Specifying Time-Out Points in Surgical EMRs–Work in Progress

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Abstract. Workflows for surgical procedures have built-in time-out points to minimize occurrences of unintended faults and omissions during surgeries. They have been recommended in the best practices of appropriate surgical sub-specialties, as well as the Joint Commission. At these timeout points, designated team members perform recommended precautionary measures, such as verifying the accuracy of implants, to ensure unintended mistakes are not made before proceeding to the next stage. These precautionary measures are usually recorded in paper-based checklists and retained for a stipulated period of time. We show how these timeout points can be specified as formal workflow requirements in surgical Electronic Medical Records (S-EMRs).

Keywords: Surgical EMR, Time-out points, Surgical Errors.

1 Introduction

Due to technical advances health care procedures and workflows are becoming more complex [1], and surgical sub-disciplines are no exception to this trend. In such complex workflows, avoiding procedural errors, including incorrect diagnoses as well as medical errors and other sources of avoidable complications [2], contributes to improving quality of medical care received by patients. Wrong patient, wrong site, wrong side, wrong implant, retained sponges, unchecked blood transfusions, mismatched organ transplants are all examples of surgical errors which decrements quality of surgical care [3]. Although patient safety is taken into account when performing surgeries, all current studies show that surgical errors continue to be a significant challenge to high quality surgical care. For example, 98,000 people die annually due to medical errors [4]. A more recent study estimated that 5 to 10 of these unexpected events occur daily in the United States based on the database analysis [5].

In our paper, we suggest a methodology to study surgical safety issues in the now accepted Use Case – Misuse Case paradigm for the Requirements engineering. To the best of our knowledge, there is no formal definition or characterization of kinds of Time-out Points of a surgical Electronic Medical Records (EMRs) system, which we provide. Additionally, we also propose a potential specification and enforcement model of a workflow in surgical EMRs.

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The rest of the paper is written as follows. Section 2 reviews related work. Section 3 provides an overview of our surgical workflow models and the insertion of time-out points into the workflow. Section 4 introduces our method of specifying time-out points within the workflow. Section 5 describes a case study of inserting time-out points into an existing surgical workflow. Section 6 describes how we can move some "show-stopping" time-out points as early as possible in order to avoid abandoning the procedure at later stages. Section 7 concludes the paper.

2 Related Work

Surgeries are complex procedures that require the cooperation of many actors with numerous sub-procedures. Some institutions, medical practitioners, and researchers devote themselves to reducing preventable deaths and complications in surgery, including designing and enforcing surgical safety checklists [6-8], new policies, guidelines, and standards [9, 10] to govern surgical procedures. The World Health Organization (WHO) developed a checklist to ensure the safety of surgical patients worldwide [11]. The Joint Commission approved the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery, which became effective July 1, 2004 for all accredited hospitals, ambulatory care and office-based surgical facilities. However, mistakes still occur and in addition, cultural factors also act as a barrier to implementing surgical checklists [8].

Many healthcare organizations have already employed computerized devices and/or computer systems for improving patient safety. These medical systems include Context-aware systems for the Operating Room (OR) [12, 13] and Workflow-driven information management systems that help healthcare providers in reducing communication misunderstandings and coordinating work.

The 'Context-Aware Peri-operative Information system' [12] can use many monitors and sensors collect OR data, that are analyzed using a rule base and displayed on an OR-Dashboard to help healthcare providers detect complex surgical events, and document these events in EMRs automatically. The 'Context-aware Patient Safety system' takes patient safety concern to a higher level by extending others' previous work, providing additional safety-critical contextual reasoning, and by utilizing information about the accuracy of contextual data [13]. These technologies allow systems to improve the overall surgical care quality by monitoring key attributes. However, some researchers have argued that context-aware computing is error-prone and sensors such as RFID readers have high failure rates (false positive and false negative). False readings at best cause stress and annoyance to the healthcare providers, and at worst could be harmful or even fatal to patients.

