

Increasing Patient Safety and Efficiency in Transfusion Therapy Using Formal Process Definitions

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The administration of blood products is a common, resource-intensive, and potentially problem-prone area that may place patients at elevated risk in the clinical setting. Much of the emphasis in transfusion safety has been targeted toward quality control measures in laboratory settings where blood products are prepared for administration as well as in automation of certain laboratory processes. In contrast, the process of transfusing blood in the clinical setting (ie, at the point of care) has essentially remained unchanged over the past several decades. Many of the currently available methods for improving the quality and safety of blood transfusions in the clinical setting rely on informal process descriptions, such as flow charts and medical algorithms, to describe medical processes. 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. One alternative to these informal descriptions is to use formal process definitions, which can serve as the basis for a variety of analyses because these formal definitions offer precision in the representation of all possible ways that a process can be carried out in both standard and *exceptional* situations. Formal process definitions have not previously been used to describe and improve medical processes. The use of such formal definitions to prospectively identify potential error and improve the transfusion process has not previously been reported. The purpose of this article is to introduce the concept of formally defining processes and to describe how formal definitions of blood transfusion processes can be used to detect and correct transfusion process errors in ways not currently possible using existing quality improvement methods.

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THE ADMINISTRATION OF blood products is a common, resource-intensive, and potentially problem-prone area that may place patients at elevated risk in the clinical setting. Despite regulatory and accreditation oversight by governmental (eg, Food and Drug Administration) and professional healthcare organizations (eg, Joint Commission on Accreditation of Healthcare Organizations, American Association of Blood Banks, American College of Pathologists), errors and adverse events in transfusion medicine are a significant concern, and many problems may be unappreciated and likely underreported.

Aside from therapeutic correction of hematologic deficits, optimal outcomes from transfusion therapy also include patient safety and efficient resource use. Though transfusion medicine professionals were one of the first groups to design and implement methodologies for classifying medical errors that impact patient safety and efficiency, much of the emphasis in transfusion safety has been targeted toward quality control measures, error reporting systems, and process automation in laboratory settings where blood products are prepared for administration.¹⁻⁹ Such measures have had a profound and lasting positive impact on both patient safety and efficiency. In contrast, the process of transfusing blood in the clinical setting

(ie, at the point of care) has essentially remained unchanged over the past several decades. Most of the processes related to blood transfusion that occur outside the laboratory continue to rely heavily, if not solely, on human verification and monitoring. Experts have suggested that efforts to improve transfusion safety must extend beyond the laboratory if a “full quality system” is to become a reality in transfusion medicine.¹⁰

Formal process definition, also called *process formalization* by computer scientists, is an innovative technique that uses technology based on computer programming languages to define complex processes precisely and clearly, and to any desired level of detail. The resulting process definitions can then be used to evaluate whether or not the process adheres to predefined safety

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Table 1. Examples of Desired Properties Related to the Management of a Suspected Transfusion Reaction

Transfusion is stopped immediately when transfusion reaction is suspected.
Patient identification and blood product check is repeated when transfusion reaction is suspected.
Transfusion services and the patient's physician are notified simultaneously of all suspected transfusion reactions.
Appropriate transfusion services workup occurs (eg, appropriate blood/urine specimens are sent to the laboratory as needed) before a transfusion can be started.
After an occurrence of a suspected transfusion reaction, the reaction is documented in the patient's medical record.

properties (see Table 1 for examples of safety properties) and, in some cases, to automate processes. The value of formal process definitions has been demonstrated in such domains as industrial engineering,¹¹ digital government,¹² business process management,¹³ and software development.^{14,15} The purpose of this article is to introduce the concept of formally defining processes in the context of what is currently known about transfusion safety in the clinical setting. Our goal is to describe how formally defining transfusion processes can be used to detect and correct transfusion process errors in ways not possible using existing quality improvement methods.

