A Context-aware Patient Safety System for the Operating Room

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ABSTRACT

Most context-aware systems have been designed for non-safety-critical environments such as offices, museums, and university campuses. This paper argues that context-awareness can be used for safety-critical systems too. But since the consequences of errors or failures in safety-critical systems are potentially severe, we should have a high degree of confidence in these systems. We present the design, implementation, and evaluation of a context-aware patient safety and information system (CAPSIS) designed for use during surgery. Specifically, our study indicates that CAPSIS could improve patient safety in the operating room. More generally, the paper suggests that context-aware technologies offer a promising step forward in the design of safety-critical systems.

ACM Classification Keywords

H.5.m Information Interfaces and Presentation: Miscellaneous; J.3.2 Life and Medical Sciences: Medical information systems

Author Keywords

CAPSIS, Context-aware Computing, Safety-Critical Systems, Pervasive Healthcare, Operating Room

INTRODUCTION

According to the Institute of Medicine (IOM) report "To Err is Human" [18], more Americans die each year from medical errors than from traffic accidents. The report shows that health care safety is more than a decade behind other high-risk industries such as commercial aviation, which has cut its mortality rate by 66% by focusing intensively on safety. A study in Utah and Colorado [23] reveals that surgically adverse events comprised 44.9% of all adverse events, of which 16.9% where caused by negligence, and 16.6% resulted in permanent disability. International follow-up studies, for example in Denmark [22],have to a great extent confirmed these figures.. The IOM report suggests a number of strategies for improving patient safety, some of which may be supported by computer systems.

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This paper presents a context-aware patient safety system for the operating room. The system has a general awareness of the working context inside the operating room, such as the staff, the patient, equipment, and medical material. By drawing logical inferences from such lower level context information, the system is able to provide the surgical team with important clinical data at the appropriate moment, as well as to detect potential safety-critical situations. For example, by identifying the surgical team, the patient, and the scheduled procedure, the system automatically presents relevant clinical data such as medical images and medical records. And if the wrong patient is detected or if the surgery is started before the team is ready, the system will fire warnings.

Our work extends existing research on context-awareness by investigating how ubiquitous computing in general, and context-aware technologies in particular, can be used in building safety-critical systems. Most work within context-aware computing has so far addressed non-critical environments, such as smart rooms [24, 14], shops [1], museums [11, 20], tourism [6], universities [12], conferences [8], and offices [25]. To our knowledge, however, no context-aware technologies or applications have so far addressed safety critical applications. This is understandable, because context-aware computing is error-prone, and because – philosophically speaking – it is impossible correctly to *really* infer the intention behind human activity solely on the basis of sensor input [9]. The consequences of error in context acquisition, distribution, or reasoning could be catastrophic in a safety- critical environment — especially if the operators are relying on the system to be accurate. As Bardram *et al.* argue [5], the triggering of a context-awareness action depends upon the *accuracy* of the context information sensed by the system, the degree to which you *know* what action to take in a certain situation, and the *consequence* of performing this action. And in safety-critical situations, false alarms (false positives) are extremely stressful and annoying, while missing alarms (false negatives) may be fatal.

Despite this rather discouraging outlook, we nevertheless propose to use context-aware technologies for patient safety in the operating room. We do this for three reasons: first, computerized assistive technologies for providing the right information at the right time in the right place have proved helpful in streamlining the workflow, which, according to the IOM report, is key to reducing stress and improving patient safety. Second, warnings are needed in a hectic work environment where the many different processes and people involved must be aligned in preparing for

and performing surgery. Third, compared to existing solutions which focus on singular context information such as the patient's ID, the concepts and technologies of context-aware computing can leverage computer support for patient safety to incorporate much more of the surgical context — both physical and clinical. Taken together, we argue that by using context-aware technologies we will be able to improve patient safety in the operating room. Related work is discussed in further detail in the next section.

Our work makes three main contributions. First, the paper presents the design and implementation of a context-aware patient safety system for surgical procedures called CAPSIS[1]. The system architecture extends previous work on context-aware systems by adding safety-critical context reasoning and by utilizing information about the accuracy of the context data. Furthermore, the interaction design of the system contributes to knowledge about how to design patient safety systems for use in the operating room. Second, the paper presents a clinical evaluation of the system, which shows that the system improves safety awareness, catches several important types of surgically adverse events, and is perceived as useable and useful during surgery. Third, on the basis of our experience in designing, implementing, and evaluating the patient safety system, the paper discusses the use of context-aware technology more generally in safety-critical systems engineering.

RELATED WORK

As part of the 'iHospital' project, a number of context-aware technologies have been deployed for a substantial period of time in a Danish hospital [13]. These include the AwareMedia and the AwarePhone applications, which help clinicians to coordinate work around and inside the operating room. The research demonstrates that context-aware technology is beneficial to work on a surgical ward [5], but these systems provide no support for improving patient safety.

