requires developers of health IT systems to include this capability in their products: "Before a medication order is completed and acted upon during computerized provider order (CPOE), interventions must automatically and electronically indicate to a user drug–drug and drug–allergy contraindications based on a patient's medication list and medication allergy list."⁽⁵⁾ In other words, to meet meaningful use criteria participating hospitals must be able to identify drug–drug interactions and drug allergies and they must be capable of automatically signaling these to the ordering provider.

An additional meaningful use criterion that applies to this case involves the ability to electronically transmit a summary of care record between facilities.⁽⁶⁻⁹⁾ This gets to the heart of interoperability. Care summary records are required to have the 16 elements listed in the [Table](#). Note that element number 10 is medication allergies.

With the foundation of these elements, we can see how the requirements, if met, could potentially prevent adverse events such as the one described in this case. Ideally, both hospitals would have health IT systems that were certified by the ONC. According to a recent report on the adoption of EHR systems among US non-federal acute care hospitals, the vast majority of hospitals now use certified health IT systems.⁽¹⁰⁾ If the hospital had a certified health IT system, the patient's adverse reaction to the antibiotic would have been documented in Hospital X's medical record as a medication allergy. Note that documenting the medication allergy in an allergy list is not explicitly required by the hospital for meaningful use, but the inclusion of the patient's allergies in the care summary record is required. Of course, the allergy couldn't be expressed in the care summary record if it had never been captured via an adequate history, which illustrates that having a well functioning medical record system is no substitute for good medical practice.

In this case, it appears the allergy was documented in the records of at least one of the patient's prior hospitals, since it was listed in the record that eventually arrived—too late to prevent the event—at Hospital Y. Once the allergy had been recorded in Hospital X's record, ideally, this record would have been instantly transmitted to Hospital Y when the patient presented to its ED since Hospital Y requested records from Hospital X. Hospital Y could use several methods to request this information. For brevity, let's just assume that an ED nurse in Hospital Y called another nurse in Hospital X and asked that the records be electronically transmitted. After such a transmission, Hospital Y would need to incorporate the information in Hospital X's care summary into its own system and then reconcile it so that the information is available in Hospital Y to be used by providers and in its health IT system. This may sound easy, but it's not—particularly since there is every chance that Hospital X's computer system is made by a different developer than Hospital Y's. Once reconciled, the allergy would be in the patient's allergy list. Given the

clinical decision support requirement above, any provider ordering piperacillin-tazobactam would receive an alert, informing him or her of the allergy and hopefully preventing an adverse drug event.

In addition, reconciliation is challenging and requires multiple steps to ensure accuracy and safety. A document that arrives in a hospital's IT system has segments that align with the sections of a medical record. The first step at the receiving hospital (Hospital Y) is to confirm that the document refers to the same patient. While computer algorithms can perform patient matching calculations using various attributes, there is no national patient identifier in the US. So, unlike your bank account, cell phone number, or license plate, there is no unique method by which both hospitals refer to the same patient. Hurdle number one, therefore, is to ensure that the document arriving in an inbox with information intended to be included in a given patient's record is in fact for that patient. In most systems, this involves a clerk or nurse comparing the name, address, phone number, and birthdate of the patient, a system that introduces both uncertainty and the possibility of human error.

The next step in accurate reconciliation is to verify key information and decide if it should be added to the official medical record at the receiving hospital. For allergies, medications, and medical problems, most organizations require that a health care provider review each entry and decide if it should be added to the patient's medication list, allergy list, or problem list. It's important to understand how this is different from the way, for example, an ATM in Moscow interacts with your bank in New York. With this exchange of financial information, an encrypted request from Moscow arrives and asks "John Smith, with account # 12345 and password 'ABCDE' requests \$50. Can we give it to him?" The New York bank replies with a set of discrete information including the current balance, approval, etc. No human needs to look at this information, convert one concept to another, make sure that it's the right John Smith, or decide if the request is big or small. The ATM and the bank are interoperable. Are the two hospitals? Not yet. The information that hospitals are transmitting is much more complex. Hospital X may have transmitted that the patient got a rash from amoxicillin. Would this translate to "allergy to penicillin?" Most clinicians would agree that it does. How about "diarrhea from Augmentin?" Probably not. For many reasons, the interoperability process in health care is much more complex than the ATM.

Hopefully, this explanation makes it clear why the ultimate goal of total interoperability in health care has been so elusive. We see fundamental questions that need to be answered, including (i) What does interoperable truly mean? and (ii) What are the main barriers to achieving interoperability across information technology systems and across institutions? The best definition of interoperability is "the ability of two or more systems or components to exchange information and to use the information that has been exchanged."[\(11\)](#) The definition illustrates that true interoperability is not simply the exchange of information, but an exchange that allows the information to be used effectively by the receiver. The barriers to the rapid and accurate transmission of information are many and beyond the scope of this discussion. But one key factor is the siloed nature of how care is delivered. Our care delivery processes have neither encouraged nor facilitated data sharing, in part because we've come to not expect it. As information liquidity now grows, we need to build the processes so that we can not just expect information, but manage it well as we receive it and incorporate it into our clinical decisions.

