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Formalizing and Verifying Workflows used in Blood Banks

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Abstract

Blood banks use automation to decrease errors in delivering safe blood for transfusion. The Food and Drug Administration (FDA) of the United States and other organizations recommend blood banks to validate their computer system process, which is resource and labor intensive. For this reason, we have created a formal workflow model for blood bank operations and used an automated tool to verify that it satisfies safety properties. Our methodology started by understanding and gathering information about blood bank procedure. Then we mapped all procedures into processes in a workflow engine. Then we used the verification packages provided by the workflow engine to check the safety properties.

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Keywords: Workflow; Blood Banks; Safe Blood

1. Introduction

Blood banks provide the critical functions of collecting, testing, separating components and transporting blood components for blood transfusions. As their numbers grew and complexities expanded, standards in processing of blood products came about to ensure patient safety. Over the years, the Federal Food and Drug Administration (FDA) in the United States, regulatory authorities in other counties, and professional organizations have updated their standards to ensure that blood banks deliver safe and clean blood. This expansion has resulted in two types of standards:

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regulatory (i.e. U.S Federal) standards and Voluntary standards. The US Federal government creates federal standards that are to be followed in processing blood products used in the United States. Voluntary standards have been created by many domestic and international organizations, such as the formerly known as American Association of Blood Banks (AABB), the World Health Organization (WHO) and other standards. In some countries, blood banks adhere more strongly to voluntary regulations, depending on their own policies, resource limitations and needs. For example, in developing countries, there is a need for quicker large scale processing compared to developed countries because of the limited number of available blood banks.

Additionally, blood banks have taken advantage of new technologies, one being the automation of systems and processes and services like blood testing, blood storage, donor scheduling, donor deferral, and reporting. Due to this change, the FDA has recommended blood bank computer systems to be validated for blood bank safety against procedure requirements [1,2]. Procedure requirements include staff training and qualification, process performance and accuracy check, records maintenance and traceability to confirm all processes meet the requirements for product safety [2]. The validation of a blood bank processes is a labor-intensive process that takes a long time and resources. However, formally modeling workflows and verifying their properties can aid in the validation process by automating the verification process itself. Towards achieving that objective, this paper models workflows used in processing blood from the donation to transfusion and shows how to verify these workflows with respect safety properties.

Healthcare professionals knew the regulatory requirements to varying level of details, as no single person is responsible for the end-to-end processes. We modeled the processes utilized in blood banks and used a workflow engine to check if all processes are performing correctly. We checked that our workflow can be stimulated with no errors, ensuring that the modeled workflows were verified against reachability, structure, soundness and performance. Reachability [3] is to find all reachable states in a workflow. The workflow engine verified that all states were reachable in our modeled workflow, ensuring that the process does not specify tasks that will never be performed in a functional system. In addition, our workflow structure passed the structural verification. Structural verification ensures that a workflow contains one input and output, all tasks are performable, all tasks can be reached and finally leads to the end state, no loops or endless iterative tasks exists and all tasks come to an end with no tokens left in the workflow. The latter condition ensures that all enabled workflows executes in the workflow system. In addition, we also verified that the modeled blood bank workflow are free of dead locks [3]. Prior to deployment this work needs to be validated by healthcare organization and is beyond the scope of this paper.

The rest of the paper is written as follows. Section 2 describes Blood Bank Operations. Section 3 describes validation and analysis. Section 4 defines related work. Section 5 is the conclusion.

2. Blood Bank Operations

Blood bank operation consists of several processes and sub-processes that are executed in a specific sequence. This sequence is based on the regulations and standards set up to increase donor and patient safety. The major processes used in blood banks are given in Figure 1. They consists of donor registration, physically examining the donor for conditions such as age ≥16 years old, Temperature ≤ 37.5°C =99.5°F, Hemoglobin/Hematocrit ≥ 12.5 g/dL ≥ 38%, not pregnant, free of major organ diseases, and asking the donors to fill out a questionnaire and reviewing the answers to determine the eligibility if the donors, labeling the blood units and sampling tubes, drawing blood, post-donation processing of blood and transfusing blood products.

