

Designing Property Specifications to Improve the Safety of the Blood Transfusion Process

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Computer scientists use a number of well-established techniques that have the potential to improve the safety of patient care processes. One is the *formal definition of a process*; the other is the *formal definition of the properties of a process*. Even highly regulated processes, such as laboratory specimen acquisition and transfusion therapy, use guidelines that may be vague, misunderstood, and hence erratically implemented. Examining processes in a systematic way has led us to appreciate the potential variability in routine health care practice

and the impact of this variability on patient safety in the clinical setting. The purpose of this article is to discuss the use of innovative computer science techniques as a means of formally defining and specifying certain desirable goals of common, high-risk, patient care processes. Our focus is on describing the specification of process *properties*, that is, the high-level goals of a process that ultimately dictate why a process should be performed in a given manner.

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CASE STUDY

MR. J was a 70-year-old man admitted to the intensive care unit after a gastrointestinal bleed and elevated troponin consistent with a non-Q wave myocardial infarction. A hemoglobin level drawn at 5:00 AM was below normal, prompting his physician to place an order for 2 units of packed red blood cells (RBCs). The nurse caring for Mr J called the blood bank at 9:00 AM to see if the units of blood were ready to be picked up. The secretary in the blood bank informed the nurse that they were still waiting for a type and screen on Mr J. The nurse asks the intensive care unit technician to draw a type and screen from Mr J and send it to the laboratory.

At 11:00 AM, the RBC units are now ready to be picked up from the blood bank. As the nurse fills out the paperwork to send to the blood bank, she realizes there is no informed consent for transfusion in the patient's chart. She immediately notifies the physician who says he will come up and talk to the patient.

At noon, Mr J's physician obtains informed consent from the patient, and on his way out of the unit, expresses his concern to the charge nurse over the delay in his patient receiving the blood transfusion he had ordered. The charge nurse, without conferring with the patient's nurse, sends the unit secretary to pick up the first RBC unit.

In the meantime, Mr J has been ordered to receive a new cardiac medication to be administered intravenously (IV) by continuous infusion, and as a result, he no longer has an appropriate IV access for the blood transfusion.

The RBC unit is delivered to Mr J's nurse who is confused because she had not requested it be picked

up from the blood bank. She is primarily concerned because, per policy, the unit of blood must be infused within 30 minutes of arriving on the unit, and the patient has not yet had a new IV line inserted.

The charge nurse helps out by starting a new IV line for Mr J. Mr J's nurse and the charge nurse then initiate the 2-person "double-check" process of "verifying" that the correct blood was about to be transfused into the correct patient. As they begin the verification process, Mr J's nurse realizes that Mr J has no identification (ID) band. She and the charge nurse stop the verification process, realizing that the lack of ID band also meant the type and screen was obtained incorrectly, hence the transfusion could not be performed safely.

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The patient, physician, and blood bank are informed of the need to restart the transfusion process, and the RBC unit is returned to the blood bank.

This case describes a scenario where a serious delay in performing a potentially lifesaving process (ie, blood transfusion) occurs despite all parties diligently working to provide safe and effective patient care. What is also evident in this case is the complexity involved in carrying out a process in a fast-paced environment with multiple, interdependent components, numerous interruptions, and very ill patients. The Institute of Medicine (IOM) has suggested that these factors are responsible for many errors and must be addressed if patient safety is to become a reality.¹

Significant resources have been allocated to improving health care processes, in particular high-risk processes such as blood transfusion.²⁻¹⁰ Despite this effort, there has been a lack of attention to technological innovations that could support delivery of care that is safe, effective, timely, patient-centered, efficient, and equitable—the 6 quality aims described in the IOM report entitled *Crossing the Quality Chasm*.¹

Computer scientists use a number of well-established techniques that have the potential to improve the safety of patient care processes. One is the formal definition of a process; the other is the formal definition of the properties of a process. We have previously described the formal definition of processes and only briefly consider this technique here.¹¹ Our experience suggests that many health care processes, including those that appear to be simple, straightforward tasks, are in fact very complex. Even highly regulated processes, such as laboratory specimen acquisition and transfusion therapy, use guidelines that may be vague, misunderstood, and hence erratically implemented. Examining processes in a systematic way has led us to appreciate the potential variability in routine health care practice and the impact of this variability on patient safety in the clinical setting.