MEDICAL ERRORS AND ADVERSE EVENTS RELATED TO BLOOD TRANSFUSION

There are many opportunities for medical errors and adverse events to occur during the process of transfusion therapy in the clinical setting. (See Table 2 for examples of potential medical errors related to transfusions.) Researchers in transfusion medicine have been at the forefront in the investigation and the categorization of the root causes of errors.^{6,16} Much of the emphasis in transfusion research and quality improvement has been on the description of errors that result in actual or potential serious or fatal outcomes (ie, ABO mismatch). Fortunately, serious adverse events, such as hemolytic transfusion reactions from mismatched incompatible transfusions, are rare. A variety of errors, however, have been found to occur in both the laboratory/blood bank and the clinical setting that mainly involve nurses, clerks, and technologists.¹⁷⁻²¹ Common errors involve specimen labeling,¹⁹ patient identification,^{17,22} and patient monitoring.^{18,22} Errors occurring at the bedside, involving mislabeling the blood

specimen vials or requisition forms and drawing the specimen from the wrong patient, are now recognized as among the most common errors with potentially serious consequences.^{19,23-26}

The ability of researchers to identify errors in transfusion medicine is impacted by many of the same obstacles that plague other healthcare processes. Chart reviews and clinician self-report often provide data that underestimate the true scope of the problem. Direct observation has been successfully used to identify errors, but it is extremely resource intensive and impractical outside a research setting. Regardless of the method used, all traditional approaches to error detection rely on a preexisting knowledge and recognition about potential types of errors. It is likely that a subset of medical errors remain undetected simply because they have not been previously identified and, hence, are not being monitored.

The high-risk nature of the transfusion process has made it the focus of a variety of quality and patient safety activities,^{7,22,27-29} including hemovigilance, and failure mode effect analysis (FMEA).^{7,29} Hemovigilance is a surveillance system that monitors the entire transfusion process from beginning to end, starting with the collection

Table 2. Examples of Potential Medical Errors Related to Blood Transfusions

A type and screen is not ordered on a patient with potential need for blood products (eg, preoperative surgical procedure with high blood loss).
A transfusion is ordered for the wrong patient.
Blood is ordered for a patient without informed consent.
The laboratory specimen for type and cross is drawn from the wrong patient.
The laboratory specimen for type and cross is sent to the laboratory unlabeled/mislabeled or incompletely labeled.
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.
The unit of blood is hung with an incompatible intravenous solution (eg, dextrose).
The unit of blood is transfused through the wrong type/size of filter (or no filter).
A patient receives a unit of ABO-incompatible blood.
The unit of blood is not hung within the required timeline.
The unit of blood is not infused within the appropriate timeframe (too slowly/too rapidly).
The patient is not monitored during the transfusion process (eg, the patient's vital signs are not taken and/or documented before the start of the transfusion).

of the blood and its components and ending with the follow-up of recipients. Data obtained from the hemovigilance process are ultimately used to reduce or prevent unexpected or undesirable outcomes by identification of their underlying causes.

Failure mode effect analysis has also been used to reduce risk in blood transfusion. The FMEA methodology examines processes for possible system failures and seeks to identify the possible causes and effects of those failures. Both hemovigilance and FMEA, despite being extremely resource intensive, have been shown to be valuable in identifying potential safety issues related to transfusion processes.^{7,29}

In addition, some progress has been made in applying new technologies^{30,31} to transfusion processes at the point of care. One technological innovation is the “Bloodloc” (Novatek Medical, Greenwich, CT), a product intended to reduce the risk of transfusing a patient with the wrong blood. The Bloodloc delivery mechanism requires a unique patient identifier be entered into the lock. Researchers evaluating the Bloodloc reported its effectiveness in reducing error and potentially fatal adverse events. Other researchers have evaluated the effectiveness of a bar code patient identification system in reducing errors related to transfusion practice.^{30,31} The results of these studies suggest that technologies such as bar coding can reduce errors related to patient identification and the labeling of blood specimen vials.^{30,31}

Process control techniques, another innovation, are used to ensure that processes are operating within their prescribed limits. For example, Jensen and Crosson³² introduced an automated process control system designed to improve verification of bedside patient identification and documentation of the transfusion episode. Results of a pilot study suggest that the method has potential in reducing the risk of inappropriate or mismatched blood transfusions. Process control techniques demand a clear understanding of the performance expectations and the operating parameters that impact the achievement of those expectations.³³ The success of any process control system in healthcare will therefore rely on a comprehensive understanding of the process and the interactions between members of the health care team.