Figure 1 High Level Blood Bank Operation

Blood banks staff is expected to follow standard operating procedures (SOP) that are based on standards and regulations. These procedures are decomposed into multiple tasks and requirements are placed on each task prior to starting, similar to a checklist used in surgical procedures. Goodman et. al [4] say that the donation process provides

donors with a checklist prior to donating blood. The same applies to all processes in blood banks as each process has requirements checklist prior to starting [5].

2.1. Blood Bank Workflow Process

In this section, we illustrate the steps taken to model blood bank workflow. The first step was understanding blood bank process collecting information from blood bank regulations and standards such as AABB, FDA, The Joint commission and ISBT128[2,6–8]. The second step was learning the sequence of processes through interviewing hematologists, transfusion safety officer, blood bank technician, blood bank Staff, Donation/Transfusion staff) [9, 10]. In addition, obtaining a month of training with close-up observation of all blood bank and IT process interaction at King Abdulaziz University [11]. In Figure 2, illustrates the methodology for modeling the blood bank workflow which is an iterative process. The color blue in the diagram indicates completed processes while green indicates currently being completed processes.

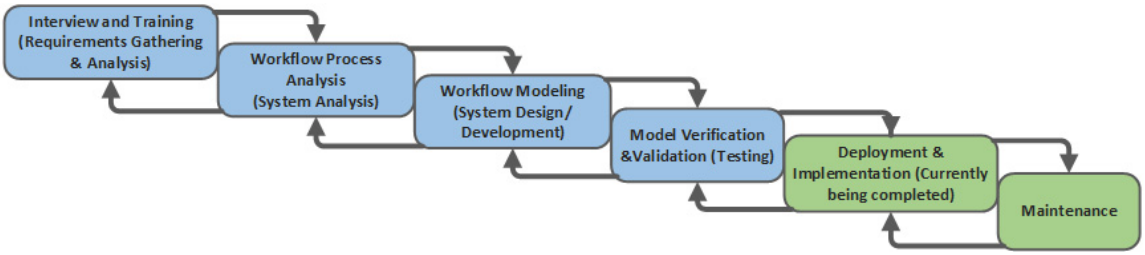

Figure 2 Methodology for modeling blood bank workflow

In this paper, we will first describe the high level workflow that shows the overall donation process. The donation process starts with donor registration task that can be a walk-in or showing up for a scheduled appointment. Then we will explain the sub-processes and the transitions between processes.

