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Integrating Automatic Monitoring of Accreditation Regulatory Compliance within Computerized Laboratory Information Systems

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Abstract

Most current computerized laboratory information systems (LISs) are designed to facilitate specimen tracking from accessioning (entry) to final test result reporting, so that such information is quickly available to health care providers who are utilizing a computerized health information record system. It is now well recognized that achieving regulatory accreditation is by far more challenging to most labs than the actual performance of often automated testing. Few, if any, LISs have begun the task of incorporating the relevant regulatory standards in their workflow monitoring. At least one such system that appears to completely automate monitoring of regulatory compliance in the blood bank section (blood transfusion services) of the laboratory is hereby reviewed

Introduction

Laboratory operations in general and Blood product procurement and disbursement in particular have been technically made easy thanks to the availability of automated instrumentation and computerized tracking systems. However, errors in specimen processing, analyzing, reporting or dispensing do happen with variably negative impact on the patient's well-being. In case of blood transfusion, such errors can be fatal. Thus, the drive continues to make these procedures absolutely safe or at least safer than before. To achieve that goal, numerous standards and guidelines for laboratory operations and specifically for blood collection and transfusion had been established and many had been made mandatory if the lab or its blood transfusion service (TS) is to be accredited or legally permitted to operate within the US healthcare environment. Compliance with these standards by the various facilities is subject to inspection and certification by agencies with direct or deeming authority like the US Food and Drug Administration (FDA) [1], the American Association of Blood Banks (AABB) [2], the College of American Pathology (CAP) [3], the Joint Commission, state regulatory agencies and others.

Lab Information Systems that are currently in the market provide an excellent safeguard against specimen mishandling, maltesting or inaccurate reporting. In doing so, the typical LIS assists in ensuring partial compliance with the regulatory standards. However, keeping track of all regulations, for instance those that apply to each phase of blood product handling and processing is a cumbersome task that demands expense and labor with an ever-present chance of a safety item omission or processing error that may result in dire health consequences for the patient and immerse the facility in either negligence litigation or loss of accreditation (closure of business) or both. Conversely, in view of the vast advances in information technology (IT) and digital workflow automation, the challenge is on for any futuristic looking LIS, especially its blood transfusion section, to incorporate more automated monitoring of regulatory compliance. In the following sections of this review, as a prototype, we take a closer look at the feasibility of such automation as reflected in a TS compliance monitoring software developed by one of this report's authors (Dr Hazzazi; PhD thesis) [4].

Compliance-Monitoring Software Design

The referenced software is a workflow-tailored design that checks the process for each major compliance point (standard) before authorizing the subsequent step. A workflow is a representation of the multiple sequential tasks within a process. Each workflow has a start, ending and interim tasks. The workflow is constructed by starting with a single task or a short sequence of individual tasks and combining simpler workflow sequences, using the so called in IT language "task combinators", to create more complex workflows to any desired

depth. Combinators used here included sequencing, parallel executions, conditional branching and repetitions [5-8]. This workflow design incorporates as executable tasks or steps all major compliance standards set in one or more regulatory agency's checklists. Each task is dependent on the execution of the previous task with satisfactory (predetermined or expected) results, that are supposed to move a blood product safely along the blood supply chain [9,10]. CAP checklist for transfusion medicine is used for illustration (checklist items are numbered as TRM.xxx). Accordingly, incorporated in the design are CAP standards that apply to the following checklist sections: Blood Component; Donor Selection and Collection; Quality Management and Quality Control; Donor Apheresis; Component Preparation, Storage, Modification and Testing; and Transfusion Procedures including adverse reactions. The workflow is organized so as to cover the pre-procedural, intra-procedural and post-procedural phases in each of the processes of donation, laboratory testing and transfusion. This coverage is detailed below:

The donation process

Pre-donation: This is the first phase in the donation process. It consists of completing the registration and ensuring the donors suitability to donate blood. In the registration process, the donor is identified as either a previous donor or as a new donor. However, returning donors with deferrals are also identified. The donor deferral period (temporary or permanent) is checked either allowing the donor to donate or not. Donors with permanent deferrals are automatically deferred. In all cases, donor's identity is verified using two pieces of acceptable identity documents. The system then checks donor's suitability based on the standard for donor demographics (at least of age 17 for allogeneic donations and parental consent is required if underage; CAP TRM.45256). An apheresis donor eligibility is also checked by identifying donation interval if previously donated and completing a standard questionnaire regarding suitability requirements prior to donating (CAP TRM.42214, 42215, 42220, 42222, 42240, 45276).