The 'Context-Aware Peri-operative Information System' [2] focuses on automatically building an Electronic Medical Record (EMR) from significant medical events inferred in a telesurgery environment. This EMR is then displayed in the operating room. Sensor input includes contextual data from RFID readers, physiological data from patient monitoring systems, and message data from a tele-surgery system. The OR-Dashboard [19] similarly displays patient ID, allergies, case description, planned procedure, procedure check lists, critical information, and live data collected from the physiological monitors in the OR. The presence/absence of key staff is monitored by an RFID/infrared location tracking system, and a semi-automatic progress log and a video feed of the surgical field reduces the need for explicit communication and helps streamline the workflow. Although patient safety is not the primary focus of either of these projects, the use of RFID would in principle allow the systems to detect potentially significant errors (e.g. wrong patient or medication) before allowing the procedure to continue. Such automated warnings were not however implemented as part of the system and thus have not been evaluated.

[1]Context-Aware Patient Safety and Information System

A number of companies are developing commercial solutions aimed at averting wrong patient, wrong site, and wrong procedure errors in the OR. One example is the Captus process monitoring system. By comparing real-time input from a location-sensing system, and expected patient location based on a process model, the system is able to detect potential 'wrong location' errors and send alert messages via the hospital paging system. If a patient remains in an unexpected position for more than 2 minutes, an error is flagged [21].

SurgiChip is a system that focuses narrowly on supporting the Joint Commission (JCAHO) "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Patient, also called the "3 W's". Surgery" [16]. The JCAHO protocol requires three steps to be taken: (1) pre-operative verification; (2) marking the operative site; (3) taking a "time out" immediately before the procedure for final verification of patient ID, procedure and site etc. SurgiChip supports a workflow in which patient data, procedure, site, date of surgery etc. are electronically written into an RFID chip. The data are verified (step 1) by both patient (if competent) and by a member of the surgical team, and the RFID chip is affixed next to the surgical site (step 2). Finally a "time out" (step 3) is taken when the surgical team reads and reviews the information on the RFID chip using a PDA in the OR. While no research on the SurgiChip system is available, the company claims that their system helps prevent the "3 W's".

Both the Captus and the SurgiChip systems are examples of specialized systems that address important aspects of patient safety during surgery. They focus on specific context information such as the location or identification of the patient. Unlike our system, however, these systems are not context-aware, in the sense that they are not designed to sense and draw inferences from a broad set of context information in relation to surgical procedures.

RESEARCH METHODS

The Context-aware Patient Safety System has been designed, refined, and evaluated through a user-centered design process involving a range of clinicians, including surgeons, anesthesiologists, nurses, operation technicians, and hospital managers. This user-centered design was based on previous observational studies of the work in operating rooms, interviews with clinicians, and a thorough study of the literature on patient safety in general. The user-centered design used three main design and evaluation sessions: (i) a Future Workshop, (ii) a Paper Mock-up Evaluation, and (iii) a Prototype Evaluation. In total, 12 different nurses and doctors participated in these workshops.

Future Workshop

The future workshop [17] was used to define the vision and scope of the system. In the critique phase, the problem of patient safety was discussed in very broad terms, including e.g. logistical problems. However, it was interesting to see that in addition to the expected concerns about ensuring the correct patient, procedure and surgical site, a number of issues came to light that had not been identified in the initial literature survey. These issues included problems such as the operating table not fitting to the patient which could cause him or her to fall off; the patient not being ready for surgery; problems in locating support staff; and the fact

that it is very time consuming to bring up all the medical records and images. In the workshop's vision and realization phase, the group settled on creating a system that would focus on:

- Patient identification, including ID, name, allergies, pictures, etc.
- Tracking of patient location and status, e.g. whether the patient is ready for surgery in the ward.
- Context-aware access to relevant information regarding the patient and the current procedure.
- Tracking of the surgical team, including supporting staff such as surgical technicians.
- Automated warnings if dangerous situations are predicted from context clues: Wrong patient, wrong blood, wrong instruments, patient too heavy for the operating table, etc.

Paper Mock-up Evaluation

Based on this input, an initial paper mock-up was made by the designers. The design assumed that a large interactive screen would be available in the OR, much like that provided by e.g. the OR-Dashboard. Moreover, it was envisaged that equipment, personnel, patients, and medical supplies such as blood would be tracked using RFID technology. The paper mock-up was taken to the hospital and used for scenario-based evaluation in an OR with a team of surgeons and nurses. The scenario of a surgical operation, including various 'problems', was played out by the OR team. The whole session was video recorded for later analysis. The evaluation provided significant improvements to the interaction design. For example, an overall system for signalling patient safety status (red/yellow/green) was proposed, and a suggestion concerning audible warnings (e.g. having the system say out loud "Warning – wrong blood in surgery!") was enacted and subsequently rejected because the patient might be awake during surgery with only local anesthesia.