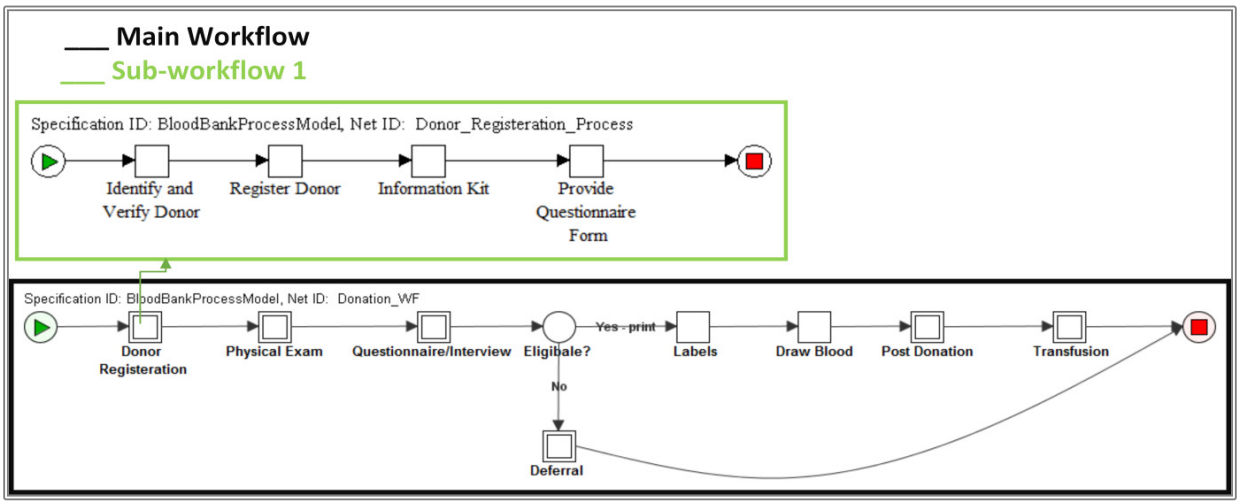

Figure 3 High Level Modeled Blood Bank Workflow

Figure 3 shows the modeled high-level blood bank workflow in Yet Another Workflow Language (YAWL) [12], an XML-based workflow languages that has been used to model business and healthcare processes. YAWL uses a graphical representation of the workflow and provides an executable that can be used as an input to software. Each

workflow consists of a beginning and an end. In Figure 3, we used sub-workflow, which consists of processes that needs to be completed prior to moving to the next task. An arc is used in the model denotes the transition of data from one task to the other. In Figure 3, the donor registration process has to be completed before a physical exam process. The workflow engine is used to ensure that each task in a workflow specification meets the requirements prior to moving to the next task. This can include the performance of a task based on a certain order, data, or condition needed [12].

2.2. High Level Donation Workflow (WF1) Details

The following steps show the high level workflow (WF) in a blood bank:

Step 1. Start Condition

Step 2. ***Donor Registration Process*** **(SubWF1.1):** Starts with blood bank staff identifying and verifying the donor identification. Then register the donor and provide him/her with educational materials and questionnaire.

Step 3. ***Physical Exam Process*** **(SubWF1.2):** Starts with identifying and verifying the donor. Then check donor vital signs, haemoglobin level and if donating platelets then check PLT count.

Step 4. ***Questionnaire/Interview Process*** **(SubWF 1.3):** starts with identifying and verifying donor. Then review filled questionnaire. Then go through the interview.

Step 5. **Checking *Eligibility*?** (Decision)The result can be qualified or unqualified decision.

Step 5.1. Donor qualifies to donate then *Prepare labels* for the blood bag, sample tubes and forms and *Draw Blood*. Unqualified donor be deferred and the deferral process is in SubWF1.4.

Step 6. ***Post donation process*** **(SubWF1.5):** Monitor the donor for any adverse events or reactions. Also, send donated units and samples to the sub-process Blood Transfusion System *(BTS) Lab Unit for processing*

Step 7. ***Transfusion Process*****(WF2):** Consists of sub processes Transfusion Request, Transfusion Process, and Post transfusion

Step 8. End Condition

We stated, the donation workflows consist of sub workflows that model sub-task that contain the details abstracted at the higher level. The following section describes the details of the "Post Donation" process named (SubWF1.5) in Figure 3.

2.3. Post Donation (SubWF1.5)

In Figure 4, shows processes after the donor has completed a donation. Once a donor completes donation, there is a need to closely monitor the donor in order to ensure that no adverse reactions or events to the donor. If such an adverse reaction occurs, then donor might need treatment, depending on severity of the reaction, there are several interventions, ranging from repositioning the donor, to giving medications, to extensive medical care and record the event. Also, all donations have to be transferred to the Blood Transfusion Services (BTS) Lab for testing. Figure 4 provides the next level of details of the post donation process.

