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Preface

The EICS4Med workshop brings together and develops the community of researchers and practitioners concerned with the design and evaluation of interactive medical devices and systems, to deliver a roadmap for future research in this area.

The workshop involves researchers and practitioners designing and evaluating dependable systems in a variety of contexts, and those developing innovative interactive computer systems for healthcare. These pose particular challenges because of the inherent variability — of patients, system configurations, and so on. Participants will represent a range of perspectives, including safety engineering and innovative design.

The purpose of this workshop, then, is to build a community of researchers developing complementary but interconnected approaches to engineering dependable and innovative interactive medical systems.

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The visible and the invisible: Distributed Cognition for medical devices

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ABSTRACT
Many interactive medical devices are less easy to use than they might be, and do not fit as well as they could in their contexts of use. Occasionally, the deficiencies lead to serious incidents; more often, they have a less visible effect on the resilience and efficiency of healthcare systems. These issues remain largely invisible as they are not reported and have rarely been studied. In this paper, we report on the use of DiCoT as an approach to representing and reasoning about medical work, and about the role of device design within that work. We focus in particular on the design and use of infusion devices. This work highlights the value of observational studies for engineering interactive medical devices, and illustrates the value of a systematic approach to gathering and analyzing qualitative data.

Keywords
Distributed Cognition, medical devices, DiCoT, situated interaction, infusion devices.

INTRODUCTION
To improve the engineering of interactive medical devices, it is essential to understand how those devices are used in context, as well as considering the engineering of the devices in isolation (e.g. ensuring consistency, reliability and safety of interactions). In this paper, we focus on the use of infusion devices, relatively simple devices that are used by both clinical professionals and lay people, but particularly by nurses. The use of such devices is inherently complex: even if the devices are configured as simply as possible, they are used in a variety of environments, as part of a complex set of tools and procedures.

One source of information about the impact of device design on use is to be found in incident reports, particularly root cause analyses, such as the reports in the MAUDE (Manufacturer and User Facility Device Experience) database [12]. Occasionally, incidents hit the headlines and provoke further discussion – e.g. the cases of Denise Melanson [10] and Lisa Norris [16]. However, such high profile incidents are mercifully rare, and many incidents are minor and may not be reported at all. For example, Husch *et al.* [7] suggest that few incidents are reported. In a study of infusion pump use in a busy hospital, covering 426 intravenous infusions, they identified a total of 389 errors, occurring in 285 of the infusions. In other words, 2/3 of the infusions on which data was gathered involved at least one error. Many of these errors would be classed as minor, but 55 were either rate deviation or incorrect medication errors, which had the potential to be serious. For comparison, only 48 incidents in the same categories had been reported through the formal reporting system over the previous two years from the same hospital. As discussed below, it might have been inappropriate to class all 389 events as "errors", but this study highlights what a small proportion of errors are reported.

However, error cases alone are not sufficient to engineer good systems: it is also necessary to have a good understanding of normal practice. In this paper, we present a study of normal practice in an oncology day care unit, focusing particularly on the use of infusion devices. We use DiCoT (Distributed Cognition for Teamwork) [3] as a framework for structuring observations and to support reasoning about design. We illustrate modes of reasoning about design by discussing two design requirements that were identified in our studies.

DISTRIBUTED COGNITION
Distributed Cognition has emerged as an approach to reasoning about system design that starts from the premise that the ways that people make decisions and interact are dependent on the external environment as well as internal cognitive processes: that the environment provides resources to support thinking [5]. Furthermore, the structure of the environment can be analyzed from a cognitive perspective; i.e. the people, roles, tasks, artifacts and the physical layout of the system will impact the way information is processed. For example, a bridge of a ship [8] and an aircraft cockpit [9] have been analysed in this way. Distributed Cognition therefore describes how socio-technical systems are structured to process information.

Properties of the system that help or hinder the processing of information can then be identified and engineered.

Distributed Cognition has been applied as an approach to understanding healthcare systems; for example, Nemeth et al [13] and Xiao [18] analyse the roles of artifacts in supporting communication within clinical teams. However, the focus of these studies has been on facilitating communication rather than supporting the situated work of an individual nurse, or reasoning about the design of a particular device.

Distributed Cognition (DC) has traditionally involved a high degree of craft skill on the part of the analysts. Two different approaches to codifying DC have been proposed. Wright et al [17] present the Resources Model as a structured approach to reasoning about the design of an interactive computer system from a DC perspective, focusing on the resources that the system makes available to its user. The Resources Model approach is tailored to the analysis of individual human–computer interactions. In contrast, the Distributed Cognition for Teamwork (DiCoT) [3] approach focuses attention on interactions between multiple people and multiple artifacts, and how the design of technology influences those interactions. A DiCoT analysis involves constructing five interdependent models: information flow, physical, artefact, social and evolutionary. These models each have associated principles from the distributed cognition literature. The method provides a structured approach for engaging with socio-technical systems. In the study reported here, we focus on the use of DiCoT to reason about the design of infusion pumps.

Furniss and Blandford [4] identify four ways in which DiCoT can assist in moving from analysis to design and engineering:

1. To explain the basic mechanics of a system, e.g. so its structure and functions are understood.
2. The development of deep conceptual insight, e.g. we found the property of 'buffering' is particularly important to the performance of ambulance dispatch [3].
3. Identifying opportunities for incremental developments to improve the system.
4. Considering revolutionary designs where the system may work in a fundamentally different way.

In this paper we focus on two incremental design considerations from disturbances that were observed in practice.

BACKGROUND: INFUSION PUMPS

Infusion pumps are important ubiquitous devices in hospitals. Volumetric infusion pumps are typically used to pump nutrients or medications from bags into patients intravenously. They control the rate of fluid in the line that connects the patient to the bag. These devices can be programmed at specified volumes, times and rates. The interface on the pump broadly consists of a number entry system and a display.

Infusion pumps are commonly configured for the different needs of intensive treatment units, paediatrics units and more general wards. This study focuses on an Oncology Day Care Unit. The unit provides treatment to patients on a day basis, i.e. typically patients will come in, get treatment and return home on the same day. This includes the use of infusion pumps for intravenous treatment; e.g. chemotherapy treatment.

Due to their wide use and importance it should be no surprise that others have studied the broader class of infusion pumps. Lin et al. [11] assessed a PCA (patient-controlled analgesia) pump, identified HCI issues and proposed a redesign with a lower likelihood for error. Obradovich and Woods [15] evaluated a syringe pump that patients take home to use. Through interviews and evaluation, they found complex sequences, mode confusions and arbitrary alarms that needed redesigning. More recently, pro-formas have been proposed to standardise the observation of infusion pump use [1]; and nurses' acceptance of infusion pump use with error-reducing software has been studied [2]. Our study took an exploratory approach to investigate HCI issues with volumetric infusion pumps in use in the Day Care Unit (DCU). To our knowledge the two issues we highlight have not been reported elsewhere.

METHOD

Data for this study were gathered by conducting observations in the DCU. In addition, two members of staff in the unit were interviewed to clarify issues that had arisen in the observations. For the observations, extensive field notes were taken, structured according to the themes of DC. Interviews were audio recorded and transcribed. Data gathering lasted for 5 days. These were spread over a number of weeks to allow for reflection between data gathering days. Our primary focus was on the design and use of infusion pumps. A secondary focus was to understand the context in which they are used. Here we focus on how the pumps were set up and used.

We focused on the information flow, physical and social models – to build an understanding of the infusion pump programming task and the environment in which they worked. We gathered data to describe the system in terms of the models, and used the associated principles to help embellish this picture. Disturbances in performance were noted in conjunction with direct observations and by interrogating the developing models. The models' representations would often crystallise observations and raise questions that would need further data gathering.

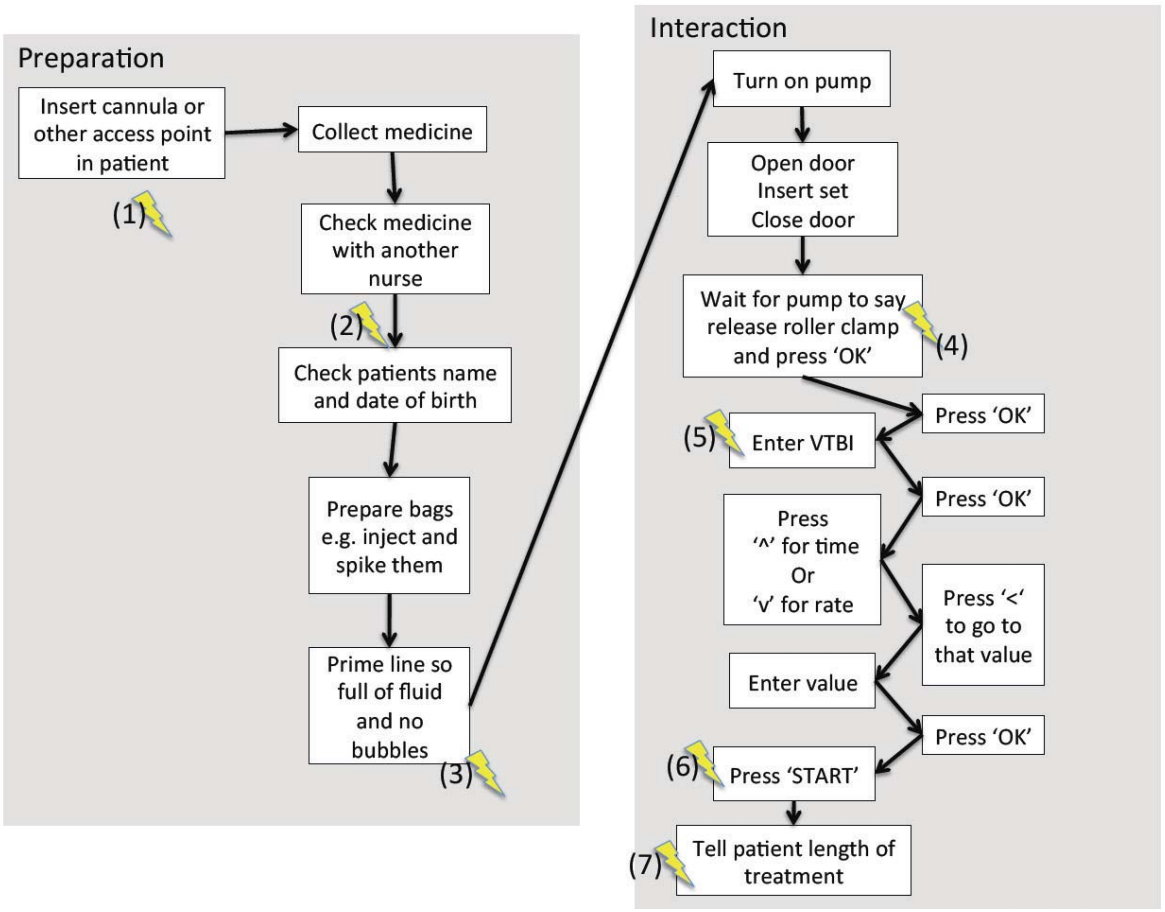

Figure 1: Task steps and disturbances in infusion pump interaction

OBSERVATION RESULTS: NORMAL WORK

31 programmable infusion interactions were observed over the 5 days; not all observations were complete because key presses were not always visible. The nurses' interactions were often very fast and without error or issue.

We first describe the normal stages of setting up a pump, and then describe two of the disturbances that were observed. The normal stages for programming an infusion pump, which we observed in most cases, are as follows (see Figure 1):

- The pump is turned on.
- The eject button is pressed to open the pump's door. The tube that connects the bag to the patient is inserted and the door is closed.
- The pump asks the user to release the roller clamp and press OK when they have done so. The roller clamp's release allows the fluid to flow from the bag to the patient.
- The pump displays zero values for the VTBI. The value needs to be entered by the user before pressing OK to confirm the value.
- The nurse can then enter either the time or infusion rate. Once they have confirmed either of these values by pressing OK, the pump calculates the missing value; i.e., if the pump knows the VTBI and time it can work out the rate, and if the pump knows the VTBI and the rate it can work out the time.
- Once all these values have been checked, the user presses the START button and the infusion commences.

Over the course of the observation period, several kinds of disturbance to this normal flow of activities were observed. Here, we discuss two of them.

VTBI (Volume To Be Infused) issue

This issue relates to the stage in programming the infusion pump that needs the VTBI value. It is the first value that is required by the pump; it is a stage that cannot be skipped, and sometimes nurses do not have this value so it needs to be calculated manually. This is noted as disturbance 5 in Figure 1.

As well as specifying the type of medication, the prescription should detail the VTBI, the infusion rate and the time. However, in the incident that drew our attention to this issue, this was not the case. In this incident, the observer (hereafter referred to as A1) observed a nurse interact with the pump far more than normal. A1 overheard the nurse tell the patient that maths was not their strong point to make conversation and to allude to the difficulty they were having. A1 observed the nurse turn the pump on and off, and then program the pump with little difficulty. The nurse was too busy to discuss the matter at the time but we later found out the VTBI was not on the prescription chart and so they had to work it out mentally.

The prescription instructed the nurse to set up an infusion with a rate of 15ml/hr over a 20 minute period. This is a standard calculation a nurse should be able to perform mentally, but the nurse reported that the calculation was just not working for them at that point in time. The nurse proceeded by entering a trial value of 10ml for VTBI to go through to the time and rate settings. The nurse then entered one of these given values and saw what the pump calculated for the remaining value. They could then see the calculated figure for the remaining value and deduce whether their guessed VTBI was higher or lower than that needed, and by what sort of margin. By performing this trial and error workaround, the nurse worked out the correct VTBI. The nurse then restarted the pump and programmed it correctly.

Battery issue

The second issue we discuss is marked as disturbance 6 in Figure 1: an infusion was manually stopped as soon as it was started because the device had a low battery. Typically all pumps are charged overnight on the Day Care Unit ready for the next day. Pumps are run on their rechargeable battery rather than being plugged in. One of the main reasons for this is for mobility, both in terms of staff moving them around the unit and the patients remaining mobile while receiving their treatment, e.g. so that they can go to the toilet.

A1 watched a nurse at intermittent times throughout the day setting up successive parts of one patient's treatment. The nurse explained that some treatments last all day with a succession of different infusion programs. S/he remarked that you needed to be careful toward the end of the day because the device's battery charge would not last for the last treatment. S/he said that forgetting this was highly frustrating because you have to program a new pump to finish the infusion with unfamiliar partial values.

Later that day, A1 was watching the nurse; s/he seemed to program everything correctly, pressed start, but then immediately paused the pump. S/he pointed to the battery charge indicator, which was low, and said that it would not last. The nurse looked for a convenient socket to plug it in, but then went to get a new pump that was fully charged and reprogrammed the infusion with this new pump.

DISCUSSION

We have presented an example of normal work and two disturbances to that work (drawn from a larger set, to illustrate the roles of observation and structured analysis in informing design). The description of normal work, which forms a basis for part of the DC analysis of nurses' work in the DCU, could, in principle, have been based on documentation of how to use the device, but was validated through observations of nurses at work. The disturbances that we observed are undocumented, and can only be identified through observation. They are not sufficiently disruptive to feature in incident reports, and therefore would not be identified if incident reports were the major source of information to inform new design; nevertheless, they are significant disturbances to normal work, and highlight possibilities for better engineered future designs. The description of normal work provides a structure for making sense of the disturbances.

In this section, we consider three themes: the role of observation in revealing such interaction issues; the role of DiCoT in structuring the analysis; and possible interventions to improve future designs.

Revealing invisible interaction issues

Early discussions with the nurses indicated that there was little wrong with the infusion pumps: they used the pumps frequently, they felt that they were well designed and they did not have any interaction issues to report. However, results reported here, in response to observational work rather than self-report, did find interaction issues.

We speculate that self-reporting failed because of the nurses' "can-do" attitude in the face of problems; time pressure; lack of vocabulary to articulate these HCI issues; and that they do not have the interest a HCI expert has in these interaction issues. Interviews and questionnaires alone are limited for revealing these problems.

As noted above, the issues discussed here have not featured prominently in reported incidents that have, typically, resulted in serious harm. Reported battery life issues are more commonly associated with the poor retention of power, or battery failure, rather than cuing the user to insufficient power at the point of programming. This design intervention has the potential to improve device and battery management for nurses. Low battery power can be a problem when a socket is unavailable, e.g. when a patient is in transfer from one ward to another. In these situations the normally invisible interaction issue would become a significant problem.

We note that clarifying the need for entering VTBI for the safe use of the pump has been remarkably difficult. It is important to do this to understand the space for reengineering; however, the reasons for choosing VTBI as the first value to be entered were not known by the clinical staff we had contact with, either on the day care unit or their

management team. In this sense, potentially important interaction design rationale is not known or visible.

Due to their contextual nature, it is unlikely that these issues would have been discovered by analytic methods or laboratory studies alone. For example, it is recent advances in pump design that have introduced the battery issue: advances in technology have made infusion pumps small enough to be easily mobile; older, larger pumps were difficult to move around, and were therefore commonly stationary. Whilst stationary, their battery would only be used for back-up, and so the battery issue would not have been a problem.

These two results were unremarkable disturbances in the nurses' normal work which, without observation, would remain unreported, unnoticed and invisible. For the nurses we observed having the difficulties, these are merely frustrations that could be alleviated. For the VTBI issue one might need to use a bit more caution and mental effort to work out the VTBI manually. For the battery issue one might need to plug the infusion pump in to one of the many sockets around the unit, or programme a new pump partway through an infusion.

However, we could imagine rare situations where these could contribute to an incident if unresolved. Indeed, the safety literature often refers to accidents as an unfortunate combination of multiple minor failures rather than having a single main cause [6]. For example, imagine a novice nurse, in an emergency, who is trying to work out the VTBI manually because s/he cannot skip this stage. At the same time another pump's alarm disturbs her/him to signify it is running out of battery charge: s/he forgot to check the battery indicator when s/he programmed it. S/he switches attention to changing the second pump. In trying to calculate the dose for the new pump s/he confuses it with the other VTBI calculation and enters too high an infusion rate; the patient comes to harm. This is only illustrative, but experience tells us to prepare for the unanticipated [6].

The role of DiCoT in the analysis

The process diagram shown above (Figure 1) is one of many representations developed as part of this analysis. Others include representations of the device interface and of spatial layouts. As others (e.g. [14]) have noted, the details of healthcare work are messy, and it is essential to have an appropriate structuring representation to guide observations, and to organize information to support sensemaking. DiCoT served such a role in this study. Without such a structuring representation to focus data gathering and analysis, the task might have become intractable.

Socio-technical intervention

Ideally, we would like to make interventions to alleviate interaction issues. We discuss different socio-technical interventions in response to our results below; this work is on-going, so we report it as work-in-progress. An important concern is the lack of clarity on what is possible and what is current practice, making definitive recommendations difficult:

Manufacturer

In terms of the VTBI issue, the device's instructions tell us that the pump has been configured so the VTBI is a 'target value'. This means that it must be entered first, then either the time or the rate, before the machine calculates the third. If the second or third value is manipulated then the target value should remain the same whilst the corresponding third or second value is automatically adjusted; e.g., if the time is changed then the VTBI should remain the same and the rate should adjust accordingly.

Discussions with health services staff have revealed that the device can be configured so that values can be entered in any order (this is the set-up in the intensive care unit). However, devices in the Day Care Unit have been configured so that the user must enter the VTBI as the 'target value'. An untidy workaround to enter the time and infusion rate so that the pump calculates the VTBI has been developed by technical staff, but nurses do not know this, and it is far from ideal.

The battery issue is more clear-cut, in that this is a manufacturing design intervention, and not to do with local training, configuration, or management; i.e. the device could be designed to warn the user if the programmed treatment time will outlast the battery at the point of programming. During introductory meetings with the manufacturers of the observed pumps we raised this issue and proposed this intervention; this suggestion was well received.

Local Training, Configuration and Management

In terms of the VTBI issue, some staff assert that all prescriptions have the VTBI available, which contradicts other accounts. The nurse we observed understood that the VTBI value was not available to her. We speculate that some doctors or pharmacists might not include this in their handwritten prescriptions if they do not recognise the importance of doing so. If VTBI is always present, then training should focus more on where the VTBI can be found; otherwise, training needs more focus on how to quickly and reliably calculate VTBI from time and rate. Alternatively, management might review policies and procedures. For example, if not entering the VTBI first does not pose any risk to patient safety then the pumps could be configured so that any value can be entered, which is the set-up in the intensive care unit. Alternatively the policy would need to state that there is an accurate VTBI for every prescription.

CONCLUSION

In this position paper, we have discussed the roles of observation and analysis structured around Distributed Cognition in informing the engineering of medical devices that are better suited to their intended context of use. This

work is at an early stage of development; for example, it is essential to conduct similar studies in different wards, in different hospitals, and with devices from different manufacturers. However, this study has illustrated the value of DiCoT as a framework for structuring data gathering and analysis, and has also highlighted the importance of conducting observational studies of normal work, and of not relying on incident reports or self-report as the principal data sources for informing future design decisions.

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WOAD, A Platform to Deploy Flexible EPRs in Full Control of End-Users

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ABSTRACT
In this paper we present the architecture of WOAD, a framework that we propose to make clinical end-users more autonomous in tailoring Electronic Patient Records (EPR) to their changing needs. We provide a short overview of the main concepts of WOAD and then we present the two visual tools that we developed to allow end-users to create their own templates and endow these with proactive and context-aware mechanisms. Finally, we outline the main flows of interaction that have been implemented in ProDoc, a WOAD-compliant prototypical patient record.

Keywords
WOAD, ProDoc, Datoms, Didgets, Electronic Patient Record, End-User, Visual Editor

INTRODUCTION
Electronic Patient Records, under the promises of facilitating accountability and research and improving care efficiency and patient safety, have stimulated important investments in the last twenty years. Therefore this kind of applications are nowadays become more and more common in clinical settings all over the world, although at a diffusion rate that is much lower than initially expected [1]. Recently, an increasing number of scholars propose to ascribe this phenomenon also to the rising perception that going paper-less in hospital wards is but a trivial endeavor [3, 14, 16]. Thus, although it is not an easy task to define what failures in ICT projects really are [4] and although publication bias (i.e. the tendency not to report bad results or failures) certainly affects ICT literature [18, 2] (as indeed many other disciplines), the best estimate is that most EPR projects fail in some way [13]. Analysing the deep reasons why this can happen is out of the scope of this paper. In short, we can summarize these reasons with the fact that traditional EPRs are developed by ICT professionals with scarce or no experience about the clinical domain, and this leads them to not consider the existence of specific local needs (e.g. the needs of a single hospital ward), developing extremely rigid EPR systems. Yet, to present our technological solution we start by taking the stance that designers of EPRs should focus on interaction first and foremost, rather than, e.g. exclusively on data types and data-oriented functionalities. Within the health informatics field, this stance is in line with those who advocate to adopt the interaction design tenets [8] to design information systems that keep the people who will use them "in the loop" and, more yet, give them the control of how the application must be tailored to their specific and local needs.

In this line, in the past years we conducted a number of observational studies (reported in [6]) to elicit the requirements that doctors and nurses perceived as the most important ones to avoid that the incumbent EPR project would end by blowing up in their face, either by requiring them more effort in documental work than the paper-based counterparts, or by imposing organizational constraints and procedural bottlenecks that made sense only on paper. We categorized the main requirements in three classes: *support*, *autonomy* and *flexibility*. In the light of these requirements we conceived an architecture, called WOAD (described in [5]) and realized ProDoc, a prototypical EPR that is based on this architecture, which we described in [7]. While the class 'support' is conceived general enough to encompass all those traditional data-oriented functionalities that support practitioners in carrying out their tasks (e.g., retrieving records by multiple parameter queries, chart printing, calculating liquid balances and other scores), ProDoc was intended as a proof-of-concept application of the latter two: autonomy and flexibility. Obviously these latter are not uncorrelated, indeed we consider flexibility as a necessary requirement to make EPRs "malleable" and tailorable to the ever changing needs of their users; but, differently from the mainstream approaches, we do not think that flexibility can be bestowed on practitioners "from above" but that rather they have to make their EPR flexible "on their own", in an autonomous manner with respect to both the ICT vendor and the ICT specialists. Thus in this paper we intend autonomy as a precondition for actual flexibility and as something that must be guaranteed toward concrete purposes. Specifically, we will present a computational platform that is aimed at making practitioners autonomous in, on the one hand, building and maintaining over time their own electronic documents (seen as modular and reusable components of the EPR user interface); and, on the other hand, in endowing these documents with simple rules that are executed asynchronously by the system according to the context and the content that practitioners progressively fill in.

This platform, WOAD, is then an end-user programming environment where the application layer of the EPR, like

ProDoc is, aggregates patient data in *sets of electronic documents*, as if they were physical sheets of the paper-based record; and where users can employ a specific editor to create the data types they need to document their work almost "on the go" and place the corresponding fields and input elements in the templates of these sheets, in a manner that purposely mimic the way they used to edit the templates of their paper-based charts with a regular word processor. In addition to the template editor, WOAD also encompasses a visual rule editor, by which practitioners are facilitated in creating small bunches of if-then logic; these simple rules are intended to be local to the clinical documents and to be defined according to the conventions currently in use in a specific department [6]. To this aim, the editor allows the practitioners to create specific conditions or data patterns over the templates they have previously created. Although rules can act on any part of a document, we advocated their creation especially to modulate how the document's content looks like, and therefore to convey what in [6] is called Awareness Promoting Information (API), i.e., any additional indication that could help practitioners become aware of what is going on in their setting [10] and recall knowledgeable ways to cope with the situation.

In the following sections, we will briefly outline the WOAD architecture and see how its components, including the template and rule editors, interact with the end-user to present clinical data with the typical flexibility provided by the still efficient and versatile paper-based patient record [11].

THE WOAD FRAMEWORK

WOAD is a *design-oriented* framework that encompasses both a *conceptual model* and a *reference software architecture*, and is grounded on the concepts of "active document" and "web of documental artifacts" [5]. In WOAD, documents are composed by two intertwined parts: a *passive part* and an *active part*.

The passive part contains the content users fill in and arranges it according to a *template*. This defines how *didgets* ('documental widget') are topologically arranged. A didget represents the reusable instance of a *datom* ('documental atom') within a specific document. Datoms are modular data structures encompassing a set of data fields that coherently represent a specific aspect of the reality of interest. The active part is composed by a set of mechanisms, i.e., specialized 'if-then' statements that augment the passive part of a document with context-aware and proactive behaviors. A mechanism can be defined over either datoms, didgets or their content and is triggered according to the current contents of the document.

DOCUMENT TEMPLATE EDITING

The Active Document Designer (ADD) represents the means that allows the end-users to create the WOAD document templates, and consequently the datoms, that they need. To this aim, the ADD (Figure 1) encompasses two distinct visual editors: the Datom Editor (DE) and the Template Editor (TE). While the DE allows the users to create the datoms by defining both the data model (e.g., the data type of a field) and the layout model (e.g., the visual aspect), the TE allows for the graphical design of the topological arrangement of the documents.

A user who wants either to create or edit a document template has to pick up the datoms from a palette (or stencil), which contains all the datoms that have been previously created with the DE, and place them into the drawing area that represents the document. Once a datom has been placed in the template, the corresponding didget is created and added to another palette, which makes available the didget outside of the document in which it was created and allows for the reuse of the same didget into other document templates.

The reuse of the didgets allows for sharing data between different documents, either if those documents are based on the same template or on a different one. Moreover, the didgets can be also used for sharing data regarding different resources (e.g., all the patients of a hospital ward). This feature of the didgets is specified through their `global` attribute, which can assume four different values (see Table 1): G0) the didget holds some pieces of data that are local to a specific instance of a document (*local data*), e.g., the value of the daily measurement of the patient's temperature that practitioners inscribe on the *Daily Sheet* (DS); G1) the content of a didget is shared between all the instances of a document based on a particular template and related to a specific resource; G2) the didget shares some pieces of data between the instances of some documents that are based on different templates, but that are related to a single resource, e.g., some portions of a patient's personal data (like the patient ID, her name and surname); G3) the contents of a didget are shared between all the document instances without any constraint both on the template and the resource. When a user who is editing a template drops a datom and creates the related new didget, the latter will hold only local data by default (i.e., the `global` attribute is set to the G0 value). The user can set the desired level of globality of a didget simply using a graphic menu that appears directly under the graphic representation of the didget in the template draw area.

In a similar way, through the same graphic menu, the users can also specify if a didget must display its set of fields only once ("single didget") or if this set of fields has to be repeated in tight succession ("multiple didget") for a certain number of times. For instance, the latter case is useful to handle the need to organize some data in tabular format that could be repeatable on the same instance of a document (e.g., the vital parameters of a newborn within few moments from delivery), using the structure of the didget (i.e., the related datom) to define the organization of the rows.