Prototype Evaluation

Once the system was implemented, a final 'dry-run' of the system was performed at the hospital, involving 7 participants. The evaluation took place in a large conference room, different parts of which were used to simulate a patient ward, the operation ward, and the OR. We did not have access to an OR during this workshop. The evaluation resulted in a range of detailed but important improvements to the system; e.g. it was deemed important that the system not only issued a warning when something went wrong but that it also confirmed that things were going right. Another important issue that arose from the workshop concerned the accuracy and reading range of the RFID technology. By actually experimenting with the technology, including its reading range, update frequency, accuracy, etc. the clinicians could for the first time relate to the use of RFID in the system. This led to a number of improvements, the most important being that we chose to use passive (i.e. short-range) instead of active (i.e. long-range) RFID for patient identification.. We return to this issue in the discussion below.

CAPSIS

The design goal of the CAPSIS system is to turn the operating room into a context sensitive place, i.e. one in which a context-awareness system constantly monitors the room and provides timely information to the clinicians. This information will include relevant clinical data and status updates, as well as feedback on important safety-relevant aspects of the workflow.

Design Principles

CAPSIS was designed using the user-centered design process outlined above. This led to the establishment of six design principles.

First, the system should promptly identify safety hazards in the OR. For example, the system should be able to detect that a given patient is not ready for surgery in time for the team to cancel the operation; it should be able to detect a wrong piece of equipment (such as the wrong operating table) as soon as possible; and it should be able to detect a wrong patient immediately. Timing is of crucial importance in keeping the number of adverse events down.

Second, the design should help hospitals to meet best-practice standards of patient safety in operating rooms. Thus CAPSIS should support relevant recommendations from the IOM report [18] and the JCAHO protocol [16] as well as national and local regulations.

Third, the system should augment – rather than automate – current patient safety procedures. It was seen as important to keep the clinicians in the loop and thereby maintain their active participation in the procedure. Thus current manual safety procedures, such as asking the patient for his/her name and social security number, were maintained but augmented by the CAPSIS system.

Fourth, the system should both help in finding and displaying relevant information during surgery, and issue warnings when a potentially dangerous situation is detected. Thus it was seen as important that the system addressed not only the 'negative' part of patient safety (i.e. warnings) but also the 'positive' parts, for example by displaying information on the patient and relevant medical data during surgery. Easy and timely access to relevant information has a positive effect in terms of reducing stress and the time spent on information seeking, which in turn has been shown to have a positive effect on patient safety.

Fifth, sensing and reasoning accuracy should be high because of the safety- critical nature of the system. Thus it was considered important to build on hardware and software technology that would enable sensor accuracy to be assessed and maintained during context-aware reasoning and use.

Finally, the system should remain unobtrusive and require as little user feedback as possible. Ideally the system should reduce the total amount of work required by the clinicians while at the same time supporting and extending the existing patient safety protocols.

Figure 1. The CAPSIS user-interface and use. A: patient safety window, B: medical record, C: medical images, D: checklist, E: interaction, and F: reading safety status.

Interaction Design

Figure 1 shows the user interface of the CAPSIS system, which consists of 4 windows: (A) is the main patient safety window, which provides an overview of the patient's safety status for the operation in question; (B) shows the patient's medical record; (C) shows the patient's medical images; and (D) shows the relevant checklist for the given surgical procedure.

The patient safety window (A) is composed of three panels: the patient panel, the staff panel and the patient safety panel. The patient panel aggregates important information about the current patient and surgery, including the patient's name, social security number (SSN), allergies (CAVE), picture, scheduled surgery, and current status and location. The main purpose of this frame is to help the surgical staff avoid the three big wrongs: wrong patient, wrong procedure and wrong surgical site, as well as presenting vital information on the safety of the patient such as the CAVE list and patient status.

The staff panel lists the surgical team scheduled to perform the operation. Each thumbnail displays the initials, role and present location of each team member. If the team member is present in the OR the border of the thumbnail is green, otherwise it is red. This makes it easy to verify at a glance - e.g. just before the required safety protocol time-out - whether the surgical team is complete.

The patient safety panel displays a list of patient safety issues that are being monitored by the system. The system employs a traffic light metaphor using red, yellow, and green lights; green signals that no safety problem is detected, yellow that safety status is undetermined, while red indicates that something is wrong. The safety issues detected by the current version of CAPSIS include six items: (i) patient ready for surgery, (ii) correct patient present in the OR, (iii) blood bags used during surgery match the blood type of the patient, (iv) the operating table in use is appropriate for the patient and the surgical procedure, (v) the surgical team is complete, and (vi) the JCAHO time-out has been carried out. If all issues are green, the overall status (in the upper right corner of the safety window) is also green; otherwise the overall status is that of the most serious safety violation.