The purpose of this article is to discuss the use of innovative computer science techniques as a means of formally defining and specifying certain desirable goals of common, high-risk, patient care processes. Our focus is on describing the specification of process properties, that is, the high-level goals of a process that ultimately dictate why a process should be performed in a

given manner. Before describing the properties, we first present an example of a formal process description.

FORMALLY DEFINING PROCESSES

Attempts to improve the quality and safety of health care processes traditionally rely on informal process descriptions, such as checklists, flowcharts, medical algorithms, and textual descriptions. These informal descriptions, although useful in presenting an overview of standard processes, can be ambiguous or incomplete. For example, they often describe only the standard process and leave out how to handle possible failures or exceptions.

Figure 1 is an example of a very detailed checklist from a nursing textbook, which guides the nurse in the process of administering a blood transfusion. Despite the comprehensiveness of the procedural checklist, it addresses only standard conditions and does not address exceptions (eg, what to do if the patient has no ID band, consent form, or intravenous IV access).

Formal process definition is an innovative technique that uses technology based on computer programming languages to define complex processes precisely, clearly, and to any desired level of detail. The resulting process definitions can then be used to evaluate whether the process adheres to desired properties (ie, goals), which describe how that process should behave so that it supports patient safety. The value of formal process definitions has been demonstrated in other domains such as industrial engineering, digital government, business process management, and software development.¹²⁻¹⁶

A number of approaches for formally defining processes (termed “process languages” by computer scientists) have been proposed and evaluated. Different process languages offer different advantages, and the choice of process language must be dictated by the intended use of the process definitions produced. For example, to detect and correct medical errors via the analysis of formal process definitions, certain process language attributes, such as semantic richness and precision, are particularly critical. Few process languages are strong in all aspects, but research continues to lead to steady improvements in process language constructs. For the purpose of this paper, we use only one process language, Little-JIL, which has been developed by some of the authors of this paper.^{11,17}

PROCEDURE CHECKLIST

1. Verifies that informed consent has been obtained.
2. Verifies the physician's order, noting the indication, rate of infusion, and any premedication orders.
3. Administers any pretransfusion medications as prescribed.
4. Obtains IV fluid containing normal saline solution and a blood administration set.
5. Obtains the blood product from the blood bank according to agency policy.
6. Wears procedure gloves whenever handling blood products.
7. Rechecks the physician's order.
8. With another qualified staff member (as deemed by the institution) verifies the patient and blood product identification, as follows:
 - a. Has the patient state his full name and date of birth (if he is able) and compares it to the name and date of birth located on the blood bank form.
 - b. Compares the patient name and hospital identification number on the patient's identification bracelet with the patient name and hospital identification number on the blood bank form attached to the blood product.
 - c. Compares the unit identification number located on the blood bank form with the identification number printed on the blood product container.
 - d. Compares the patient's blood type listed on the blood bank form with the blood type listed on the blood product container.
 - e. If all verifications are in agreement, both staff members sign the blood bank form attached to the blood product container. Contacts the blood bank immediately if any discrepancies occur during the identification process; and does not administer the blood product.
 - f. Documents on the blood bank form the date and time that the transfusion was begun.
 - g. Makes sure that the blood bank form remains attached to the blood product container until administration is complete.
9. Removes the blood administration set from the package and labels the tubing with the date and time.
10. Closes the clamps on the administration set.
11. Removes the protective covers from the normal saline solution container port and one of the spikes located on the "Y" of the blood product administration set. Places the spike into the port of the solution container and opens the roller clamp closest to that spike.
12. Hangs the normal saline solution container on the IV pole.
13. Compresses the drip chamber of the administration set and allows it to fill up half way.
14. Primes the administration set with normal saline.
15. Attaches the blood filter to the second "Y" port on the administration set and primes it with normal saline solution by inverting it.
16. Inspects the tubing for air. If air bubbles remain in the tubing, flicks the tubing with a fingernail to mobilize the bubbles.
17. Gently inverts the blood product container several times.
18. Removes the protective covers from the administration set and the blood product port. Carefully spikes the blood product container through the port.
19. Hangs the blood product container on the IV pole.
20. Slowly opens the roller clamp closest to the blood product.
21. Obtains and records the patient's vital signs, including temperature, before beginning the transfusion.
22. Using aseptic technique, attaches the distal end of the administration set to the IV catheter.
23. Using the roller clamp, adjusts the drip rate, as prescribed. (Keep in mind that blood administration sets have a drip factor of 10 drops/mL).
24. Remains with the patient during the first 5 minutes and then obtains vital signs.
25. Makes sure that the patient's call bell or light is readily available and tells him alert the nurse immediately of any signs or symptoms of a transfusion reaction, such as back pain, chills, itching, or shortness of breath.
26. Obtains vital signs in 15 minutes, then again in 30 minutes, and then hourly while the transfusion infuses.