When a user has finished the composition of the document template, she stores it into the *Template Manager* (see below for details about this component). If the user has opened an already existing document template in order to modify it, the storing operations are not destructive and adopt a simple versioning system: each version of a template is labelled with the timestamp of its creation.

Making the users able to build their documents in a what-

	Data Shared Between		
	Instances	Templates	Resources
G0	✗	✗	✗
G1	✓	✗	✗
G2	✓	✓	✗
G3	✓	✓	✓

Table 1. The levels of the `global` attribute of a didget.

you-see-is-what-you-get manner allows for increasing timeliness, high flexibility and 'tailorability' with respect to both creating and modifying operations.
An exemplificatory scenario is the need to add an element to a document (e.g., a checkbox) by which clinicians can indicate whether the patient has expressed the informed consent or not. Here the constraint associated with this document element is that all fill-in operations on any part of the document must be inhibited if the informed consent checkbox has not been marked.
Usually, in a traditional information system, addressing this need would require to apply a set of changes that may potentially involve the whole system and that have to be necessarily call for the involvement of software analysts and developers. Adopting this approach requires the users to wait until the software professionals have completed all the necessary tasks to make the required changes to the system.
On the other hand, using the ADD, the users can directly and quickly add any new feature to their documents, without involving any other professionals. They have just to edit the document template that has to be modified, opening it with the TE. Once the template has been opened, the user has just to select the previously created (with the DE) "Informed Consent" datom, dragging it over the template, and drop it at the desired place. In a similar way, also the application logic that prevents from or enables the editing of the fields in the same document could be added using the *Mechanism Editor* (see the next section for more details).

Currently, the TE is a prototypical application based on the *Oryx Editor*[1] (see [9]). The Oryx Editor is a web-based, extensible editor, that has been initially conceived to model business processes. This editor adopts a plug-in architecture that facilitates its extension by adding other graphic editing features (e.g. the set of third party plug-ins to model the XForms, Workflows or the Petri Nets).
The Oryx Editor is also coupled with another web application, the *Oryx Repository*, which acts as a simple "file manager" and allows for storing, browsing and managing the various models that the users create through the Oryx Editor. Due to its simplicity, we used the Oryx Repository as the user frontend of the Template Manager.

MECHANISM EDITING

The Mechanism Editor (ME) is the tool that allows the end-users to create and edit their mechanisms. ME is a web editor based on Oryx Editor, as well as the TE and the DE. ME provides users with a simple GUI that allows to create the mechanisms. The composition of the mechanisms is mainly based on drag & drop, in order to facilitate the use of the ME for those users with little or no experience in programming. The GUI is split into three areas (see Figure 2). The top section of the left area contains the list of all existing templates (previously created with ADD). A template can be dropped both to the central and the right areas, in order to respectively build the if-part and the then-part of the mechanism. The bottom section of left area contains the list of all the saved mechanisms. A user can load an existing mechanism by performing a double click on the mechanism item in this list. The left area also contains the trash area (like in modern desktop environments) in which users can drop any action or condition that they want to delete.

The if-part of a mechanism contains the conditions that the system must match to the document content; those conditions are defined on one or more didgets that are contained in one or more templates, as well as on basis of environmental variables, like system time and current users. A condition is composed through an interface that appears when a template has been dropped into the central area. This interface is unique for each of the dropped templates, and is composed by a form and a table where all the created conditions are listed. The users compose their conditions through the form area that contains three dropboxes and a textfield. The dropboxes allow respectively for the selection of the didgets, the fields and the constraints. The constraints are filtered according to the selected field data type (e.g., for a numeric field, the constraints will be "greater", "lower", "equals" and "not equals"). The textfield is used to complete the condition with the value of the constraint. The then-part contains the actions to be triggered when the above mentioned conditions are met. An action can be composed in the same way of the conditions, but in this case the third dropbox contains the list of the available API (e.g., any annotation, graphical clue, affordance, textual style and indication that could make actors aware of something closely related to the context of reading and writing). The execution of the mechanisms can be seen as the process of API generation, i.e., some operations by which the affordance and the appearance of the documents and their content are modified, and additional information (e.g., some messages), if any, are conveyed to the user. Each type of API has unique parameters. When a new action is added, the ME shows a property window that contains a form with the API parameters (e.g., the *Criticality API* changes the field color, and consequently the related property window contains a color palette).
The actions can be defined to act both on the same document in which conditions are met (e.g., an action modifies the color of the temperature field when its value is higher than 40 degree) and on some other documents (e.g., an action creates an alert message in all the documents if the patient suffers drugs allergy).

In our scenario, the user needs to create a mechanism that inhibits the fill-in operations on the document where the Informed Consent checkbox is placed, if this has not been checked. The user starts the composition picking up the document template from the list in the left area and dropping it

[1] *Oryx* is an academic project that is mainly developed by the *Business Process Technology* research group at the *Hasso-Plattner-Institute* (`http://bpt.hpi.uni-potsdam.de/Oryx/`).

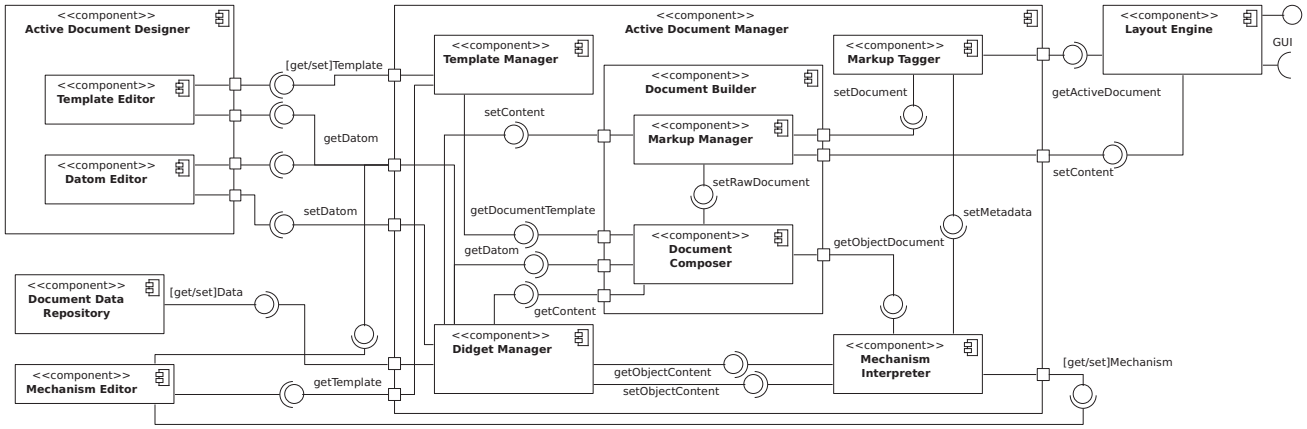

Figure 1. The UML diagram of the components of the WOAD framework.

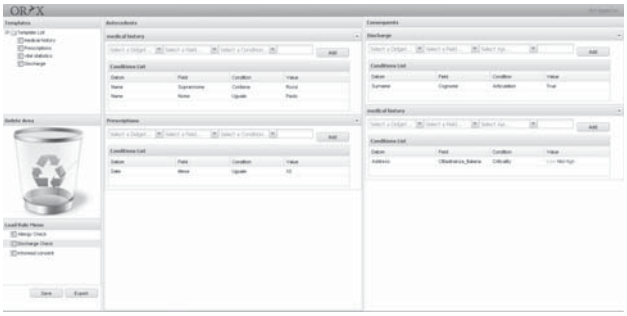

Figure 2. The Mechanism Editor user interface.

into the central area. Then, she selects the informed consent field from the fields dropbox, and "equals" from the constraints. Finally, she writes in the textbox the "false" value and pushes the "Add Condition" button. Once the if-part has been created, the user starts to compose the then-part. The user drops the previously chosen template in the right area, and selects all the fields that she needs to protect. Then she adds the action that makes a field read-only, and pushes the "Add Action button" to complete. Once mechanism is defined, the user saves it into the local repository (for future modifications), and then she converts the mechanism into the rule engine dialect (i.e., the Drools DRL) in order to make it available for the *Mechanism Interpreter* (MI).

INTERACTIONS BETWEEN WOAD COMPONENTS

With respect to the architecture depicted in Figure 1, in this section we describe how WOAD components interact when a user requires to read and update an active document (see also the steps in Figure 3); at the same time, we will provide a short description of these components and some details about their current implementation in ProDoc. This description is based on the assumption that the document templates have already been created with the ADD and stored into the TM. Similarly, we describe the process of mechanism creation.

When a user asks for a document, the GUI of the application sends the request to the *Layout Engine* (step 1 in Figure 3). The LE allows for displaying and interacting with the documents, and currently it is any regular web browser that is fully compliant with the W3C standards (i.e., HTML, CSS and JavaScript). The request is forwarded (step 2) to the *Active Document Manager* (ADM), the main component of the WOAD architecture, which builds the passive part of the document, and provides the data structures to support the execution of the mechanisms. Due to its complexity, the ADM is composed by five subcomponents: the above mentioned *Template Manager* (TM), the *Didget Manager* (DM), the *Document Builder* (DB), the *Mechanism Interpreter* (MI) and the *Markup Tagger* (MT).

The TM manages the templates and the related versioning capabilities, and provides the access to the templates to the other components of the framework. The DM creates and manages the didgets, provides the other components with the access to the definition of the datoms, and works in conjunction with the *Document Data Repository* (DDR), a component that provides data persistence features[2], to keep the didgets synchronized with their contents.

The DB builds an empty document and, if needed, fills in it with the related contents of the didgets. To accomplish this complex task, also the DB is divided into two subcomponents: the *Document Composer* (DC) and the *Markup Manager* (MM). The DC composes the document (steps from 3 to 12) by coupling the topological arrangement, the datom definitions (both UIs and data models) and the contents of the specific document instance, if any, and produces the representation of the whole document using an intermediate format (i.e., XHTML and XForms). The DC retrieves the instance of the document from its internal memory, and queries the TM and the DM respectively for the template, the datoms and the contents. In this phase, the MM acts as a translator[3], getting the intermediate representation of the document from the DC and transforming it into a markup language expression (i.e., HTML) that the LE is able to render (steps 12 and 13), with no additional tool. Once the MM has finished with

[2]The DDR is a Java package based on the *HyperJAXB* library (`http://java.net/projects/hyperjaxb3/`).

[3]The MM is a customization of the *betterFORM* XForms processor (`http://www.betterform.de/`).

the intermediate document, it sends the passive part of the document to the MT (step 13). The MT[4] forwards the received document to the LE, and this latter displays the document to the user (steps 14 and 15).
On the way round, if the user makes some changes on the document content (step 16), the LE forwards them to the MM (step 17). Consequently, the MM invokes the DM (steps 18 to 21) to update its internal data structures. Finally, the DM sends the new contents to the DDR (step 19) for the sake of data persistence.

Asynchronously with respect to the other operations, the MI[5] constantly monitors both the data structures that the DC and the DM maintain in their working memory and the execution context. When the MI detects that something has changed (e.g., the user edits some document), it checks the mechanisms, activating and executing those in which the if-part is satisfied, following a resolution strategy that is based on specificity and currentness [12]. When a mechanism is activated, the MI executes the operations defined in the *then-part* (`alt` in Figure 3) that can either modify the contents (step 25) or generate some *metadata* (step 22) to alter either the document aspect (e.g., changing the appearance of a field) or its behavior (e.g., making a field not writable).
When the MT receives the metadata, it translates them into rendering attributes (e.g., CSS classes) and procedures (e.g., JavaScript functions), and sends the latter to the LE (step 23). Finally, the LE updates the active document, displaying the new styles and running the new procedures (step 21).

The users can create their own mechanisms (step 1 in Figure 4) using the Mechanism Editor (ME). The ME is a standard component that allows the users to create, edit and export mechanisms. ME requests to the TM the list of available templates (step 2). The TM returns the current template list (step 3), and the ME fills its template menu and creates an empty mechanism (step 4).
The user starts to compose a mechanism (step 5) picking up a template in the list and droping it in either the if-part or the then-part areas. When a template has been dropped, the ME requests to the TM the list of the datoms that have been used in this template (steps 6 and 7). Once the ME has received this response, it fills the list of datoms, and for each of these datoms the ME requests the list of their fields to the DM (steps 8 and 9).
Since the ME gets all these data, the user can start to set the conditions and actions that define the mechanism (steps 10 and 11). Once the composition of the mechanism has been completed (step 12), and the user has requested to save it, the ME processes its internal data structures (i.e., the lists of conditions and actions) and stores them into a persistent storage medium (e.g., a file). When the mechanism has been saved, the user can convert it, and this process consists in the translation of the mechanism into the Drools language, and makes the result available to the MI.

[4]The MT is a Java class that makes active the document coupling its passive part with the metadata produced by the MI.

[5]The MI is based on JBoss Drools (`http://jboss.org/drools/`)

CONCLUSIONS AND FUTURE WORK

The paper illustrated two main functionalities of the WOAD architecture: the first one allows for the flexible and modular definition of the structure of the electronic charts, forms and documents that mediate care and collaboration in hospital settings. The second functionality allows practitioners to define simple rules and associate them to the documents so that their content can be visually and textually enriched (e.g., in terms of different affordances) according to the context and at various levels of scope, from the hospital-wide level to even the single practitioner one. In this paper we described these functionalities in terms of both the user interface that supports them and the architecture that realizes their implementation. Both the prototypes have been tested and used in a laboratory environment for one month by volunteer students that were called to digitize the charts and forms used in two real hospital settings. This user session helped the development team detect and correct the main anomalies and identify improvement areas in the experience of unskilled practitioners.

As said in the Introduction, these two features are intended to enrich a prototypical application we deployed in the hospital domain as an innovative and yet lightweight EPR, ProDoc. Yet, this application can be also seen as a demonstrator of a wider class of applications supporting collaborative work. In WOAD compliant applications, coordination is achieved mainly through documents, with respect to both their visible structure and to that particular kind of additional information that can be conveyed through the user interface to promote "collaboration awareness" [10]. In particular, this information is conveyed according to simple rules that end-users are called to visually create even if they have no specific IT skill, let alone programming skills. This is the most challenging part of our research program, which places it within the scope of both the End-User Development and Interaction Design fields.

Consequently, our future work will focus on how to present and afford these functionalities for different classes of users in order to modulate this kind of support according to their technical skill and domain expertise. To this aim, the empirical work that inspired the conception of the WOAD framework and its proof-of-concept application, ProDoc, will continue to both improve its "malleability" [17] to the work context and to validate its applicability in other domains where we have gained an initial positive feedback [15].

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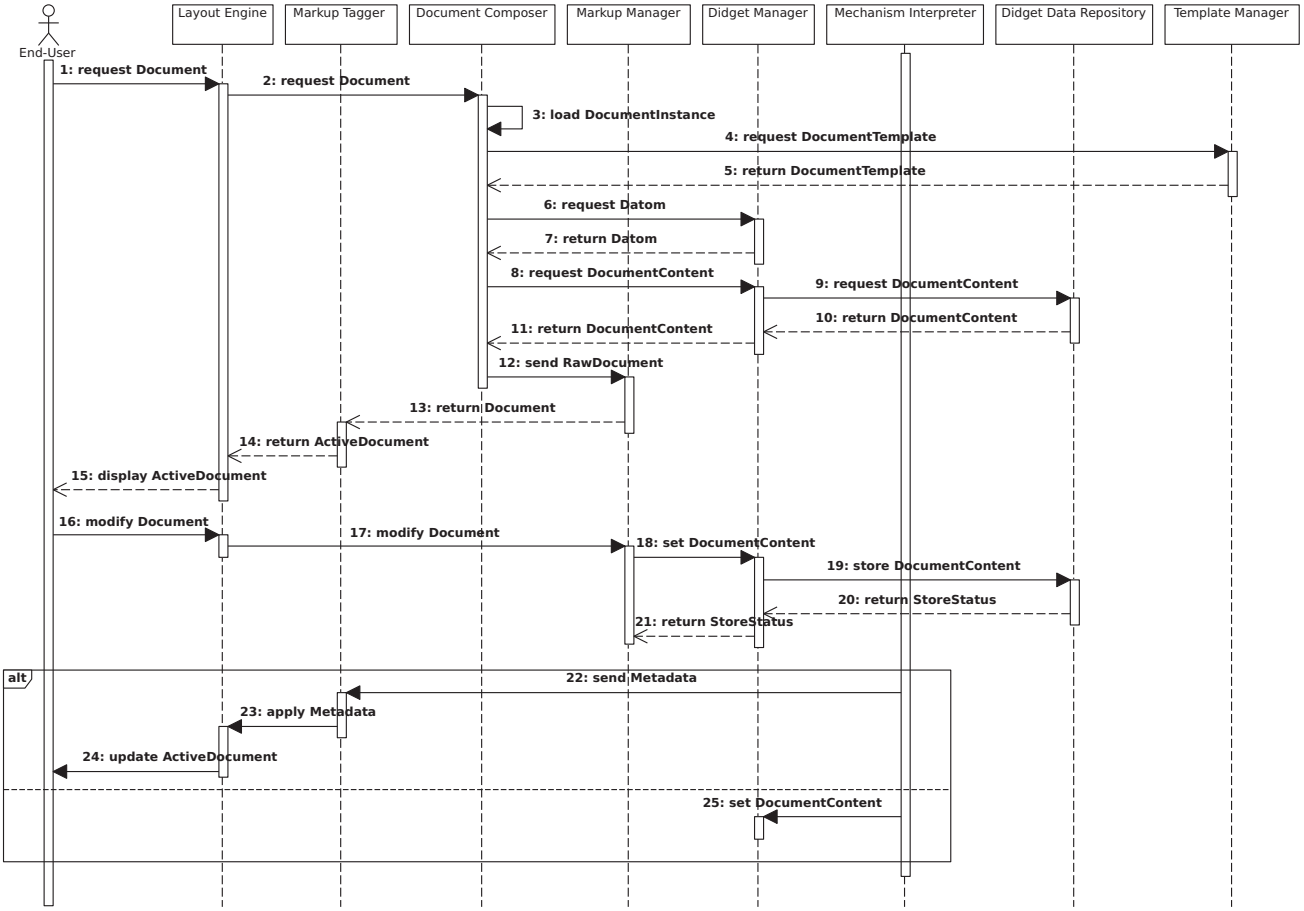

Figure 3. The UML sequence diagram of the typical interactions between the components of the WOAD framework.

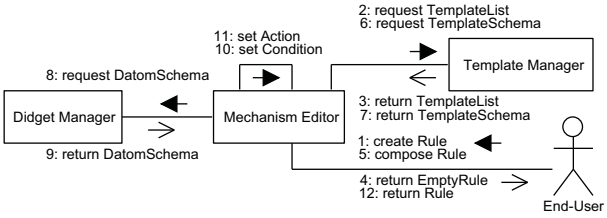

Figure 4. The UML collaboration diagram of the rule creation process.

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Surgical simulators integrating virtual and physical anatomies

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ABSTRACT
According to literature evidences, simulation is of utmost importance for training purposes and for innovative surgical strategies assessment. Nowadays the market offers mainly two kind of simulators: rubber anatomies or virtual environments, each one with advantages and drawbacks.

In this paper we describe a strategy to develop patient-specific simulators using a hybrid approach: silicone models of abdominal organs sensorized with electromagnetic coils, to acquire deformations, coupled with a virtual scene. As demonstrated, this approach allows to mix benefits of a real interaction with the physical replicas with the possibility to enrich the virtual visualization with add-ons and features difficult to obtain in the real environment.

Keywords
Patient specific simulator, hybrid simulation, segmentation, silicone phantom, surgical training, abdominal surgery

INTRODUCTION
Recent developments in minimally invasive surgery, both traditional and robotic, have strongly promoted the development of simulation technologies in order to help surgeons in the acquisition of the required psychomotor skills.

Medical simulators are rapidly evolving from primitive plastic mannequins to machines with embedded technology and, recently, computer assistance capable of creating realistic physiological and patient scenarios. Consequently many types of simulators of varying complexity have been developed and marketed. The existing trainers can be essentially divided into two groups: virtual reality (VR) and physical simulators, while a third innovative approach to the simulation is now finding its space in market and research: hybrid simulation[2; 14].

Virtual Reality (VR) simulators virtually reproduce the surgical scenario and allows the user to interact with the anatomy through different interfaces that could be surgically realistic or not and that can or can't embed some kind of haptic feedback. Even if during last decade many companies proposed virtual simulators, well described technical challenges must be still overcome to permit varied training in a realistic computer generated environment. These challenges include the development of realistic surgical interfaces and environments, and most of all the modelling of realistic interactions between objects and rendering of the surgical field [17]. Excellent results are anyhow reached in the VR simulation of endoscopies [7; 10; 18] or endovascular treatments [12; 20], where the involved anatomies are simple tubular structures and there are no complex tasks to simulate.

Simulation using physical objects usually involves plastic, rubber and latex models arranged in boxes. These objects are used to render different organs and pathologies and allow to perform specific tasks such as cutting, suturing, grasping or clipping structures. The repetitive performance of a single task allows the trainee to develop the hand-eye coordination and the motor skills before entering the real-patient setting. The actual interaction with simulated anatomy can be considered the principal advantage of physical simulator that, on the other hand, are limited by being restricted to single or few standard anatomical structures and by requiring to buy a new phantom (usually expensive) for each destructive trial. Physical simulators can also be employed as testing environment for the in-vitro assessment and validation of innovative surgical technologies (like surgical instruments, robots or navigation) [4; 6; 8].

In the last years to overcome limits of the two former described approaches a new concept of simulation has been developed: hybrid simulation. It combines synthetic models with VR, deploying for example mixed-reality, to bridge the gap between the synthetic mannequin and the computer. This avoids some of technical difficulties associated with reproducing the feel of instruments and of human tissue in a complete virtual environment, while still allowing access to the advantages of computer simulation in particular for

the trainee performance evaluation, the possibility to enrich the scene with virtual elements and to give instructions for the surgical tasks execution [9]. This kind of simulators require sensors to quantitatively evaluate the trainee's performance.

This paper describes a fabrication strategy to build patient-specific hybrid simulators mixing patient specific synthetic anatomies with virtual reality features. The idea is to overcome the limit imposed by standard anatomy, starting from the elaboration of radiological images to develop a simulator including realistic synthetic organs paired with electromagnetic position sensors and enriched with consistent virtual model of the entire abdomen.

MATERIALS and METHODS

The goal of the present work is to define a strategy to manufacture patient specific silicone organs and pair it with sensors in order to build a physical test bed enriched by a virtual environment in the direction of an hybrid simulators for abdominal surgery.

The simulator is to be used for surgical training, with the chance of surgical performance evaluation, but also as testing environment to assess innovative surgical technologies like surgical robots or surgical navigators.

The development of the simulator starts from the segmentation and surface extraction of anatomical components of interest from real medical image data sets.

The obtained 3D virtual models are then employed on one side to build the graphic interface, on the other side as starting point to design the moulds for the silicone organs models.

A commercial torso phantom (CLA® OGI Phantom) is used to enfold synthetic organs models in a realistic environment (14). Moreover supporting structures are designed to guarantee the correct positioning of synthetic models inside the commercial mannequin and replicate space constraint and relationships between organs.

In this work NDI Aurora® electromagnetic (EM) tracking sensors have been used (Aurora® 5DOF Sensor, 0.5 mm x 8 mm, 2 m) to sensorize organs[3; 16].

Physic simulator fabrication

The fabrication steps is divided into two principal phases:

- Images acquisition and elaboration for the 3D virtual models extraction
- Fabrication of the sensorized synthetic organs

Image acquisition and elaboration

The virtual environment is obtained through the segmentation of actual radiological datasets. In this first phase it lays the key to obtain non standard anatomies and to choose real anatomies to build up surgical theatre challenging for the trainee.

As first simulator we selected an healthy patient, anonimized, dataset. The dataset has been segmented to obtain organs frontiers. For this purpose we used a semi-automatic tool previously developed in our lab: the EndoCAS Segmentation Pipeline[5] integrated in the open source software ITK-SNAP 1.5 (www.itksnap.org) [21].

The whole segmentation procedure is based on the neighbourhood connected region growing algorithm that, appropriately parameterized for the specific anatomy and combined with the optimal segmentation sequence proposed, allows optimal segmentation results. The results of a complete upper abdomen segmentation are shown in Figure 1a.

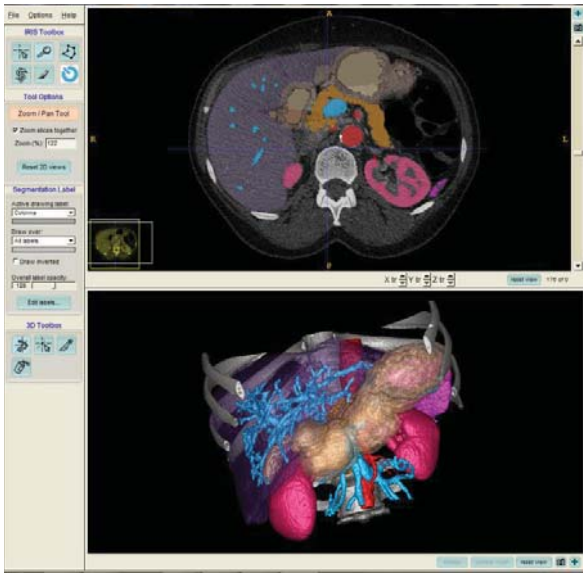

Figure 1: 3D models of the upper abdomen and its segmentation in the segmentation software.

Fabrication of synthetic organs

The class of silicone rubbers, which allows an easy reproduction of objects with complex shape, and an agarose hydrogel, which closely mimic the mechanical properties of soft tissues [1], have been selected to fabricate the synthetic organs.

More in particular the employed silicones are RTV-TIXO, and GSP 400 from Prochima® while an agarose powder from Sigma [19] (Type I-A Low EEO) is used for the hydrogel preparation. We set up two fabrication procedures to reproduce different anatomical sensorized structures, respectively sensorized hollow organs and sensorized solid organ.

Regarding hollow organs, for example stomach and gallbladder, a process has been studied to embed sensors inside the organ wall, between two layers of silicone. In the following is detailed the procedure for fabricating a sensorized gastric model.

First the positions of 8 Aurora electromagnetic sensors have been identified on the 3D virtual model in function of

the clinicians needs. Then it has been fabricated a mould replicating the gastric lumen, with holes in correspondence of planned sensors positions. Figure 2 shows the gastric mould with planned, in virtual Figure 2a, and actual screws positioning used for an exact sensors positioning Figure 2b. In Figure 2c, a first layers of silicone RTV TIXO has been applied on the gastric model; after the silicone curing, Aurora sensors have been positioned between each couple of screws; the thin screws have been removed from the rigid gastric model and a final layer of GSP 400 has been applied, Figure2d.

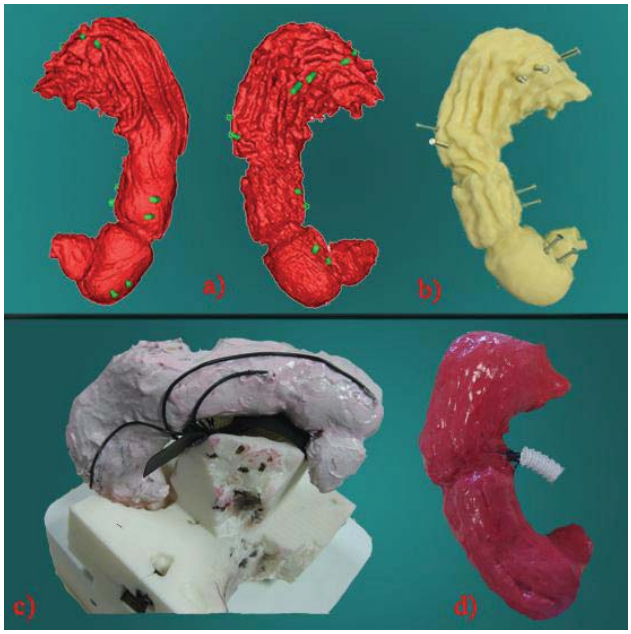

Figure 2: Silicone stomach fabrication and sensorization: a) virtual position for sensors, b) prototyped mould with screw to locate sensors' position, c) first silicon layer and sensors deposition, d) final stomach model.

RTV TIXO has been chosen to fine reproduce gastric folds, the outer layer of the model instead has been fabricated using GSP 400 that allows to obtain a more uniform and smooth surface.

The solid organs have instead been fabricated building mould where to inject silicone or hydrogel. In the following is detailed the procedure for fabricating a sensorized liver model. In particular the agarose powder has been mixed in water, heated until almost boiling, and then poured into the designed mould. Since liver Young modulus varies around 20 KPa [15] an agarose concentrations of 0.5 % has been used for obtaining gel with a consistent elastic modulus [1].