CAPSIS is notified by the operation scheduling system when surgery has commenced. This context event brings up all relevant patient information, including information on the patient and the procedure in the patient safety window (A), the patient's medical record (B), and relevant medical pictures (C). In the picture (F) the surgeon and the scrub nurse are using these medical data in preparing for surgery. Typically, medical information (such as the record and the images) are stored in legacy hospital information systems such as the Electronic Patient Record (EPR) and the Picture, Archiving, and Communication System (PACS). Thus CAPSIS interfaces with these systems and asks them to display relevant data in the current context. This relieves the hospital staff of the tiresome task of operating several heterogeneous systems by ensuring that the right information is shown in all of them.

Finally, the checklist for this type of surgery is shown in (D) and the patient's name and SSN are added to it. Again, the checklist is typically part of another system which CAPSIS integrate to.

During surgery, CAPSIS monitors the operating room and status with regard to the six patient safety issues. The status of each of these issues is determined by a set of rules in the context-awareness infrastructures (see below). For example, the rule for the 'correct patient' states that if we have sensed a patient tag with 100% accuracy and the input indicates the wrong patient, the status is red; if we have the right patient, the status is green; otherwise, status is yellow. Another rule relates to the 'time-out status' and states that if time-out has been documented in the checklist (window D), then the status is green; otherwise it is yellow.

Each of these safety issues can be disabled for the rest of the ongoing operation. For example, if a patient arrives without an RFID armband, the 'Correct patient' safety issue can be disabled. In the user-interface, the button becomes gray and this issue is no longer taken into account in the overall safety status. The scrub nurse can disable an issue by pressing the line on the screen, as shown in the inserted picture (E) in Figure 1.

Software Architecture

The CAPSIS software architecture is illustrated in Figure 2. It is a layered architecture, similar to that of other context-aware systems which transform lower level sensor input into higher level contextual relationships and reasoning.

The CAPSIS system is built using the Java Context-Awareness Framework (JCAF) [3] where the context sensor layer is responsible for context acquisition and the context service is responsible for context modelling and distribution. JCAF has been extended to include a 'Safety Service' component, implemented by using the Java Expert System Shell (Jess) [15], which has a set of associated rules and facts in the Jess database. The context client layer contains the user interface clients described above.

The CAPSIS system applies three types of monitors. The 'Operation Schedule Monitor' monitors the operation schedule and provides information on operation status (e.g. operation start, time-out, etc.) and patient status (e.g. ready for surgery). In addition, it supports two general classes of RFID monitors. One class consists of the passive RFID sensors operating in the near electromagnetic field, which limit the activation range of the passive RFID tags to approximately half the radius of the reader's magnetic loop antenna [10]. The second class consists of the active RFID far field monitors, which detect active tags being activated by the far electromagnetic field, extending their range well beyond the close vicinity of the reader antenna. Team members and equipment (such as the operating table) are monitored using active RFID tags, and patients, medication, and blood bags are monitored using passive RFID tags (see also Figure 4).

In JCAF, a monitor can report the accuracy of the information sensed from 0.0–1.0. In CAPSIS, we have defined an accurate reading as one in which the reading range of the RFID antenna is less than the physical object it is tracking, i.e. $accuracy = 1.0$. Thus passive RFID tracking of patients is considered accurate,

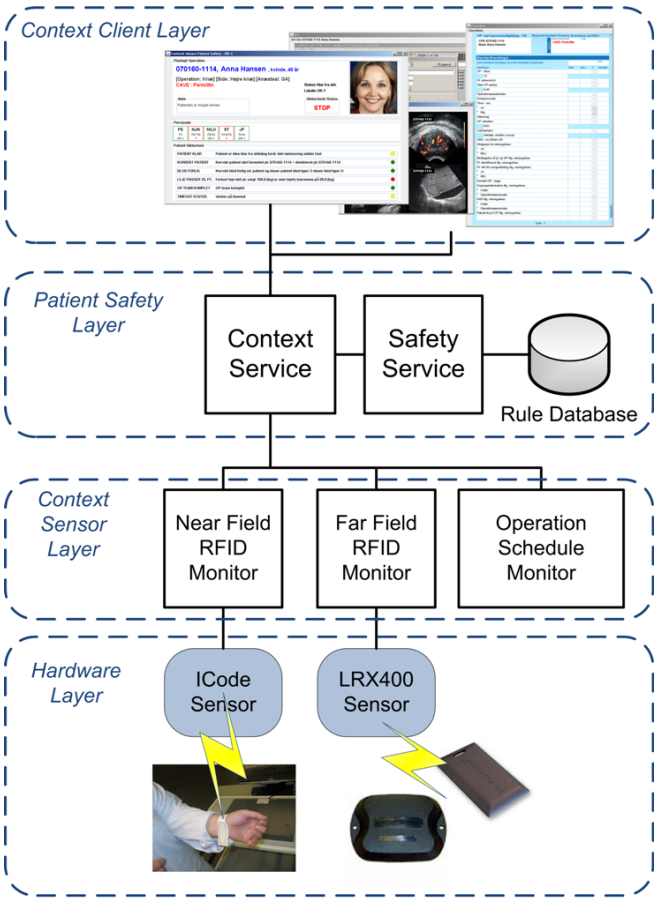

Figure 2. The CAPSIS Architecture consisting of four layers.

whereas active RFID tracking of patients is considered inaccurate[2]. In JCAF, these accuracy reports are maintained and can be accessed by the different context services and clients.