Figure 1. Procedure checklist for administering a blood transfusion. Copyright © 2007, F. A. Davis Company, Wilkinson & Van Leuven: Fundamentals of Nursing, Procedure 36-7: Administering a Blood Transfusion, p 914.

Figure 2 is a simplified version of the formal process definition for the "perform inpatient blood transfusion" process. The formal definition of the blood transfusion process identifies the major steps and substeps of the process, indicates the order they are to be done (whether in a particular order or in parallel), and also addresses exceptional conditions (eg, what to do if the consent form or ID band

is missing). Each of the substeps of the "perform transfusion" process can represent its own complex process, which can itself be specified to any desired level of detail. For example, the substep "Prepare document for blood pick-up" includes both patient and blood product ID and matching, but the details of those subprocesses are not shown in Figure 2.

FORMALLY DEFINING PROPERTIES

Computer scientists define a *property specification* as “a concise description of a system’s goal.” The word “system” in this context is used in a generic way to describe a process that might involve hardware, software, or people. A single property specification may focus on one particular aspect of the system’s behavior. For example, in health care, we may wish to specify properties for verifying a patient’s identity, obtaining laboratory specimens for a type and screen, or performing a blood transfusion.

Property specifications describe goals of processes, many of which are abstract. They are useful because they help to make explicit what are often unwritten or unstated assumptions about how and why a process is performed. The most widely recognized property related to blood transfusion therapy is that the correct patient should receive the correct blood product. This very high-level property is accomplished by ensuring that other properties hold. Another example of a property of the

blood transfusion process is that the presence of a signed consent document must be confirmed before a blood transfusion is performed. Of course, there would be exceptions to this property (eg, an unconscious patient with a traumatic injury), but these conditions are recognized as exceptions and not the norm. Table 1 lists examples of some of the desired properties related to the inpatient blood transfusion process.

The elicitation and specification of the properties of health care processes are not a simple task. Many of the processes used in health care (eg, blood transfusion) are based on tradition and long-established policies and procedures. In many instances, the persons involved in oversight or conduct of the process have had little involvement in how the process was originally constructed and toward what aim. Thus, it makes it difficult for many practitioners or administrators to explicate the properties of any given process. The justification for a process being performed in a particular manner is often “it’s the way we’ve always done