As showed in Figure 3a,b the mould is composed of two joinable external shells that are the negative copy of the 3D liver model. The positions for 8 Aurora sensors have been identified on the 3D virtual model of the liver, Figure 3c shows the assembled mould.

The process of fabrication started with the application of a layer of silicone RTV TIXO in the internal surface of both the mould parts. Then, after silicone curing, Aurora sensors have been positioned in correspondence of the predisposed screws. A new layer of RTV TIXO silicone has been applied to properly cover sensors. When the silicone cured, after removing screws, the mould has been closed, ensuring the proper alignment of the two mould parts and using additional silicone to attach the two silicone shells.

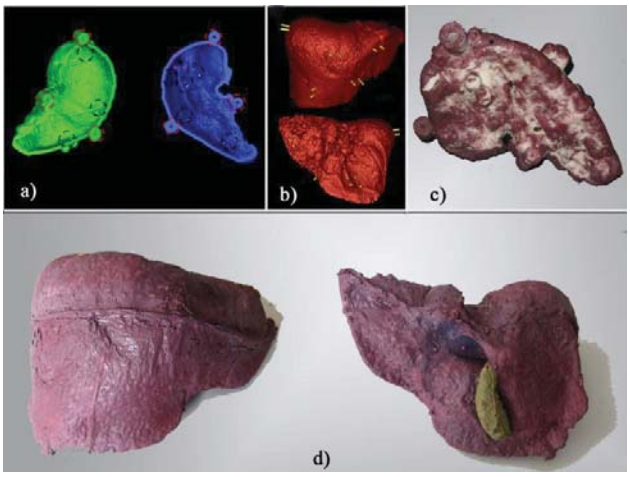

Figure 3: a) Designed mould for the liver reproduction. In red dotted circles. b) Selected positions for eight Aurora sensor; c) Prototyped mould after silicone injection. d) Final silicone liver front (sx) and back (dx).

Finally the prepared agarose gel has been injected into the closed mould. The final result can be seen in Figure 3d.

In order to guarantee the correct positioning of synthetic organ models inside the commercial mannequin it has been decided to fabricate a supporting structure, that fits perfectly inside the commercial mannequin, and allows to insert synthetic organs models respecting their actual anatomical location in the patient.

At this aim, after positioning some radio opaque markers on the mannequin, another CT scan has been executed, then a registration between patient images and mannequin ones has been performed and finally the segmentation obtained from patient CT images has been loaded on the mannequin greyscale images.

This allowed to segment the empty space between the mannequin abdominal cavity and the organs models and thus to extract the 3D model of a supporting structure for patient silicone organs that fits perfectly inside the commercial mannequin abdomen.

Then the segmented model has been refined to optimize its shape and allow an easy positioning inside the mannequin and an easy insertion of the organs. Finally the designed supporting structure has been fabricated using the 3D printers.

A set of abdominal walls has been built to complete the simulator. Such walls have been added in order to simulate

the pneumoperitoneum during robotic or traditional laparoscopic interventions.

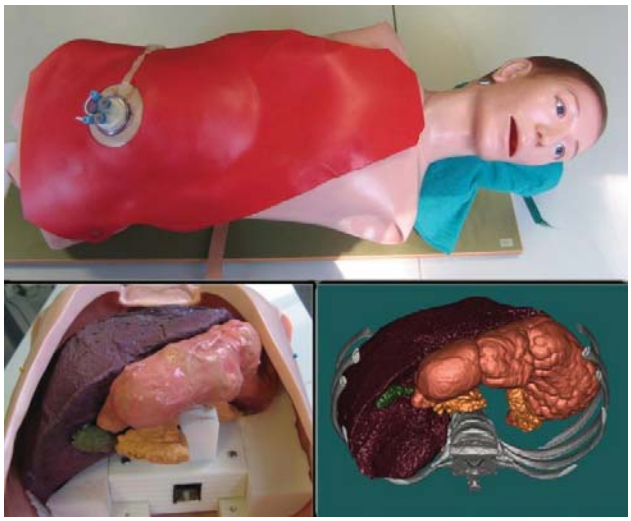

Figure 4: Assembled mannequin covered (up), the phantom organs inside the mannequin (down left) ant the virtual used to obtain internal organs (down right)

The covers are fabricated in thermoformable plastic material modelled in the right shape. They are provided with some soft silicone windows in strategic positions to allow the insertion of the instruments access ports.

In Figure 4 it is showed the mannequin with 4 organs inside: liver gallbladder stomach and pancreas. The organs are correctly arranged thanks to the supporting structure[3].

Design and build of the graphic interface for the hybrid environment

A software interface that acquires signals coming from the embedded sensors and emulates organs deformations on a virtual scenario (Figure 5) has been implemented to show the potentialities offered by hybrid simulation.

The software is written in c++ and deploys the openSG opensource libraries to deal with openGL window and the Qt libraries to build the interface.

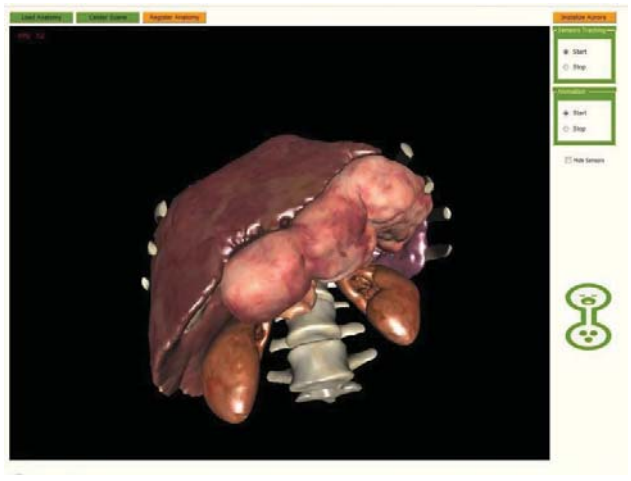

Figure 5: Graphic Interface and texturized virtual anatomy rendering.

The 3D model of the organs are visualized inside the software.

It is important to underline that the virtual environment is enriched respect to the real one by the possibility to add all abdominal segmented structures, i.e. vessels and kidneys.

Color information are added to virtual model using vertex coloring techniques in order to increase the realism of the virtual scenario.

The physics mannequin is registered with the virtual anatomy with a point based registration algorithm. This is necessary to align the reference frame of the aurora localizer, that read the sensors inside the mannequin, with the CT reference frame in which the virtual anatomy is referenced.

The transformation between CT and Aurora reference frames is computed using the radiopaque artificial markers positioned on the commercial mannequin. Marker positions are acquired with the Aurora digitizer. Then the registration matrix is calculated through a least square error algorithm.

Starting the simulation the Aurora localizer starts reading position information coming from sensors.

Each sensors position is registered to find its coordinates in the mesh reference frame; these coordinates are then considered as “control points” to apply the deformation function for reproducing the deformation actually imposed to the organs.

The class of Free Form Deformations methods are the most spread methods to modify the shape of geometrical objects when described with vertices and faces [11]. The inquire on deformation strategies to be followed is broad and literature is very rich about this field. Different decision has to be taken for different organs according to its morphology.

At this moment we implemented deformation only for the stomach. We implemented a point based deformation method[13]. As said each sensors position is used as control point for the mesh of the organ to be deformed. When a sensors moves a Gaussian distribution function is evaluated at each mesh vertex, and its displacement is calculated with this distribution function. The 3D coordinates of each vertex on the mesh are then coherently updated, changing the shape of the 3D organ model, and hence deforming it.

Below the mathematical description of the method is showed.

$$p_x^t = p_x^{t-1} + \sum_{n=1}^{8} \left(s_{n_x}^t - s_{n_x}^0\right) e^{-\frac{d_n^2}{\sigma}}$$

$$p_y^t = p_y^{t-1} + \sum_{n=1}^{8} \left(s_{n_y}^t - s_{n_y}^0\right) e^{-\frac{d_n^2}{\sigma}}$$

$$p_z^t = p_z^{t-1} + \sum_{n=1}^{8} \left(s_{n_z}^t - s_{n_z}^0\right) e^{-\frac{d_n^2}{\sigma}}$$

$$d_n = \left|\overrightarrow{p^0} - \overrightarrow{s_n^0}\right|$$

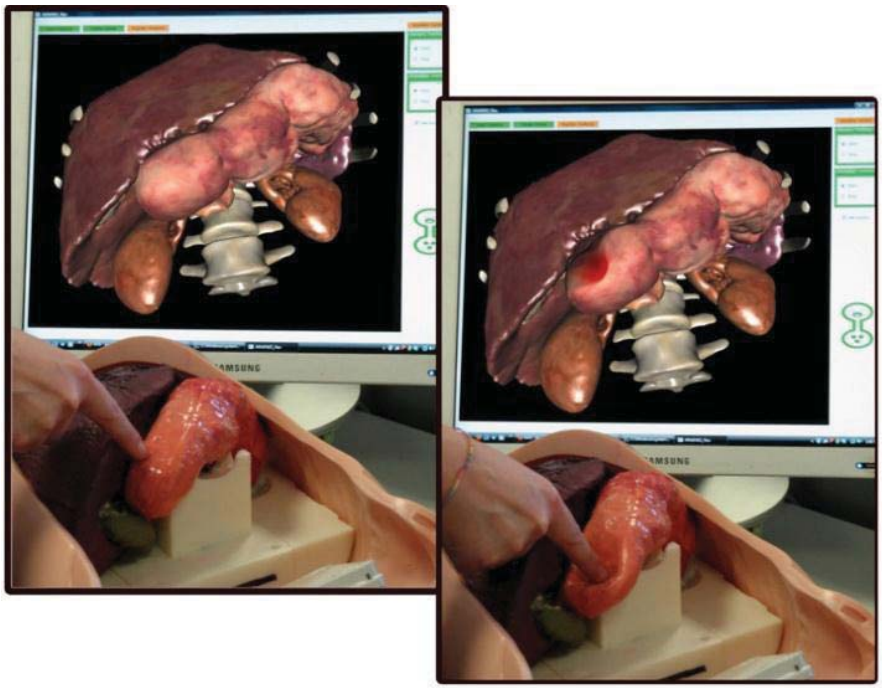

Figure 6: Example of real time deformation of the virtual environment. The stomach is highly deformed so in virtual it is highlighted in red to underline the entity of deformation

where

$\vec{p}^t$ is the position of a mesh vertex at the instant *t*
s_n^t is the position of the sensor *n* at the instant *t*

n is the sensor number (in our case from 1→8)

d_n is the Euclidean distance between the mesh vertex and the sensor *n*

σ is the standard deviation of the distribution.

The latter parameter describes the amplitude of the gaussian bell and in this application it somehow reflects the material property of the organ describing how much wide the deformation is. The Gaussian distribution of the distances, $e^{-\frac{d_n^2}{\sigma}}$, is evaluated for each mesh vertex and each sensor "off line" when the mesh is loaded. So that, during the simulation, the amount of computational load to be done on the fly is reduced and the simulation is speeded up because it's only needed to check precomputed values in a local area only.

Steering the σ parameter we obtained a simulator that reproduce virtually the physical interaction with the anatomy (Figure 6).

Moreover in order to add preliminary metric features to the simulator we inserted a visual effect that colours the deformed part in function of the deformation entity.

This is to virtually transmit if a deformation is too strongly imposed and furthermore represent the first step to go towards bleeding anatomies and more complex virtual features.

CONCLUSIONS

In this work we describe how to develop surgical simulators using a new paradigm.

In particular it is shown a strategy to build up a complete hybrid simulator for surgical training.

Regarding the physical phantom the strategy easily allow to modularly build surgical scenarios. The mannequin was showed to clinicians that confirmed the high degree of realism and the correct arrangement of organs inside the abdomen.

Regarding the correspondence between real and virtual deformation real-time performances have been reached.

At this moment only a simple deformation for the stomach is implemented but an integration of more complex functions is planned. The aim is to reach integration of enough functions in order to simulate a complete intervention.

For example next steps will regard the development of virtual deformation for liver and gallbladder in order to simulate a complete colecistecthomy.

This type of simulator overcomes the limits imposed by the use of standard anatomies and represents the first step for developing more complex hybrid platforms, that links benefits coming from having physical scenario to interact with (mostly in terms of force feedback) with virtual elements that enrich the realism of the simulation and can offer to trainee a complete environment to learn surgery from a single task to more complex ones.

While a complete evaluation as for this training purpose is currently underway, initial feedback from clinicians using the system has been positive. The winning strategy to build simulators not starting from standard anatomies but describing a wide variety of anomalies and pathological scenarios is very encouraged from surgeons.

ACKNOWLEDGMENTS

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Video see-through in the clinical practice

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ABSTRACT
In this paper, we discuss potentialities and technological limits to overcome for the introduction in the clinical practice of useful functionalities, using video see-through visualizations, created mixing virtual preoperative information, obtained by means of radiological images, with real patient live images, for procedures where the physician have to interact with the patient (palpation, percutaneous biopsy, catheterism, intervention, etc…).

Keywords
Mixed reality, surgical navigation, general surgery.

INTRODUCTION
Modern CT and MRI scanners coupled with new contrast mediums allow the acquisition of volumetric datasets describing human anatomy, functionality and pathology, with high level of detail.

The detailed information contained in a volumetric dataset are fully used during the diagnostic phase, but are partially lost passing from the radiological department to the surgical department.

In fact, generally, surgeons plan interventions just using limited information provided by the radiologist and consisting in the textual diagnosis coupled with few 2D significant images selected from the volumetric dataset.

The application of the "computer assisted" model to the patient workflow, consisting of computer aided diagnosis (CAD) and computer aided surgery (CAS) technologies, allows the optimal use of medical dataset and to overcome the above cited limitations of the current clinical practice. The 3D visualization of patient specific virtual models of anatomies [23; 24], extracted from medical dataset, drastically simplifies the interpretation process of exams and provides benefits both in diagnosing and in surgical planning phases. Computer assisted technologies allow to augment real views of the patient, grabbed by means of cameras, with virtual information[26]. This augmented-reality, or in general mixed-reality techniques [20], introduces many advantages for each task where the physician have to interact with the patient (palpation, introduction of biopsy needle, catheterization, intervention, etc.) [9; 10; 25]

The next figure shows a binocular see-through mixed reality system at work implemented using a HMD (Head Mounted Display) and external cameras [8].

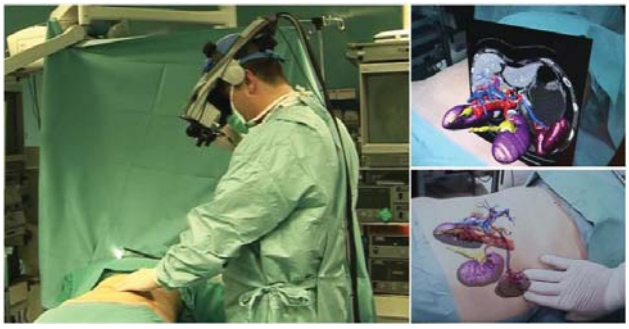

Figure 1: Stereoscopic video see-through in the operative room

To implement this kind of systems is generally required to localize the anatomy in respect to the real video source and to determine its projection model in order to coherently mix virtual and real scenarios. Localization can be done using commercial tracking systems, introducing additional costs and logistic troubles in the traditional clinical scenario, with large errors on soft tissues, while the projection model of the video source can be calculated using theoretical algorithms that impose some constrains for the real camera.

In the following is described in the detail the problem and possible solutions to avoid the need of the tracker or to improve the localization quality on soft tissues taking into account the limits of the current images source used in surgery.

HOW TO OBTAIN A MIXED REALITY VIEW
The following picture essentially describes the video see-through concept.

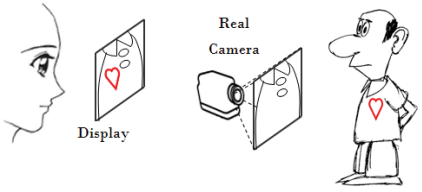

Figure 2: Video see-through concept

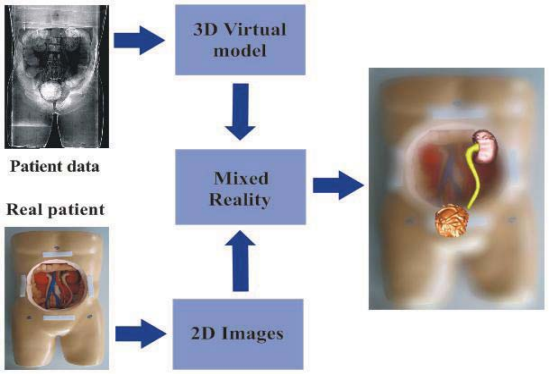

Figure 3: Functional scheme of a surgical see-through system

Real video frames, grabbed by of real camera/s, are mixed with virtual objects not visible in the real scene and shown on a display/s. This virtual information can be obtained using radiological images as depicted in the next figure.

The using of volumetric scanners, like CT (Computed Tomography) or MRI (Magnetic Resonance Imaging), allows to obtain a 3D virtual model of the anatomy [4; 6], which can be loaded in a virtual scene, running on a computer, rendered from a point of view coherent with the real point of view.

The mixing of the real (2D) images with the virtual (2D) rendered images can be done using a hardware video mixer or using the real images in the scene graph as foreground or background [19]. The concept and the work to do are similar: in the first case the mixing is done by external hardware after the rendering of the virtual scene, while in the second one by the GPU during the rendering. Figure 4 shows this concept. The real camera acquires video frames from the real environment (a spleen in this case). Video frames are shown as background of the virtual scene. Virtual objects are positioned in the scene (green flashes in this case) and rendered from a virtual camera.

In order obtain a coherent fusion we have to obtain a virtual scene where:

virtual camera projection model ≈ to the real one
virtual camera position ≈ to the real one
virtual objects positions ≈ to the real ones

The following paragraphs describes how to obtain the previous three conditions.

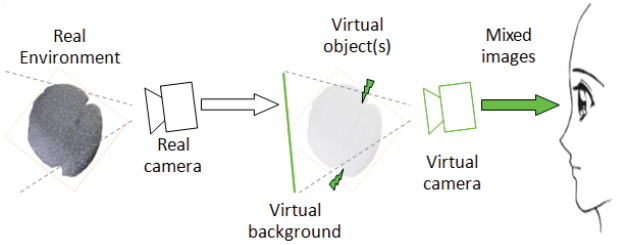

Figure 4: Implementation of mixed-reality in a virtual scene

How to determine camera projection model

Line scan and telecentric cameras are used for particular industrial applications, while for all visualization purposes, including laparoscopy, the perspective projective camera is the only used, because it offers the most similar images in respect to human vision.

Regarding the sensor, two technologies are predominantly applied: CCD (Charge Coupled Device) and CMOS (Complementary Metal Oxide Semiconductor). In each case unitary elements (pixels) are disposed on a regular grid (with fixed resolution).

Each camera, composed of a projective optics and a grid sensor, can be represented by the following model:

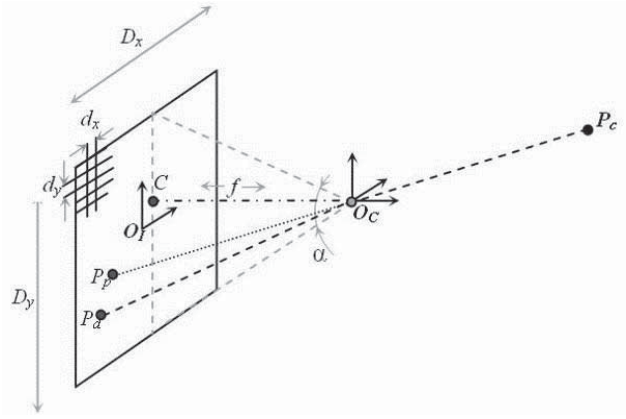

Figure 5: Schematic representation of the pinhole camera model: the generic point Pc is ideally projected on the image sensor of the camera (the plane with origin O_I) through the projection center O_C (where the origin of the camera reference frame is fixed)

The perspective projection matrix Mp, mapping a generic 3D point Pc = [x, y, z, 1]^T, in the camera reference system, to the corresponding 2D point Pp = [u, v, 1]^T in the image reference system (fixed on the center of the sensor), i.e.:

$$P_p = M_p P_c \qquad (1)$$

is defined starting from the internal camera parameters (f, C_x, C_y) as follows:

$$M_p = \begin{bmatrix} -f & 0 & Cx & 0 \\ 0 & -f & Cy & 0 \\ 0 & 0 & 1 & 0 \end{bmatrix} \qquad (2)$$

where f is the focal distance and (C_x, C_y) are the coordinates of the projection of the O_c on the image reference frame (with origin in O_I).

Other internal camera parameters parameterize the model of the radial distortion, introduced by common lens, by means of which the projected point P_p is deviated on P_d.

The pixelization process is defined by the pixel dimensions d_x and d_y and the image sensor dimensions D_x and D_y. These

internal parameters of the camera allow to convert measurements done on the image (in pixels) in real measurements (in millimeters) and vice-versa.

All internal camera parameters can be determined in a calibration phase acquiring some images of a knowing object in different positions with fixed camera configuration (in terms of diaphragm and camera focus) and using calibration routines like described in [30].

These parameters have to be used to adjust the virtual camera to the real one.

Using traditional surgical endoscopes a new camera calibration and virtual camera adjustment is required whenever either the optic zoom or the diaphragm opening are changed. Another important source of error can be determined by the mechanical joint between the optic and the camera body. Their relative movements can determines a shift of the center of projection C up to tens of pixels.

How to localize the camera

Camera position and orientation can be obtained using a tracker able to track a sensor mounted on the camera body as shown in the following figure.

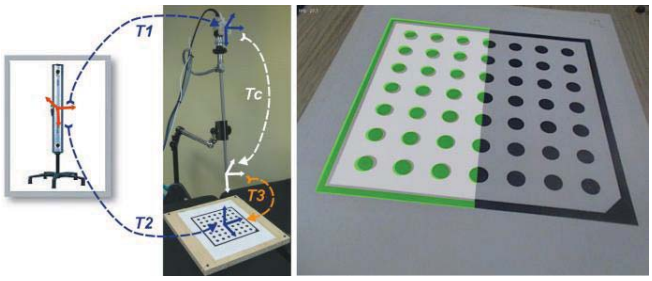

Figure 6: Camera localization and calibration process using an optical localizer and a sensor mounted on the camera body

The tracker offers in real time the transformation matrix T_1 relative to the sensor. The calibration matrix Tc, representing the relative transformation of the camera viewpoint with respect to the sensorized frame, necessary to determine position and orientation of the camera projection center O_C, can been computed using a sensorized calibration grid. During the calibration T_1 and T_2 are given by the localization system, while the transformation T_3 is determined using computer vision methods that allow to localize, in the camera reference frame, objects with known geometry (the sensorized calibration grid).

Another approach could be the localization using directly video frames acquired by the cameras as done in some applications. Several computer vision libraries (OpenCV or Halcon by MVTec) offers many tools for this purpose.

Using a single camera, we could localize objects with known geometry or texturing [11] as in the case of EasyOn by Seac02 *(www.seac02.it)*. The localization accuracy is enough for many applications, but requires knowing in advance the dimensions and the texture of a rigid object in the scene (or different objects rigidly linked together). Interesting monoscopic solutions have been applied using laparoscopic images: see-through systems applying on organs artificial markers [SOFT TISSUE], recovering the position of needle [29] and the pose of surgical instruments [5].

How to register the patient

In surgical applications, virtual objects, representing patient anatomies, are acquired in the reference frame of the radiological instrumentation just before or days before the surgical procedure, whereas the intra-operative information is related to the reference frame of the surgical room (generally defined by means of a tracking system) during the intervention.

In case of rigid objects like bones, a changing of reference frame, performed aligning fiducial points or fiducial surfaces, acquired on the radiology department and in the surgical room, can be enough [1; 3]. Deformations of the fiducial structure composed by elements, such as points of a cloud or points characterizing a surface, introduce systematic errors in the registration. In order to minimize the registration error, at least on fiducials elements, each fiducial point (or fiducial surface) in the proximity of steady element on the patient has to be chosen, and its configuration has to be as replicable as possible [19].

In case of soft tissue, further than the changing of reference frame, there are many deformation effects to avoid or to compensate, due to: changing of patient decubitus, changing in bed configuration, physiological movements (breathing, heart beating, gastrointestinal movements, etc…), constraints due to the radiological scanners (breath hold, arts positions, etc…).

To reduce these movement effects we can employ practical and useful artifices, used routinely by radiotherapists reproducing meticulously the patient settings during the treatment as in the planning room. By following their work, bed positioning and its shape, during the acquisition of medical datasets, can be chosen accordingly to the bed configuration used inside the surgical room for the specific intervention (considering the requirements of the used radiological device and the type of intervention to be performed). Furthermore during the intervention, the exact decubitus of the patient during radiological scanning requires to obtain the same relative position of the basin and the thoracic cage. A realignment of these structures needs immobilization devices and/or additional iterative work in the surgical room in order to find a perfect correspondence between pre-operative and intra-operative patient positioning [15].

The using of intra-operative imaging devices like 3D RA (Rotational Angiograph), which could be diffused in the early future, thanks to the decreasing of their price and the possibility to be portable (Ziehm Vision FD Vario 3D or Siemens ARCADIS Orbic 3D), allows to avoid the change of reference frame for each patient. These scanners, positioned in the operating room, can be easily and precisely calibrated with the localizer by means of sensors. Furthermore the acquisition of the anatomy directly on the

surgical bed allows to dramatically simplify the problem, by removing error due to the change of bed and patient decubitus. This simplification will allow to obtain high precision also on soft tissues. As proven by experimental results, the application of predictive models of organs motion due to breathing, driven by simple intra-operative parameters like the trajectory of a point on the patient skin or the time over the breathing cycle, can be applied in the real surgical scenario [14; 22].

ALTERNATIVE SOLUTIONS

Head mounted tracker-free stereoscopic video see-through

Depth perception can be drastically increased using head mounted stereoscopic devices [17], that allow to evaluate object depth dislocation, like in the natural binocular view. The use of localized head mounted displays (HMD), like the one shown in figure 1, allows to see a synthetic scene from a point of view aligned with the real user's point of view.

For the implementation of head mounted mixed reality systems, the video see-through approach, based on the acquisition of real images by means of external cameras, is preferable to the optic see-through approach that projects virtual information on semi transparent glasses. This is due to the fact that tracking of eye movements, strictly required for optical see-through approach, is very difficult to be performed with sufficient precision [16; 18]. On the contrary, head tracking, required for video see-through approach, can be performed with high precision using external localizer based on different technologies [2; 12], like described before.

We implemented a head mounted stereoscopic video see-through system, that does not require the use of an external localizer to track head movements [8]. Our system implements mixed-reality aligning in real-time virtual and real scene just using geometric information extracted by segmenting coloured markers, attached on the patient's skin, directly from couples of camera images.

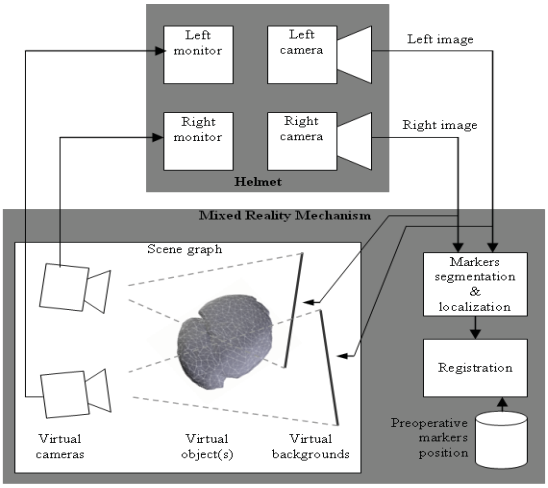

Figure 7: Schematic representation of our stereoscopic mixed-reality system

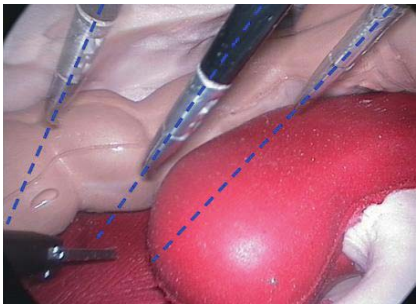

Figure 8: Image composed by 3 frames of a laparoscopic video with fixed camera and a moving instrument. The projections of instrument axes, represented with blue lines, are constrained to pass through a point representing the projection (on the image plane) of the insertion point (on the abdominal wall)

Figure 7 shows the functional scheme of our system, where video frames are used, not only as background of the virtual scene, but also to localize the cameras and to register the patient.