In recent years, different kinds of workflow management techniques have been used in the medical field. Workflow-based systems help in diagnosis of disease, assist in medical decision making, optimize scheduling medical events, such as OR, and aid in therapy [14-16]. Surgical Workflow predefines surgical procedures, in which documents, information or tasks are passed from one healthcare giver to another based on procedural rules [17]. The significant benefit provided by using workflow into a surgical management system is delivering systematic management among surgical processes. It can also be used for qualitative reviews of the procedures and outcomes.

3 Time-Outs in Workflow-Based Surgical EMR Systems

An EMR of a patient includes his/her complete medical information, such as medical history, diagnoses, allergies, treatment plans, consents, etc. During a surgery, all or part of such patient's information will be used and/or updated. The challenges, however, are how to retrieve information completely whenever needed, and how to ensure that information transferred between healthcare providers are accurate and relevant. Surgical workflow processes have well-designed sequence executable tasks. Each task needs different patient information; therefore, a workflow-based surgical EMR system allows required information to be retrieved automatically when a task needs them. However, existing surgical support software is not robust enough to alarm on all potential human errors that could occur during a surgical procedure. A time-out point is one in which the whole surgical team in attendance stops all other tasks and checks a pre-defined condition before proceeding to the next step.

Definition (Time-out Point): A time-out point is a triple < Condition, Type, Alternatives> where the three components are defined as follows:

- Atomic condition:= [attribute_value] [comparison operator][attribute_value] | value [comparison operator] attribute, where comparison operator:= $\{=, \neq, <, \leq, >, \geq\}$
- Condition:= Atomic condition | condition [Boolean Operator] condition, where Boolean Operator: = $\wedge, \vee, \neg$
- Type: non-detrimental , detrimental
- Alternatives are a non-empty, prioritized list of actions. If the type is non-detrimental, then the last action is "Record all attributes of the condition and proceed to the next stage". If the type is detrimental, then the alternatives list is empty.

The previous definition formally captures the essence of a time-out point. The first component, condition, specifies a check that is inserted in order to prevent one or many errors or omissions. This condition is a Boolean combination of attribute value comparisons constructed out of some attributes that could generate an alarm of a potential error or omission before it occurs. The second component, type, takes the value of non-detrimental or detrimental. The distinction is that the condition stated in a detrimental time-out point must be satisfied in order to proceed to the next stage of the workflow. If not, the rest of the procedure must not occur. The third component is a list of prioritized alternative actions that can be taken if the condition fails at a non-detrimental time-out point. The last alternative on this list says that if all other alternatives fail, to record the attribute values used to specify the condition and to proceed to the next stage.

There are two objectives to having time-out points. The first is to ensure that there are sufficient time-out points inserted to ensure that all conceivable Misuse Cases are covered and that the time-out points are appropriately categorized as detrimental or non-detrimental. The second objective is to ensure that checks performed during a detrimental time-out point can be done as early as possible in the workflow.

In our approach, we combine time-out point enforceable surgical workflow with a Clinical EMR system (C-EMRs) to create a more robust S-EMR model. Our model consists of: User Interface (UI), Time-out Point Manager (TPM), Workflow Engine (WE), C-EMRs. Fig. 1 shows the architecture for designing our proposed time-out point enforceable workflow-based S-EMR systems.

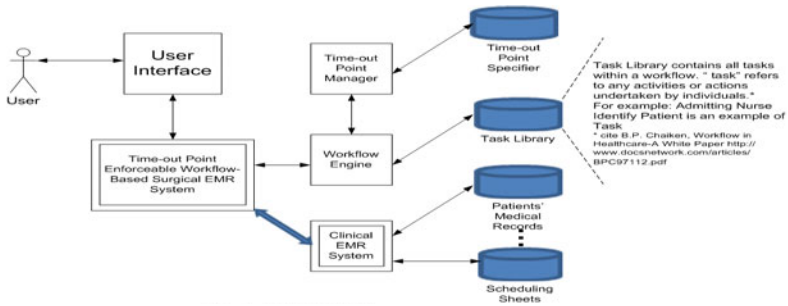

Fig. 1. Architecture

- Users are humans who interact with the system, such as surgeons, nurses, anesthetists, patients, etc. Patients have the right to view surgical logs in case they want to audit their own surgical procedures [18] and the quality care team also may want to review the logs.
- WE controls the process tasks of a workflow, triggers other cooperating systems to retrieve required information, notify or alarm users to interact with the system or to follow standard procedures.
- TPM is an additional control to the surgical workflow. It ensures that time-out points are enforced before proceeding to the next stage of the workflow process.