Many of the currently available methods for improving the quality and safety of blood transfusions in the clinical setting rely on informal

process descriptions, such as flow charts and medical algorithms, to describe and improve medical processes. 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.

One alternative to these informal notations is to use formal process definitions, which can serve as the basis for a variety of analyses because these formal definitions offer precision in the representation of all possible ways that a process can be carried out in both standard and *exceptional* situations. Formal process definitions have not previously been used to describe and improve medical processes. The use of such formal definitions to prospectively identify potential error and improve the transfusion process has not previously been reported.

FORMAL PROCESS DEFINITION

If the definition of a process is meant to be used as the basis for analyses, the definition must be formal; that is, it must have well-defined semantics, like those of computer programming languages. A number of approaches for formally defining processes (called *process languages* by computer scientists) have been proposed and evaluated. It has become increasingly clear that different process languages offer different advantages, and that 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, we regard the following process language attributes as being particularly critical:

- rigor: the semantics are precisely defined, generally by means of a mathematical system that is amenable to definitive reasoning;
- accessibility: the representation of the process is readily understood by humans;
- precision: the process can be defined down to the desired level of detail;
- semantic richness: the process language offers a breadth of semantics that is easily able to capture the complexity of intricate processes. For medical processes, this attribute is particularly important because these processes require the careful coordination of a variety of agents

(eg, nurses, physicians, technologists, computer systems) performing complex tasks. Medical processes require the recognition of a variety of types of conditions and the careful orchestration of the response(s) to these conditions. A process language would thus have to be able to depict the coordination of possible concurrent activities, areas in which human choice is allowed, and timing constraints to be used effectively to define medical processes.

The Little-JIL Process Language

Few process languages are strong in all of the previously mentioned aspects, but research continues to lead to steady improvements in process language constructs. For the purpose of this article, we will use only one process language, Little-JIL, which has been developed by some of the authors of this article.³⁴

Little-JIL has many features that make it useful for the healthcare domain. It uses graphical icons to enhance understanding by non-computer scientists and it is able to capture the intricacies and complexities of medical processes. In addition, its semantics address such critical issues as error-condition detection and the specification and coordination of multiple agents (eg, nurses, technologists, and physicians). Little-JIL treats processes as a set of steps and substeps arranged in a hierarchy and enforces rules concerning how the

steps can safely interact, thus, enabling the specification of fine-scale process details.

Although Little-JIL was originally created to represent software development processes,^{14,15} research demonstrates that it is effective for defining processes drawn from a variety of other domains. For example, Little-JIL has been used to represent digital government processes³⁵ and scientific data analysis processes.³⁶ Some of these processes have then been made the subjects of rigorous analysis in which errors were detected, and then corrected versions of the processes were subsequently formally proven to be free of those errors.³⁷

Experiences such as these suggest that Little-JIL and similar process languages can be used to facilitate improvement of medical processes by either identifying the presence or assuring the absence of errors. In the case of blood transfusions, for example, Little-JIL can be used to define the process and the appropriate responses to unusual or exceptional conditions. Transfusion-related errors, such as those listed in Table 2, can then be formulated as properties, and automated reasoning techniques can be used to determine if any of these errors could indeed occur in the process as it is defined. Although it might appear that it would be relatively easy to detect such errors in a process definition by mere observation, the wide range of alternative ways that a process could be carried out precludes such comprehensive manual inspection.