Epipolar geometry [13], using two or more cameras, allows to detect the 3D position of each conjugate points, identifiable in the images. In a stereoscopic configuration, knowing the internal camera parameters, for each marker position, in the image plane, the relative projection line in the 3D world, defined as the line l passing through the camera center of projection O_c and lying on the point P_c, is determined. These steps, performed both on left and right images, identify respectively two projection lines l_l and l_r. Knowing the relative pose of the right camera to the left camera (expressed by a roto-traslation matrix determinable in a calibration phase), the 3D position of each marker is then defined as the intersection point between l_l and l_r. Since l_l and l_r do not intersect (due to pixelization process and noise in marker identification) the 3D marker position is approximated with the position of the closest point to both projection lines. After fiducials localization a rigid registration is performed using a point based approach.

Results demonstrate that stereoscopic localization approach, adopted in our system, is enough for system usability.

Laparoscope auto localization

As described before, localization using monoscopic cameras can be done in case of objects with known geometry or texturing. In case of laparoscopic interventions the localization of the endoscopic camera can be determined using information offered by endoscopic video images without the introduction of any artificial add-on in the scenario[7].

The position and orientation of the endoscopic camera can be determined, with respect to a reference frame fixed to the access ports configuration, elaborating video images and knowing the distances between insertion points. During laparoscopic interventions, camera movements are minor respect to instruments movements. Therefore the laparoscope can be considerate steady in a time interval,

and a reference frame fixed on the camera can be used to perform measurements **[21; 28].**

The projections of instrument axis on the image plane (projection lines), which can be simply determined using HSV color space and Hough transform [27], are constrained to pass through the projection of the insertion point on the image plane [28] (figure 8).

Insertion point projection on the image plane can be calculated as the barycentre of the intersection of couples of projection lines, for each instrument. It allows (after camera calibration) to determine the direction of the insertion point in the camera reference frame (Fig. 9 Left). Therefore, versors $\boldsymbol{T_l}$ and $\boldsymbol{T_r}$, representing respectively the direction of the left and the right instrument insertion point, are determined. The versor $\boldsymbol{T_c}$, representing the direction of the camera insertion point, lies on the Z axis of the camera reference frame (using 0 degree optic).

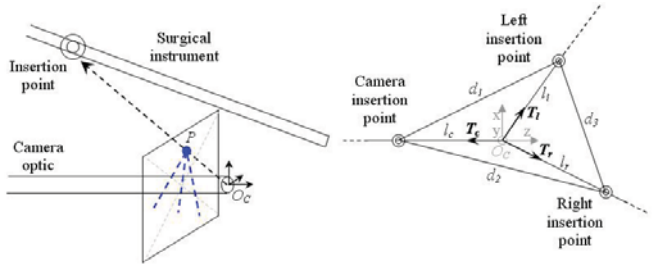

Figure 9: (Left) The projections of instrument axes (blue lines) allow to calculate the projection of the insertion point on the image plane P, which allows to determinate the direction of the insertion point in the camera reference frame fixed on OC. (Right) Geometric relations involved in the insertion points configuration that allow to localize the laparoscope

The geometrical relations between $\boldsymbol{T_l}$, $\boldsymbol{T_r}$, $\boldsymbol{T_c}$, and insertion points are shown on the right of figure 9. In the figure l_c, l_l and l_r represent distances of the insertion points from the camera origin, which have to be chosen in order to guaranty the distances between access ports d_1, d_2 and d_3. The tetrahedral configuration allows to determine univocally l_c, l_l and l_r and consequently, having $\boldsymbol{T_l}$, $\boldsymbol{T_r}$ and $\boldsymbol{T_c}$, to localize the access ports respect to the camera (and vice versa).

The localization accuracy depends on the instruments configuration and on their movements. The proposed solution allows to provide a cheap and tracker-free implementation for a class of computer assisted surgical systems that do not require extremely accurate localization. For example, offering 3D pre-operative model visualization with automatic point of view selection and remote assistance using virtual objects on the laparoscopic monitor.

CONCLUSIONS

The development of video see-through systems is useful and possible using various approaches.

In order to reduce misalignment errors, between real and virtual world, using commercial trackers, it would be necessary, in the future, the development of endoscopic cameras taking into account the previous considerations. Endoscopes should natively integrate sensors for their localization and manufactures should take into account the stability of the joint between optic and camera body.

On the other hand it is possible the development of tracker-free implementations elaborating camera images, allowing to reduce costs and logistic troubles related to the need of sensors and the tracker in the operating room.

The using of intra-operative imaging devices like 3D RA, which could be diffused in the early future, thanks to the decreasing of their price and the possibility to be portable, will allow to obtain high precision in see-through systems also in case of soft tissues.

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Survivable and Scalable Wireless Solution for E-health and E-emergency Applications

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ABSTRACT
Most conventional medical systems use fixed wired LAN, cable, and other land line systems to transmit medical data or operations. As wireless technology becomes increasingly pervasive, e-health professionals are considering wireless networks for their mobile medicine systems with the advent of e-health care, a wide range of technologies can now be applied to provide medical care products and services. Wireless Sensor Networks (WSNs) are composed by small devices that possess the ability to measure and to exchange a variety of vital data. In this paper we evaluate the performance of wireless sensor network technology for patient's remote monitoring. The system is mainly composed of static biomedical sensor nodes, which are mounted on the patient body in under to collect the main vital data such as temperature, ECG etc. The main characteristic of the networks such as the throughput and ratio delivery packet have been evaluated in this paper.

Keywords

E-health application, wireless body area sensor networks, IEEE 208.15.4

INTRODUCTION

The world is facing problems to provide high quality healthcare services at a reasonable cost to the citizens due to the increasing percentage of graying population.

As the population ages and the risk of chronic disease increases, the cost of healthcare will rise. The solution to decrease both the cost of healthcare services and also the load of medical practitioners requires a dramatic change in the way future healthcare services are provided [1]. The expected necessary changes are: moving from reactive to preventive medicine [2], [3].

By the summer of 2005, the initiative of marrying information technology to medicine seemed clear, and the media was heralding what some called "the e-health" revolution [4].

The employment of new technologies for medical healthcare could reduce the cost and improve the efficiency of treatment.

Wireless technology capabilities are growing at a fantastic rate. There appears to be no limit to what technology might accomplish, given infinite resources [5].

In this paper, we analyze a survivable and scalable wireless solution for E-health and E-emergency applications. We focus mainly of the performance of wireless body area sensor networks for remote monitoring application.

Using this architecture, patients, doctors, and nurses could be empowered to receive or provide real-time, distant health care services. Both patients and providers would have the freedom to be anywhere in the world while sending, receiving, checking, and examining medical data in a timely fashion.

At the health institutions, patients are monitored during treatment and recovery. This will be the monitoring of vital body functions such as ECG and blood pressure. Compared to wired solutions, the wireless transmission for monitoring provides several advantages [6].

The patient mobility will be improved, and that it will provide the opportunity for monitoring patients outside the health institutions. Patients' well-being and retention of health care has also influenced the recovery time. A transition to wireless systems will therefore help to improve patients' wellbeing and reduce recovery time.

In addition, we describe a global mobile system to provide unconfined e-health services, one that combines WLAN (Wireless Local Area Network) with wireless body sensor networks (WBANs), and the Internet or UMTS (Universal Mobile Telecommunications System, or GSM).

The reminder of the paper is organized as follows: section II gives an overview of a scalable wireless solution for e-health and e-emergency applications. In section III deals with system description. The performance evaluation of the

wireless body area sensor networks is given in section IV. Finally, we conclude the paper in section V.

SCALABLE WIRELESS SOLUTION FOR E-HEALTH AND E-EMERGENCY APPLICATIONS

The recent advances in wireless technology have led to the development of wireless body area sensor networks (WBASN), where a set of communicating devices are located around the human body [7].

The application and use of wireless devices and computer-based technologies in health care have undergone an evolutionary process. Advances in information, telecommunication, and network technologies have led to the emergence of a revolutionary new paradigm for health care that some refer to as e-health [8].

These systems use modern wireless communication and information technologies to provide clinical care to remote located individuals. With more research progresses in this field it will be possible to provide a better quality of life to patients while reducing healthcare costs.

Enabling underlying infrastructures such as wireless medical sensor devices, wearable medical systems integrating sensors on body's patient can offers pervasive solutions for continuous health status monitoring through biomedical, biochemical and physical measurements.

Remote monitoring systems typically collect these patient readings and then transmit them to a remote server for storage and later examination by healthcare professionals [2]-[3].

Once available on the server, the readings can be used in numerous ways by home health agencies, by clinicians, by physicians, and by informal care providers. However remote healthcare monitoring systems will be exploited to their full potential when the analysis is also performed automatically through clinical decision support systems fed by expert knowledge.

A clinical practice guide line constitutes the most suitable source of information for building such clinical decision support systems [3].

In this scalable wireless solution for E-health and E-emergency applications, we select several wireless communication standards with publicly available specifications, which are namely Bluetooth (IEEE802.15.1.), Wi-Fi (IEEE 802.11), WPAN (IEEE 802.15.4 / ZigBee) and wireless Mesh networks (IEEE 802.11s).

While comparing all wireless technologies, we had to choose relevant criteria for an evaluation. The main criteria that should be considered in this architecture were robustness, range, energy consumption, availability, usability and security.

This system interfaces to healthcare providers, doctors, care-givers and the medical call centers (see Fig. 1) and also is integrated with a mobile platform for the occupant to remote control his home and another mobile platform for the doctors and nurses to view the state of their patients.

Typically they will receive an alarm in case of a health problem of their patients. This figure shows that the system is integrated with vital sign monitoring devices and sensors.

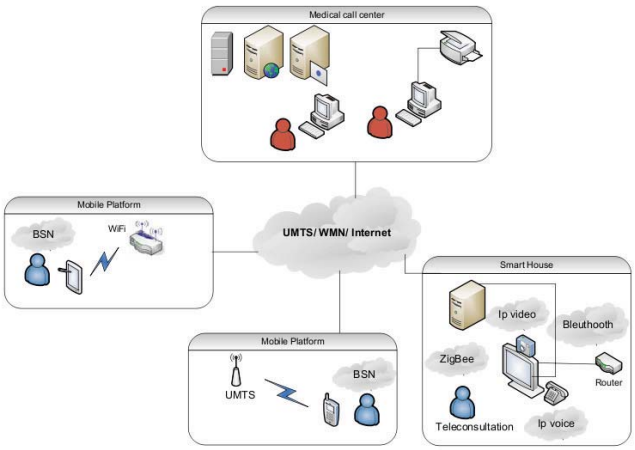

Figure 1: Survivable and scalable wireless solution for E-health and E-emergency applications

WIRELESS BODY AREA SENSOR NETWORKS

In general, wireless body area sensor networks (WBASNs) are wireless networks that support the use of biomedical sensors and are characterized by its (1) very low transmit power to coexist with other medical equipments and provide efficient energy consumption, (2) high data rate to allow applications with high QoS (Quality-of-Service) constraints, (3) low cost, low complexity and miniature size to allow real feasibility [9].

BSN, unlike wired monitoring systems, provide long term and continuous monitoring of patients under their natural physiological states even when they move. The system allows unobtrusive ubiquitous monitoring and can generate early warnings if received signals deviate from predefined personalized ranges.

Figure 2 illustrates the architecture of body sensor network. One patient is equipped with several sensors monitoring different parameters. A WBASN is made up of one or more body area networks and a base station. When the information has been gathered in the sensor network it is forwarded to this base station.

The information is then received at a relay station and passed on through a backbone network. In the end, the information can be viewed at terminals or monitoring stations that are connected to the network. This system has the potential of making remote monitoring and immediate diagnostics a reality [10], [11], [12].

Sensors are heterogeneous, and all integrate into the human body. The number and the type of biosensors vary from one patient to another depending on the state of the patient. The

most common types of biosensors are EEG "Electroencephalography" to measure the electrical activity produced by the brain, ECG "Electrocardiogram" to record the electrical activity of the heart over time, EMG "Electromyography" to evaluate physiologic properties of muscles, Blood pressure, heart rate, glucose monitor, SpO2 "Oxymeter" to measure of oxygen saturation in blood, and to measure temperature of the body [13], [14].

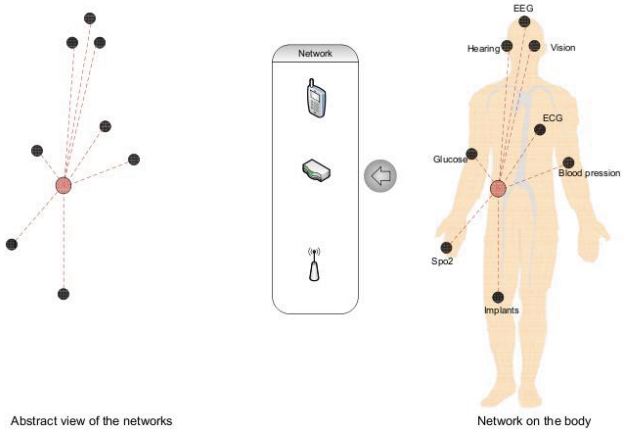

Figure 2: Wireless Body Area Sensor Network organization

As shown in the Table 1, according to the characteristics of physiological measurements or type of application services which can be real-time or non real-time with high or low rate.

Type of Service	Data rate	Latency	Class of Service
ECG	High	Low	Real-time high rate
EEG, EMG	Low	Low	Real-time low rate
Blood pressure, body temperature, heart rate, glucose monitoring	Low	High	Non real-time low rate
Medical image, X-ray, MRI	High	High	Non real-time high rate

Table 1: Service Classification of Physiological Measurements

SIMULATION AND RESULTS

We investigate on wireless body sensor network architecture for smart healthcare that possesses the following proprieties:

- Real-time and long-term remote monitoring;
- Tiny sensor with very low complexity;
- Can be integrated with existing medical practices and technology;

To meet these requirements, we have planned scenario where a patient has been equipped with an important biosensors nodes. Ns2 simulator with WPAN models is used [15].

We have considered a wide range of network topologies and test-validated the performance of WBASN with all considered topologies.

Due to the posed space limitation, we present our results for a static network. We set a 2 m x 2 m area to simulate patient body. We consider a static network configuration with six nodes and a gateway.

These nodes are mounted around his body (Fig. 2). Each node is implemented with one medical biosensor ECG, SpO2, body temperature, glucose monitoring, respiration and blood pressure.

All sensors, including sink node (gateway) are considered static (see fig 2). Transmit power of devices are configured based on the realistic radio map of sensor node around body network. In addition, the propagation model between nodes which are different from general indoor/outdoor models [16].

In the simulations, we evaluate system's the throughput, and latency of WBASN architecture.

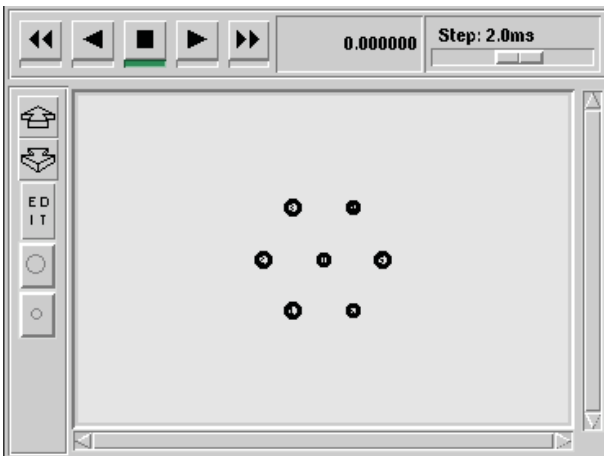

Figure 3: Deployment of WBASN using NS2

Throughput Analysis and packet delivery ratio

In order to analyze the drawbacks of CSMA/CA, we performed simulations of traditional IEEE 802.15.4 network. A beacon-enabled slotted CSMA/CA was chosen where beacons are sent by the PAN Coordinator and all nodes in the network synchronize with the beacon. A single-hop Star topology was considered.

The network performance was analyzed using two transmission scenarios; first where a single node sends data to the cluster head or PAN Coordinator, and, second, where 6 nodes send data to the PAN Coordinator. The traffic load was varied from 10 to 500 kbps. The highest throughput achieved when there is one source is around 160 kbps as shown in Figure 4.

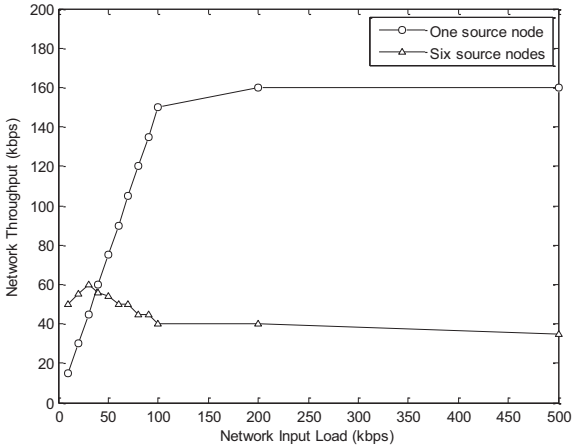

Figure 4: Throughput of the patient monitoring system

The packet delivery ratio also falls drastically with an increase in data rate as shown in Figure 5.

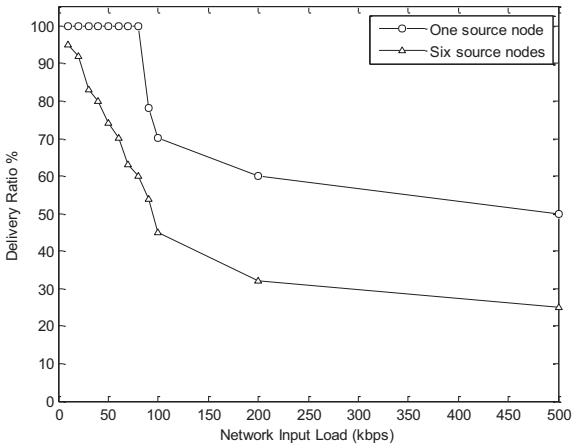

Figure 5: Packet delivery ratio of the patient monitoring system

CONCLUSION

The overall goal of this paper was to contribute and help through simulations towards dimensioning of the sensor networks for patient's remote monitoring. We examined the reliability for both the point-to point communication and multihop communication using IEEE 802.15.4 standard.

These performances are measured in term of throughput and packet error rate. The first results show that it is possible to use wireless body area sensor network to remote the vital data of the patient with reasonable throughput. In the future, more scenarios will be investigated.

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Care & Prepare – Usability Engineering for Mass Casualty Incidents

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ABSTRACT
Best possible pre-hospital treatment in the event of a mass casualty incident (MCI) is related to prioritizing rescue tasks and using rescue resources efficiently. Currently, information is almost always documented on paper-based forms and communicated by one-to-one talks, messengers, radio and mobile phone. Pervasive computer-based solutions are not established yet. Although the mere technological challenges are on the way of being solved within the near future, questions of usability remain. Concerning this matter, we propose an entangled User Centered System Design (UCSD) and Feature Driven Development (FDD) process and introduce the principle Care & Prepare. It is based on two fundamental assumptions. First, the whole design process has to care for the rescue personnel's' needs in these challenging situations and second, the rescue personnel has to be prepared for using these specialized computer applications in case of an MCI. Therefore, daily routine has to be the training foundation for these extraordinary operations.

Keywords
Mass Casualty Incident, Usability Engineering, User-Centered Design, Feature Driven Development

INTRODUCTION
Without regard to differences in national regulations and exact wordings, a mass casualty incident (MCI) can be defined as "an event, which generates more patients at one time than locally available resources can manage using routine procedures. It therefore requires exceptional emergency arrangements and additional or extraordinary assistance [30]. Due to the disproportions between casualties, rescue workers and material resources, dedicated tactics are necessary. Managerial structures and forms of organization must be adapted as circumstances demand [23]. Therefore, an MCI is very different from the sum of many individual emergencies. In order to ensure optimal pre-hospital medical treatment, patients and the severity of their injuries have to be the basis for all interaction.

Today paper-based forms, tables, patient records and plastic tags are used to gather and document required information (Figure 1). Depending on the specific system identification numbers or barcodes are used. These are supposed to ensure assignments of various documents to a single person. Communication, coordination and cooperation needs are met by a complex mix of face-to-face communication, radio calls, mobile phone talks and messengers.

Figure 1: Current documentation and information tools

Pervasive computer-based tools and systems are not established even in otherwise highly developed countries. Rather, most emergency medical services (EMS) still rely on paper to carry out daily job routine. Mobile solutions are introduced gradually. As an informal survey on the leading European professional fairs "RETTmobil 2010" and "Interschutz 2010" revealed, most stakeholders believe that it will take at least some months, if not years until a paperless workflow from patient to accounting is the rule rather than the exception.

A computer-based solution replacing and possibly extending the current paper-based systems has to be designed in due consideration of the following aspects:

- Its advantages will only be effective, if data can be entered and accessed efficiently and securely.

- Time consuming adaption and learning phases are not acceptable during an MCI. Any delay has to be avoided. The ability to use the system instantly in an effective and efficient way is of utmost importance.
- MCIs are rare events for a single EMS [1].

Disregarding these points can and most likely will result in faults and inefficiencies, which not only endanger general usability but can – in this field of application – as well cause a threat to the life or the physical conditions for the patients involved.

We pursue four objectives within this contribution. First we describe the state of the art of how EMSs are currently handling MCIs using classical means. Then we sketch how – mainly research projects – use advanced technology in order to improve the handling of MCIs. Third we present our approach Care & Prepare, where the focus is shifted from what can be done with modern technology to how technology can be applied to support the users in order to perform their demanding tasks. Finally we draft our specific development process that we use to ensure that our system will meet the demands of the users.

BACKGROUND AND RELATED WORK

Although first publications (e.g. [27]) pointed out advantages of computer-based solutions as opposed to paper-based ones almost 20 years ago, MCIs have not been high on the agenda of research and development departments. This changed rapidly after the terrorist attacks on September 11th 2001. As a consequence of these incidents and in preparation for upcoming major events, (e.g. the Soccer World Championship in Germany 2006) numerous research projects have been launched. Due to the various challenges associated with MCIs, they differ in scope and scale.

With a specific view to usability, two basic approaches can be distinguished:

- providing support of subtasks,
- providing pervasive solutions.

Supporting Subtasks

In the event of an MCI, paramedics and emergency physicians are confronted with several activities, which are not part of daily job routine. The 5-T-rule outlines the main task areas as follows [6]:

- tactics,
- triage,
- treatment,
- take care,
- transport.

Triage, as the process of determining a patient's priority of treatment based on objective criteria, is of particular importance. It can be called the single most import task except for basic life support [23]. It implies an order which is geared to saving as many lives as possible and utilizing resources efficiently.

Triage algorithms have been developed to ease the assessment of patients. Most of them (e.g. SALT, START, and CareFlight) are based on vital signs (e.g. respiratory rate) that can be determined without special utilities [10], [14]. In the end, patients are typically classified into one out of four or five categories.

Tactics, treatment and transport are often interrelated aspects of more extensive approaches. For that reason, our literature reviews showed no usability-related work which addresses one of these topics separately.

Taking care of people who are not seriously physically injured but affected by the incident is in the realm of interpersonal relationship. In order to handle, for example, missing person reports or contact witnesses later on, those persons have to be registered in the system as well.

Contrary to tactics, treatment, taking care and transport, triage has been addressed as a singular subtask by different projects and researchers. Jokela et al. presented an application system to simplify the process based on commercial mobile networks and regular mobile phones with integrated RFID technology [9]. Usability aspects had a lower priority. Inoue, Sonoda and Yasuura prototypically realized a triage system with RFID tags [8]. They measured times for input operations according to single text fields (e.g. name, sex and age) and compared performances with and without the application system. The TUMult-project concentrates on developing user interfaces for mobile devices to support rescue workers in performing triage [19]. They designed several concepts for keyboard and multi-tap input and proposed adaptive user interfaces [18], [20].

In addition, essential usability issues, e.g. combining electronic and paper-based approaches, related to MCIs were and are considered [17]. One of their findings is that "the introduction of RFID technology in MCIs leads to more challenges as […] expected" [16].

Addressing System Solutions

Besides designing and implementing extensive application systems, projects like WISTA, WIISARD, AID-N, SpeedUpor ALARM challenge several technical and organizational questions with reference to MCIs, e.g. how to deal with stampedes or how to define common quality standards and indexes [26], [29]. They are primarily focused on MCIs and widely disregard daily job routine of emergency medical services.

Chu and Ganz designed and prototypically implemented WISTA, a wireless telemedicine system for disaster patient care [3]. Instead of deploying proprietary hardware, they used off-the-shelf PDAs and based their two-layered system architecture on Bluetooth and 802.11g wireless connections. Main aim of the project was to demonstrate a budget-friendly solution in a testbed. In addition, simulation results proved the scalability of the system. Usability aspects had a lower priority.

The WIISARD project (2004-2008) addressed the issue whether medical care could be improved by means of wire-

less network technologies in the event of an MCI. Designed for the American Incident Command System (ICS) which differentiates three types of first responders, the final system consists of several hardware and software components [12]. Frontline workers who are responsible for triage und treatment on site are equipped with the WIISARD First Responder (WFR), a PDA with wireless network adapter and barcode scanner [11]. Mid-tier supervisors and team-leaders exchange clipboards and forms with tablet PCs [2]. The Command Center System, which is used by third-level first responders, is not explicitly connected to a certain type of hardware but features like maps or diagrams require a lager screen size than PDAs provide [4]. Furthermore, Intelligent Triage Tags (ITT) and different vital sensors are used to document and monitor patients' conditions [13].

Figure 2: WIISARD equipment [www.wiisard.org]

All components are interconnected by a mobile ad-hoc network. Special-purpose computers, so-called CalMesh nodes, provide a self-scaling network infrastructure and act as both wireless routers and access points [12]. Figure 2 gives an overview of the WIISARD hardware components.

WIISARD followed a classic participatory development process, which integrated first responders into the design teams. In addition, designers attended first responder exercises. Iterative refinements, based on experiences of five simulated MCIs, and a final evaluation study were accomplished.

The WIISARD system was evaluated according to the following key measures:

- decision and information quality,
- speed of patient processing,
- system scalability.

The results revealed potential advantages of a computer-supported mass casualty management system in comparison to paper-based solutions [12]. WIISARD was renamed to WIISARD-SAGE and is under ongoing development.

The Advanced Health and Disaster Aid Network (AID N) was following the same goals as WIISARD. Requirement analysis, technology development and evaluation framed the three main phases of this project. Development was organized as a "cyclical build-demonstrate-rebuild process" [28]. The overall system was tested in a simulated mass casualty event and evaluated with the aid of a questionnaire. The results indicate that EMS personnel, hospital administrators and other public health staff could improve their understanding of processes and conditions. Nevertheless, one main finding was that "technologies must be used every day, if they are to be successfully used in a critical situation" [28]. Furthermore, the principle of familiarity is introduced as follows: "Match the system with current practice: Integrate systems to in non-disruptive ways to promote use during routine ambulance runs" [5]. These statements indicate that the training for rare and extraordinary incidents has to be integrated in day-to-day operations.

THE CARE & PREPARE APPROACH

Designing and deploying a Mobile Data Gathering System (MDGS) for handling MCIs is a challenge for many reasons. The whole process from analyzing the working context and the needs of the users to premature test runs and field tests are ethically as well as legally very difficult.

Experiments under controlled laboratory conditions on the other hand have to be questioned as well because it is very hard to simulate the extraordinary circumstances of an MCI in all its facets. To meet these challenges we propose a new approach named "Care & Prepare" as a principle for designing and deploying support systems for handling MCIs.

A Definition of Care & Prepare

The two pillar structure of our approach is based on two basic principles:

- Care: An application for managing MCIs and its user interface in particular have to be designed in consideration of users' context (physical, mental, temporal). A system has to be tailored to meet the constraints of the human cognitive-perceptive system in these particular situational conditions.
- Prepare: The cornerstone of handling an MCI successfully is to be prepared. Highly trained routine behavior is formed in day-to-day practice of paramedics and emergency physicians. A system for handling MCIs therefore has to be a "natural" extension of MDGS for regular rescue und transport missions.

This principle is in line with Quarantelli's remark that the difference between an MCI and daily job routine "is one of kind rather than degree" [24]. While this is obviously true for medical treatment strategies and other aforementioned aspects, this statement is no indication for strictly divided application systems. Rather, this principle takes into account that MCIs are rare events in terms of a specific EMS and is based on the assessment that routine can only be derived from intense and regular application [7].

Guiding Principles: The Users Specific Situation

Drilling down the extraordinary circumstances of an MCI leads to a set of statements describing the users' (rescue personnel) situation:

- users have no or very limited experience in handling MCIs;
- users are under very high physical and mental load;
- users have to accomplish a large number of unusual tasks in parallel and under high time pressure;
- users have to act under, most likely, unique circumstances.