Users log into the S-EMR system based on their assigned roles in a surgery. The first task within the surgical processes notifies the user to interact with the system. For example, a nurse fills out a form or clicks a command button. Then the S-EMR communicates with TPM and triggers cooperating systems, such as C-EMRs, to retrieve needed information (if the task requires them), to check if previous task has satisfied the measuring criteria. If satisfied, the next task will be active upon completion of the current one.

For example, when a patient checks in or before being transferred from the ward, the admitting nurse (role) will fill out a patient identification form. After verifying the information with the patient verbally, the nurse submits the data that will be stored in a log file. In our system, time-out points are points in which systems check for a condition. The system will retrieve patient information from C-EMRs, and compare it with information submitted by the admitting nurse (role). If the information matches, a wrist band with a barcode will be created. Otherwise, the admitting nurse (role) will receive an alarm. If the identification check fails, the nurse may be required to (1) check with ward/clinic that sent the patient, (2) surgeon, (3) anesthesiologist, (4) the internist records of the pre-operative examination, in order to avoid taking the wrong patient into the OR. Doing this check will prevent taking the wrong patient into the OR.

4 Selecting Appropriate Time-Out Points within a Workflow

Retrospective studies [18] and prospective studies [19] are used to analyze the root causes of surgical errors. Seiden S. and Barach P. in their research paper

'Wrong-Side/Wrong-Site, Wrong-Procedure, and Wrong-Patient Adverse Events (WSPEs)' [20] say that the main reasons cause WSPE are 1) patient and procedure factors, like similarity of site, surgery, and patient names; 2) breakdowns in communication and teamwork; 3) failure to comply with safety checks and standards. The workflow-based S-EMR system has the capability to eliminate errors that are caused by above three reasons. However, where checks or enforcements should be applied in a surgical workflow could be a new challenge faced by developers. We introduce a methodology to select appropriate time-out points within the workflow by adopting the use/misuse cases [21, 22] to analyze possible intended and un-intended malpractices.

Use Case (UC): Surgeon uses sponges.

Misuse Case (MisUC): Surgeon leaves a sponge in patient's body.

Mitigating Use Case (MitUC): In order to prevent a surgeon leaving a sponge in a patient's body, two additional actions are taken. When sponges are introduced into the sterile field, we defined them as entering sponges. In contrast, when at the end of procedure, used and unused sponges are exiting sponges. The following actions are in the MitUC: (1) Circulating nurse counts entering sponges; (2) Scrub nurse counts exiting sponges; (3) If the counts are equal then proceed to the next step; (4) Otherwise, proceed to execute remediating treatment in order: (A) Search around for sponges, such as on the floor, in the trash can, etc. (B) take an X-ray of the patient's surgical site to confirm that no sponges are left inside the patient's body. (C) If neither works, record the failure and proceed to the next step of the workflow.

Time-out points set conditions to be checked before proceeding to the next stage. As the example shows, we will set two time-out points at before the operation start and at the end of operation but before the patient's body is closed.

Time-out point at the end of operation: {entering sponge count = exiting sponge count}, if true, proceed to the next step in task of workflow.

Type: non-detrimental

Alternatives:

(1) Search surgical site, such as on the floor, in the trash, etc.
(2) Take X-ray for radiological confirmation that no sponges are left.
(3) If all entering sponges cannot be accounted for, record the count mismatch and proceed to the next step.

} Alternatives

This time-out point is one of the non-detrimental time-out points, because the surgeon will proceed to close the open wound after all checks fail and proceed to the next stage. Furthermore, notice that we cannot add any more checks to the beginning of the surgical procedure to improve surgical safety, because the final sponge count is not available before this stage.