Passing the first process (registration) allows the donor to proceed to the next step of checking the Donor's suitability based on his/her medical history, blood counts and physical attributes (medication intake, hemoglobin level, height and weight, etc). As a component of the physical exam, the donor is also required to provide his/her consent and pass a relevant health interview (CAP TRM.42222, 45263, 45257, 45258, 45259 45261). The suitability process checks also the type of donation for specific requirements such as a physician's note before autologous donation (CAP TRM.45270, 45271).

The presented workflow is a chain of processes that is capable of logging data throughout the blood supply chain. These processes allow us to retrieve records of each step throughout that chain for auditing and tracking (CAP TRM.42223, 47320).

Donation: The donation phase (collection) starts when the donor passes all checks in the pre-donation phase. Failing to satisfy any of the pre-donation safety requirements will defer the donor. Prior to starting the donation, the phlebotomist is required to re-validate donor's identity. The next step is to check the donor arm to ensure that there is a clearly visible vein with no signs of needling CAP TRM.45275). Then, the phlebotomist prepares the arm by scrubbing and cleaning it (CAP TRM.45267). In this phase the software collects data such as blood collection date, start time, end time, product collected and any complications that arose during the blood draw. In situations where an adverse reaction occurs, the collection is terminated and the donor is treated. Otherwise, the donor proceeds to the post-donation phase.

Post-Donation: After the donor completes a donation phase successfully with no adverse reactions, he/she is discharged with educational material explaining possible delayed adverse reactions that may occur (CAP TRM.45273). The collected units are moved to appropriate storage until requested by transfusion service personnel. This portion of the model can be used separately by an independent blood collection facility that functions as blood supplier only.

The laboratory process

Transfusion services that do not collect their own blood can begin at this portion of the model. This process is the central component of the TS workflow as the donation process is the producer of the available blood inventory and the transfusion process is the consumer of that inventory. One of the main objectives of the blood transfusion service laboratory (BTSLAB) process is to ensure that all units are labeled correctly and all tests are performed properly (by validated methodology). In this process, blood and blood components are tested and inspected prior to marking the status of any output blood unit as "available" or "quarantined". This process consists of the three phases: pre-analytical, analytical and post analytical as outlined below.

Pre-analytical: The pre-analytical phase starts with the BTSLAB receiving a unit of blood along with all the data gathered during the blood collection. The unit is visually inspected for leakage and data such as color, time and temperature are entered into the BTSLAB process. The model checks for the regulatory requirements in preparing the unit for testing. However, in situations when the received unit leaks or does not pass the visual inspection, the system directs the lab personnel to dispose of the unit according to a specified disposal process handled by a third party (CAP TRM.30800).

Analytical: The analytical phase in the BTSLAB has two sub-processes that run in parallel: if necessary the unit itself is processed into final products, such as red blood cells, platelets, plasma etc, while the separate unit sample undergoes standardized testing for blood grouping, antibody screening and infectious diseases. All unit information is stored in the system and the units are labeled accordingly. The system checks for compliance with all applicable standards before releasing the unit. Recipient blood sample is also tested in the lab for blood grouping and antibodies.

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Post-analytical: In the post-analytical phase, blood bank staff review tests performed during the analytical phase. This phase moves safe blood units to storage and unsafe blood units (units that failed tests or checklist requirements) to be discarded. Units that are discarded trigger donor deferral if unsafe determination was due to positive testing for a transmissible disease. Otherwise, the unit is discarded without deferring the donor.

The transfusion process

Regulatory standards that pertain to the transfusion process are designed to ensure that the recipient will receive safe, group-compatible blood with no or minimal antibody adverse reactivity and free of infectious hazards. The model tracks the transfusion process in its three phases: pre-transfusion, transfusion and post-transfusion.

Pre-transfusion: The pre-transfusion phase begins with the "Request for Transfusion". The model uses several tasks to check the information provided in the request form, patient history and unit data to ensure choosing a compatible unit for the patient. The first task in the Transfusion Request process ensures that a valid request is received from a physician along with a patient blood sample. Transfusion Request checks patient's historical data to confirm the patient's sample blood group from historical sample results if the patient had previous but recent testing record (CAP TRM.30575, TRM.40300). For patients with no blood group histories, the workflow directs the user to request a second sample from the patient that is then tested to confirm the first sample's blood group. The next task is to test the patient's blood sample as stated earlier. Using specific compliance standards, the system then identifies a compatible blood unit for transfusion based on recorded patient's and available unit's data (electronic cross-match). The system can be designed to request also a technical (actual or manual) cross-match in cases of unusual antibody or rare blood group incompatibility. The expiry date of the cross-matched unit is captured by the "Transfusion Request" module and used to ensure that the cross-matched unit cannot be held longer than three days (CAP TRM.40500). The selected unit is signed-out or issued for transfusion.