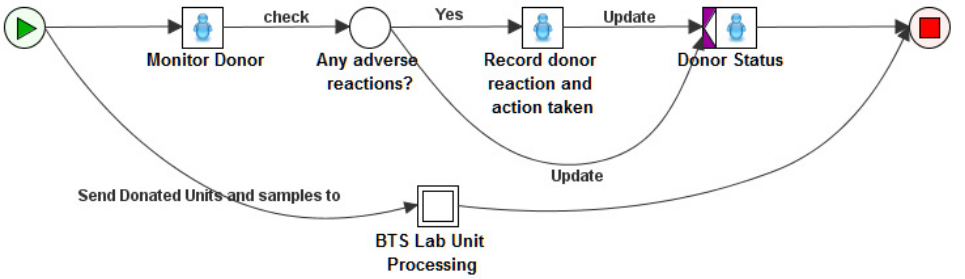

Figure 4 Post Donation Workflow

Step 1. ***Monitor Donor:*** *Nurse* → observes the donor in the rest area.
Step 2. ***BTS Lab Unit for processing:*** along with step 1 *Blood bank Technologist(s)* → test the unit and store it (carried in a sub-process), explained in SubWF1.5.1.
Step 3. ***Any adverse reactions?*** **(Decision):** *Nurse* → check the donor for any adverse reactions or events.
YES, *Record donor reaction and action taken* such as fainting and nausea.
Step 3.1. Treatments for fainting (applying a cold compress on the donor's forehead, raising the donor)
Step 3.2. Treatment for feeling nauseated or vomits, then (Instruct donor to breath slowly, apply cold compresses to the forehead, give water after vomiting has ceased)
If not, continue to step 4
Step 4. ***Update Donor status*****:** *Nurse or Blood bank Technologist* → save records of the donor conditions

2.4. BTS LAB Unit Processing (SubWF1.5.1)

The laboratory will store each donated blood unit in quarantine storage and conduct serology tests (HIV 1 and 2, HBsAg, HCV, HB c AB, HTLV 1 and 2) and blood grouping (ABO) are carried out concurrently. The ABO blood grouping process is done twice - once from the unit itself and one from the blood sample and the results are compared. Then the blood unit volume is registered and checked to be above or below the standard specified by the AABB standard. This is necessary to ensure a level of safety of the blood unit because if the blood volume is above the standard then the blood will consume the preservative nutrients quicker than other units. Conversely, a unit with a volume below the standard will contain extra preservatives affecting the equilibrium and thereby causing the dilution of plasma and platelets (except red blood cells - RBC). Whole blood units are processed to form other blood products such as Red Blood Cells, Platelets, and Fresh Frozen Plasma (FFP). If all serology tests have a negative outcome and both ABO tests are identical then the new blood components status is changed and moved from quarantine to available (ready to be stored for usage) storage. Conversely, a blood bag with a, positive serology tests gets discarded and donor is deferred from further donations. If the two ABO give different outcomes, an investigation is done, as it can be caused by an error in finding the ABO blood group or wrong unit has been tested. Our model of this process is shown in Figure 5:

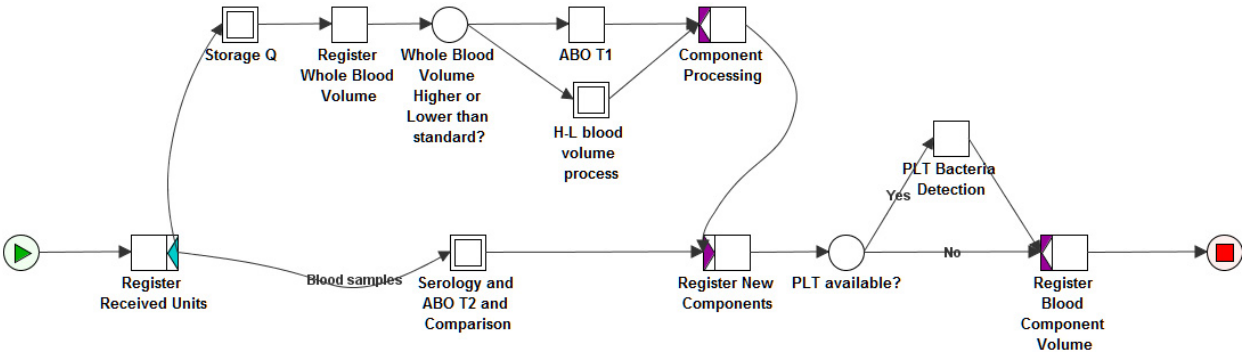

Figure 5 BTS Lab Unit Processing (SubWF1.5.1)