5 An Example Surgical Procedure

In this section, we discuss the specification of workflow that implements a sample (eye implant) procedure for cataract surgery. We use TP-n as the notation for the n^{th} time-out point. Fig. 2 shows a timeline described by an eye surgeon.

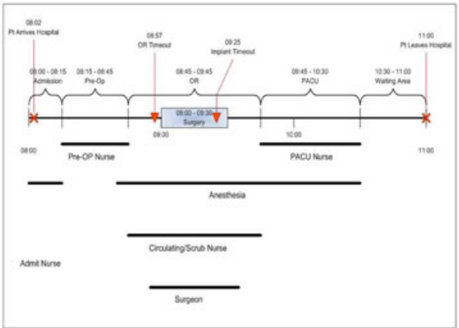

Fig. 2. Sample procedure Timeline (original)

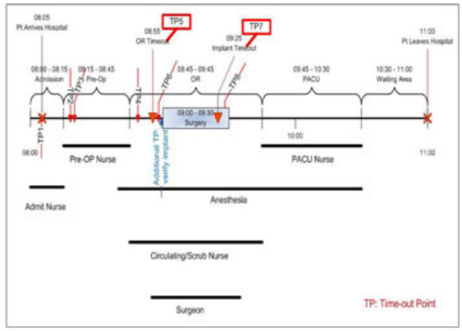

Fig. 3. Sample procedure Timeline (after analyzing, adding more TPs)

The surgical workflow (Shown in the Appendix, Fig.4) starts when the Admitting Nurse (role) identifies the patient in the EMR system upon arrival at hospital. We set our first time-out point, or TP-1, at the beginning. At this stage, in order to pass the TP-1, the identifying information needs to match the information in C-EMR. Once the patient is identified, the workflow proceeds to the next stage of wheeling in the patient. If the comparison does not succeed, the Admitting Nurse (role) has to communicate with clinic staff to recheck the patient, if the patient is not the right person, the surgical procedure is canceled.

Then the Transport Technician (role) helps transfer the patient to the pre-operative holding area. The Pre-Op Nurse (role) identifies the patient in the S-EMR system upon arrival. This is our second time-out point, TP-2, in our model. At this stage, in order to pass the TP-2, the identifying information needs to match the information in the surgical log in S-EMR and the information in C-EMR. If the comparison does not match, the Pre-Op Nurse (role) has to communicate with the Admitting Nurse (role) to re-identify the patient, and again if failed, the surgical procedure is canceled. Additionally, the Anesthetist/Anesthesiologist (role) may also meet the patient in the pre-op area to verify any allergies and medications, and may again, re-verify the surgery. It is the third time-out point, TP-3. The verification information needs to match information in C-EMR, in order to pass TP-3. The Anesthetist/Anesthesiologist (role) communicates with clinic staff to verify related information again, if failed, for example this is a wrong surgery, and the alternative would be to cancel the surgery and document it in the surgical log. After Passing TP-2 and TP-3, the patient is ready to be transported to the OR.

The Circulating Nurse (role) helps prepare the OR - places the sterilized instrument tray and other equipment into place. The Scrub Nurse (role) unwraps instruments placed on the sterile tables by the Circulating Nurse (role). Both of them are required to count “sponges and instruments”. We set the 4th time-out point, TP-4, right here. At this stage, in order to pass the TP-4, the checking information given by Circulating Nurse (role) needs to match Scrub Nurse’s (role). If the counts does not match, the nurses are required to recount. This is a non-detrimental time-out point. Then the Surgeon (role) sees the patient in the OR. The Circulating Nurse (role) will read the patient’s name, type of surgery, side of surgery before the Anesthetist/Anesthesiologist gives the patient pre-operative sedatives. This is TP-5. Before the surgeon drapes the patient and proceeds with the surgery, all information about the surgery read by the Circulating Nurse (role), should be reconfirmed by the Circulating Nurse (role), the Scrub Nurse (role) and the Surgeon (role); it also should match the information in the C-EMR. This is a detrimental time-out point. For minimizing any error at this stage, the surgical team should carefully deal with Time-out Points 1, 2, 3. The next time-out point, TP-6, will be the above Surgeon (role) checks the marked site/side. The patient's last diagnosis image retrieved from the C-EMR is shown on a screen in OR. In order to pass TP-6, the marked side must match the information on the image. If passed, the Surgeon (role) starts the surgical procedure. The Scrub Nurse (role) assists the surgeon by handing instruments, sutures, implant(s) to the surgeon when needed.