To keep these points in the focus of our process of designing and deploying, it is not sufficient to simply follow standardized system and user interface design principles as for example using the newest standard user interface style guide for the intended platform. Our review of related work (see above) shows clearly that the development of adequate and robust technology does not necessarily lead to a system that is usable in case of an MCI. However, some of the design flaws of existing systems could have already been overcome by applying standard usability engineering approaches.

To design an application system that is usable in case of an MCI, we propose an entangled approach of User-Centered System Design (UCSD) and Feature Driven Development (FDD) that is based on the Care & Prepare principle [21], [22].

To prepare users to be able to handle a system in case of an MCI, we propose that the MDGS provides training for MCIs within the regular day-to-day business. This should be accomplished by using similar support systems for handling MCIs and regular rescue and transport missions. Speaking in terms of software engineering, support for an MCI should be provided by an additional module of the same MDGS framework that is used for handling the regular day-to-day business.

As a result of different documentation and information requirements and also because of the extraordinary workload and time pressure, input masks and dialogs cannot be the same for handling MCIs and regular missions. Nevertheless, a consistent user interface can support action planning and execution. In terms of Norman's model, a familiar user interface shall minimize the gulf of execution [21]. Well-known feedback mechanisms, error messages and colors have a favorable effect on the gulf of evaluation. This will help to stabilize and deepen the users' mental models of the application system. This in turn is supposed to lead to more efficient and more effective usage patterns even in demanding situations.

Project and Development Process

As already mentioned, we follow an entangled approach that combines UCSD and FDD to keep the project and development process focused (Figure 3).

Classic elements of UCSD (e.g. user studies, interviews) will be complemented by:

- observing MCI exercises;
- accompanying paramedics and emergency physicians while they are using the MDGS in regular missions;
- evaluating the usability of the MDGS in regular missions;
- attending emergency medical aid and MCI-related workshops.

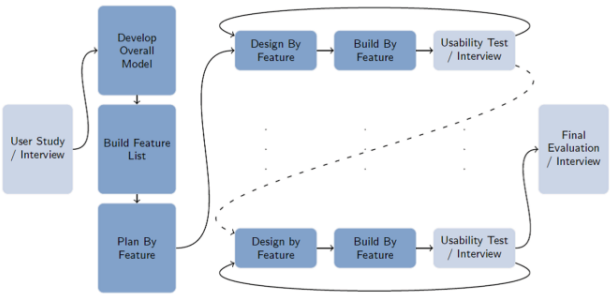

Figure 3: Process model combining FDD (dark blue) and UCSD (light blue) [25]

Combining these and scientific information, features can be derived. Natural dependencies between these "small, client-valued function[s]" [22] and a prioritization process will lead to a sorted list of feature sets. To work through the list, we use the iterative and incremental process of FDD. By using an entangled FDD/UCSD process as our software engineering paradigm, we are able to quickly roll out feature-sets, as well as keeping them close to the users' needs and expectations through repeated user-feedback.

In connection with our Care & Prepare principle, this approach allows usability tests for single features which may even be integrated in the MDGS for regular missions. Those are much less time and safety critical. Therefore, design flaws could be revealed without threatening patients. Finally, the overall system will be evaluated according to standard UCSD standards.

To summarize: the Care & Prepare principle is incorporated in our FDD/UCSD process in various ways. UCSD activities based on small feature sets that are iteratively rolled out assure that the users' needs are early and repeatedly taken into account (Care). Being able to roll out feature sets as a module of a general MDGS framework allows to test and even train them in the regular day-to-day business – even before the whole MDGS to handle MCIs is completely developed (Prepare).

General Principles for MDGSs

Figure 4 gives an overview of our proposed MDGS. The overall design is based on the assumption that an MDGS that follows the C&P principle has to be technically feasible and suitable for handling day-to-day rescue and transport missions as well as MCIs.

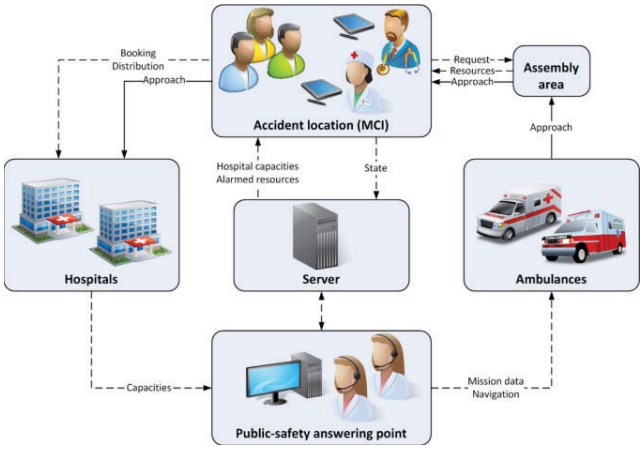

Figure 4: Handling of MCIs as an integrated part of general MDGS

The basic features as shown in the figure are:

- All rescue workers (paramedics, emergency physicians, team leader, and incident commander) are using the same handheld device, most likely a rugged tablet PC.
- All stakeholders (public-safety answering point, crisis squad, hospital staff, and rescue teams) are kept in the loop. They are aware of all necessary information. The users are guided by dialogues that are simple enough to be still useful even in very demanding situations.
- The location of every patient and rescue worker is made available by location-based services for the stakeholders in command.
- Ambulance crews are informed on their way to the area of operation as well as while waiting at the ambulance assembly area. Supplying this information to the rescue workers can help to cope with anxieties and help to prepare them for the situations they will be confronted with [15].
- All relevant information is stored on central servers for ad-hoc as well as post-hoc analyses. This information can be very useful to implement organizational learning and gradually improving the whole man-machine-system over time.

At the moment our project is still in a first prototypical state. The goal is to integrate the system as a module into the R2-System, an end-to-end solution for regular transport and rescue missions, of the DIGITALYS GmbH. The most important single maxim in order to successfully deploy a system, which is functional, usable and acceptable, is to involve the users early, repeatedly and consistently during the development process. We achieve this by following an entangled approach that combines UCSD and FDD and involves the users, as well as (at least) computer scientists, psychologists and designers.

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Coordination in Perioperative Systems – A Tacit View

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ABSTRACT
Coordination of perioperative systems is a deeply collaborative process, distributed over time and space. The paper analyses coordination in a perioperative centre along the three temporal levels suggested in [1]: allocation, scheduling, and synchronization. In particular, the tension between schedules and actual demands in synchronization work is reflected by looking at example situations. It is shown how dedicated coordination workers try to find a balance between different co-existing values and goals of all stakeholders. Their abilities to analyze a situation, to negotiate problems and to react flexibly are needed in systems such as modern hospitals. It has to be taken into account in systems design.

Keywords
Collaborative and distributed healthcare, temporal coordination, invisible work, resilience.

FRAGMENTS...

{F1} "Perioperative systems design describes a rational approach to managing the convergent flow of patients from disparate physical and temporal starting points (frequently home), through the operating room (OR), and then to such a place and time (home or hospital bed) where future events pertaining to the patient have no further impact on OR operations. This process for an individual patient can be envisioned as a nested set of timelines: a coarse-grained timeline beginning with the decision to perform an operation and ending when the patient definitively leaves the postoperative experience, and a fine-grained timeline encompassing the immediate pre-, intra-, and postoperative course... Perioperative systems design can be conceptualized, studied, and optimized like any industrial process in which many materials, actors, and processes are brought together in a coordinated workflow to achieve a designed goal" [7].

{F2} According to the business manager of OR Soft Jänicke GmbH, business directors of big hospitals wish to consider the throughput at a hospital in a holistic way to aim for meeting lower length of stay during planning at least. This can be achieved if data are promptly recorded. The application of the "Patient Manager" makes it possible to achieve this goal. By using "Treatment Patterns", the system is able to plan even before the admission of the patient to the clinic. (Treatment patterns are simplified clinical paths reduced to the description of the medical service and needed resources). The Patient Manager allocates automatically beds and time slots for examinations and operations. The system automatically fills in a variety of forms. Algorithms guarantee the availability of time slots and the absence of conflicts (translated from [4]).

{F3} The mother of the first author told her that their neighbour, a 69-year old woman, had to undergo a surgery this winter. She packed her bag and went by taxi (paid by the health insurance) to the hospital in the other town. However, after the examinations for the operation the following day she was told to go home and then come back next morning. She was not prepared for this situation, had to call another taxi (and a third one next morning) and spent an uneasy night alone at home. When talking with the nurses about these new practices they told her about a man in a similar situation whose bus was too late. When he finally arrived at the hospital he was chilled to the bone and not ready for operation. It had to be rescheduled.

{F4} "Well-defined processes enhance mutual understanding of all parties involved in the perioperative care. When each person involved has a clear understanding of his responsibilities and duties, the process can run efficiently" [5].

{F5} "Operating rooms are regarded as the most costly hospital facilities. In this context several strategies have been proposed that optimize patient throughput by redesigning perioperative processes. The successful deployment of effective practices for continuous process improvements in operating rooms will require that operating room management sets targets and monitors improvements throughout all phases of process engineering. Simulation can be used to study the effects of process improvements through novel facilities, technologies and/or strategies" [2].

{F6} "According to Valgårda (1992), the arguments behind the evolution of the modern Danish hospital organisation have been based on the production factory as an equivalent analogy. Hence, a rationalistic approach to organisations – as evident in Weberian bureaucracies, Tayloristic management theories, and Fordist rationalization of the production of goods – has also been one of the most influential conceptualisation of organisations and

cooperation within hospitals. This rationalistic organisation of collaborative work emphasises that (i) there is a functional division of work, (ii) the responsibility for organising work should be shifted from workers to management, hence separating planning from implementing work, (iii) control of time becomes the key to control labour, by paying salaries in based on workhours, and (iv) work is production-oriented" [1].

{F7} "The presence or participation of a resident physician prolongs the duration of the surgery up to 70% increasing costs accordingly. Adequate resident training, possibly with the aid of a simulator and experienced assistance should be provided to the residents starting to operate more independently. Even small reductions in operative time can increase OR throughput...Teaching a resident seems to delay the anesthesiologist only by 2–3 min. Covering more than one room statistically causes a delay of 6 min" [5].

{F10} "Intra-organisational coordination requires planning, and sophisticated schedules become necessary to provide a degree of predictability. The operation schedule is clearly an indispensable mediator for temporal coordination at the surgical clinic. However, as pointed out by Zerubavel (1981), one of the most significant consequences of the invention of the schedule has been the consolidation of the element of routine in collaborative work, which is essential antithetical to spontaneity. In general, there is an inherent trade-off between the static quality of pre-set plans and schedules and the dynamic quality of ongoing collaboration" [1].

…of an Introduction

Hospitals are sensitive and well-studied working environments. The above fragments show that they are studied by people with different backgrounds, assumptions, methods and intentions. And of course, they are reflected by people in their everyday life (e.g. {F3}). This paper adds a report about an analysis of coordinating activities in a perioperative centre where different surgical departments share ten operating rooms. Perioperative systems, their underlying rationale and assumptions are explained in {F1}, {F2}, {F4} and {F5}. Their development is critically reflected in {F6} and {F8}. The case study shows how important it is in the current system that coordination workers are able to negotiate and solve problems and to react flexibly to unexpected or only vaguely expected situations. Improvements to the system will have to take into account these aspects.

THE CASE STUDY

The analysis was conducted as part of the Perikles project with two other partners to support "flexible work processes" in perioperative systems.

Objective and Research Approach

The goal of the analysis was to gain a deeper understanding of coordination in perioperative systems. On the one hand, such systems need a sophisticated scheduling of operations and examinations and are mainly measured in terms of operation room throughput. On the other hand, the personnel have to react flexibly to emergencies, complications during an operation or patients who are not ready for the operation. They may be confronted with staffing shortages[1] or a lack of resources. Last but not least, they may be confronted with a mismatch of organisational goals and their own values. We were particularly interested in how people who perform coordination work actually cope with these tensions. How do they use their skills to coordinate the work as smoothly as possible?

The analysis was based on an activity-oriented, tacit conception of work[2]. This view was not fully shared by all participants of the project but helped to counterbalance other interpretations of data. Just to give a small example, we could observe several "methods" the operation manager applied to track the situation in the first floor of the operation suite. For example, she explained: *"The first point in room 1 is finished now. I heard the anaesthetist talking".* She asked the storage male nurse to do her a favour and check whether room 4 is already dark (meaning here that the operation is almost finished). She was also aware of equipment and patients passing her open office. One interpretation was that this behaviour is error-prone and should be replaced by reliable tracking mechanisms automatically recording relevant points of time[3].

Our work was influenced by studies grounded in conceptual frameworks such as activity theory or distributed cognition, e.g. [1,6,10]. Data collection was conducted from spring 2009 to fall 2010. It involved participative observations (e.g. of the operation manager, the head nurses, the head anaesthetist, a storage male nurse), interviews at workplaces (e.g. anaesthesia consultation, central patient management of the general

[1] "In many countries shortage of anesthesiologists or anesthesia nurses restricts the availability of ORs." [6]

[2] In [9] an "organizational, explicit view" and an "activity-oriented, tacit view" on work are distinguished. While the first perspective conceptualizes work in terms of defined tasks, processes, and work flows to achieve business goals, a tacit perspective focuses on analyzing everyday work practices. Sachs shows general design implications from taking one or the other view. For example, people are rather considered as producing errors and deskilling is desirable in an explicit view. Social interaction is seen as nonproductive. In contrast, people are considered as able to discover and solve problems and skill development is desirable in a tacit view. Communities are seen as funds of knowledge and a system is flexible if people are skilled. Sachs argues that a balance of the two views is needed but rarely achieved in design activities.

[3] In [10], the interweaving of coordination and control in computer-based information systems and possible effects are discussed. "Resources for action should be separated from accounts of action" is recommended in [3]. However, operation management systems such the one in this study show an opposing trend.

surgery unit) and studies of documents[4]. Audio tapes were transcribed. Photographs were taken. Information artefacts such as schedules and allocation plans were collected. Visual materials were processed to remove any patient identifying information. Accumulated data were discussed and analysed in individual work and in group meetings.

ANALYSIS

Within this paper, we focus on some aspects of the analysis only. First, perioperative processes and the studied system are briefly described. Second, the distributed nature of coordination work is described along three temporal levels as suggested in [1]. Third, a glimpse of the work of the operation manager in the study is given by a reflection of situations where she used her skills and spontaneity to respond to actual demands during continuous temporal coordination. We argue that dedicated workers try to find a balance between different co-existing values and goals of all stakeholders. The paper closes with a discussion of how to support the flexibility of systems such as modern hospitals.

Description of the Analyzed System

In perioperative systems, the treatment of patients follows a scheme called *perioperative process*. A short explanation of this model is already given in fragment {F1}. Figure 1 shows typical 'patient movements' with a focus on the fine-grained timeline (see {F1}). The perioperative process in a hospital includes all clinical steps from admission of the patient on the ward, examinations and anaesthesia consultation through surgery (including premedication and anaesthesia care) to care and patient release from hospital.

However, the treatment of a single patient is seen through the lenses of the whole perioperative system which aims to reduce costs. The main goals are maximizing the use of operating rooms (OR) and reducing staff. Hence, most perioperative systems have OR-suites and so called nurse pools for a shared use by different surgical departments. In addition, single ORs consist of different areas for anaesthetic preparation, the actual surgery and emergence from anaesthesia to allow an overlapping of surgeries.

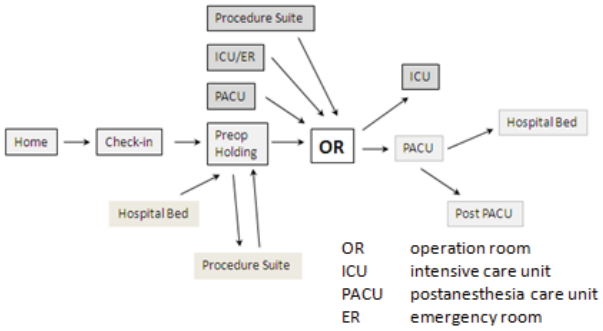

Figure 1. Perioperative movement of patients, in [7].

[4] Interviews were conducted in other hospitals as well. They are not subject of this paper but helped to understand the impact of the specific constraints on the overall perioperative system (e.g. physical constraints, permanent staff shortage and actual division of labour).

Figure 2 partly illustrates the specific situation in the analyzed perioperative centre which is part of clinical centre with different locations. The OR-suite consists of two floors with four and six ORs respectively. The physical layout of an OR and of the first floor is to be seen in the figure. The centre is at the main location of the clinical centre and accommodates many surgical departments, the radiology and the anaesthesiology department with two ICUs. The anaesthetists are in charge of five functional areas spread around the whole clinical centre. Bottlenecks in this system are shortages of nurses, anaesthetists and beds in the ICUs.

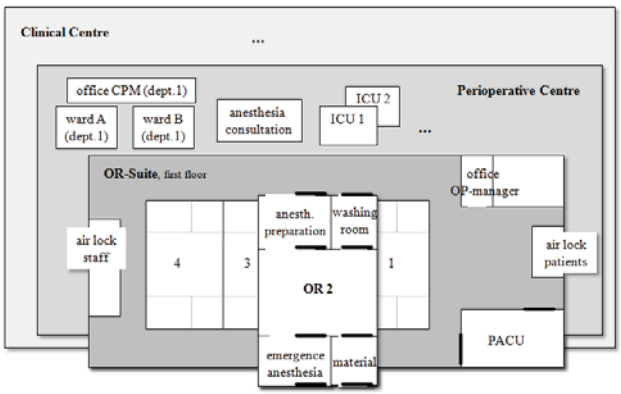

Figure 2. The perioperative centre – overview.

The coordination of the perioperative system is a deeply collaborative process, distributed over time and space. Some members of the staff are exclusively concerned with coordination tasks to ensure a proper treatment of all patients. Other people such as the head surgery nurse, the head anaesthetic nurse and the head anaesthetist in the OR-suite coordinate the work of their co-workers but are also involved in the actual surgeries.

At the time the participative observations were conducted, an operation manager (OP-manager) was responsible for the coordination of work in the OR-suite. She was directly responsible to the head of the clinical centre. For reasons of brevity, the description of coordination work is mainly restricted to the central patient management (CPM) of one department with two wards (called department 1, ward A and ward B), to the anaesthesia consultation (AC) and to the work of the OP-manager. This is indicated in Figure 2.

Distributed Coordination of Perioperative Processes

On the one hand, distributed collaborative coordination helps to consider multiple interests by gradually shaping future activities in a working system. On the other hand, coordination is an activity itself and participants develop activity rhythms which have to be coordinated as well. This also includes the development and appropriation of artefacts. In the example, all coordination work is constrained by the organisational goal to achieve a high throughput through the ORs. More specifically,

– Two nurses in the CPM are responsible for the inpatient planning of department 1. This includes appointments for necessary examinations and anaesthesia consultations, if possible prior admission at the ward.

– The nurse in the AC has to organize appointments with anaesthetists for the perioperative centre and other departments of the clinic to ensure that all patients had a consultation at least 24 hours before the operation.
– The OP-manager has to schedule operations for the next day and to synchronize actual activities in the OR-suite.

In the first case, the urgency of an operation is considered but also time constraints of doctors and patients. It is aimed for reduced costs of the wards and less waiting time for patients. In the second case, the safety of the patients during the surgery is in the focus of interest. The OP-manager has to consider, for example, the demands of all surgery departments but also has to act in the interests of the staff in the OR-suite[5].

We apply the approach taken in [1] and describe aspects of coordination along three macro-temporal levels of collaborative work: *synchronization* (continuous temporal coordination), s*cheduling* (planned temporal coordination), and a*llocation* (coordination temporal motives).

Scheduling

Figure 3 sketches some schedules with different time granularities and different level of detail as they are created and used by different stakeholders. They are indicated by encircled numbers.

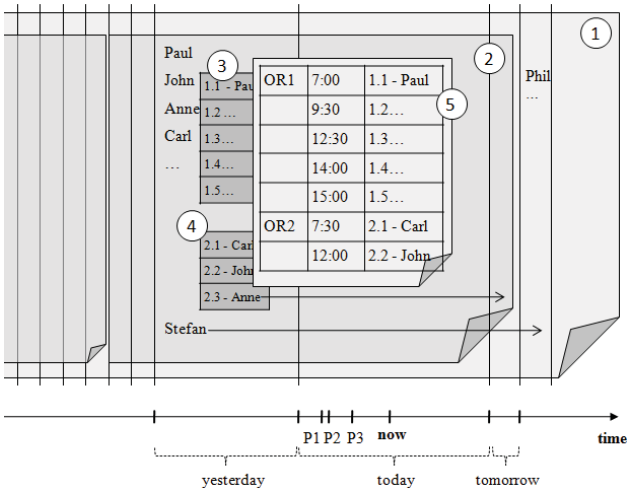

Figure 3. Different schedules in use: long-term schedules, weekly schedules, and days schedule of the OR-suite.

(1) is a long-term schedule maintained by the nurses in the CPM. It contains appointments for operations of department 1 planned up to several months in advance because this department has many elective patients. The nurses use a blackboard, their own software system, printouts and paper for scheduling. (Other departments use e.g. operation books as described in [1] and Excel for planning.)

(2) Every Friday, the CPM nurses send their operation schedule of next week to the OP-manager (by fax) and the weekly lists of admissions to the wards A and B. *"Always only for the next week...Something can change though. A new patient can come. Okay, the ward will tell her [the OP-manager] that. Or, a doctor realizes that he doesn't need to operate this patient. This is only a preview. She gets the real [plan] every day from the wards."* (nurse CPM)

(3),(4) The wards inform the OP-manager every day (officially until 11:00, often between 11:00 and 12:00 due to work overload) about their surgeries planned for the next day by registering them in the central management system (called CoMed here).

(5) The OP-manager uses CoMed to create the next day's schedule for OR-suite usage (day plan). A first and second version is given e.g. to the wards, the AC, labs (fax), head anaesthetist, head nurses, storage male nurses and cleaning service (printout). She pins a printout to the wall outside her office. *"There, the nurses already take a look and prepare themselves for tomorrow. And also the surgeons, when they have a break, take a look at tomorrow."*

Allocation

Allocations can be considered as long-term agreements on the usage of shared resources. They often have a rhythmic structure to support their internalization by collaborators. An example is the allocation plan of the OR-suite which has existed for many years. It says, for example, that trauma surgery can use OR1 on Mondays from 8 to 14, that OR3 and OR4 are always reserved for heart surgery, that OR6 is a "long table" every Thursday and so on. An exemplar of this plan hangs in the office of the OP-manager (Figure 4) but is internalized by her.

Allocation is important for constraining scheduling problems. Another example is reflected in the following explanation of a CPM nurse: *"Monday is visceral consultation, Dr. X cannot be in the OR then. Dr. Y is here in the consultation on Tuesday. He makes small surgeries, laparoscopic galls, hernia and so on, we cannot check in him on Tuesday..."* Due to their stability allocation plans can also cause permanent conflicts. For example, a mismatch between the OR allocation plan and the actual needs of a surgery department developed in the studied system because that department grew larger.

Figure 4. Artefacts of the OP-Manager. Top: CoMed system, preview of weekly schedule of a department (Excel), OR allocation plan. Bottom: paper calendar for prebookings (e.g. ICU beds), notes, "done".

[5] A big calendar sheet is pinned to the wall in her office quoting Laurence Sterne: "The art of drawing up a budget is to spread the disappointments evenly." (transl.)

Synchronisation

Synchronisation is fine-grained temporal coordination and is prepared by scheduling. For example, the nurse in the AC is waiting for the day plan at lunchtime (first version) in order to select at least those of the patients waiting for an anaesthesia consultation who will be operated the following day. "*That's why I always push a little bit. With her [OP-manager] it works very well. If she has a substitute, I have to push sometimes. OK, they are substitutes."*

In Figure 5, three "instances" of the day plan are shown which serve to coordinate the actual events in the OR-suite. On the left, part of the day plan is hanging in an OR. The printout was annotated and copied by anaesthetists during their afternoon meeting the other day to convey important information about patients to colleagues. The screenshot detail in the middle illustrates how the CoMed system helps to keep track of events. The staff members have to enter relevant points of time of each perioperative process (e.g. patient enters OR suite, patient in OR, surgeon arrived, begin blood arrest...).

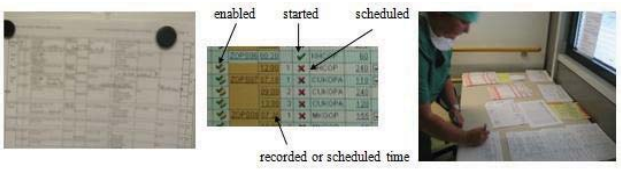

Figure 5. "Instances" of the day plan for synchronization.

The picture on the right shows the so called "table of anaesthetists" in the floor of the OR-suite with different forms and a printout of the day plan which is continuously annotated by the OP-manager to show the course of events.

A Glimpse of Continuous Temporal Coordination

Although the actual course of events in a perioperative system is shaped a great deal by schedules, there are often unexpected or only vaguely expected situations. Emergencies and complications during a surgery can happen anytime. As another example, schedules are known as being too optimistic very often [5]. Communication plays an important role for establishing relationships, shared understanding and commitment. This is needed to be able to respond adequately to the demands in this working environment. Two interleaved "small" situations which required flexible behaviour are described from the perspective of the OP-manager (in the following called OM).

Situation 1: Rescheduling of 3.3

Five surgeries were planned in OR3: point 3.1 at 7:00[6], point 3.2 at 9:30, 3.3 at 12:30, 3.4 at 14:00 and 3.5 at 15:00. All surgeries were planned by the department which permanently lacks of OR capacities. The second point started very late. OM was called at 12 o'clock by the surgeon of point 3.3 asking her whether they couldn't operate this patient in parallel in another OR.

- [12:20] OM calls the head nurse. She tells her that the point in OR4 is almost finished and asks whether they could move point 3.3 to OR4. *"I would call him [the patient] then. OK, let's say he will be in the room at three quarter to or even at one. Thanks. Bye."*
- OM calls a ward but the patient is at a different ward.
- OM calls and asks whether OR4 is now ready.
- OM calls the other ward and asks them to premedicate the patient and bring him to the OR-suite[7].
- OM goes to OR4 and informs them about the movement of 3.3 to OR4.
- Head nurse and OM are looking for a team for OR4.
- OM is back in her office and enters the movement of 3.3 into the CoMed system.

Situation 2: "Emergency heart"

OM sees in the morning that the heart surgery expects to operate an "emergency heart" today. She opens the weekly plan of the department to get more information about patient H who will come by helicopter. She looks for H in the CoMed system but can't find the patient. She knows from experience that there can be a spelling mistake in the name. She thinks that she will need an additional ICU bed.

- [9:30] OM talks with the head anaesthetist (HA) about "the heart" and that the arrival is not to be expected too soon.
- [10:30] OM calls ward W and ICU, but H is not there.
- [11:30] OM calls ward W, H hasn't arrived yet. But the nurses will call her back.
- [12:05] A doctor calls OM and tells her that he can hear the helicopter. OM tells him to bring H to the ward for preparation. OR5 will be ready soon.
- [12:30] OM calls ward W to be sure that H has arrived.
- [12:34] HA comes and asks OM whether H is at ward W or at the ICU.
- OM calls a doctor for the surgery of H.
- OM (still at the phone) and HA decide to premedicate H in the OR-suite and not send an anaesthetist to the ward in order to save time.
- OM explains to the doctor on the phone their decision to have him earlier in the OR suite.
- [12:39] OM calls the nurses in OR5 and prepares them for the next steps.

In the first situation, the OP-manager knows that the late point in OR3 will likely result in the cancellation of an operation. She also knows that this department generally needs more OR capacity. When the surgeon calls her she initiates the formation of an OR team. She knows that this means extra work for the nurses and helps them.

In the second situation, the OP-manager needs to coordinate an additional operation with a high priority. She has to keep track of the situation to prepare her colleagues. The doctor who informs her about the arrival of the helicopter is aware of her role in the overall process. The OM and HA decide to modify the premedication process in the interest of the patient and the nurses who otherwise will probably have to work overtime. They have to do it too often.

DISCUSSION

Flexibility by or despite Information Technology?

At the time of the analysis, a central management of patients and the coordination of perioperative processes were partly supported by the system CoMed. The nurses in

[6] A surgery in the OR-suite is also called point. 3.1 refers to the first surgery of the day in OR3, 3.2 to the second etc.

[7] Normally, the nurses would call the ward.

the CPM of department 1 and in the anaesthesia consultation were promised to get access to the system as well. The information system's infrastructure was heterogeneous. For example, anaesthetists had to enter some data multiple times into different information systems (additionally, handwritten documents are required in some cases). They had no direct access to archived data of patients. We often observed that people were wondering what of the information they have access to can be accessed by colleagues using CoMed in a different role. For each perioperative process relevant points in time had to be recorded, but were sometimes not promptly entered.