The *Context Service* holds context information about all entities in the OR. The context service is in many ways the hub of the entire system, tying everything together and providing life-cycle management and storage for the JCAF entities that model real-world entities. The entities themselves, as well as having contextual relationships to other entities, are modelled using JCAF in a rather straightforward mapping of physical entities onto JCAF entities.

The *Safety Service* contains the logic relating to patient safety reasoning based on context events from the context service, including the accuracy of the acquired context information. The safety service uses the Jess rule engine for machine reasoning, storing all relevant rules and facts in the Jess database. These rules contain the main safety logic and will fire appropriate events, such as 'Wrong Patient Detected' or 'Correct Blood Detected'. Using Jess, the safety logic is maintained in one place, rather than being programmed as part of the JCAF event-handling procedure,

[2]In CAPSIS we considered only 'accurate' versus 'inaccurate'. Hence, any accuracy weight below 1.0 was considered inaccurate.

as normally happens when JCAF applications are programmed. Centralizing the responsibility for reasoning significantly reduces the complexity of event handling and reasoning. The safety service keeps the Jess fact database up to date by listening to changes in the context information managed by JCAF.

The *user interface layer* contains the main patient safety windows shown in Figure 1. Each client applies an MVC pattern and the controllers subscribe individually to JCAF context events arising from the context and safety services. For example, the patient safety window and the checklist window each listen to the 'Operation started' context event, which arises when the operation is started in the operation scheduling system.

The CAPSIS architecture is quite easily extended both as regards new sensor hardware and new safety issues. For example, the existing method of patient identification could be replaced with another sensing technology such as barcode or fingerprint scanners by adding a new JCAF monitor to the sensor layer. New safety issues can be modelled by a new Jess rule in the safety service and a corresponding line could be added to the patient safety window in the lower panel. In this way safety procedures pertaining to the verification of the presence of correct medication or implants can be added to the system.

Because JCAF is designed as a distributed system, all communications between the individual layers take place via remote mechanisms: either directly as remote calls to the JCAF context server API, or indirectly as JCAF context events that are themselves based on the Java RMI mechanism. The different layers can therefore be deployed individually.

CLINICAL PROOF-OF-CONCEPT

In order to evaluate the system, a Clinical Proof-of-Concept [4] was carried out. A Clinical Proof-of-Concept (CPoC) involves a real world deployment of a pervasive healthcare system for a 'non-trivial' period of time by end-users with no interference from the researchers. The purpose is to provide sufficient evidence for the applicability of the system to merit further development and potential clinical trials. Thus the aim is not to provide 'hard' medical evidence of clinical benefits, but rather to justify further investment in research and development toward this end-goal. The time period is adjusted to the specific purpose of the CPoC and may range from one day to several months.

In this case, the purpose of the CPoC was to seek initial evidence as to whether CAPSIS could improve surgical working conditions in general and patient safety in particular.

The Deployment Setting

The system was deployed inside an operating room using two 42" touch screens for displaying the context-aware patient safety system (Figure 3). Active tags (WaveTrend LRX400) were used to track clinical personnel and equipment such as the operating table, and passive RFID tags (NXP ICODE) were used for patient identification and tagging of blood bags (Figure 4).

The system was used over one full day by an operating team consisting of a surgeon, an anaesthesiologist, three nurses (one being the scrub nurse), and an operation technician. In addition, a number of nurses and surgeons participated as observers and helped to evaluate the system. This group of clinicians to some degree overlapped with the participants in the user-centered design process, but also included four clinicians who had never seen the system before. Two staff members from the hospital (a nurse and an IT technician) acted as patients. No real patients were involved. The acting patients were however treated as if they were real patients; for example, they were admitted to ambulatory surgery and scheduled in the scheduling system. All operations were carried out as if they were genuine operations, except that the 'patient' was not actually sedated or cut.

Figure 3. The deployment of the system in the OR; the surgeon and the sterile nurse read medical data on the screen to the right while the scrub nurse interacts with the patient safety system on the screen to the left.

Evaluation Methods

In total, 8 operations were performed during the day. These included both operations in which the system delivered no warnings and ones in which various types of warnings were issued: for example wrong patient, wrong operating table, wrong blood, and incomplete team. In addition, medical records, radiology images, and the operation checklist were presented on displays using the context-aware triggers.

The goal was to provide objective measurements of the usefulness and usability of our design while at the same time doing a detailed and more qualitative investigation of the underlying detailed user reaction to the system. For this purpose we (i) asked the users to perform the operations while thinking aloud, (ii) investigated perceived usefulness and usability on the basis of a questionnaire [7], and (iii) did a semi-structured follow-up interview with the clinicians involved.