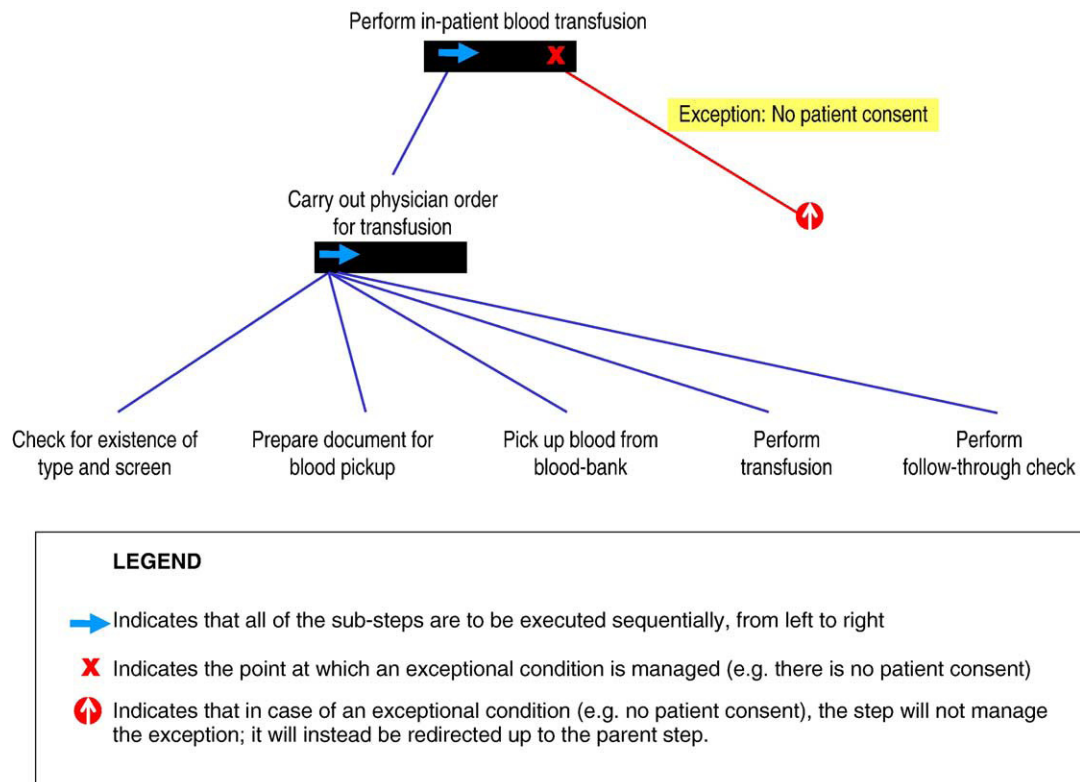


Figure 2. A simplified version of the Little-JIL formal process definition for the perform inpatient blood transfusion process, including examples of a major step (ie, carry out physician order), substep (eg, check for existence of type and screen) and the exceptional condition of “no patient consent.”

Table 1. Examples of Desired Properties Related to the Inpatient Blood Transfusion Process

Before performing a blood transfusion for a patient, the presence of a signed consent document must be confirmed
A patient must be assessed for appropriate intravenous access before the units of blood product are allowed to be picked up from the blood bank
Before administering each unit of blood product into a patient, the following activities must be performed: (in this order)
It must be confirmed that the patient has exactly one inpatient ID band
The patient must be asked to state their first name, last name, and date of birth
It must be confirmed that the patient's stated information matches the information on the ID band
It must be confirmed that the patient's first name, last name, date of birth, and medical record number match the same identifiers on the physician order for a blood transfusion
It must be confirmed that the patient's first name, last name, date of birth, and medical record number match the same identifiers on the tag affixed to the blood product
The infusion of a unit of blood product must begin within 30 minutes of the unit of blood being picked up from the blood bank
If the expiration date/time for a unit of blood product has been exceeded, that unit of blood product is not allowed to be infused into a patient
If it is suspected that a patient is having a transfusion reaction to an infusion of a blood product, the infusion of blood product must be stopped immediately

it,” with little insight into how or why a given process has been adopted.

Many health care organizations use policies and procedure checklists to direct caregivers about desired practices. Although these techniques are useful, they often do not make explicit the goals of the process but rather just outline the requisite steps to follow when carrying out the process. Moreover, these checklists and policies often use ambiguous language, which may result in the process being erratically followed.

Because the goals of the process are not made explicit or may be ambiguous, a health care provider may misinterpret the goals of the process and unintentionally perform procedures in ways that have the potential to compromise patient safety. For example, the first step in the procedure checklist (Fig 1) states, “Verifies that informed consent has been obtained.” The associated property specification in Table 1 reads “Before performing a blood transfusion for a patient, the presence of a signed consent form must be confirmed.” Although at first glance these 2 statements appear similar, they are not. The statement in the procedure

checklist uses the word “verify,” which is ambiguous. It is possible that verbal informed consent has been obtained but that no document has been signed. One interpretation of the procedure checklist statement is that the patient, physician, or nurse just states that consent has been obtained and their word is the basis for considering that verification step completed. The property specification, on the other hand, makes explicit that the person administering the blood transfusion must confirm the presence of a signed consent document. This property specification supports the real goal of ensuring that the patient has agreed to the procedure and that there is clear, legal documentation.

Several steps are needed to formally define a property. They include identifying an abstract (high-level) goal that a property should specify, stating the property clearly, formalizing the property using a mathematical logic, and, when dealing with multiple properties, organizing that set of properties. This article will discuss the first 2 steps in more detail because they are most relevant to health care providers and administrators.