A more homogeneous information structure certainly improves the quality of the whole system. The operation manager may work more efficiently if CoMed would record some more relevant points of time. The nurses in the CPM and AC criticized that they did not get enough information about cancellations of operations. In a more matured management system, such information could "flow back" to them. However, flexible systems require a healthy co-development of skilled workers and new information technology (e.g. [8]). From our point of view, the interdependencies of distributed activity cycles concerning scheduling and synchronisation of perioperative processes have to be understood much deeper. What makes planning more robust? For example, scheduling includes negotiating and ensuring commitment of collaborators [1]. Too restricted synchronous communication for scheduling may affect continuous temporal coordination as well.

Smart scheduling also means to find an appropriate level of detail of plans. It does not make much sense in the analyzed system to plan with an exact number of free beds in the two ICUs. If necessary, some patients have to be moved to the PACU in order to have ICU beds available. And this is a matter of negotiating and problem solving. A revision of concepts such as "complete" or "precise information" which often guide the design of management systems (see e.g. {F2} in the introduction) may be useful.

Invisible Work?

The studied system was often described to us as "chaotic". Indeed, there is a high turnover among nurses and anaesthetists. In this paper, we could only touch on activities and attitudes of some of the coordination workers. Their dedicated work maybe often remains "invisible". The nurses in the CPM realized e.g. that doctors often do not have enough time to find out side diseases of patients. *"And then we ask here and hear stories! That we sometimes have to send the patient back to the doctor and the doctor thanks for that… you just have to talk with each other."* The situations described in the previous section reveal the ability of the OP-manager to respond spontaneously to actual demands and to make decisions in order to support colleagues and patients. The importance of this ability is pointed out in {F8} (introduction). We could also observe the OP-manager giving colleagues background information or preparing them for their next task. This awareness is only achievable by experience and deep reflection.

SUMMARY

Surgery environments are dynamic and high risk. "They require coordination across multiple groups whose incentives, cultures, and routines can conflict" [6]. Perioperative systems even increase the coordination effort and the potential for conflict. A system can be considered as flexible if it allows achieving multiple goals with varying priorities according to the actual context. The presented study analysed coordination work in a concrete perioperative system. The need for workers who are able to react flexibly and negotiate problems has been revealed. We think that a too strong focus on the improvement of information systems does not necessarily result in more flexible systems. This requires the co-development of skilled and dedicated workers and technology.

ACKNOWLEDGMENTS

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Design of Perceptualization Applications in Medicine

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ABSTRACT
We are in this position paper presenting the experiences we have from three medical application projects. A user centered design methodology have been applied in order to ground the design in requirements gathered from field studies of professional medical environments. Methods used have been interviews, user observations in the work context and cooperative evaluations of prototypes. With a particular focus on haptic (touch) feedback, we are exploring how novel medical applications can benefit from feedback to more senses than vision and how needs can be revealed and transformed into effective design.

Keywords
User centered design, perceptualization, haptics, medical applications

INTRODUCTION
In this position paper we will report on the application of User Centered Design as a valuable method when developing medical applications that aim at exploiting the benefits of perceptualization techniques, i.e. visualization extended to audio and haptic feedback. We propose that grounding medical software design in user requirement data gathered from field studies and prototype-based user studies are an effective and efficient way of improving complex medical procedures of today. This will be discussed based on the following three cases:

Case 1: Oral surgery simulator
Case 2: Liver surgery planning
Case 3: Heart simulation

The radiologist and researcher Ratib [23] argues that ”It is important to convey to device manufacturers that a wider adoption of multi modality imaging techniques such as PET/CT in clinical routine will be properly enhanced only if the technology has an effect on the whole process of patient management and not just on achieving higher diagnostic accuracy” and that “an important step in the process of patient management is the collegial discussion between interpreting and referring physicians, surgeons, and oncologists who review the images together to make an appropriate decision” [23]. We suggest that applying a User Centered Design method that also addresses aspects of collaborative work is very well suited to fill these needs.

BACKGROUND
We will here give a brief description of User-centered design and how we applied it, perceptualization theory and the field of surgical simulators.

Application of UCD in the medical domain
A method is qualified as a User Centered Design method as defined by ISO 13407 if the method includes four distinct design activities that form one development iteration [11]:

1. understand and specify the context of use
2. specify the user and organizational requirements
3. produce design solutions
4. evaluate design against requirement

The iterative nature of this process leads to gradual improvements of the product, as well as allowing for early changes of the direction of application development.

To understand and specify the context of use contextual inquiry [4] is used which involves field studies with observations of the intended users workplace and on-site interviews to elicit user needs. Much emphasis is put on understanding how the future users of the system carry out their tasks today, and the field studies are rather designed to get a broad description of the workspace than of obtaining detailed requirements. In an ethnographic study of multi-disciplinary medical team meetings, Kane et al. [13] show the importance of the radiologist and pathologist being able to point to specific areas in the medical information (radiology images and pathology samples), as it is an essential part when presenting their statements to the other participants in an inter-disciplinary meeting. This kind of information is fundamental to consider in a design process in order to develop a system with good validity. In our studies annotations are made of video recordings and audio recordings of interviews. The results of the analysis of the data gathered in field studies together with concurrent technical feasibility studies informs the requirements and design recommendations. These recommendations are in turn used as a basis for implementation of lo-fi or hi-fi prototypes. The primary evaluation methods used are cooperative evaluation and observations of groups of collaborating users. Cooperative

evaluation is a method where the user is given a task to solve with the prototype, and the user and the evaluator is allowed to discuss the interface during the session. The user is also encouraged to "think aloud" [20]. A rather new approach to "think aloud" is evaluating users that collaboratively solve tasks which allows the researcher to observe the complex and often more realistic use of a system [19]. The users discuss the task with each other while using the system and that result in a more natural kind of "think aloud" data that most probably does not add as much to the cognitive load of the users as traditional "think aloud". The analysis of the dialogue provides information about problems in the design of the system. This method also reveals how well the system supports social interaction.

Perceptualization

Perceptualization is an emerging research field that expands visualization to utilizing several senses such as hearing and touch. Just as the purpose of visualization is mainly insight, and not necessarily realism, the purpose of perceptual-ization is insight and to afford exploration of data in an effective and efficient way. The research presented here aims at exploring how advanced interaction devices can support medical professionals analytical work by providing feedback to more senses than vision.

One example is making it easier to analyse the images from ultrasound-based diagnostic medical imaging. Already today colours in Doppler echocardiography represent information such as the direction and velocity of blood flow. Researchers have however shown that temporally distributed events such as velocity and direction are easier to perceive kinesthetically (touch modality) than by vision and even better by hearing the information [15]. In a perceptual perspective colour coding is might not an optimal way of representing that kind of information.

The most spread use of haptic feedback systems in medical applications are simulators for training surgical procedures and robot assisted surgery [21]. Haptic sensing is defined as "The use of touch in combination with motor behaviours to identify objects" [2]. With a haptic feedback system it is possible to feel the shape, weight, texture, friction and stiffness of an object and for example collisions between objects. In collaborative virtual environments it is also possible for each user to feel the other's persons pulling and pushing forces on shared objects or the other persons cursor.

Our sense of touch and kinaesthetics is capable of supplying large amounts of intuitive information about the location, structure, stiffness and other material properties of objects. Providing feedback to more human senses in interfaces makes it possible for humans to access more of their brain capacity [15] or more popularly stated, it increases their cognitive bandwidth. It has been shown [5] that the integration of senses in multimodal environments is done implicitly in the perceptual system by statistically optimal integration. This means that the addition of touch is of increasing importance with decreasing quality of the visual impression. While some applications may see only marginal improvement in user performance and understanding others may depend entirely on the successful integration of the haptic modality. Also, with the increasing size, detail and complexity of data presented in volume visualization environments it is of increasing interest to augment the visual impression with information obtained via other complementary sensory channels. Thus, the integration of haptics with volume visualization has potential to significantly increase the speed and accuracy of volumetric data exploration as well as improved interactivity.

It has also been shown that the design of the haptic feedback is of utmost importance. Choosing the wrong haptic representation of a feature in data may result in poor understanding or even misinterpretation of the features at hand [22]. This further stresses the importance of user centered design in the application development.

Surgical simulation

Simulation of surgical procedures is a popular and important application of perceptualization technology such as haptic feedback. The goal with a simulator is usually high realism that makes the person using it feel that it is a real patient or object she is handling. Meijden and Schijven [18] review a number of studies with VR-simulators and results indicate that haptic feedback is especially useful when it comes to achieving psychomotor skills. Haptic feedback has been implemented in applications for surgery simulation, bone drilling and virtual prototyping [3, 21].

Simulation-based training of laparascopic procedure has proved to improve the performance of novice surgeons as well as ensure they reach required skill level prior to practice in real operations [1, 17]. The conventional apprentice-based training of surgery is being challenged, since supervised practice in operating theaters are expensive and occupies teachers for long time. In 2009 United Kingdom implemented the European Working Time Directive to limit surgeons working hours to 48 per week. This have led to complaints by the president of Royal College of Surgeons who argue that trainees do not gain enough experince anymore [10].

In the field of medical simulation for training a distinction can be drawn between scenario mannequins and task trainers. The scenario mannequins often consist of a full scale human mannequin with some simulated behavior and it is often remotely controlled by a technician that can suddenly invoke a heart stop or something similar. The scenario is prepared in beforehand by the teacher and technician and the purpose is often to teach team skills in critical situations. The task trainers, on the other hand, often simulate a specific procedure or are designed to improve the student's fine motor skills. Many of the laparoscopy trainers are of this type. According to Johnson

[12] this type of simulators builds “on an understanding of medical practice as being made up of constellations of discrete skills that can be learned separately and out of context, and then put together in the examination or operating room to create a complete medical procedure”. That implicit knowledge or situation-based experience is important, is also argued by Giles when he states that the simulators (task trainers) only cover a small part of the surgical curriculum, even though he acknowledge their value and fit for purpose [10].

CASE 1: ORAL SURGERY SIMULATOR

The first case in this paper concerns a surgery simulator for teaching. The purpose of this project is to allow for dental students to practice surgical extraction of wisdom teeth in a risk-free virtual environment together with a supervising teacher.

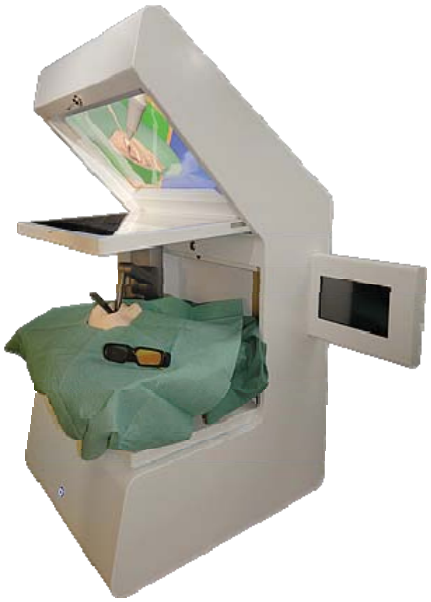

Figure 1 Oral surgery simulator

Design process

To form a mental model of what was possible to implement within reasonable time, a technical feasibility study was conducted in advance. Previous work, such as a temporal bone surgery simulator [3] shows that haptic feedback enabled virtual reality based simulations can well be used for training of bone drilling tasks. To find out what is the most important aspects of the procedure that is new to the students, a contextual inquiry method was applied that involved observations, interviews and experimentation. These studies revealed some of the tacit knowledge the surgeons depend on such as haptic perception of different tooth and bone material.

Application

The oral surgery simulator consists of a physical and visual model and provides haptic and audio feedback. The monitor is aligned in a way such that the user looks with stereoscopic shutter glasses through a mirror that makes the visual and virtual haptic model co-located and that allows the user to feel the model where she sees it (figure 1). In the image, a ray-cased based volume rendering of bone and teeth are projected within an artificial 3D face model. The purpose of the face model is to limit the view as is the case in real life. A physical head model (mannequin) is also used where the haptic device is located to limit the physical work space of the haptic device and to give the correct hand support. With the haptic feedback device, the user can feel the shape of the teeth and resistance and vibrations while drilling with differences depending on material such as bone, enamel and dentin. A segmentation map of the volume also keeps track of where the user should and should not drill, and which parts can be removed with the tools (drill and elevator). A state-machine progress the user through the procedure. These features are all designed based on data from field studies [7].

Results

The work has resulted in an open architecture and open source software, as well as a particular simulation model for training of surgical extraction of wisdom teeth. Results from cooperative evaluation sessions showed important design considerations such as shading and coloring of the teeth, physical hand support and positioning of dental instruments. Shading is an important clue for seeing texture and depth in the rendering [6].

In an independent course intervention study of the oral surgery simulator conducted by Karolinska Institutet in Huddinge, 73% of the 60 course participants very much agreed on that this simulator training should be a permanent part of the course [24].

Preliminary results from the latest evaluation suggest that the best benefit from the simulator is the opportunity for the teacher and student to discuss the procedure freely while performing it repeatedly. The simulator is used as a mediating artefact that makes it easier for the teacher and the students to contextualize theory, makes instructions more concrete and makes it possible to teach tacit knowledge like what forces to apply, drilling angles and depth etc.

CASE 2: LIVER SURGERY PLANNING

Our second case is a visualization tool for supporting decision-making. In the liver surgery planning project, the objective is to explore multi modal technologies for enhancing communication in medical multidisciplinary team meetings concerning patient specific liver surgery planning.

Design process

In these multidisciplinary team meetings, a patient case is introduced by a surgeon and discussed while a radiologist presents radiological diagnosis along with the patients' medical images as shown in figure 2 [9]. The images are mostly contrast-enhanced computed tomography (CT) but also magnetic resonance imaging (MRI) and ultrasound

images are displayed. Although they occasionally display pre-computed (non-interactive) 3D volume renderings, gray-scale 2D slices are the standard way of presenting.

Figure 2 Multi-disciplinary team meeting

An understanding of the context of use has been obtained by observation analysis of video recordings of real meetings. The radiologists use their standard workstation for this demonstration, but utilize scrolling and pointing with the mouse cursor to indicate regions of interest. The discussion is often related to the location and dimension of one or several tumors in relation to blood vessels and other organs. The surgical audience has to mentally reconstruct the region of interest in the 2D images to the 3D anatomy, which can be challenging. When the radiologist is absent, as when a surgeon is revisiting the case report before a surgery, the surgeon has to depend on their ability to perceptually link the verbal descriptions in the reports even though some markings in the images exist. For this reason, have our research group proposed an interactive radiology report system where verbal statements can be directly linked to image annotations [14].

Furthermore, our observations showed a need for improved visualization and for new ways for the audience to interact with the data to enhance communication between radiologists, surgeons and other specialists. In one case, a surgeon uttered "oh, is it that big?" referring to a tumor, half-way through the discussion, although the radiologist had shown images and attempt to state the size prior to the discussion. Gestures were also made in the air by the surgeons in the audience that indicates a need to point at specific parts of the patient images, to get the radiologist to show more of some specific data or zoom in on details or to show where the surgeon planned to cut in order to take out the tumor. These pointing behaviors were however very imprecise as the surgeons did not have access to any other means of interaction than gesturing with their hands.

Application

To allow for a richer visualization while leaving the radiologist with a familiar interface we developed a software solution that combined visualization of 2D slices of a Computed Tomography volume, with a stereographic visual and haptic rendering of iso-surfaces of the same volume (figure 3). With a haptic feedback device, the surgeon is able to feel the size and shape of a pre-segmented tumor, and distances to contrast-enhanced tissues. The two views are linked in such a way that the radiologist can scroll the stack of slices and point with the mouse cursor, which is shown simultaneous in the 3D view along with the position of the current slice. The position of the haptic device proxy is also displayed in the 3D view.

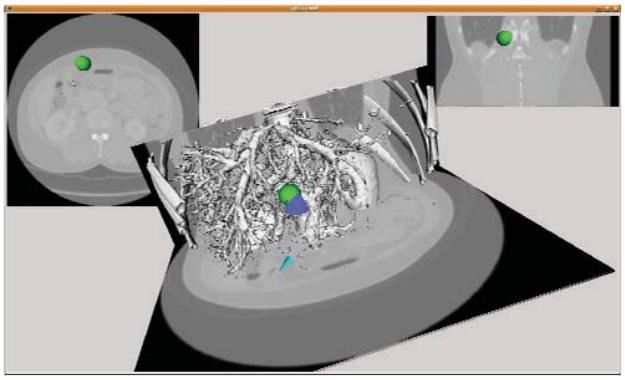

Figure 3 Collaborative surgical planning tool

The purpose of the haptic rendering in this case is not to simulate the feeling of performing surgery, but rather as an additional perceptual channel to explore the dataset. In the prototype, a binary classification based on the attenuation level in the images is used, and all voxels (after filtering) above a threshold are perceived as hard material.

To support several haptic feedback devices, a custom network haptic device proxy has been implemented, where each haptic device is controlled by a dedicated computer sending position and receiving calculated force over a local network with a measured ~800 Hz update rate.

Evaluations of the system with expert users are currently performed and it is too early to report on results from those. Suggested future work is to evaluate the concept in the natural setting, the medical multidisciplinary team meetings concerning patient specific liver surgery planning, as well as improving the feasibility of multiple haptic devices.

CASE 3: HEART SIMULATION

In the third project the added value is investigated of including multi modal feedback in a simulation of a human heart that is based on ultra sound data with the purpose to support experts that perform physiological examinations. In this recently started project the requirements are currently gathered for the design of a future simulation-based diagnostic tool for clinical physicians.

Design process

Based on a finite element method simulation of blood pressure and velocity inside a geometrical model of left ventricle of a human heart, derived from a arbitrary patient, the goal is to be able to predict heart dysfunction of a specific patient given certain attributes as input to the

simulation. Both the parameter input and the resulting simulation should be perceptualized to allow a trained physician to draw quantitative as well as qualitative conclusions regarding a patient's health .

It is too early to report on results from evaluations of the system. However, findings regarding the context of the clinical physician's workplace show conspicuous differences between dedicated machines and workstations. The ultrasound machines used (GE Vivid 7 Dimension) provides sonification of ultrasound data that might assist in detecting abnormal heart rhythms. The machine also provides an interface with physical knobs, sliders and buttons. However, for post-processing and analysis, the physicians use a conventional keyboard-mouse workstation, even if the software comes from the same vendor.

The interface differences motivate further investigation, especially regarding useful sonification and tangible interface properties. Interpretation of ultrasound data is a complex practice that involves both quantitative estimations and qualitative conclusion generation. We are currently exploring the technical feasibility of perceptualizing both visually and haptically the geometrical deformation of the simulation as well as simulated blood flow.

DISCUSSION

While all three of the presented cases in this paper are related to surgery and uses similar technology, only the oral surgery simulator is focused on training. In the heart project, the application data comes from a simulation but the application itself should not be considered a simulation since the data is pre-computed. It is important to distinguish between a data-altering simulation and a pre-computed simulation based perceptualization where the goal is to perceive the data that has been generated as a result from a simulation.

The simulator we have developed for training surgical extraction of wisdom teeth is primarily a skill trainer, but in our studies of how the teacher supervising students uses the simulator results indicate that the learning it supports depend a lot on the communication between the student and the teacher that is mediated by the simulator. This is in accordance with the theories of Johnson regarding what she calls reconstitution to "create medical practice out of simulator practice" [12]. That is, during the simulation the participants, a student and a teacher, help each other to mentally create a patient out of the simulated patient and to make a surgeon of the student including the embodied knowledge that is needed (the way the student is positioned etc). Johnson mentions a situation with a laparoscopy simulator where the teacher explains the relative position of the instruments by pointing to his own leg. The same job could be achieved by using a mannequin leg but that would be more expensive and the point is that the teacher's gestures were sufficient. Also known as suspension of disbelief, this is a requirement for users to accept the simulated artefact as real enough for the purpose, in this case learning a surgical procedure.

The transition of focus from the simulator working as a stand-alone surgical trainer to primarily being an artefact that mediates and enhances the discussion between the student and the teacher suggests the need for additional alternative design solutions. Future research will include functionality that specifically support the dialogue between the teacher and student such as non-realistic rendering of the tooth and jawbone. Future evaluations will focus on how knowledge gained from training on such simulation would transfer to skills performed in the operating room.

When the focus is on supporting communication the whole design process shifts towards designing for mediation of dialogue and then designing specific functionality for mediated communication becomes important. Making that focus shift is rather novel in the area of simulation and perceptualization but is inevitable when applying a user centered approach today as most systems are used by groups of people as well as by individuals.

CONCLUSIONS

We have demonstrated the potential of applying user centered design methods to design and engineering of medical applications that strive to exploit the benefits of perceptualization, with a particular focus on haptic feedback. By following the proposed method, engineers could arguably design innovative systems that have larger impact on real work. In a recent issue of Communications of the ACM, the future of haptic feedback is discussed with the underline "After more than 20 years of research and development, are haptic interfaces finally getting ready to enter the computing mainstream?" [25]. Several haptic scholars are interviewed and the speculation is that haptics might take the same path as touch screens, that has existed for a long time but suddenly - with the iPhone - took off as a mainstream technology. Professor Colgate states the requirements for such to happen: "The technology has to be sufficiently mature and robust, there has to be an active marketplace that creates competition and drives down costs, and it has to meet a real need." [25]. We hope this paper has contributed with examples of how a user centered design process can support system designers in finding the required real needs of the professional users in the medical domain.

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Virtual Reality Based Rehabilitation and Game Technology

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ABSTRACT
Virtual Reality technology is currently part of advanced physical rehabilitation therapy. However, several questions remain unanswered: Can this technology improve or even substitute the traditional methodologies? Can it really influence the nervous system or does moving within a virtual environment just motivate the individual to perform? In this paper we present the state of the art, the new advanced technology available and the most promising applications in this field. Finally we will introduce our research as a case study in the area.

Keywords
Rehabilitation, Therapy, Virtual Reality, Motor Disorders, Game Technology

INTRODUCTION TO VIRTUAL REHABILITATION

Following an authoritative description of traditional rehabilitation therapy of motor disorders [1] *it is by its nature repetitive, and repetition tends to "decouple" the mind, and reduce patient's motivation*. In other words: it is boring.

There are several universally accepted definitions of Virtual reality (VR). One of the most clear was provided in [2]: *VR is an immersive, interactive, 3-dimensional computer experience occurring in real time*.

Virtual reality has the ability to simulate real-life tasks [3] and comes together with several evident benefits for rehabilitation:

1) specificity and adaptability to each patient and disease;
2) repeatability;
3) ability to provide patient engagement;
4) tele-rehabilitation and remote data access;
5) capability for precise assessment;
6) safety.

VR offers the possibility to be precisely *adapted* to the patient's therapy and to be specific. VR environments can provide realistic training for the patient in different scenarios and phases of the rehabilitation.

Repetition is crucial for the re-learning of motor functions and for the training of the cortical activity. This task has to be connected with the sensorial feedback on every single exercise.

Patient *motivation* is fundamental because active cooperation of the patient is needed to achieve a more functional outcome of the therapy. Motivation can be improved by assigning a serious game format to the therapy. In this way the training activity becomes more attractive and interesting [4, 5].

Remote data access is a fundamental requirement, especially for rural patients, since they do not have to travel to urban clinics.

In addition, VR represents a precise tool for the *assessment* of the therapy during each session. The (tracked/saved) data can be used by the rehabilitation specialists for monitoring and managing the therapy [6].

By using VR in conjunction with Human Computer Interfaces (HCI) the training of daily life activities can be much improved in terms of time and quality. This approach permits a realistic and ergonomic training in a safe, interactive and immersive environment. In particular, VR provides the user with the possibility to perform tasks with a degree of safety which is normally not possible in the traditional rehabilitation. VR provides the rehabilitators with the possibility to influence qualitatively the training program, even in real-time. Another evident benefit is the patient's engagment which is a key factor in rehabilitation (especially for children).

Examples of interfaces able to interact with VR are mice, joysticks, haptic interfaces with force feedback and motion tracking systems.

Several researches have shown that, during VR rehabilitation, the movements are very similar to those used

in traditional therapy. Although they appear to be a bit slower and less accurate, [7, 8] show that they are anyway appropriate for rehabilitation. Finally, [9] have proven good results in executing the movements trained in VR in reality. In [10], [11], and [12] good results are shown in improving of motor skills for post-stroke rehabilitation of functional deficits in reaching, hand function and walking, respectively. A personal computer based desktop VR system was developed in [13] for rehabilitating hand function in stroke patients. The system uses a tracking system based on gloves to exercise four parameters of hand movement: range, speed, fractionation, and strength. Their results show that each patient showed improvement on most of the hand parameters over the course of the training and that some of the subjects have re-learned difficult functions of daily life like buttoning a shirt.

Some of the significant studies on the application of robotics and VR for rehabilitation purposes shall be introduced briefly. In [14], results were presented obtained from the comparison of a training with a robot-virtual reality system with a robot alone on the gait of individuals after stroke.

[15] presents a development of an advanced upper extremity prosthesis with the potential to restore full motor and sensory capability to upper extremity amputee patients. In addition, a GUI interface for patient training and therapeutic applications was developed during this research. The Rutgers Arm [16] is one of the first prototypes composed of a PC, a motion tracking system and a low-friction table for the upper extremity rehabilitation. The system has been tested on a chronic stroke subject and has shown improvements in arm motor control and shoulder range of motion (Fugl-Meyer [17] test scores). The same group has developed the Rutgers Ankle [18] for the lower extremity rehabilitation. It is a haptic/robotic platform, which works with six degrees of freedom, driving the patient's feet movements (Fig. 1, up). The tests of the Rutgers Ankle system have shown that the group of patients trained with the robotic device coupled with the VR demonstrated greater changes in velocity and distance than the group trained with the robot alone [19]. Most of the gait rehabilitation systems currently used for therapy are based both on treadmills and body weight support. The state-of-art in rehabilitation using virtual reality (VR) and robotics is provided by Lokomat® and Armeo® (from Hocoma) for the lower and the upper extremity, respectively (Fig. 1 down left and right).

These two systems are validated by the medical community and used in several rehabilitation centers [20]. Both are completed by an augmented feedback module which extends the conventional hardware with a computer and a large monitor with acoustic stereo feedback together with software for the interactive training tasks. This option provides various engaging virtual environments to motivate your patients, adjustable level of difficulty and intensity according to the cognitive abilities and the specific needs of each patient.

Low Cost VR based Rehabilitation using game technology

Recently there has been an explosion of new technologies: especially low cost gaming devices based on optical tracking systems, radio frequencies, infrared cameras, and haptics are accessible to almost everybody.

Considering the general trend to decrease the costs for the health systems all over the world one question comes up urgently: can low-cost gaming technology serve the needs of at least not severely injured patients with motor disorders?

In terms of costs and deployment logistics it is evident that a transition of the rehabilitation from traditional hospitals or clinics to home environments can be a winning challenge [21].

Many research groups have started the exploration of the use of such systems like Nintendo Wii® or more recently Kinect® as tools for rehabilitative therapy, including occupational and physical therapy.

An exploration of researches and low-cost programs is presented below.

An example of tele-rehabilitation can be found in [22], where a home-based tele-rehabilitation system based on low-cost haptic devices (game pad and joysticks) is described. The system focuses on a series of virtual reality therapeutic exercises for upper limb motor rehabilitation. It provides effective visualization and quantification of the patient's motions and associated pathologies. Therapists can access remotely the collected data.

Figure 1: Successful examples of applied technologies for rehabilitation. They are all based on robots/exoskeletons and VR. Upper left: Rutgers Ankle, lower left Armeo® and right Lokomat®.

Sony PlayStation2® was successfully used as low-cost VR system in home environment by [23] to improve sensory/motor recovery on an individual two years poststroke with residual sensorimotor deficits.

Sony PlayStation3® was used for tele-rehabilitation of children with hemiplegia togheter with 5DT 5 Ultra (five sensor) glove for the hand tracking, a computer, display, keyboard and a mouse [24].

The release of the Wii® Fit (software) and Wii Balance (platform) has stimulated new researches. The system eBavir is a low-cost balance virtual rehabilitation system based on the Wii® balance board.

[25] has presented a comparison of the feasibility, safety, and efficacy of virtual reality using the Nintendo Wii gaming system (VRWii) versus standard rehabilitation to evaluate arm motor improvement. They have shown that gaming technology represents a safe, feasible, and potentially effective alternative to facilitate rehabilitation therapy and promote motor recovery after stroke.

Another reference research group in the field is working about virtual rehabilitation using Kinect® [27]. In particular they are developing a high level library (the Flexible Action and Articulated Skeleton Toolkit) which can be used upon the open source library OpenNI [28] to produce virtual rehabilitation software.

Case Study: the HYPER project

We are currently working on providing a VR rehabilitation platform for the HYPER project [29]. This research involves different results in neurorobotics (NR) and motor neuroprosthetics (MNP), both for rehabilitation and functional compensation of motor disorders.