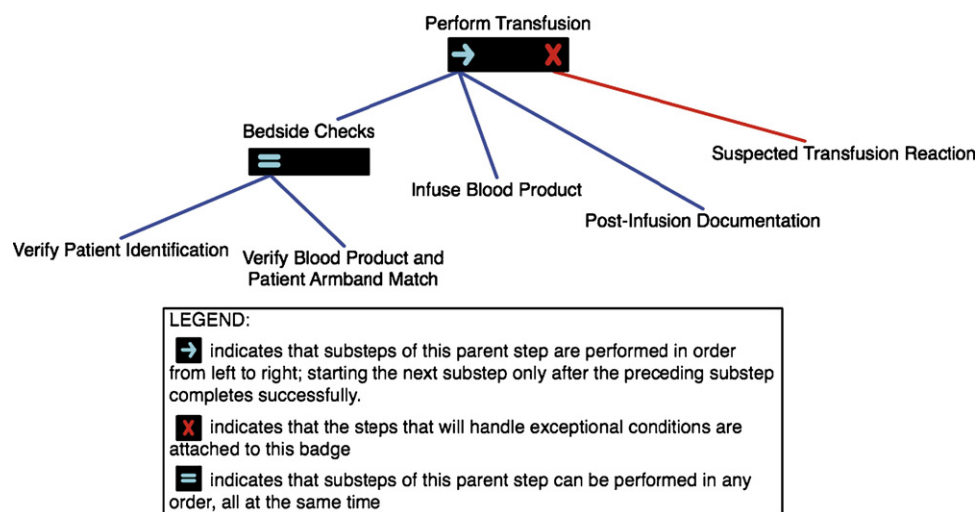


Fig 1. Simplified Little-JIL process definition for perform transfusion, which includes the major steps, substeps, and exceptions (ie, transfusion reaction) related to the clinical administration of a single unit of blood.

Automated analysis techniques developed to verify properties of computer systems, however, can be used to verify that medical processes adhere to important safety properties, even when exceptional conditions arise.³⁸

An Example of Formally Defining a Blood Transfusion Process

The blood transfusion process in its entirety is complex and includes both a laboratory and a clinical component. Ensuring quality and safety in transfusion practice demands that attention is paid to all aspects of the transfusion process, starting with the verification of patient identification and ending with documentation after the transfusion is complete.

In this article, we provide 2 examples of formal process definitions to demonstrate how they can be used to improve quality and safety in blood transfusion. The “perform transfusion” process represented in Figure 1 is a high-level description of a step in the blood transfusion process, using a simplified version of the Little-JIL process language. It represents the portion of a blood transfusion that occurs directly before, during, and after a single unit of blood is transfused into a patient. Figure 1 defines multiple aspects of this

portion of the transfusion process, including the ordering of the steps to be performed and *how to react to variation in the process*. Each of the substeps of the perform transfusion process, represented by black boxes in the figure, are themselves complete processes with their own substeps and exceptions.

Substeps of the perform transfusion process include bedside checks, infuse blood product, and postinfusion documentation. The process definition for perform transfusion specifies the order in which steps must be carried out and gives direction about how to respond to unusual or exceptional conditions. As represented in Figure 1, the perform transfusion process definition specifies that bedside checks must be successfully completed before the unit of blood is infused. It also specifies the process to follow if an exceptional condition (in this case, a suspected transfusion reaction) arises at any point during this portion of the transfusion process. The portion of the diagram in Figure 1 representing the exceptional condition “suspected transfusion reaction” is in itself a complete process, starting with the stopping of the blood infusion and ending with the documentation of the results of the suspected transfusion reaction workup.