Identifying an Abstract (High-Level) Goal That a Property Should Specify

The concept of identifying properties was new to the health care experts on our team. At the same time, the computer scientists had experience with the development of properties in other domains (eg, software) but were unfamiliar with the health care field. Examples from these other domains were generally not helpful to the health care experts because the content differed so much from our areas of expertise. As a result, it took some practice and multiple iterations before any properties were

Table 2. Examples of Actual and Potential Medical Errors Related to Blood Transfusion Identified in Case Example

A type and screen is not ordered on a patient with potential need for blood products.
Blood is ordered for a patient without informed consent.
The patient does not have an ID band.
The laboratory specimen for type and cross is drawn from the wrong patient.
The incorrect unit of blood is obtained from the blood bank.
The procedure for verifying the patient identity at the bedside is not followed.
The unit of blood is obtained from the laboratory, but the patient has no intravenous access.
A patient receives a unit of ABO-incompatible blood.
The unit of blood is not hung within the required timeline.

Table 3. Glossary of Terms for Formal Process Definitions and Properties Related to the Blood Transfusion Process

Term	Definition	Example of the use of the term
Blood transfusion	The process of administering a single or multiple units of blood products to a patient. The blood transfusion process begins with the ordering of the blood product and ends with an evaluation of the patient's response to the blood transfusion process.	The patient has received multiple blood transfusions in the past.
Single unit transfusion	The process of administering one unit of a blood product	The patient has received a single unit (transfusion) of blood.
Administer	The process of delivering a single unit of blood product; includes the infusion of the blood product and patient evaluation before during and after the process	Do not administer a unit of blood product if the patient cannot be carefully monitored during the process.
Infuse	The physical process of facilitating the flow of the blood product into the patient	To infuse of a unit of blood product requires opening a clamp to allow the blood product to flow into the patient's vein.
Match	To be the same (equivalent)	The patient's stated name and date of birth match the name and date of birth on the ID band.
Confirm	Determine the existence	Confirm the presence of a physician's order before notifying the blood bank.
Confirm that an informed consent document is in the medical record.		
Confirm the presence of an ID band on the patient's limb.		
Verify	Compare the data from 2 sources/items to make sure they are consistent	Verify that the type and number of unit(s) of blood product match the physician's order for the type and number of units to be transfused.
Unit(s) of blood product, unit (s) of blood	An amount or package of a blood product	The patient has received 6 units of packed RBCs over the last 3 days.
ID band (wristband, armband)	Plastic band containing patient ID data that wraps around the patient's wrist or ankle	The policy is to compare the patient's stated name and date of birth to the information on the ID band.
Blood expiration date/time	The date and time after which a blood product cannot be infused into a patient	The blood expiration date/time must not be exceeded.
Blood product hang time	The length of time over which a single unit of blood product should be infused into a patient	The normal blood product hang time for a single unit of packed RBCs is 4 hours.
Stop the infusion of blood product	Temporarily interrupt infusion	At the first sign of a suspected transfusion reaction, the nurse should stop the infusion of blood product.
Discontinue the infusion of blood product	Permanently stop the infusion of the single unit of blood product	Based on their evaluation of the reported transfusion reaction, the blood bank informed the nurse to discontinue the infusion of blood product.

specified at a suitable level of abstraction and with enough accuracy to satisfy both groups. (See [Table 1](#) for examples of properties related to the blood transfusion process.)

We found that the most successful approach to identifying properties was to describe an existing process and discuss how it could be improved. Casual conversations, “war stories,” and examples of poor patient outcomes were useful in increasing the insight of all team members into the goals of many current care processes. Discussion about “why” a process needed improvement often led to insight into the

abstract goals of the process that a property should describe. For example, in the case presentation in this article, there are multiple events that result in the possibility of error and adverse events, including a delay in the patient receiving the blood that was ordered. The review of a case such as this one helped the health care experts articulate desired goals of the transfusion process that support the overarching goal of “right product for the right patient.” (See [Table 2](#) for a list of actual and possible errors related to the blood transfusion process identified in the case study at the beginning of this article.)

Stating the Property Clearly

In addition to being able to identify an abstract goal that a property should specify, there is also the need to state properties clearly, accurately, and consistently. During the course of formally defining processes and specifying properties, we found problems with inconsistent terminology being used. A common problem was having one term (noun or verb phrase) being used interchangeably for describing different concepts. For example, the term “transfusion” was sometimes used to describe the process of infusing of a single unit of blood product and in other cases to describe the entire transfusion process, which could include multiple units of blood product being administered over time. Another example is the term “verify,” which is sometimes used to describe the process of checking that a procedure is performed on or a medication is administered to the correct patient, but which carries the possibility of a number of interpretations. For instance, sometimes the term “verify ID” was used to mean “establish the existence of an ID band” and other times to mean “confirm that the name and birth date on the ID band match the name and birth date stated by the patient.” There was also a problem with different terms being used to describe the same process or object. The term “unit,” “blood product,” and “bag of blood” all were used to refer to the same object.