The project focuses its activities on new wearable NR-MNP systems that will combine biological and artificial structures in order to overcome the major limitations of the current rehabilitation solutions to Cerebrovascular Accident (CVA) and Spinal Cord Injury (SCI).

VR, an important part of the complex system, was initially based on radio frequency tracking technology. This solution offers good tracking performances but it suffers from the use of many cables.

Considering the patient's needs it is therefore not an optimal solution. Therefore we are now exploring a new wireless and inexpensive technology: Kinect®.

First results (see Fig. 2) are very promising and even if the accuracy of the tracking has to be measured exactly it seems that for this type of application the needs in terms of accuracy are not highly demanding. Additionally the tracking system appears to be robust enough to track the patient and the related robotic exoskeleton or neuroprosthetic devices on both upper and lower part of the body.

A limitation to be considered is that the Kinect® IR tracking suffers when the subject is illuminated strongly by the sun light. This is, however, a merely technological limitation which can be overridden.

Finally, a further part of our research concerns the conjunction between a Brain Computer Interface and virtual reality in order to create a good diagnostic and personalized environment in which it is possible to study the brain signals as answers to external (VR) stimuli or to assess the progress of the patient in the rehabilitation therapy.

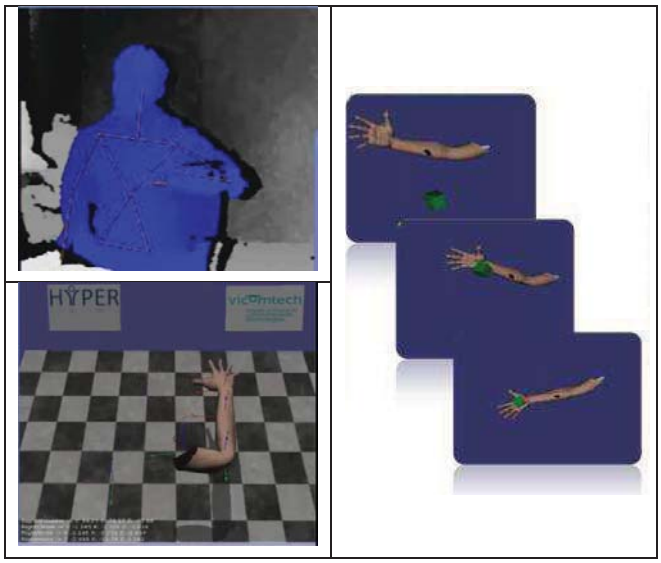

Figure 2: Snapshots of simple VR scenes: reaching, moving and grasping a virtual object. Kinect® is used for the tracking of the upper part of the patient body

CONCLUSIONS

This paper reviews the state of art, advantages and perspectives of Virtual Rehabilitation used in various forms of therapy. The recent introduction of new technology, originally developed for game purposes, provides a number of challenges and increases the possibilities of Virtual Rehabilitation to gain wide acceptance.

We have presented, as a case study, the first development status of an advanced system that combines VR based on game technology with a hybrid NR and MNP system for functional compensation of motor disorders.

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Towards Dependable Number Entry for Medical Devices

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ABSTRACT
Number entry is an ubiquitous task in medical devices, but is implemented in many different ways, from decimal keypads to seemingly simple up/down buttons. Operator manuals often do not give clear and complete explanations, and all approaches have subtle variations, with details varying from device to device. This paper explores the design issues, critiques designs, and shows that methods have advantages and disadvantages, particularly in terms of undetected error rates.

Author Keywords
Medical devices; modelling; formal methods; HCI; healthcare; number entry

Note. *This is a working paper that we will develop further through interactive workshop participation. We will engage additional authors as necessary for continued work to progress towards a high-quality journal paper fully covering the relationship of all relevant medical, manufacturing and computing factors. It is an important topic that we want to get right.*

1. INTRODUCTION

There are many applications where numbers have to be entered into computer systems, from setting alarm clocks to programming infusion pumps. In most applications the consequences of mistakes are limited, but in many cases—in particular with medical devices—they are potentially critical. Mistakes in entering numbers into infusion and syringe pumps could lead to incorrect doses being delivered, causing harm.

There are several inter-related properties of importance in a safety-critical number entry system: efficiency in entering numbers, the likelihood that errors are made and the efficiency of recovery from error [1]. In a hospital it is vital that nurses can use pumps efficiently as they are very busy and multitasking is the norm. Observational studies have suggested that nurses may frequently make minor mistakes in entering numbers, for example not following the 'golden path' that is the most efficient way of entering a particular number, but that these errors are caught and corrected. Thus it might be argued that number entry is not a particularly severe safety critical problem; however, efficiency remains an important concern in a busy ward. Therefore a device where such mistakes do not need to be constantly corrected or where the golden path is most often the one naturally followed would provide significant benefit, given the number of times such devices need to be set. Furthermore, work in resilience engineering suggests that single mistakes rarely lead to disasters. It is when a range of different causes combine. If a large number of trivial and normally unproblematic errors are being made then this increases the potential for other rarer causes to interact with them and lead to a critical incident—as in Reason's "swiss cheese model" [5].

If a patient is given an incorrect drug dose, perhaps ten times higher than intended, the patient may die or have some other adverse outcome. It is therefore crucial that number entry is dependable, that there are no design defects, no mismatches between user conceptual models and device behaviour, and that users can (so far as reasonably possible) detect and correct their errors. This paper shows that this problem is more intricate than might appear at first sight, that many medical devices and their operator manuals fall short, and that better solutions are possible.

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Our goal is to identify a set of properties that programmers of medical devices should implement—or if we cannot do that, to recommend a set of key properties to consider before implementation—to minimize error rates, specifically for number entry. It is not obvious how to do this, as it involves a variety of tradeoffs, and thus we propose a debate within the EICS4Med workshop to explore the issues. We bring to the debate prepared material and a variety of demonstration resources to explore ideas. In this paper we highlight the issues involved to promote that debate.

1.1 Typographic conventions

We render arrow keys pressed by users as: ◄ ► ▲ ▼. We represent number displays with a box around each visible digit, some of which might be empty. For example, | 2 | 0 | 9 | . | 4 | shows a six-digit display with two decimal places, showing the number 209.4, with the cursor in the tens column; if the display were reduced to only one decimal place, we'd write it as | 2 | 0 | 9 | . | 4 |

2. PRIOR WORK

There is much prior work on user interface design principles in general, such as Nielsen's Usability Engineering [4], but they are very vague for programmers. For example, undo (which Nielsen recommends) can be implemented in many ways.

Work on human computer interaction specifically linked to number entry is varied and little has been applied specifically in the medical domain.

For example, Hourizi and Johnson [2] consider a number entry error that resulted from a mode error, and which led to the crash of an A320 airliner with loss of life. They argue that this should not be seen as a perception or knowledge error, but rather as due to an inadequate communication protocol between pilot and autopilot; a variation on the design based on this hypothesis was found to eliminate the error in simple user tests.

Brumby et al. [1] investigated trade-offs between efficiency of entering mobile phone numbers vs avoiding errors in driving. Their analysis suggests that interleaving number entry at chunk boundaries efficiently trades the time given up to dialling with that of ensuring enough attention is paid to driving to avoid drifting.

It is well known that device design can encourage certain number entry errors in medicine. For example Zhang et al [7] report an incident where a nurse intending to program a pump at 130.1ml/h inadvertently programmed the pump at 1301ml/h — a rate 10 times larger than the intended rate. Unknown to the nurse, the decimal point on the interface of the pump only works for numbers up to 99.9.

Thimbleby and Cairns [6] show that out by 10 errors in number entry systems, like the one described above, can be halved with better interaction design focussing on error management.

Figure 1. Screenshot of interactive Alaris GP simulation

3. EXAMPLE DEVICES

We have investigated and simulated a number of medical devices in order to explore their behaviour and related HCI issues; in this section we introduce the two particular devices, both infusion pumps, whose number entry behaviour is both typical and interesting, and around which the rest of this paper is built.

The Alaris GP infusion pump (figure 1) exemplifies a number entry interface style found on a variety of syringe and infusion pumps: two pairs of buttons change the displayed value; one pair increases the value, the other decreases it. In each pair, one of the buttons causes a bigger change than the other. Each button can also be held down to increase the rate of change of the number on the screen.

The B.Braun Infusomat Space pump (figure 2) has three distinct number entry systems used for different tasks, all based around a set of ◄ ► ▲ ▼ buttons; it exhibits a number of interesting behaviours. It is a good example of the way in which number entry is widely perceived as unproblematic and trivial, while in fact harbouring potential for surprises and difficult. Its user manual has very little to say on the topic: "When editing parameters, switch digits/levels using ◄ ►. White background indicates current digit/level. Use ▲ or ▼ to change current setting." Elsewhere in the manual, the arrows are described as: "Arrow up and down: Scroll though menus, change setting of numbers from 0-9, answer Yes/No questions. Arrow left and right: Select data from a scale and switch between digits when numbers are entered. Open a function while pump is running or stopped with the left arrow key."

This description is inadequate; for example, it suggests

Figure 2. Screenshot of interactive B.Braun simulation

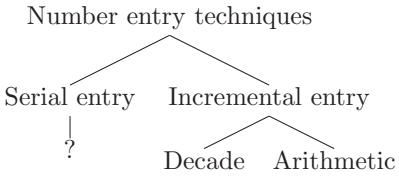

Figure 3. Number entry—basic classification

that if the display is _ _ 9 . _ _ (say) and ▲ is pressed, then the display will become _ _ 0 . _ _ In fact, it becomes _ 1 0 . _ _, i.e. an arithmetic operation was performed (9 + 1).

More concerningly, if the display is _ _ 1 0 . _ and ▼ is pressed, it becomes _ 0 0 0 . 1. The arithmetic operation performed in this case was 10 - 100 = -10, which result was then clamped to a minimum value, 0.1. It is easy to imagine scenarios in which this behaviour leads to an underdose, perhaps harmfully. The pump has similarly surprising and inconsistent behaviour around the maximum value. These issues are described further in the next section.

For a new user, the infusion pump is likely to behave unpredictably, though we do not know what implications this unpredictability has on safety in medical scenarios. The lack of symmetry between minimum and maximum behaviour might have an impact on usability, as do the arithmetic operations, particularly when subtracting a value which results in a number less than 0.

4. RESOURCES FOR DEBATE

In order to support debate around these issues, we will bring a range of resources to the workshop.

Simulations — We have implemented a variety of user interfaces for entering numbers, closely based on real infusion pumps, specifically those described above. These simulations allow detailed exploration of the properties of the devices' number entry systems, and comparisons between different designs—there are many possible variations to experiment with, as described in more detail in the next section. In particular, several variants of the B.Braun Infusomat Space VTBI number entry interface have been implemented.

Workshop annotation mechanism — We also introduce the concept of state annotation as a research tool to enhance collaborative critique of an interactive system. Members of this session will be able to add annotations to any states in the interactive simulations to identify or mark issues regarding the usability, safety or design of the system being evaluated. Annotations will be automatically saved with information about the current state of the system as well as the user interactions that led to that state starting from power up, and are automatically shared among all clients connected to the simulation.

Commercial simulations — We have some commercial simulations, intended for hospital training purposes, including for versions C and D of the B.Braun; our physical pump is version E. The simulation diverges from observed behaviour (at least) in that it does not clamp to a minimum value as described above, but rather to 0. This suggests that the defaulting minimum value is introduced in version E.

Physical devices and manuals — Finally we will bring some real physical devices together with their operator manuals for comparison with our and the commercial simulations.

5. A TAXONOMY FOR NUMBER ENTRY

In order to support discussion in the workshop, in this section we propose an initial 'taxonomy' of features and behaviours of number entry interfaces, particularly considering some of the behaviours described above. We hope that further debate will refine and augment this list. As we describe the taxonomy we make some observations and speculations about relevance to usability, simplicity of conceptual models, etc. but our main purpose in this paper is to ask questions and so promote discussion, not provide answers specifically — most of this space remains intellectually unexplored.

At the top level, we distinguish between serial and incremental entry. Serial entry involves entering the number as a string, usually via a numeric keypad; consider entering a number into a desktop calculator, for example. Conversely, incremental entry involves making a series of incremental changes to some displayed value in order to obtain the desired value — often but not necessarily on a digit-by-digit basis. As incremental entry can be implemented using just a few keys, typically ▲ ▼ ◄ ►, which may already be present for navigational purposes, it is a common style on the kinds of medical devices we are interested in. As such, and as it is used by each of our example devices, we concentrate on issues surrounding this style, though serial entry is still interesting and appropriate further exploration, are questions as to which style is preferable in general and in particular situations, and why.

Focusing on incremental number entry, we identify three major aspects of interest: basic behaviour (decade vs arithmetic, see figure 3); behaviour at minimum and maximum values (see figure 4); and digit visibility.

First we consider basic behaviour, which may be decade

or arithmetic style. In decade style, each digit is edited independently, and typically subject to wraparound at 0 and 9. For example, given a display of 1 9 2 . 4, if the user hits ▲, the new value is 1 0 2 . 4—the 9 increased by 1, modulo 10, wrapping round to 0, and all other digits are unaffected. In this style the number really must be dialled in one digit at a time.

In arithmetic style, user actions cause arithmetic modifications to the value displayed: add 1, subtract 10, etc. On the Alaris GP there are dedicated up/down buttons of differing magnitude; on the B.Braun ◄ and ► navigate between digits and ▲ and ▼ modify values. Repeating the previous example in arithmetic style leads to a display of 2 0 2 . 4 with the increment in the tens column being 'carried' to the hundreds. It is unclear if or when this would be preferable to users, though one can imagine that for fine adjustments around some value it is easier and would involve less ◄/► actions.

Either of these 'starting points' may be implemented using little code, and with very simple logic. (See our example simulations.) They each provide a clear conceptual model of the interface which users ought to be able to fathom completely with very little experimentation. Edge cases are often where problems arise; thus, what happens around the maximum and minimum values? There are a number of subtleties, not immediately obvious. First: what are the maximum and minimum values? Either might be a function of what we can fit in the display (which might change over time — see below), or some semantically-relevant value. The minimum could be the negative of the maximum, or (more often) zero, or something else. For VTBI entry on the B.Braun, the minimum is either 1 or 0.1 depending on digit visibility (see below), and can only be zeroed by an exact operation. Thus, for example, 0 1 . followed by ▼ leads to 0 0 . 1 ('minimum' value), whereas 1 . followed by ▼ leads to 0 . (true zero). This leads to some strange behaviour and a messy conceptual model, and we are presently unable to imagine any user-driven motivation for implementing this feature, though we note that 0 is not an allowed value for VTBI (the OK button doesn't work when the display is 0).

Assuming we know what the maximum and minimum ought to be, how should a device behave at those values? For the decade interface this issue can be ignored: the interface 'wraps round' naturally; one could in fact apply the following strategies in that context instead, but doing so breaks the conceptual model badly.

Arithmetic entry can also wrap round between min/max values, but now we are wrapping on the total value, not individual digits. Consider 0 0 0 on a display with boundaries at 0 and 9999, followed by ▼; this subtracts 100, taking us to 9 9 0 0. Then ▲ undoes this, adding 100 with wraparound, returning to

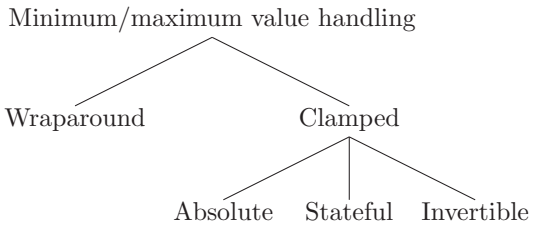

Figure 4. Number entry—boundary value handling

0 0 0. This retains a clean conceptual model, but with the danger of allowing large numbers to be easily entered accidentally: a single ▼ takes us from an initial (and safe) 0 to 9 9 9 9—though at least this is easy to undo.

More commonly, arithmetic interfaces restrict ('clamp') numbers to the boundaries. Here, we identify three approaches, which we call absolute clamping, stateful clamping, and invertible—see figure 4.

In *absolute clamping*, an attempt to move the value beyond a limit stops at the limit. E.g., 9 9 4 5 then ▲ leads to 9 9 9 9; similarly, 0 9 5 3 then ▼ leads to 0 0 0 0. This is a fairly natural behaviour, easy to program and conceptually clear once discovered; however, as it throws information away it could be annoying to users. In the face of annoyed users, a natural extension is *stateful clamping* where some state is introduced allowing accidental clamping operations to be undone. Here 9 9 4 5 then ▲ gives 9 9 9 9 but an immediate ▼ restores 9 9 4 5 (without state, we would get 9 8 9 9); anything other than ▼ throws away the state and disallows the undo. This is how VTBI entry on the B.Braun operates, for example.

In decade style ▲ and ▼ are inverses of each other, and it's always possible to undo the last change easily. This is lost with absolute clamping, even with state, e.g. 9 9 4 5 then ▲ ▲ ▼ ▼ gives 9 9 9 7 not 9 9 4 5. An extension which seeks to fix this without introducing wraparound is to make all successful operations *invertible*. Here, if an operation would take the value beyond its maximum or minimum, it doesn't happen, and this is indicated to the user via a beep (say). Now 9 9 4 5 then ▲ leaves the value unchanged, but the user is alerted that this is the case. The more general rule is: *any operation that does not have an inverse has no effect other than a warning such as a beep*; now the user knows, if they hear a beep, the normal inverse behaviour doesn't apply; otherwise, they know without looking that they can undo the last operation.

The third general area of interest we identify is that of digit visibility, around which there are several related issues. First, consider a decade-style system implemented in hardware — a physical device with one

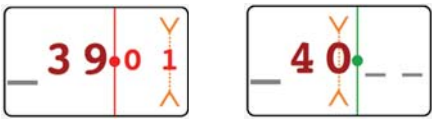

Figure 5. An improved number entry interface in action.

wheel per digit: spinning the wheel naturally wraps around modulo 10 (indeed, we obtain the name 'decade system' from such devices, which have one wheel per decade to be entered). On such a system, every digit is always visible, which can lead to confusion: for example it can be hard to distinguish 0 8 0 . 0 0 from 0 0 0 . 0 0. We are aware of two strategies for mitigating this: blanking leading/trailing zeros, and hiding digits entirely. The first strategy is obvious: only show significant digits. There are (at least) two questions to ask: what to display for blank (a space? an underscore?) and whether to 'follow the cursor' filling in zeros prospectively (e.g. do you display 0 0 1 or 1?); the cognitive implications of either choice remain uninvestigated. On some systems we also see use of a second strategy, where digits are shown/hidden depending on the magnitude of the value being entered, usually on grounds of semantic relevance. For example and in particular, for VTBI mL entry, the B.Braun hides the hundredths and then tenths digits if the hundreds and thousands digits (respectively) are non-blank (including while 'following the cursor' as described above.) Similarly, ten-thousands is only shown if tenths is hidden. This is semantically sensible, but slightly disorienting to the user as the display is always right-aligned, so sometimes one digit disappears, another disappears, and the whole thing shifts to the right. Related to this: is the decimal point visible if no fractional digits are filled in? Canada's Institute for Safe Medication Practices (ISMP) says it should not be — and also mandates reducing the size of fractional digits, to more clearly distinguish 5.0 from 50 (say); changing colour may also be a worthwhile tactic here [3]. On the B.Braun, the decimal point is visible while the tenths column is visible, whether it is empty or not.

We've identified a large design space for the apparently simple question of incremental number entry; the task remains to identify the trade-offs each of these choices involves, and how they affect the conceptual mappings users build between their actions and their effects.

6. A SAMPLE BETTER INTERFACE?

Figure 5 shows a working mock-up of a potentially better user interface, to be operated by ◄ ► ▲ ▼ keys as on the B.Braun. It has several interesting features:

- The cursor (shown on the right-most digit position) and the decimal point are highly salient.
- Digits to the right of the decimal point are highlighted and smaller. The decimal point remains but is dimmed when the decimal digits are zero.
- Following good practice, leading and trailing zeroes are suppressed (shown as _). However, they behave *exactly* like 0 in how they are controlled by ▲ ▼.
- The number has upper and lower bounds (for the 5-digit example shown below, the bounds must be within 0 to 999.99).
- There is no hidden state. The behaviour of the interface is predictable from the display alone.
- Sometimes keys cannot work: as shown the ► cannot move the cursor further right; or if the display showed 9 9 9 . 9 9 no digit could be incremented; and so on. Whenever a key is pressed that cannot do anything, the interface beeps and otherwise does nothing. (Thus adding 1 to 999.00 does not increase it to the maximum value 999.99.)
- **Always**, a key beeps or its effect can be cancelled by pressing the opposite key: thus always ◄ ► and the other 3 pairs do nothing unless the first key pressed causes a beep, in which case the second key behaves normally.
- The rule above can be followed with the arithmetic style of interaction or with decade style. We prefer the arithmetic style, since after pressing ▲ or ▼ the number is *always* changed by $\pm 10^n$ or 0 if the key beeps. With the decade style, there can be a beep (if the number would hit a limit) or the number may change either by $\pm 10^n$ (most often) or at most $\pm 9{\times}10^n$ (about 1 in 10 times); this behaviour is much less predictable.
- Hence, ▲ ▼ work on arithmetic; that is, they always add $\pm 10^n$ to the displayed number (n depending solely on the cursor position), or they beep (and otherwise do nothing) if $\pm 10^n$ would have resulted in overflow.
- The design generalises readily, for instance to times by using different bases for each digit (i.e., base 10, 10, 6, 10 respectively, with an upper bound of 2359).
- If the application requires a movable decimal point, then ► pressed when the cursor is in the right-most column *and* the left-most digit is _ then the decimal point will move left (and conversely for ◄). This behaviour ensures no significant figures are ever lost and that the decimal point is always shown within the display. Again, the precision is limited by bounds and if the decimal point cannot move, then the key beeps.

Starting with the example on the left in figure 5: pressing ► (beeps and otherwise does nothing) then ▼ ◄ ◄ ▲ obtains the view on the left in figure 5. Notice number carry, moved cursor and changed decimal point style.

7. DISCUSSION AND FUTURE WORK

Our aim here is to start debate and exploration of these issues; future work is to continue that systematically. Here we identify some key challenges and opportunities.

A problem with work of this sort is that seemingly sensible design properties have unexpected impacts on how users behave. Therefore the workshop must help identify issues for empirically-based research. Consider, for example, the 'undo' design heuristic recommended by Nielsen [4]. How might we arrive at a more detailed set of properties for programmers of medical devices? Let us suppose we start by asking the following two research questions: 1) Is the 'undo' heuristic a significant affector for both serial and incremental number entry in terms of error rates? 2) Are error rates on systems in the same 'class' effected in similar ways by the level of undo offered? Formally-guided experimental investigation could help answer these questions. To avoid empirical experimentation on every possible variant of number entry, we might identify a set of distinct 'centroid-cases' (specific variants representative of some 'cluster' of similar variants), by preliminary exploration via a formal model of human-device interaction; this process could also produce a suitable feature-set for classifying different kinds of number entry system, formalising and completing the taxonomy suggested above. The results from experimental investigation following the formal modelling step would give a more precise description of the trends seen for these determining features of keypads with respect to 'undo' and error-rate.

The question of how users' mental models of number entry systems develop and relate to the developers' models and the code they write, is of particular interest. We propose that users of medical devices largely develop their mental models of device behaviour through interaction with the devices themselves, and by existing conventions; how can devices be designed to optimise this learning process, guiding users to the 'golden path'?

This paper has mainly described incremental interfaces; serial entry of course also needs to be explored. The related task of time entry is also critical and worthy of attention. For example, in the B.Braun most of the interface principles of the VTBI and Rate number entry interface are found in the time entry interface: pre-set maximums and minimums, jumping to the minimum if the edited number is less than the minimum, for example. Interestingly, if the VTBI is set to 99999 and we try to set the time, when we press ▲ on any position the time jumps up to 83:20; we remain unable to explain this behaviour.

8. CONCLUSIONS

Interactive number entry is deceptively complex, and particularly for dependable applications — medicine and healthcare — must be done well on the basis of a thorough analysis of requirements. This paper has therefore explored the related design issues and principles, and through case studies and analysis, developed potentially more dependable approaches. Ideally after appropriate empirical testing (particularly in real environments) and iterative design, this work will lead to a definitive approach for dependable number entry.

9. ACKNOWLEDGMENTS

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Comparing Actual Practice and User Manuals: A Case Study Based on Programmable Infusion Pumps

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ABSTRACT

We report on a case study investigating current practice in the use of a programmable infusion pump. We start by formalising an existing description of the procedure followed by nurses for setting up a commercial infusion pump obtained via observation and interview. We then compare and contrast this procedure with a formal description of the sequence of actions reported in the pump's user manual. Mismatches were validated by a training manager. The aim of this comparison is to point out how minor mismatches between the two descriptions can be used to reveal major safety issues. Our contributions are: first, we analyse a real-world system and show the importance of having a clear and consistent specification of the procedures; second, we show how a graph-based notation can be conveniently used as the basis for building non-ambiguous and intuitive specifications in higher-order logic. We argue that this can provide support to an investigator when building a description of actual practice in that it can help focus attention on areas to observe more closely and on questions to ask to understand why procedures, as followed, are the way they are.

Keywords

Medical devices; Formal methods.

1. INTRODUCTION AND MOTIVATION

The use of medical devices such as infusion pumps is safety-critical and therefore it is vital that safe procedures are followed. Manufacturers set out such procedures in the manuals. However, with any complex technology there is often a mismatch between the prescribed usage and the actual behaviour of people using it. Such behaviour is not necessarily unsafe or even wrong. It can occur due to differences in context from the expected, or workarounds to improve efficiency for example.

Manuals can be used as one of the approaches for designers to express their conceptual model. Furthermore, manuals can be one of the approaches used by designers to communicate their conceptual model of the system to users. However, when device users are developing their mental models of the same system, the manual only fills part of the picture. The procedure recommended by the designer is first interpreted by the training staff, before it reaches the nurses. The nurses then construct their mental models of how the system should work through training and interaction before using it in practice. In both stages, the model is influenced by other factors, such as existing conventions used to program other devices, personal preferences and sometimes the capability of interpreting technical terms.

However, if there is such a mismatch between what nurses are *trained to do*, what the manual says or what happens in reality, then this mismatch might be dangerous. It could be for example, that those who developed the workarounds were not aware of the reasons for the prescribed procedure and so are omitting safety checks [6]. It is therefore important to have a clear, rigorous and consistent way to analyse the procedures prescribed in training, those in manuals and actual practice in fine detail. This would allow us to better understand these procedures and so detect potentially dangerous mismatches to ensure that we do not facilitate the widespread acceptance of these potential "latent errors".

We use a graph-based notation for building an abstract description of current practice and user manuals, and we translate such a description into higher-order logic for generating a non-ambiguous specification suitable to be analysed in automated reasoning tools, such as PVS [7] or SAL [2]. In order to trial our ideas, here we consider a case study on programmable infusion pumps: we show how actual practice and user manuals can be specified in higher-order logic,

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Figure 1: B.Braun Infusomat Space

and we present the insights we gained on the design of procedures by analysing such a formal specification.

The paper is organised as follows. In Section 2, we report on related work on formal methods applied to the analysis of procedures and user manuals. In Section 3, we overview the procedure followed by nurses for setting up an infusion pump. In Section 4, we describe how we translated informal descriptions into a higher-order logic specifications. In Section 5, we present the analysis carried out and the obtained results. In Section 6, we conclude the paper.

2. RELATED WORK

Several projects have explored how to combine formal modelling with user models as a way to obtain accurate user manuals. For example, [9, 11] show how a user manual can be automatically generated from a logic specification of a design and that such an automated process can help detect errors in the design.

Massink et al. [4] explore how model checking can be used to generate traces from a specification to answer how to and what if questions posed in temporal logic. Weitl et al [12] explore how to maintain consistency of context dependent documents including training manuals, focusing on user support by a pattern-based specification methodology. They combine temporal logic, ontologies, and a pattern-based specification approach.

Hebert [3] investigated the degree to which manuals were user tested to check their quality in six high-tech companies through interviews with key people. Where testing was done, testing methods were generally found to be limited.

3. PROCEDURE FOR SETTING UP A PROGRAMMABLE INFUSION PUMP

In this section, we overview the description of the procedure followed by medical practitioners for setting up programmable infusion pumps as analysed in the study [8] that the work described here is based on. For the purposes of this paper, we focus on the sequence of actions carried out by nurses for starting a constant flow rate infusion. For clarity of exposition, we use a slightly re-worded version of the original description here.

In the particular hospital studied, the B.Braun Infusomat Space infusion pump was used (see Figure 1). The pump has up, down, left and right arrow buttons for navigating through menus and entering numbers. The dot matrix display of the pump shows the current state of the pump as well as instructions of what the buttons do in that current state to aid user interaction.