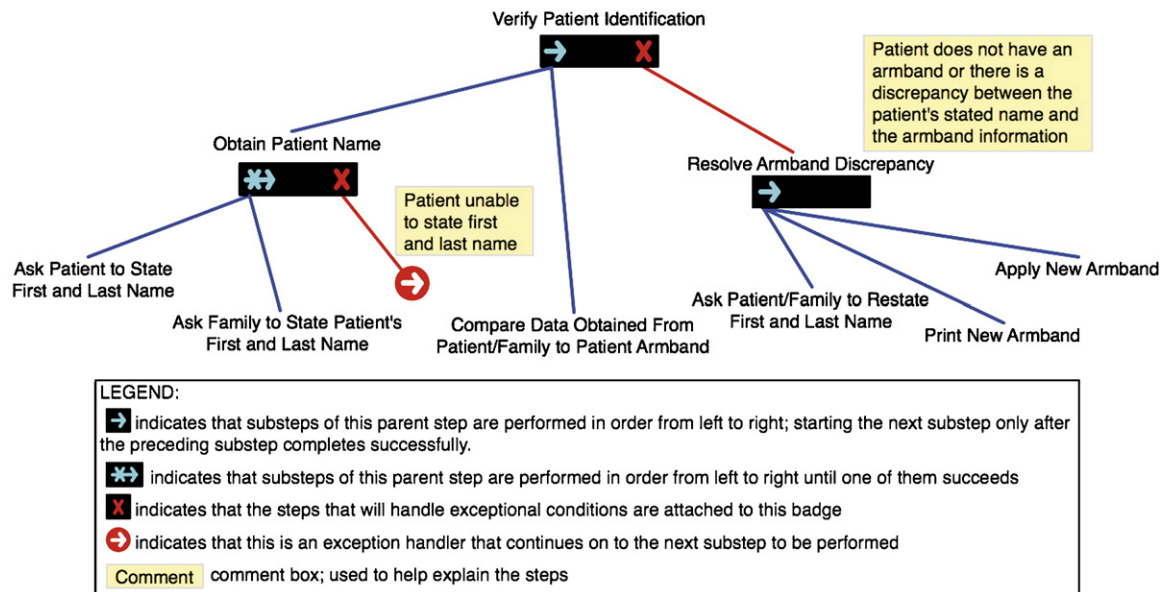


Fig 2. Little-JIL process definition for verify patient identification, which includes the major steps, substeps, and exceptions related to the process in which the patient’s identity is verified. Verify patient identification is a substep of the perform transfusion process (Fig 1).

The perform transfusion process has a number of substeps, including the substep titled “verify patient identification.” This substep has been included to illustrate how Little-JIL can be used to define a process to a fine level of detail. For example, as illustrated in Figure 2, the process definition for verify patient identification requires that the clinician ask the patient (or a family member if the patient is unable) to state both their first and last name. It also includes information regarding how to handle an exceptional condition, such as when there is a discrepancy between the information obtained from the patient and the data on the patient armband.

The examples used in Figures 1 and 2 illustrate the complexity of the processes that are required to ensure that appropriate steps are taken directly before and after blood is transfused into a patient. It is important to note that, although these Little-JIL process language features are (incompletely and imprecisely) described in this article in English, they are elsewhere defined completely, precisely, and rigorously by means of a mathematical formalism.³⁹

USING FORMAL PROCESS DEFINITIONS TO IMPROVE TRANSFUSION THERAPY

Developing formal process definitions has the potential to improve transfusion therapy in numerous ways, including increasing insight into care processes, facilitating the education and training of healthcare providers, evaluating the performance and outcomes of processes, and automating parts of processes. We are currently in the early stages of using process formalization to improve the safety of blood transfusion. To date, we have focused on eliciting and adequately representing a blood transfusion process. In the future, we will be conducting an evaluation of these formalisms in both simulated and clinical settings.

Increased Insight Into Care Processes

Developing a formal process definition requires content experts (ie, transfusion medicine specialists and practitioners) to describe a process in minute and focused detail with follow-up collaboration with experts in computer science who can then define the process in a process language’s notation. This defining of the process often requires the collaborative efforts of experts from several different disciplines, each bringing their

unique perspectives to the process. For example, in a setting where laboratory technologists, nurses, and physicians are involved in the development of a process that is focused on recognizing and reporting a suspected transfusion reaction, each contributes their own expertise to the activity, resulting in a global assessment and critique of the process. This very act of developing the definition gives new insight for all the experts in terms of recognition of the interdisciplinary nature and complexity of the reaction investigation process.

The detection of shortcomings in the transfusion process may become evident because computer scientists, who often do not have medical expertise and thus are not aware of common implicit assumptions medical professionals might make about the process, begin to question gaps and overlaps in the process. For example, a basic prerequisite for administering blood products is to properly identify the patient, but hospital policies typically do not describe what to do if the patient is unable to confirm their identity (eg, is comatose) or if the patient has no armband. Being able to point out the possibility of such exceptional conditions and to develop the appropriate response to them are a critical part of the activity of developing a process definition. Dealing with exceptional conditions is a way of life in hospitals, but their frequency and potential impact on patient safety become more evident because they are made explicit when the full transfusion process is formally defined.