It became evident early on that a glossary would be necessary to ensure consistency in our terminology. Carefully thinking about how to define terms led to even more insight into the complexity of the patient care processes. (See [Table 3](#) for examples of terms used in the blood transfusion process.) Note that the terms from the glossary are the terms that are actually used in the properties in [Table 1](#).

Formalizing a Property

After the properties are identified and stated clearly, it is necessary to formalize the property. In computer science language, formalizing a property is the translation of the property from the English language into a mathematical formula, which is amenable to analysis.

Organizing a Set of Properties

As can be seen just from the small set of properties in [Table 1](#), the number of properties for a single process can become quite large. Given how many properties there are to keep track of, we found

that it was necessary to impose various types of organizational structure on the set of properties. For example, the properties can be listed in the same order that their tasks are first mentioned in the process definition. There are also several ways to group the properties. One type of grouping puts all the properties associated with selected terms from the glossary together. For instance, all the properties that reference a unit of blood product can be shown as a group. In addition to making it easier to navigate through a set of properties, looking at related sets of properties when they are grouped together is one way to detect inconsistencies, omissions, or implicit assumptions that need to be made explicit.

PROCESS DEFINITION VERSUS PROPERTY SPECIFICATION

Our experience suggests that formally defining processes can proceed in parallel with defining properties and that each activity has unique but important contributions to make toward supporting patient safety. Process definitions describe the ordering of tasks and exceptional conditions, whereas property specifications describe abstract goals that often put restrictions on how the processes can safely occur. [Figure 2](#) is a simplified representation of the blood transfusion process, and [Table 1](#) shows some of the properties related to that process.

As demonstrated in the example in [Figure 2](#), the formal process definition gives a detailed set of ordered steps to complete a particular task. This is obviously important information for carrying out a patient care process. The added value of the property specification, however, is the focus on the underlying patient safety issues that influence why the steps of a process are conducted and in what order. Property specifications make explicit the often abstract patient safety goals. The awareness of these goals is a critical step in the evaluation, redesign, and safe performance of health care processes.

POTENTIAL USES FOR PROCESS DEFINITION AND PROPERTY SPECIFICATION IN THE CLINICAL SETTING

Research suggests that the benefits of many evidence-based health care processes are often not realized by patients or their family members. Experts suggest that poor outcomes often result from the failure to implement and evaluate processes

appropriately.¹⁸ The ability to define processes and identify process properties has the potential to impact the way that health care processes are designed, implemented, and evaluated.

When processes are found to have resulted in a poor outcome (eg, the wrong patient received a blood transfusion), the process is often redesigned without a real understanding of how and what went wrong. In addition, the consequences of changing the process (typically adding a double-check or second check) may have unintended consequences that are poorly appreciated. Access to formally defined processes and properties offers new opportunities to evaluate circumstances where error and adverse events occur and to use that information to improve clinical practice.

CONCLUSION

Despite the increasing focus on patient safety, there has been little progress made in using technology to improve the processes used in the clinical setting.^{1,19} Advances made in transfusion therapy and research efforts to reduce transfusion administration error are noteworthy.²⁰⁻³⁶ Nonetheless, even this high-risk process has largely focused on advances in the laboratory setting vs at the bedside where the complexity of the clinical environment presents many challenges. Experts

have suggested that true excellence in health care will only be realized when transfusion safety extends beyond the laboratory^{10,37} and the quality aims envisioned by the IOM become a reality.³⁸

Advances in patient safety depend, in part, on the development and evaluation of processes that attend to the inherent complexity of caring for patients. The effective use of technology has the potential to address many of the challenges associated with common, yet complex, high-risk processes such as blood transfusion. In particular, innovations that recognize the safety risks associated with processes that involve multiple providers and environments fraught with interruption and ever changing conditions are needed.³⁷

This article discussed the use of innovative computer science techniques as a means of formally defining and specifying the properties of patient care processes. Formal process definition allows for the precise, detailed description of processes in both standard and exceptional conditions. The specification of properties makes explicit the often unstated goals of health care processes. Both formal process definition and property specification offer new opportunities for evaluating and improving existing processes and ultimately providing greater support for ensuring patient safety.

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