The Anesthetist/Anesthesiologist (role) monitors the patient's vital signs throughout the procedure. This monitoring information is automatically stored in a surgical log. If a surgery includes an implant, the point of asking for the implant is the TP-7; the implant type, power, etc. is verified from the records and repeated by the Surgeon for verification. If they do not match, the alternatives are 1) Get new implant; 2) if new implant is not available, cancel surgery, report it in surgical log. This is a detrimental time-out point. At the end of operation, TP-8 occurs. The Circulating Nurse (role) and Scrub Nurse (role) count "sponges and instruments". They count separately and compare with each other. Unlike TP-4, it is possible that this post-surgical/exiting count will not match the pre-surgical/entering count. Detailed information is described in the last section. At the end of the case, the patient is transported to the Post-Anesthesia Care Unit (PACU).

The Circulating Nurse (role) may also help the Transport Technician (role) transport the patient to the PACU after the surgery is completed. The PACU Nurse (role) accepts the patient upon arrival, monitors the patient during the recovery period, and reports any concerns to the anesthesiologist. The PACU Nurse (role) will document patient status, drinking fluids, vomiting and other clinical observations necessary for discharge. Once the patient has recovered, the PACU Nurse (role) will discharge the patient from the PACU. Discharge orders from the surgeon would determine what happens next as well as follow-up instructions. Because we have analyzed a non-detrimental time-out point in the previous section, we now show a detrimental time-out point TP-7. Here the implant will be checked for the compatibility before the surgeon inserts it into the eye of the patient.

Condition: (Observed_implant type = prescribed_implant_type)

Type: detrimental

Alternatives:{1. Get new implant}

Here the attribute Observed_Implant_type is observed by the surgeon and/or the circulating nurse. The variable prescribed_implant_type can be obtained from the C-EMR. This time-out point says that if the implant types do not match, then abandon the surgery. Although this time-out point is a detrimental one, checking that the available implant is type compatible with the precribed implant type could be moved to the beginning of the surgical procedure, because values of both attributes are available at that time. Thus we can either move this time-out point to the beginning of the surgery, or insert the same time-out point at the beginning of the surgical procedure.

6 Moving Detrimental Time-Out Point as Early as Possible

In this section we informally describe an algorithm to move the detrimental time-out points as early as possible. Our algorithm is as follows:

1. For each detrimental time-out point, get the stage, say E of the workflow, where all the variables of the condition are instantiated.
2. Create a time-out point at E and assign the same actors the responsibility of checking the condition of the new time-out point.

This algorithm can also be optimized by combining the conditions of multiple detrimental time-out points at one point of the workflow. This way all “showstopper” issues can be addressed at an early stage. Because attending to time-out point also consume valuable time during the surgery, combining them would save having multiple stops in the workflow. Another possible optimization is to verify if the condition of a time-out point logically implies the condition of a timeout that occurs later in the workflow, because in that case (unless the attributes change between them) then the later time-out may be safely removed because of the earlier one. This analysis would require a more detailed specification and an analysis of variable mutability during the workflow, which we are addressing.

7 Conclusion

In this paper, we presented a framework of time-out point enforceable workflow-based surgical EMR system. In order to do so, we formally defined a structure to specify time-out points and categorized them as detrimental and non-detrimental. Because it can stop a surgery in the middle of a procedure, we proposed how they can be moved to an as early as possible point in the surgical workflow. We also suggested how detrimental time-outs can be combined to minimize the time taken to address them during a procedure. Although time-out points are inserted in order to minimize errors and mistakes, they also consume valuable surgical time and cause the whole team to stop all other work and perform these checks. This procedure elongates the total time of the procedure, which results in the patient being under anesthesia for a longer time, distracting the surgical personnel and consuming valuable OR time. In our ongoing work, we plan to investigate these tradeoffs.