Many would envision the true ideal state to be similar to the Moscow ATM and New York bank example described above—that is, with the push of a button, after the accuracy of the exchange is verified, the key

and necessary information would be transmitted electronically from Hospital X to Hospital Y. The current health IT infrastructure has many barriers to overcome before it can achieve seamless electronic integration. These include optimal user experiences to facilitate the reconciliation processes above, which would ideally include semantic assistance. For example, the system would learn that diarrhea from Augmentin should not be mapped to "penicillin allergy" while "hives from amoxicillin" should be, and it would suggest to the user that "penicillin allergy" would be a concept to incorporate into the record if an incoming document included "hives from amoxicillin." In this way, the computer would assist providers by sifting through the mountains of incoming data to help us identify the salient elements. Today, this doesn't happen.

Let's imagine, though, that the information is efficiently and accurately transmitted. As you can see, if the information arrives but is not used (or usable), then true interoperability would not have occurred. The example above illustrates the first hurdle in making the transmitted data usable: patient identification. There is ongoing discussion about whether we need a national patient identifier in order to eliminate this challenge.⁽¹²⁾ After the patient's identity is confirmed, most current systems do not leverage technology to assist in the incorporation and reconciliation of this new information.

In many cases, the user experience of the reconciliation process leaves something to be desired: complex screens with multiple items that may seem similar or not—depending on the perspective of a clinician. For example, the patient above may have had more than one allergy on his record. Would he have had penicillin listed as an allergy? Would he have had piperacillin-tazobactam listed? Perhaps he had both of them listed. How would we want this incorporated into his record at Hospital Y? Would "penicillin: rash" and "piperacillin-tazobactam: hemolysis" be seen as redundant? What about just "allergy to PCN" added—as free text—into the patient's problem (not allergy) list by a harried surgical resident at Hospital X? Would this transfer over into Hospital Y's system automatically? Would it somehow have made it into Hospital Y's allergy list?

There are great opportunities through truly interoperable IT systems to prevent errors like the one in this case and many others too. Interoperable systems can reduce redundant lab tests and improve care transitions. My father recently transferred his care from one "best" hospital in Boston to the other "best" hospital in San Francisco. How were records transmitted? By fax. How did the San Francisco hospital insist on receiving them? Hand delivered—on paper—by the patient. They refused to accept digital records (in interoperable form) or even as PDF via email. After \$12 to print a copy of the records and \$15 for transportation, the San Francisco hospital had my father's records. What a shame. In this case, it was the policy not the technology that limited interoperability and threatened care quality.

We have a long way to go. The solution must include significant evolution in three different domains: people, process, and product. The *people* need to accept change and embrace the tools—even if they remain imperfect. The *processes* need to be redesigned so that we can leverage the tools to their full potential. Finally, the *products* need to follow the standards, anticipate our needs, and help guide us toward an ideal future state. Several technical activities are underway (stage 3 of the meaningful use programs, enhanced health IT certification requirements) that will focus and improve the IT-related regulations issued by both ONC and CMS, but these changes won't take effect until at least 2017.

The technical challenges won't be solved until or unless we all engage in focusing on what's best for the patient. This case describes a patient who wasn't served well by the people, processes, or products. We must do better. Interoperability will be a byproduct of these three components aligning, rather than simply a technical feat.

Take-Home Points

- The HITECH Act of 2009 outlined criteria for the meaningful use of health IT systems, which intended (among other things) to facilitate the transmission of patient information instantly and seamlessly between health care institutions.
- The HITECH Act requires current health IT systems and health care institutions to be able to rapidly and accurately transmit a summary of care record that includes essential patient information, such as medication allergies.
- The barriers to using transmitted information between hospitals include accurate patient identification and easy reconciliation into the medical record at the receiving hospital.
- True interoperability is defined as the ability of two or more systems or components to exchange information and to use the information that has been transmitted.
- The barriers to rapid and seamless transmission of patient care data include financial incentives that prevent institutions from sharing data, IT system usability, and the cost of connecting systems to each other.

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Table

Table. Information Required in Care Summary Records.

- 1 Patient name
- 2 Sex
- 3 Date of birth
- 4 Race
- 5 Ethnicity
- 6 Preferred language
- 7 Smoking status
- 8 Problems
- 9 Medications
- 10 Medication allergies
- 11 Laboratory test(s)
- 12 Laboratory value(s)/result(s)
- 13 Vital signs: height, weight, blood pressure, BMI
- 14 Care plan field(s), including goals and instructions

15 Procedures

16 Care team member(s)

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