Results

From a technical perspective, the system proved to be rather robust for use in a safety-critical environment; the context-awareness sub-system and the reasoning engine ran without any breakdowns, and the various parts of the RFID technology worked as expected within their performance envelopes. The

Figure 4. The RFID tags used: Passive tags are part of the patient armband used for patient identification (top), as well as for identification of blood bags (right). Active tags are used to track personnel wearing badges (left) and to tag the operation table (not shown).

near-field reader detected any passive tags within a maximum distance corresponding approximately to the diameter of the transmission antenna, after which detection cut off sharply. The far-field RFID sensor reliably detected the tags and badges in the OR, and did not detect tags outside the OR. Thus the arrival of personnel in the OR and their departure from the room were reliably detected.

The results from the perceived usefulness/ease of use questionnaire are shown in Table 1 (1–5 Likert scale, N=11). Overall, the system is perceived as very useful (4.03, std. dev. of 0.89) and easy to use and learn (4.40, std. dev. 0.66). If we look at specific aspects of the system – the use of RFID to tag patients, the use of the traffic light metaphor, the RFID tagging of tools and material, and the provision of context-aware information during surgery – they all score high on perceived usefulness. It is particularly gratifying to note that the clinicians judge the system to be able to improve patient safety; they agreed with a score of 4.18 to the statement: "The system will improve patient safety in the OR".

During the follow-up interviews issues regarding patient safety, context-aware information display, and the use of the system during surgery were discussed.

First of all, our study confirmed the core hypothesis in context-aware computing that it is useful to retrieve and display information relevant in a specific context. There was general agreement among the clinicians that the context-aware display of timely and relevant medical information during surgery was very beneficial in streamlining the workflow, especially in the preparatory phase of the operation. As two nurses explained:

> *In relation to the EPR, it is beneficial that the system looks up the right parts of the medical record. This means that we do not need to spend so much time navigating round the data to find the current operation. [...] Some patients may have many concurrent treatments...*
>
> *Also, having the right x-ray images displayed on the spot means that we don't need to locate a lot of images, but are presented with the most relevant ones.*

Perceived usefulness	*Avg.*	*Std. dev.*
System usefulness	4.03	0.89
Ease of using and learning	4.40	0.66
RFID tagging of patients	4.61	0.49
Location of team members	3.98	0.73
Traffic light dashboard	4.56	0.56
RFID tagging of tools etc.	4.52	0.57
Context-aware information display	4.57	0.55

Table 1. Perceived usefulness summary.

Second, in accordance with the results from the questionnaires, the clinicians agreed that CAPSIS would improve patient safety, especially because it was a good supplement to – rather than a replacement for – existing safety procedures. The surgeon called it a "*very sensible extension*" to existing procedures, and the scrub nurse argued that:

> *[...] precisely the fact that you have the visual overview inside the OR – having both the patient's images as well as the name and SSN number together with the paper-based [referral letter] – that I think improves patient safety.*

An important observation is that several of the participants argued that providing a timely display of clinical data was not only convenient, but was a core component in improving patient safety. It is essential that the operating team has the most recent medical information available in order to prepare for surgery.

The warnings were considered central to the patient safety system in the sense that the system "*always stays alert*". By this the clinicians mean that, just before surgery commences, there are a lot of different issues to consider, and attending to all of them is a highly demanding task. It is therefore a great help that the system keeps track of all the safety-relevant issues, regardless of the various distractions or contingencies that may occur in the OR. As the head nurse explained:

> *It will also improve safety [...] you know, when you're in the middle of a [safety] procedure and you get disturbed by something. Then – who is supposed to be doing what? If you have looked at the screen and it has done the checking, you are much more confident [...] than if there are just two people doing it manually.*

The system was considered especially useful in relation to the verification of blood. During a traumatic surgery, numerous blood bags may be required – sometime 7–10. Manual reading of all these bags – while the surgery is ongoing and often in an acute state – is laborious and potentially subject to error. Thus the clinicians considered it a crucial point that the bags could be

automatically verified and scanned.

Third, the clinicians also commented that the use of the large display inside the OR would help everybody involved to maintain a situational awareness of patient safety. As the anaesthesiology nurse put it: "*When it is on this large screen, it becomes very visual and we are all looking at the same place*". Similarly, the scrub nurse argued that "*safety becomes much more visual and we all pay attention to it*".

Though the large display helped promote situational awareness, the system was nevertheless perceived as 'peripheral', in the sense that it ensured peripheral awareness of the status of patient safety but required little direct interaction during surgery. The typical use situation is shown in Figure 3 where the non-sterile scrub nurse is using the patient safety system and checking off items on the check list, while the operating team is orienting themselves in the system from a distance. In Figure 1 (F) the surgeon and operating nurse are checking the patient and clinical information before surgery starts. Hence, the system successfully met the sixth design principle.