Step 1. ***Register Received Units by Blood bank Technologist(s)***
Step 1.1. ***Storage Q*** **(SubWF1.5.1.2)*:*** for quarantine this contains all untested blood. New units are placed in quarantine until tested. This is a subWF that manages all storage types such as quarantine (Storage-Q), available (Storage-A) and reserved (Storage-R). *Blood bank Technologist(s)*→ moves all received to (Storage-Q)
Step 1.2. ***Register whole blood volume*** *Blood bank Technologist(s)*→ register received units volumes then complete step 1.3

Step 1.3. ***Whole blood volume higher or lower than standard?*** (Decision): *Blood bank Technologist(s)*→ Performs check if yes, then initiate the (SubWF1.5.1.3) in step 1.4. If no, Move to step 1.3.1

1.3.1. ***ABO T1***: *Blood bank Technologist(s)*→ Perform the blood grouping test (ABO) twice by different *Blood bank Technologist(s)*. ABO T1 checks the blood group from the unit and ABO T2 is performed using the blood sample as in Step 1.6. Then a sub-process preforms a check if the two tests ABO T1 and T2 (completed in SubWF1.5.1.1) are the same then no errors occurred and if the results are different then it is an indication that an error occurred which will result in an investigation

Step 1.4. ***H-or-L blood volume process*** **(SubWF1.5.1.3)**: *Blood bank Technologist(s)*→ checks if lower, then create packed RBC and if higher blood is safely discarded.

Step 1.5. ***Component Processing:*** *Blood bank Technologist(s)*→ process whole blood to create other blood products such as platelet, Fresh frozen plasma, cryoprecipitate, and RBC.

Step 1.6. ***Serology and ABO T2*** **(SubWF1.5.1.1):** *Blood bank Technologist(s)*→ checks the blood for well-known diseases based on the FDA regulation and AABB standard. Test result that is positive will result in the unit being discarded (SubWF1.5.1.4). All tests being negatives and having same ABO blood group results leads to updating the unit. Then store the unit in (Storage-A) after changing unit and donor status.

Step 2. ***Register New Components*****:** *Blood bank Technologist(s)*→ register the new components created from donated blood in step 1.5.

Step 3. ***PLT available?*** (Decision): Platelets (PLT) if YES then check then *PLT Bacterial Detection Process* – this task will check platelets for any bacteria. If NO then move to step 4.

Step 4. ***Register blood component volume:*** *Blood bank Technologist(s)*→ record the volume of the blood products.

2.5. Transfusion (WF2)

Figure 6 shows the high-level transfusion workflow. There are three essential processes needed to complete the transfusion workflow. This process begins with a physician submitting a transfusion request. The transfusion request goes through a sequence of tasks prior to moving to the next process of the Transfusion Process, in order to ensure that the appropriate blood unit is transfused at the opportune time using the safety ensuring procedures. The following sections describe details of each sub-process.

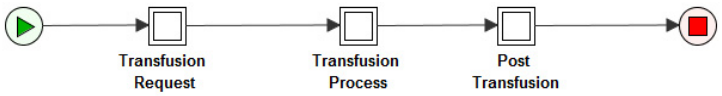

Figure 6 Transfusion Workflow

2.6. Transfusion Request (SubWF2.1)

Figure 7 shows the detailed steps of a transfusion request. This process checks documents to ensure all information are accurate and eligible. Followed by a series of steps are carried to test the patients' blood group and for anti-body screening (ABS) for whole blood/RBC requests. The blood bank technologist selects the correct type of blood and cross-match the unit with the patient's blood to ensure compatibility. The compatible unit is then relabeled and stored.