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Appendix: Surgical Workflow in YAML

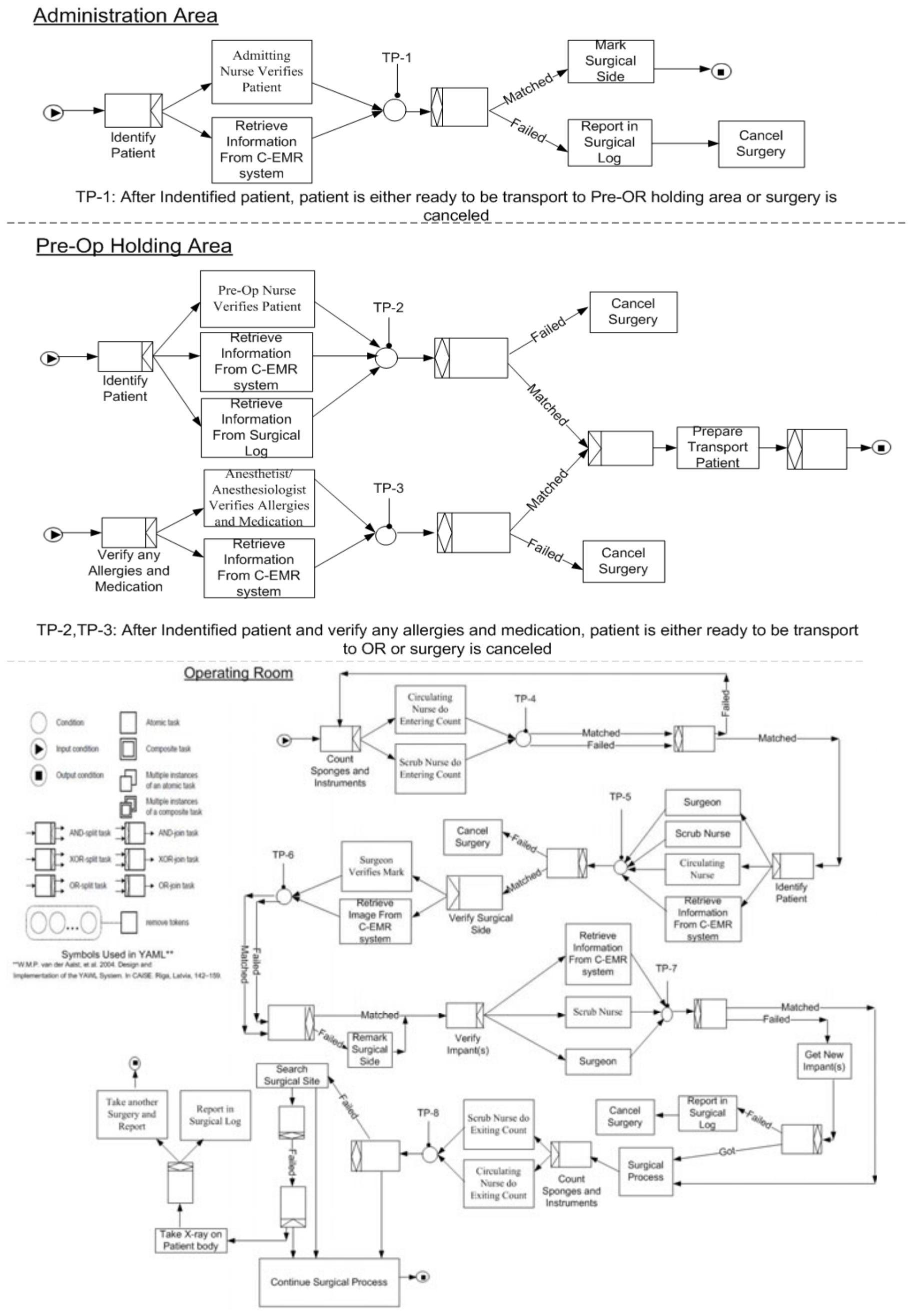

Fig. 4. Workflow of the Example Surgical Procedure