Finally, some general usability issues were also revealed during use and discussed afterwards during the interview. A series of minor improvements needed to be made; these included making the text and colours on the warnings more visible; enabling users to acknowledge that a warning has been seen; creating better feedback when scanning a passive RFID tag, and better support for handheld readers for reading patients' armbands.

DISCUSSION

In this section we discuss CAPSIS from two angles: as a patient safety system and as a context-aware system.

Patient Safety

Our clinical proof-of-concept provides good evidence that CAPSIS would help improve patient safety in the OR. The clinicians found the overall system and each of its patient safety features very useful (c.f. Table 1). During the follow-up interview, the clinicians argued that the system would be able to improve patient safety.

CAPSIS also goes a long way towards implementing state-of-the-art patient safety recommendations – c.f. the second design principle. For example, the IOM report recommends that clinicians should "avoid reliance on memory". By listing the safety features in the patient safety window, CAPSIS works as a memory aid to ensure that important safety issues are attended to. IOM also recommends that clinicians should "decrease reliance on vigilance", i.e. decrease the need to stay constantly watchful and alert. As the clinicians reported, the traffic light dashboard helped them to focus on the patient's ongoing safety status in a much calmer way, i.e. decreased the need for constant watchfulness. And, finally, in a key recommendation aimed at helping clinicians to "anticipate the unexpected", IOM recommends that "access to accurate and timely information should be improved". This requirement is met by CAPSIS's ability to show relevant medical data and images during surgery.

As a patient safety system, CAPSIS is fundamentally different from other systems such as Captus or SurgiChip. By making CAPSIS aware of as many things as possible inside the OR, and storing this information as expert system facts, we enable reasoning across the entire gamut of facts pertaining to the situation in the OR. Thus the use of a reasoning engine should be regarded not just as a convenient programming paradigm, but rather as a method of casting a net of safety rules over a complex set of interrelated contextual information, thus supporting, and in some instances even possibly extending, human safety vigilance with a machine counterpart.

It is important to note, however, that with the present evaluation setup we have not sought to provide 'hard clinical evidence' for improved patient safety. This would require a randomized clinical trial over a longer period of time involving a control group. Providing such 'Evidence-Based Medicine' is not, however, the purpose of a Clinical Proof-of-Concept; rather, the aim is to investigate the feasibility of the proposed solution with a view to further development [4]. By asking the clinicians involved how they perceive the system's potential for improving patient safety, we were given sound indications as to the feasibility of the system and directions for further development.

Context-awareness

The key characteristic of safety-critical systems is that the *consequence* of any potential error, mistake, or failure may be fatal. It is therefore of utmost importance that the context-awareness technologies can be trusted to work accurately, or, as we prefer to phrase it, that we have high *confidence* in the context-awareness system. By high confidence we mean that the system's context acquisition has an appropriate accuracy, that this accuracy is conserved for further use in the context-aware system, and that we can trust and control the reasoning that takes place in the context-awareness sub-system.

In our case, we shifted from using long-range active RFID tags to the short-range passive tags in acquiring data regarding patient location. By decreasing the reading range below the extension of the human body (approx. 30 cm.), we increased the accuracy of the context information acquired – especially with respect to false positives, e.g. reading the 'right tag' while preparing the wrong patient for surgery in the operating room. For this to happen, under our system, the armbands of two different patients would have to be within 30 cm. range of each other, meaning that the two patients would be standing next to each other in the operating room (provided the armbands were properly attached to the patients' arms). Any such situation would be caught by the clinical staff and handled using manual procedures. Moving up in the architecture layer, JCAF retains information on sensing accuracy. This enables the reasoning layer to use accuracy information in its reasoning rules. In our case, for example, the Jess rule for checking the presence of the wrong/right patient requires that patient identification data from JCAF should have an accuracy of 100%. Hence, if this method of identifying patients were replaced with another sensing technology – such as an active tag or barcode scanners – the sensor would be required to estimate its own accuracy. And if it were not 100% accurate, it would not be able to trigger the safety events concerning right/wrong patient.

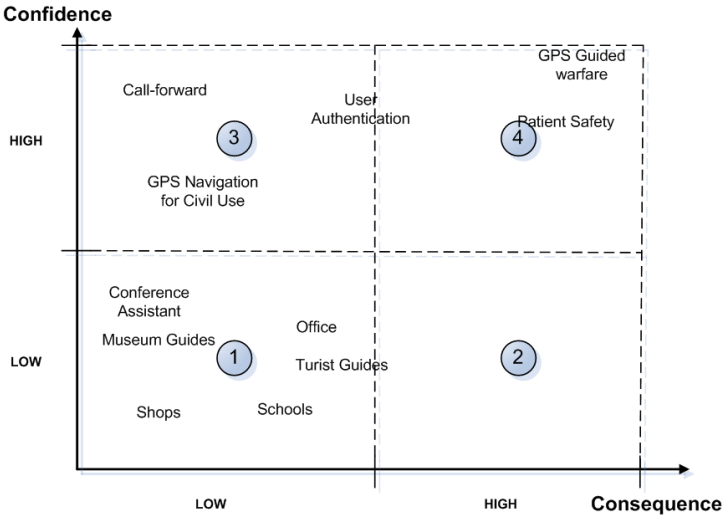

Figure 5. The relationship between consequence and confidence in context-aware systems.