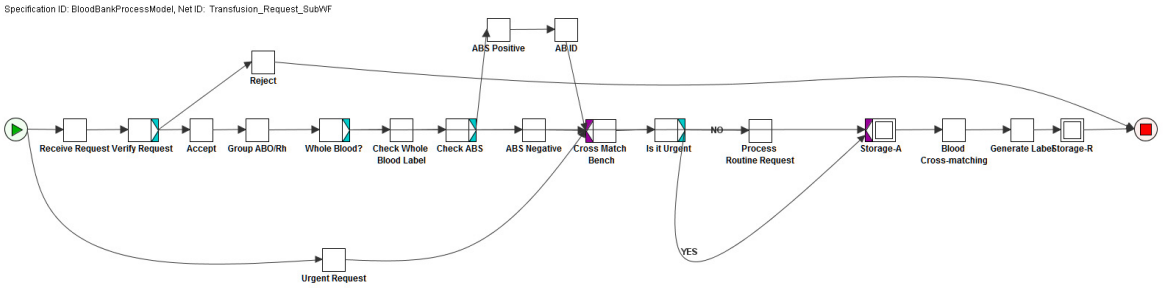

Figure 7 Transfusion Request (SubWF2.1)

Step 1. ***Receive Request*****:** *Blood bank Technologist(s)*→ receives a document request from the doctor to order to transfuse and stating the need for blood, patient name, and blood sample.

Step 2. ***Verify Request*** *(Decision)****:*** *Blood bank Technologist(s)*→ ensure all information are complete and accurate. If all information are complete perform step 2.1, otherwise go to step 2.2.

Step 2.1. ***Accept***

2.1.1. ***Group ABO/Rh:*** *Blood bank Technologist(s)*→ checks the patient's sample for their blood group through performing the task Group ABO/Rh.

2.1.2. ***Whole Blood?*** (Decision)This process checks if it is whole blood/RBC other blood products such as platelets, plasma, cryoprecipitate, and fresh frozen plasma needed. Other blood products can be directly requested without checking ABS and so *blood bank technologist* can directly select a unit from (Storage-A) from subWF1.5.1.2.

2.1.3. ***Check patient sample label***: *Blood bank Technologist(s)*→ verify the correctness of the sample label.

a ***Check ABS*** (Decision): *Blood bank Technologist(s)*→ performs Antibody screening (ABS). If the result is ABS Positive then create AB ID and everything is moved to the Cross-match Bench.

b If negative, move everything to the cross-match bench.

Step 2.2. ***Reject*****:** if the request is incomplete or erroneous (e.g. wrong patient name or date or birth), reject the request.

Step 3. ***Urgent Request:*** *Blood bank Technologist(s)*→ moves urgent requests directly to the *Cross-match Bench.* This is where the cross-match is performed to perform the compatibility test of the selected unit with the patient sample blood.

Step 4. ***Is it Urgent*** (Decision): *Blood bank Technologist(s)*→ for urgent requests directly select a unit from (*Storage-A)* Check SubWF1.5.1.2 OR

Process routine request – When there is time or no urgent requests then proceed with unit selection from *Storage-A*

Step 5. ***Blood cross-matching***: *Blood bank Technologist(s)*→ mixes the patient's plasma with a sample from the selected blood to check if they are compatible. If not then investigate (either choose another unit of blood or redo ABS). Once compatible, move to step 7

Step 6. ***Generate label:*** *Blood bank Technologist(s)*→ creates a label showing the unit is reserved for a specific patient.

Step 7. ***Storage-R*** SubWF1.5.1.2***:*** *Blood bank Technologist(s)*→ move the reserved unit from (storage-A) to (Storage-R).

2.7. Transfusion Process (SubWF2.2)

Figure 8 shows the steps carried when transfusing-blood to a patient. This process has different checks prior to transfusion in order to ensure the patient's safety. The first check is to ensure that the blood is received in the

standardized transport container with the right temperature, time, and label information. Then confirming all information of the patient, unit label and dispense report are correct. The dispense report include patient information, request blood product, number of units needed, tests required and sample labels. This safeguard ensures that the patient receives the appropriate blood unit. A detailed explanation appears subWF2.2.