Evaluation and Process Improvement

Computer scientists have been developing a range of software analysis techniques that can verify important safety properties about the behaviors of complex systems. These techniques provide automated tools that can consider *all* possible ways the process could be carried out and verify that desired behaviors occur (or that undesirable behaviors do not occur). When the properties do not hold, the tools can provide examples illustrating how the properties could be violated. For example, these tools could be used to determine that the step in which the blood product identification is matched to the patient identification is always performed before the blood transfusion begins. (See Table 1 for examples of desirable safety properties for the handling of a suspected transfusion reaction).

Little-JIL, and similar languages with detailed and precise semantics, can facilitate process

improvements by associating process modification with reverification of those same safety properties. For example, whenever the formal definition of the blood transfusion process is modified, all the relevant properties about that process could be reverified to assure that undesirable behaviors were not introduced by the changes made to the process. When an error or negative outcome does arise, the process could be analyzed to determine all the ways in which such an effect could occur and each way could be corrected, resulting in a modified process definition and subsequent reverification. For blood transfusion, the process can be evaluated to determine which steps are necessary, where redundant steps should and should not occur, and where changes can be made. Our experience has been that in the course of developing and modifying formal process definitions, potential error-prone situations that had not previously been considered are identified (eg, what to do if the patient needs a transfusion and has no armband).

Education and Training

Formal process definitions could augment current education and training strategies, such as competency checklists and periodic policy review. Complete and precise definitions may provide greater insights into both the overall process as well as into each individual's unique responsibilities, in comparison with traditional policies or standards. Use of formal process definitions in simulated patient situations is a logical extension for educating staff before they have direct patient care responsibility.

Automation

An additional advantage to using formal process definitions is that computers could one day coordinate the performance of these processes. In using computers to support processes in this way, faithfulness to the defined process is increased, reducing the possibility that the important safety properties that were verified for the process will be violated. There are other advantages to the use of computers to support process execution. A computer system working directly from an executable process definition could coordinate communication between departments, optimize pending work, and generate audit-trail information. In such a scenario, safety critical work, such as comparing the label on a blood bag to a patient's armband, could be checked using a

computer, reducing the chance of human error. Moreover, automation provides an incentive for keeping process definitions up to date.

CONCLUSIONS

Staggering numbers of patients die each year as a result of medical errors. Although fatalities associated with transfusion therapy are rare, errors are common. The Institute of Medicine (IOM) has suggested that addressing medical errors will require a fundamental change in the way health-care is delivered. Although attempts have been made over the last decade to restructure care, the IOM has stated, "What is most disturbing is the absence of real progress . . . in information technology to improve clinical processes" (Ref [40], p 3). It is now widely recognized that most medical errors are the result of system and not individual failures. The IOM has suggested that patient safety should be a system property. This suggests that reducing the risk of error and ensuring patient safety require attention to systems that prevent and mitigate error.

Formal process definitions offer precision in the representation of all possible ways that a process can be carried out in both standard and *exceptional* situations. Formal process definitions have not previously been used to describe and improve medical processes or to identify potential error and improve the transfusion process. Dealing with exceptional conditions is a way of life in hospitals, but their frequency and potential impact on patient safety become more evident as they are made explicit when the full transfusion process is formally defined.

The purpose of this article was to introduce the concept of formally defining processes and to describe how formal definitions of blood transfusion processes can be used to detect and correct transfusion process errors in ways not currently possible using existing quality improvement methods.

Dramatic changes in available healthcare resources coupled with insights into the extent of medical errors provide compelling incentive to develop new healthcare structures and processes. Effective use of information technology has the potential to address many of the issues associated with complex interdisciplinary processes, such as blood transfusions, ultimately resulting in improved patient safety. Using formal process definitions is

a promising technological approach in the realization of that goal.

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