As far as the reasoning layer in our architecture is concerned, our confidence in its accuracy is high, since it contains only a fixed number of pre-defined and deterministic rules. Hence, we do not apply any machine learning techniques that would make the reasoning adaptive and thus non-deterministic over time. In our case, once the rules have been implemented and tested, they perform consistently at runtime. Thus the degree of 'confidence' we have in the proposed architecture and implementation remains the same; once the system is verified, its context reasoning remains stable during use.

More generally, we argue that the key feature that distinguishes safety-critical environments from other application domains lies in the potential *consequence* of any errors or failures that may occur: the consequences of failures during surgery are manifestly much more serious than, say, the consequences of a system failure in a museum. For this reason care needs to be taken to ensure high *confidence*in the context acquisition and reasoning performed by the context-aware safety critical system, and hence high confidence in the actions that the system proposes or carries out. This is illustrated in Figure 5, which shows the relationship between consequence and confidence. If the consequence of errors is low, low confidence in the context-aware sensing and reasoning is appropriate (1). Most context-aware applications – such as systems for conference attendance [8], smart rooms [24], shops [1], museums [11, 20], tourism [6], universities [12], and offices [25]– lie in this quadrant. Clearly, however, one can also apply context-awareness technologies with high confidence for applications with low consequences (3). Examples of this include GPS navigation for civil use or precise in-door location for forwarding telephone calls [24, 14]. Systems on the borderline include context-aware user authentication [14]; in this case, the consequences of granting the wrong person access could be fairly severe. Safety critical systems should be designed to be in the upper right quadrant (4) where high consequences of failure are combined with a high degree of confidence in context acquisition and reasoning. Examples of systems in this quadrant include those used in the operating room, such as the 'Context-Aware Peri-operative Information System' [2] and our patient safety system, as well as GPS-guided weapons and systems used for military purposes. The second quadrant – high consequences combined with low confidence – should be avoided.

We hope that this model can help designers to reason about the nature of the systems they are designing, and especially to ensure that, if they are designing for safety-critical domains where the consequences of errors or failures may be severe, they have a high degree of confidence in the system's context acquisition and reasoning.

CONCLUSION

In this paper we have presented our work on applying context-awareness concepts and technologies to ensure patient safety in an operating room. The outcome of our work is the CAPSIS system, which is a context-aware patient safety and information system designed to monitor what is going on in the OR. This information is used to display medical data to the clinicians at the appropriate time, and to issue warnings if any safety issues are detected. CAPSIS was implemented using the Java Context-Awareness Framework (JCAF) and monitors such things as the status of the operation; the status and location of the patient; the location of the clinicians in the operating team; and equipment, medication, and blood bags used in the operating room. This information is acquired and handled by the JCAF context awareness infrastructure, and a special safety service, implemented by means of the Java Expert System Shell (Jess), is used for overall reasoning on what actions should be taken or what warnings should be issued. CAPSIS differs from other patient safety systems in being designed to monitor everything (or as many things as possible) in the OR, and therefore to be capable of reasoning across the entire gamut of facts pertaining to the situation in the OR. It thus supplements human vigilance on safety by providing a machine counterpart that is capable of drawing inferences.

CAPSIS was deployed and tested in a clinical proof-of-concept simulation where it was used for one whole day by a full surgical team performing simulated operations in an OR. On the basis of this simulation, the clinicians concluded that the system would be very useful in ensuring patient safety and that it was very easy to use. The clinicians argued that CAPSIS would be able to improve patient safety on most of the issues monitored, and several of the findings resonate with the recommendations from the Institute of Medicine. Moreover, the research has given us further insight into how context-aware systems and technologies should be designed, especially in the case of safety critical systems. In such systems it is important to consider the *consequence*, i.e. what the system is used for and the possible consequences if an error or failure occurs. The potential severity of the consequences should be compared to the degree of *confidence* we have in our context-aware acquisition, management, distribution, and reasoning: if we are designing a safety critical system with potentially severe consequences, our confidence in the system's ability to obtain accurate context-aware information and draw correct inferences from it should be high. Confidence depends on a combination of the accuracy of context acquisition, the conservation of sensing accuracy, and the reliability of the context reasoning system.

On the basis of our research, we conclude that context-aware technologies and concepts potentially offer very promising aids in safety-critical systems – provided they are designed to ensure a high degree of confidence.

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