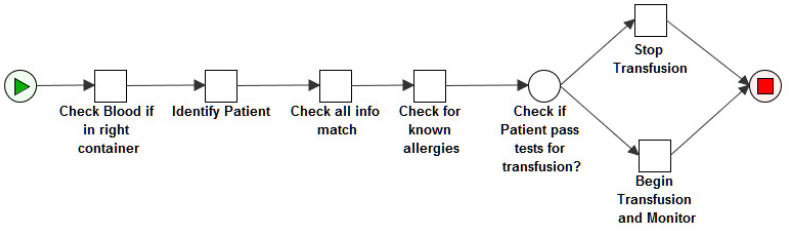

Figure 8 Transfusion Process (SubWF2.2)

Step 1 ***Check blood if in right container***: *Nurse*→Accepts blood in right container/transfer box; Rejects blood transferred in any other form.

Step 2 ***Identify Patient:*** *Two Nurses*→ checks patient and unit information. To ensure the right received unit is for the right patient

Step 3 ***Check all info match:*** *Nurse*→ confirm information such as blood request form, patient ID band, check unit of blood (type, date, and donor ID), blood product form, date match.

Step 4 ***Check for known allergies***: *Nurse*→ the patient is asked if he/she has any allergies

Step 5 ***Check if patient pass tests for transfusion*** (Decision)**:** *Nurse*→ ensure that the patient is ready, correct unit available, and all information accurate. Prior to transfusion.

Step 5.1. ***Begin Transfusion and Monitor***: *Nurse*→ initiate only if the patient passed all tests

Step 5.2. ***Stop Transfusion***: *Nurse*→ terminates the transfusion process due to patient not passing all tests or error with the blood product or information.

2.8. Post Transfusion (SubWF2.3)

Figure 9, shows processes after the transfusion process (SubWF2.2). After the transfusion process has occurred there is a need to closely monitor the patient to ensure no signs or symptoms of a reaction or events occur. In the case of any signs or symptoms occurring, then the patient is treated and an investigation is performed. On the other hand, provide informational guide to donor in case of a delayed symptoms and release the patient.

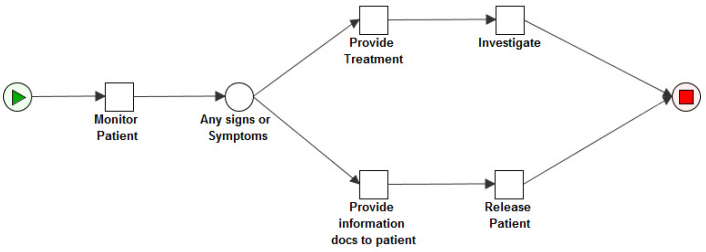

Figure 9 Post Transfusion (SubWF)

Step 1. ***Monitor Patient:*** *Nurse*→ ensure that he/she is not developing any symptoms or reactions.

Step 2. ***Any signs or symptoms:*** *Nurse*→ check if there are any signs or symptoms to the patient

Step 2.1. Yes there are symptoms then ***provide treatment*** and ***investigate*** the cause of the symptom

Step 2.2. NO then ***provide information docs to patient*** and ***Release Patient***

3. Validation and Analysis

We used YAWL to check for control-flow, that will have the order of tasks execution [13] using techniques such as reset nets helps in connecting some tasks to perform a processes through removing all tokens in that process and replace it with the new tasks and transition invariants [12]. Our verification tests ensure that the specified workflows can start, execute and end. Conversely, they also check for deeper errors such as deadlocks, unnecessary cancellations, and unnecessary joins [12]. Our blood bank process has been verified correct using the automated verifiers available with YAWL that YAWL refers to as sound workflow rules. The first rule, blood bank workflow and sub-workflows have shown that the final state has only one output. The second rule shows that the modeled blood bank workflow completes properly without having any tasks that have net been executed. That is, with respect to Petri net terminology, there do not exist any enabled but unexecuted tasks. The third rule says that there should not be any deal tasks that is our model has no tasks that will never be executed. [12]

4. Related Work

Blood banks have been operational since 1936 [14] to collect, process, store and retrieve blood products and transport them to recipient sites. Several authors have discussed blood bank process and the importance of having a workflow. As far as we know, there is no model that formalizes the workflow used in blood banks.