Transfusion: The transfusion phase workflow design checks for specific regulatory standards that include requiring two operators (transfusionists or nurses) to verify patient ID, and matching information on the unit, dispensary report and tags (CAP TRM.40235, TRM.41300). Failure to meet this requirement stops the transfusion process if the system is also used at bedside. Patient's vital data are recorded prior to transfusion as a baseline and continuously recorded throughout the transfusion procedure to capture any transfusion reaction that may occur. The length of transfusion is also recorded and monitored to take no more than approximately 4 hours.

Post-transfusion: The post-transfusion phase monitors patient's vital signs and checks for any adverse reactions (CAPTRM.41475). In situations where a patient experiences a transfusion reaction, the workflow allows the user to enter the symptoms to automatically interpret the type of reaction (hemolytic vsnon-hemolytic), and prompts the user to collect additional relevant information or order additionaltests that may help in investigating the nature of the reaction (CAP TRM.41650, TRM.42050, TRM.42150).

Discussion

The workflow design described in this report is a wholesome software that automates monitoring of regulatory compliance in all phases of blood product procurement, testing and dispensing. Automated information and task monitoring technologies, such as this model, are key players in achieving almost perfect safety levels via monitoring and forcing, in real time, compliance with established operational and safety regulations.

In addition to monitoring and prompting for regulatory compliance, this model also maintains de-tailed operational records that are easily retrievable for investigational and auditing purposes. Unlike many current TS software systems which provide functional checks that are not linked together, the presented model ensures that tasks are performed and records are collected in a chain of processes that are completely linked [4].

"Korchek Technologies" [11] provides a commercial service that validates blood banks computer system's safety. The company's website states that they use a plan that follows three steps consisting of planning, scripting and executing to validate blood bank safety. No claim is made for automating the monitoring process but it is claimed that their services had been applied to a number of systems such as Cerner, SCC Soft, eDonor, Horizon Blood Bank, and others. The website states that "Korchek Technologies" guarantees to meet FDA, CAP, AABB and Joint Commission validation guidelines. However, they do not mention guaranteeing compliance with regulations and checklist standards.

Other systems like "Vedant Health" [12], "The Summit" and "Scripting Toolkit" [13] do provide limited automation in verifying transfusion processes but fall short of addressing all phases as described above. Furthermore, in contrast with the presented model that utilizes open source coding, most of the other systems are hard coded which creates inflexibility in updating the system or making any changes [9].

In conclusion, the reviewed model may serve as a prototype for an automated electronic LIS-integrated management and compliance monitoring system that if implemented at all phases of the clinical laboratory operation (particularly, the TS or blood bank section), offers a high level of patient safety and accreditation worthiness. The system is flexible, customizable and updatable. System limitations include its susceptibility to operator interference such as inputting erroneous data in order to expedite one phase or another or bypass regulations. The system record keeping benefits can also be compromised

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if individual phases are not completely integrated within the wholesome computerized health information system.

References

1. tp://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
2. http://www.allbookstores.com/Standards-Blood-Banks-Transfusion-Services/9781563959271
3. College of American Pathologists (CAP), Master Transfusion Medicine Checklist.
4. https://pdfs.semanticscholar.org/458e/a201925af537de9b476a9e961056be95cc0c.pdf
5. N. Hazzazi, B. Yu, D. Wijesekera, P. Costa, Using temporal logic to verify blood supply chain safety, Int'l Conf. Health Informatics and Medical Systems |HIMS'15|.
6. (2010) Experience modeling and analyzing medical processes: Umass/baystate medical safety project overview, in: Proceedings of the 1st ACM International Health Informatics Symposium, IHI '10, ACM, New York, NY, USA, pp. 316-325.
7. Chen B, Avrunin G, Henneman E, Clarke L, Osterweil P (2008) Henneman, Analyzing medical processes, in: Software Engineering, 2008. ICSE '08. ACM/IEEE 30th International Conference, pp. 623-632.
8. Jiang Z, Pajic M, Alur RR (2013) Mangharam, Closed-loop veri_cation of medical devices with model abstraction and re_nement. International Journal on Software Tools for Technology Transfer 16(2): 191-213.
9. Ruan J, MacCaull W (2010) Data-aware monitoring for healthcare workows using formal methods, Proceedings of the Second Workshop Knowledge Representation for Health Care KR4HC 2010, Lisbon, Portugal, PP. 51-60.
10. Bottrighi A, Giordano L, Molino G, Montani S, Terenziani P, et al. (2010) Adopting model checking techniques for clinical guidelines verification. Artificial Intelligence in Medicine 48(1): 1-19.
11. https://www.korchek.com/Validation.aspx
12. http://www.vedanthealth.com/docs/TestStreamforSunquest.pdf
13. http://www.summit-healthcare.com/

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