Pantanowitz et al [15] articulates the need for an operational blood bank with minor or no errors. This is because any error in a blood bank can result in fatal issues to the patient. Dada et. al [16] discusses blood banks automation and how it aided in decreasing errors while increasing accuracy through changing the work arrangement. Rutle et. al recommends to create a formal workflow for blood banks that will aid in increasing safety within the process [16]. In order to ensure safety there is a need for an error free workflow in healthcare [17].

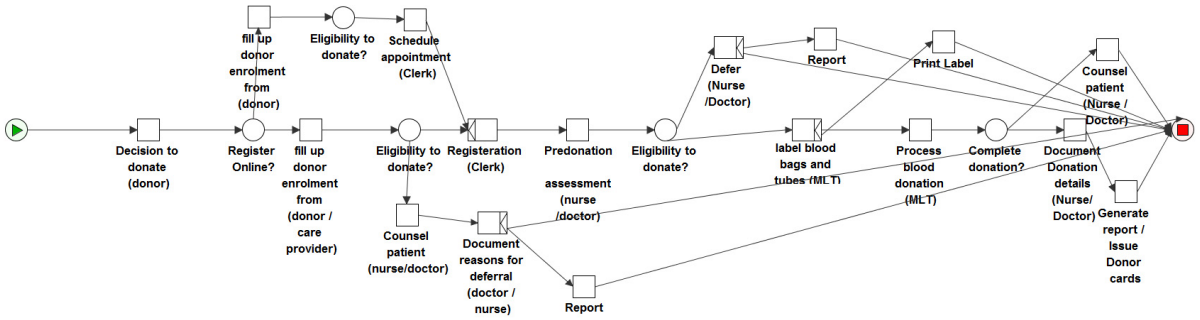

Figure 10 Workflow 1 from the Malaysian Blood Bank Information System

Most blood banks use similar procedures but differ in the methodologies used for each process. Mapping all processes to the workflow will facilitate checking, tracing and capturing errors in designed workflows. For example, we found the workflow published by the Malaysian blood [18], which was very detailed and helpful in understanding the technical aspect of the process, but it lacked a formal workflow specification. A workflow has specific rules and requirements, to ensure that all processes are carried in some expected sequence. Through mapping the Malaysian workflow in Figure 10, we have found that the workflow was capable of starting and ending properly with no errors. However, when we analyzed the workflow three errors were generated. The workflow failed to satisfy some of the soundness properties such as an option for the workflow to complete and a proper completion. This means that the workflow could not be completed and the workflow output had more than one token left in the workflow. Further, the available workflows showed only high level processes not describing the details such as some blood products request and cross-match process are different [18]. The Malaysian blood banks workflow has showed great details in

connecting all blood bank processes to the hospital but it lacked some blood bank processes details such as donor identification and verification, donated blood registration process (blood volume standard check), post donation reaction and action, and transfusion processes.

The second model we analyzed is provided by Hemosoft [19]. Hemosoft is a system currently being used by several blood banks. Mapping the blood component flowchart from [19], resulted in verification process failure. The failure was due to an infinite loop in processes Temporary Deferral, Physical exam and donor. Although this is a flowchart of an existing system, it lacks essential process details i.e. the details that compute component processing which includes testing details (ABO tests, Serology, blood volume), lab registration process, and storage process.

5. Conclusion

We have obtained a workflow process model used by an operational blood bank and modeled that process using the workflow tool YAWL. Our test that use YAWL showed that the modeled processes were sound and error free from standard workflow errors such as deadlocks, unnecessary cancellations or having unnecessary OR-joins. The modeled blood bank workflow was able to pass both the verification and analysis problems. Creating and verifying this workflow has several benefits such as quicker process validation and analysis compared to manual methodologies. Manual methodologies used to verify and validate workflows are resource intensive and complex. Another benefit is to enforce specific requirements and properties of the workflow and creating a smarter workflow. This can be created through extracting blood bank requirements and safety properties (hemovigilance) from blood bank regulations and standards then we can map those requirements to this workflow.

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