3.1 Setting up a Constant Flow Rate Infusion

In intensive care units, nurses prepare and administer drugs according to prescriptions decided by doctors. Specifically, nurses prepare the medication, fill a bag with it, and then administer it through an infusion pump. The informal description of the activities carried out by nurses follows. This description describes the process in a single hospital as obtained through observation and interviews. In the description here, we will use a level of detail appropriate for the purposes of this article only. Readers interested in the full, original description, which has been validated by a senior nurse, should refer to [8].

Preparing a bag with the medication. In the particular hospital studied, the list of drugs to be administered to a patient and the details for preparing the medication are reported in the electronic patient record. Nurses read such information and proceed as follows: they prepare the bag with the medication and stick a descriptive label onto the bag; they connect the infusion line to the bag; they prime the infusion line, i.e., they push the fluid to the tip of the infusion line in order to bleed all air bubbles from the infusion line.

Starting the infusion. The infusion pump is turned on by pressing the On/Off button. When the pump is turned on, the nurse can open the pump door by pressing the Open button, and insert the infusion line in the pump: the infusion line end connected to the bag must be placed into the Inlet Line, while the other end must be fit into the Outlet line. The pump door can be closed after inserting the line in the pump. At this point, the pump displays the main menu, and the nurse can set up the infusion rate by selecting the Infusion Rate menu item. This item is the first in the main menu of the pump, and is highlighted by default. When setting up the infusion rate, the pump displays a number of digit spots with a decimal point ("_ _ _ . _ _"), and the first digit spot is selected by default. The nurse can use the Up/Down Arrow buttons for increasing/decreasing the digit, and the Left/Right Arrow buttons for highlighting a digit. Once the correct digits have been entered, the nurse presses the Ok button to confirm the entered value. Once the value has been confirmed, the pump displays the main menu. At this point, the nurse presses the Start/Stop button to start the infusion.

4. FORMAL SPECIFICATION

In this section, we translate the informal description of the activities carried out by nurses into a formal specification. Such a specification can be mechanically analysed with automated reasoning tools, such as in [10]. The notation we use draws concepts from Activity Networks [5], a widely used formalism for modelling complex concurrent systems, and relies on higher-order logic to formally specify both the dependency relations among activities and the activities themselves.

The formal specification for the activities carried out by the

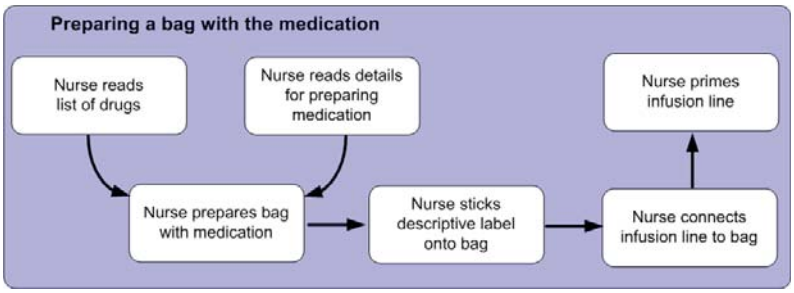

Figure 2: Procedure followed by nurses for preparing a bag with the medication

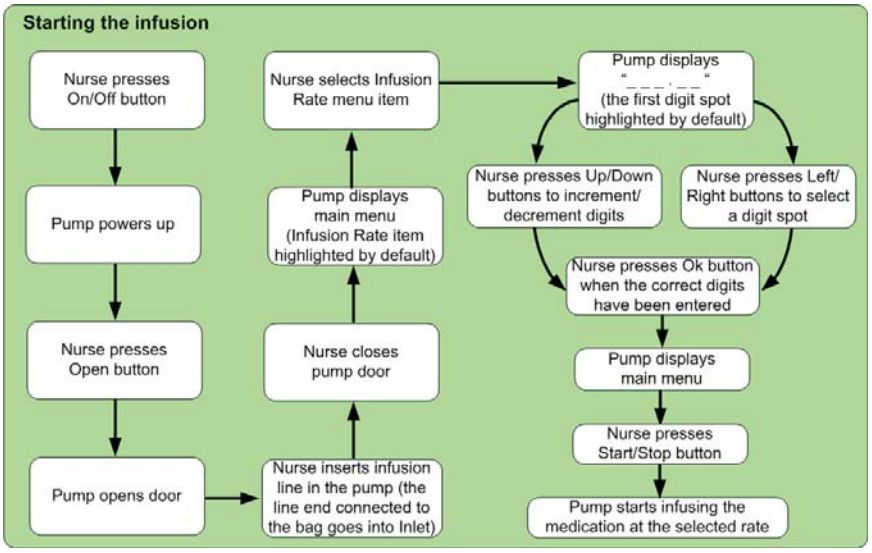

Figure 3: Procedure followed by nurses for starting the infusion

nurse in preparing a bag with the medication and for starting the infusion is graphically depicted as a labelled graph in Figures 2 and 3. In the graph, labelled nodes represent activities, and edges between nodes represent causal and temporal dependency relations among activities. An activity can be performed only if all directly connected activities have already been performed. For instance, consider the activity *"Nurse prepares bag with medication"* shown in Figure 2; such an activity can be performed only if two other activities have already been performed (*"Nurse reads list of drugs"* and *"Nurse reads details for preparing medication"*). Edges in the graph may have labels that specify control-flow conditions.

In the following, we show how activities can be specified in higher-order logic. To this end, we describe an excerpt from our formal specification developed in the PVS specification and verification system [7]. The PVS specification language builds on classical typed higher-order logic with the usual base types (e.g., `bool`, `nat`, `integer` and `real`), function type constructors `[A -> B]` (predicates are functions with boolean range type), structured data types, and abstract data types. PVS specifications are packaged as theories. PVS theories can use definitions and theorems of other theories by importing them. Providing a detailed description of the developed PVS theories is beyond the scope of this paper.

In the following we outline the formal definition of a simple activity from the theory concerned with preparing a bag. Our aim is to give a feel for the style of specification used. In the `prepare_bag_th` theory, given in Figure 4, we have two type definitions: the first definition specifies the pump state as a structured data type (`pump_state`) containing two fields (`display`, of type `message`, and `door`, of a user-defined enumerated type); similarly, the other type definitions specify the bag state as an enumerated data type, and the system state as a structured data type with four fields, which represent the pump, the bag, the infusion line, and the roller clamp.

The activities carried out by nurses are specified as transition functions over the system state. In our example, in Figure 4, we specify the activity *"Pump powers up"* as a (higher-order) function that changes the state of the pump according to the pressed button, which is specified as function parameter. The keyword `LAMBDA` here just specifies that a function follows, taking in this case a single argument —

```
prepare_bag_th: THEORY BEGIN %-- imports omitted
  pump_state  : TYPE =
    [# display: message,
       door   : bool #] %-- 1=open, 0=closed
  bag_state   : TYPE =
    {new_bag, labelled, empty}
  system_state: TYPE =
    [# pump: pump_state,
       bag: bag_state,
       roller_clamp: bool #] %-- 1=open, 0=closed
  pump_powers_up(b: button):
   [system_state -> system_state] =
    LAMBDA(sys: system_state):
      IF b = On_Off_button
       THEN LET new_pump_state = pump(sys)
            WITH [ display := turned_on ]
            IN sys WITH [ pump := new_pump_state ]
      ELSE sys ENDIF
  %-- more definitions omitted
 END prepare_bag_th
```

Figure 4: The formal specification of an example activity (pump powers up)

the system state — and returning a new system state as determined by an `IF` statement. If the button pressed is the On/Off button, then the new pump state part of the system state is the same as the old one but with the display part of the state turned on.

The activity described above is just one activity. We also formalised all other activities depicted in Figure 4. The advantage of providing a formal specification such as this is that it gives a very precise and unambiguous description of the procedure that is not open to different interpretation as with an informal description. This is because the language used has a precise and well defined mathematical meaning. This also opens up the possibility of using mathematical analysis tools to explore the consequences of the procedure and compare it with others.

5. ANALYSIS

We carried out two kinds of analysis on the formal specification of the procedure. The first analysis was intended to ensure semantic constraints, such as checking the consistency of control flow conditions, and the completeness of the activities' specification. This kind of analysis has the potential to detect inconsistencies between different parts of the specification and that nothing is missing from the behaviour described. For example it could highlight decision points where the consequences of only one branch of the decision has been specified. The second kind of analysis compares the procedures carried out by nurses in the real system (i.e., the best practice) against the sequence of actions specified in the user manual, and aims at pointing out possible mismatches that may lead to safety issues. This is done by creating two formal descriptions of the procedures, one from the observed behaviour and one based on what is described in the manual.

5.1 Checking Semantic Constraints

While translating the informal description of the procedure into a higher-order logic specification, we discovered two issues. The first issue is due to the inherently ambiguous semantics of natural language, and affects the description of activity *"Pump displays "_ _ _ . _ _" (the first digit spot is highlighted by default)"*. The activity is under-specified, since it is not clear which is the first digit spot. Is it the left-most spot? Is it the first integer spot? We checked the real pump, and the right interpretation is the latter one. The second issue is related to numeric entries. The description reported in Figure 3, indeed, reports that *"Nurse presses Up/Down arrow buttons to increment/decrement digits"*, while this is not the case in the real pump –for instance, the up button, which is used to increase the infusion rate, is also used as a *recall memory* button in certain device modes.

5.2 Actual Practice and the User Manual

In comparing the actual practice with that described in the B.Braun user manual a range of significant differences emerged.

The procedure for preparing a bag as described in the manual is relatively simple consisting of only four steps (see Figure 5). If we compare this description with the actual procedure followed by nurses (which is reported in Figure 2), we can notice two main differences.

1. In the actual procedure, nurses prime the infusion line, while the manual reports only that the infusion line must be filled from bottom to top, and postpones priming at a later stage, just before establishing the connection with the patient (see Figure 6).

2. The manual explicitly reports that the bag must not be below the pump level (see the grey box of Figure 5); this detail is omitted in the description of the actual procedure.

We have checked the procedure with a medical devices training manager. The procedure actually followed by nurses is correct: nurses should not simply fill the infusion line, but also prime the line. Also, nurses are taught to place the bag above the pump level: the omitted detail is probably due to the physical setup in the hospital observed, which constrains the bag to be always above the pump level (the bag needs to be attached to a hook which is fixed above the pump level). This effectively removes the need for the step of checking that the bag is not below the pump level, and could be why nurses did not report this step when describing the procedure they follow.

Several mismatches are highlighted in the procedure for starting the infusion with respect to the actual procedure followed by nurses. Two main types of mismatches can be evidenced:

Missing details on constraints and precautions. The manual provides a number of constraints that should be ensured by nurses while starting the infusion (e.g., nurses must ensure that the pump is properly installed before turning the pump on), and precautions during particular activities (e.g., nurses must never leave the pump unattended while inserting the infusion line).

Different sequence of actions. The manual explicitly reports that the pump can be used to prime the infusion line, but also states that such function can be disabled. When the function is disabled, the manual simply proceeds to the

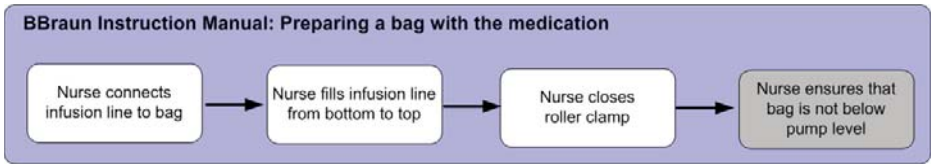

Figure 5: Procedure specified in B.Braun's Manual for preparing a bag with the medication

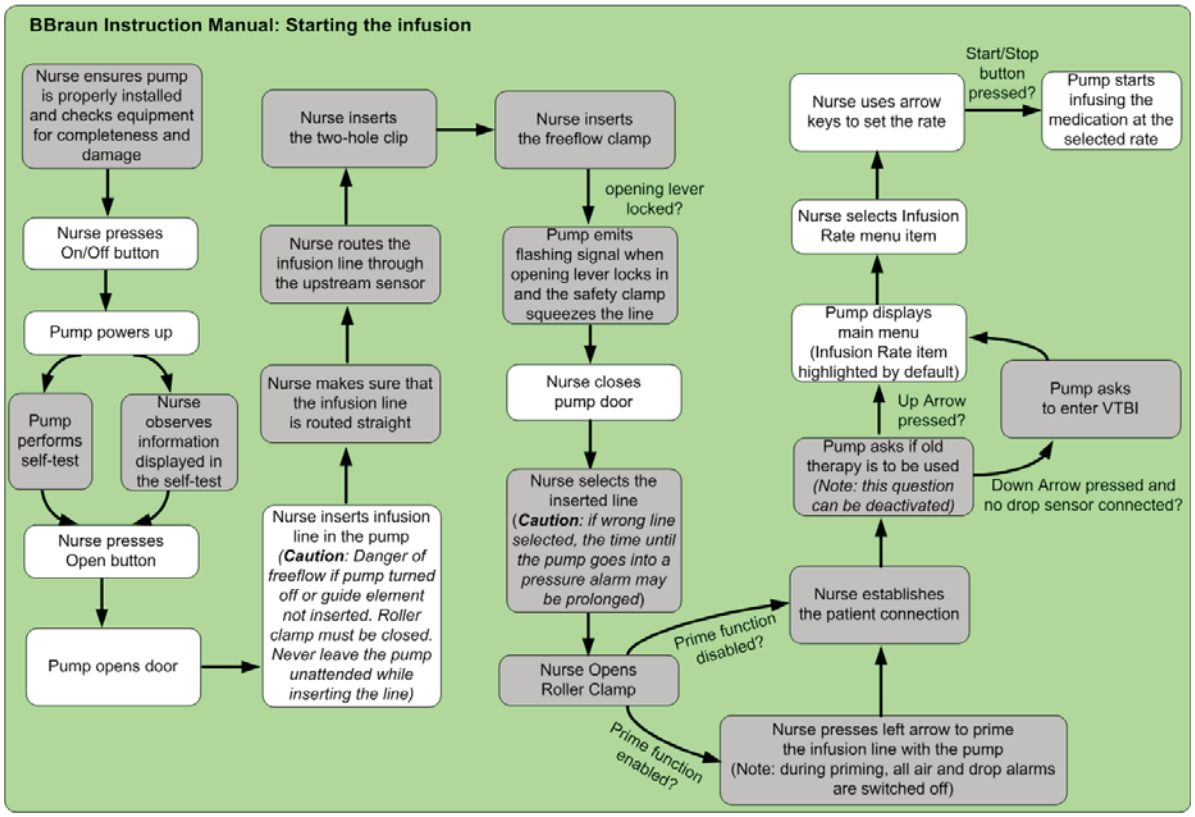

Figure 6: Procedure specified in B.Braun's Manual for starting the infusion

next step ("*Press the Up Arrow if the prime function is enabled. [...] Then press Down Arrow to proceed. Establish the patient connection*" [1]).

We engaged a medical devices training manager for discussing the above differences. It turns out that the missing details on constraints and precautions are not only related to activities that nurses simply omit to explicitly state (e.g., nurses are aware of the situations in which there is a danger of free-flow), but there are also a number of activities that nurses are actually not able to perform due to the particular work context, which is always very busy and does not allow nurses to dedicate time to certain activities, such as observing the messages shown by the pump during the self-test.

Regarding the different sequence of actions, the most critical difference is related to priming the infusion line. The manual reports that it can be done with the pump, given that the prime function is enabled on the pump; if the function is disabled, the next step is to establish the patient connection (see Figure 6). However, before starting the infusion, the line must be primed, otherwise there is a safety issue for the patient. The manual omits to point out this detail, and the procedure, as described in the manual, is not best practice. The medical devices training manager reported that, in fact, there were incidents due to nurses and trainers following procedures reported in the manuals, like the one described.

6. DISCUSSION AND CONCLUSIONS

We have described a study that compares a formal specification of actual practice for setting up an infusion pump with a formal specification of the sequence of actions described in the user manual of the pump. The study is based on a real pump and on observations made in a real hospital.

We discovered several issues and mismatches, such as ambiguity in the language used in the descriptions, and various checks prescribed in the manual of the pump but omitted in the actual practice. Our study shows how a model-based engineering approach can be conveniently used to support an investigator to understand workflow situations. Such issues are easily missed when using only informal descriptions.

The formalisation process uncovered an issue in the user manual related to priming the line (the procedure described in the manual was not consistent with the actual best practice). This demonstrates that a model-based engineering approach could be used to improve manuals and training material. Whilst this study concerned a B.Braun pump we believe that similar issues would apply with the pumps of other manufacturers and their actual use.

Understanding how devices are used in practice and pointing out issues with manuals is of potential use to manufacturers, trainers and procurement staff. For example, if staff are using workarounds then it is important for device designers to be aware of this so that they can determine whether these practices are safe.

Providing a direct support in training literature is likely to provide a commercial advantage for manufacturers: if such workarounds are adapted to context to make the pump use easier or more effective, then the pump in question would better support the nurses in doing their work. On the other hand if the practices are unsafe, it is in the manufacturer's interest to design the device in ways to remove the need or possibility of such workarounds. Similarly, if a device design is such that unsafe practices result to deal with the realities of the job, then training and procurement staff need to know how to improve procurement decisions and training regimes. Also, if training staff are aware of why procedures are the way they are, then they can help spread good practice. Formal specifications can be simulated, and this opens up the possibility of automatically generating visualisation tools of scenarios for use in training (either to show bad consequences of actions or to illustrate ways to improve performance and safety).

Whilst in this study the investigation of actual behaviour was complete when the formal work was carried out, these techniques could also help an investigator collecting ethnographical data and actually build a deeper understanding of the system as observations and interviews take place. For example, insights gained during model-based analysis can help focus attention on areas to observe more closely and questions to ask. When only an informal description is being used, such issues can easily be missed.

Current tools are not at a stage of maturity that an actual investigator could easily develop a formal specification and analyse it, though this may be possible in the future as the techniques are developed and built into tools. In the meantime, however, the approach can be applied if a formal methods expert is paired with the investigator to do model development and analysis and interpret the results in dialogue with the investigator.

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Visualization and Interaction System for Surgical Planning

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ABSTRACT
Modern technologies give a great support to the minimally invasive surgical procedures through medical image processing and visualization, 3D organ's reconstruction and intra-operative surgical guidance. The practice of Minimally Invasive Surgery is becoming more and more widespread and is being adopted as an alternative to the classical procedure. This technique presents some limitations for surgeons. In particular, the lack of depth in perception and the difficulty in estimating the distance of the specific structures in laparoscopic surgery can impose limits to delicate dissection or suturing. The presence of new systems for the pre-operative planning can be very useful to the surgeon. In this paper we present a visualization and interaction system that allows surgeon to visualize the 3D model of the patient's organs built from the CT images. Different visualization modalities are available according to the surgeon needs in laparoscopy and an Augmented Reality application permits the choice of the best insertion points of the trocars on the 3D virtual model and the visualization of these points on the real patient's body. Two case studies have been considered. The system can be used as support for the diagnosis, for the surgical preoperative planning and also as visual support during the surgical procedure.

Keywords
User interface, image-guided surgery, Augmented Reality

INTRODUCTION
One trend in surgery is the transition from open procedures to minimally invasive laparoscopic operations where the visual feedback to the surgeon is only available through the laparoscope camera and the direct palpation of organs is not possible.

Minimally Invasive Surgery (MIS) has become very important and the researches in this field are ever more widely accepted because these surgical techniques provide surgeons with less invasive means of reaching the patient's internal anatomy and allow entire procedures to be performed with only minimal trauma to the patients. As a promising technique, the practice of MIS is becoming more and more widespread and is being adopted as an alternative to the classical procedures.

The diseased area is reached by means of small incisions on the body; specific instruments and a camera are inserted through these ports and what happens inside the body is shown in a monitor. The surgeon does not have a direct vision of the organs and so he is guided by the camera images. This surgical approach is very different from the open surgery where the organs can be fully visualized and handled.

The advantages of using this surgical method are evident in the patient because the trauma is reduced, the postoperative recovery is almost always faster and the scarring is reduced. Despite the improvement in outcomes, these techniques show their limitations for the surgeons. In particular, the lack of the perception of the depth and the difficulty in estimating the distances of the specific organs in laparoscopic surgery can impose some limits on delicate dissection or suturing.

Anyway, the overall risk of complications is of 8.0% in laparoscopy versus 15.2% in laparotomy. Among these, more than 50% of laparoscopic complications occur during the initial entry into the abdomen.

The modern medical imaging acquisition associated to the medical image processing could lead to an improvement in patient care by guiding the surgeons. The medical image processing allows detecting and identifying anatomical and pathological structures and building 3D models of the patient's organs that could be used to guide the surgical procedures. Many research teams have dealt with the task of segmentation and have developed techniques that allow automatic or interactive extraction of the patient's organ models from CT-scan or MRI [1], [2].

The Augmented Reality (AR) technology can provide the advantage of a direct visualization in open surgery also in minimally invasive surgery and can increase the physician's view of his/her surroundings with information gathered from patient medical images [3]. In general, AR technology in minimally invasive surgery may be used for training

purposes, pre-operative planning and advanced visualization during the real procedure. In surgery, Augmented Reality technology makes possible to overlay virtual medical images on the patient, allowing surgeons to have a sort of “X-ray" vision of the body and providing them with a view of the patient’s internal organs [4].

Motivated by the benefits that MIS can bring to patients, many research groups are now focusing on the development of systems in order to assist the surgeons during the surgical procedures and have developed solutions to support the preoperative surgical plannings and the intra-operative surgical procedures.

Samset et al. [5] present tools based on novel concepts in visualization, robotics and haptics providing tailored solutions for a range of clinical applications. Examples of radio-frequency ablation of liver tumors, laparoscopic liver surgery and minimally invasive cardiac surgery will be presented.

Bichlmeier et al. [6] focus on the problem of misleading perception of depth and spatial layout in medical AR and present a new method for medical in-situ visualization that allows improved perception of 3D medical imaging data and navigated surgical instruments relative to the patient’s anatomy. They describe a method for integrating surgical tools into the medical AR scene in order to improve navigation.

Navab et al. [7] introduce an interaction and 3D visualization paradigm that presents a new solution for using 3D virtual data in many AR medical applications. They introduce the concept of a laparoscopic virtual mirror: a virtual reflection plane within the live laparoscopic video, that allows visualizing a reflected side view of the organ and its interior. A clinical evaluation investigating the perceptive advantage of a virtual mirror integrated into a laparoscopic AR scenario has been carried out.

De Paolis et al. [8] present an Augmented Reality system that can guide the surgeon in the operating phase in order to prevent erroneous disruption of some organs during surgical procedures. The distance information is provided to the surgeon and an informative box is shown in the screen in order to visualize the distance between the surgical instrument and the organ concerned.

In this paper we present an advanced platform for the visualization and the interaction with the 3D patient models of the organs built from CT images.

The developed application allows the surgeon to choose the points for the insertion of the trocars on the virtual model, to simulate the insertion of the surgical tools in order to verify the correctness of the insertion sites and to overlap the chosen entry points on the real patient body using the Augmented Reality technology.

The system could be used as support for a more accurate diagnosis, in the surgical preoperative planning and also for an image-guided surgery.

THE CASE STUDIES

In MIS the use of the registered images of the patient is a prerequisite both for the pre-operative planning and the guidance during the operation. From the medical image of a patient (MRI or CT), an efficient 3D reconstruction of his anatomy can be provided in order to improve the standard slice view; colors associated to the different organs replace the grey levels in the medical images.

In our case study the 3D models of the patient’s organs have been reconstructed using segmentation and classification algorithms provided by ITK-SNAP [9].

We processed two different case studies; the slice thickness equal to 3 mm has caused some aliasing effects on the reconstructed 3D models that could lead to inaccuracies. Therefore we have paid special attention to the smoothing of the reconstructed models in order to maintain a good correspondence with the real organs.

The first case study, shown in Figure 1, is a two-year-old child with a benign tumor of the right kidney.

The second case study, shown in Figure 2, is a twelve-year-old child with a tumor of the peripheral nervous system (ganglioneuroma).

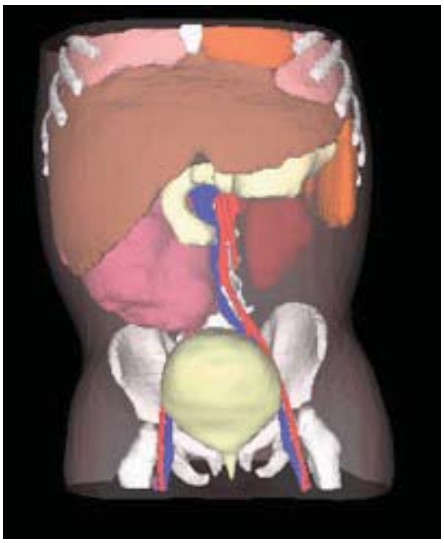

Figure 1: 3D model of a child with a tumor at the kidney

THE USER INTERFACE

The developed application is supplied with a specific user interface that allows the user to take advantage of the feature offered by the software. The application is provided of 4 sections with the aim to provide support to the surgeons in the different steps of the surgical procedure such as the study of the case, the diagnosis, the pre-operative planning, the choice of the trocar entry points and the simulation of the surgical instruments interaction.

Starting from the models of the patient’s organs, the surgeon can notice some data about the patient, collect information about the pathology and the diagnosis, choose

the most appropriate positions for the trocar insertion and overlap these points on the patient's body using the Augmented Reality technology.

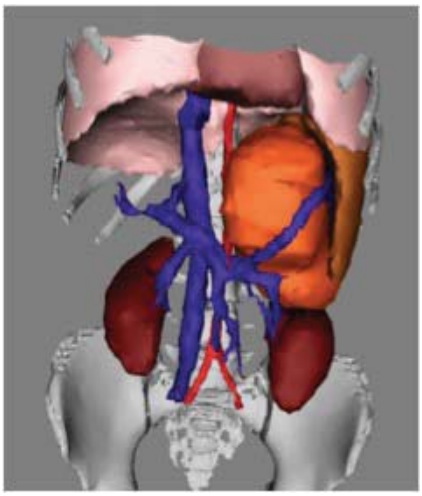

Figure 2: Virtual model of a child with a ganglioneuroma

In this way it is possible to use this platform for the pre-operative surgical planning and during the real surgical procedure too. In addition, it could be used in order to describe the pathology, the surgical procedure and the associated risks to the child's parents, with the aim of obtaining informed consent for the surgical procedure.

In the developed application, all the patient's information (personal details, diseases, specific pathologies, diagnosis, medical images, 3D models of the organs, notes of the surgeon, etc.) are structured in a XML file associated to each patient.

A specific section for the pre-operative planning includes the visualization of the virtual organs and the physician can get some measurements of organ or pathology sizes and some distances; this section is shown in Figure 3. By means of a detailed view of the 3D model, the surgeon can choose the trocar entry points and check if, with this choice, the organs involved in the surgical procedure can be reached and the procedure can be carried out in the best way.

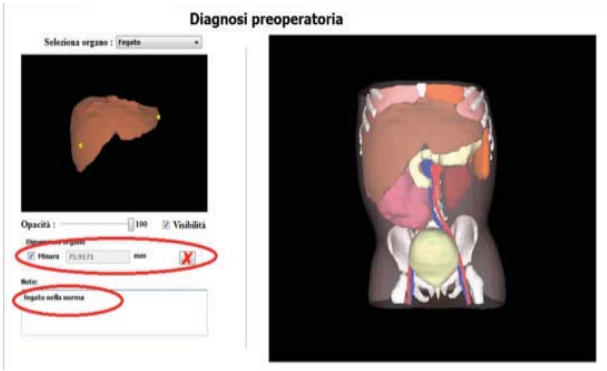

Figure 3: Measurement of organs

THE AUGMENTED REALITY SECTION

Sometimes, using the standard insertion points for the surgical tools, also a simple surgical procedure can be very difficult due to the specific anatomy of the different patients. The surgeon can have some difficulties to reach the specific organ or the interaction of the surgical tools can be very hard. In this case the surgeon has to choose another insertion point in order to be able to carry out the surgical procedure in the most suitable way.

Our aim is to avoid the occurrence of this situation during the real surgical procedure using the visual information provided by means of the 3D models of the patient's anatomy.

In the developed application, in order to verify if the chosen insertion points allow properly reaching the specific organ interested by the surgical operation and permitting to carry out the procedure in a correct way, it is also possible to simulate the interaction of the surgical instruments. We also use the AR technology in order to visualize on the patient's body the precise location of the selected points on the virtual model of the patient.

For the augmented visualization, in order to have a correct and accurate overlapping of the virtual organs on the real ones, a registration phase is carried out; this phase is based on fiducial points. Using the augmented visualization, the chosen entry points for the trocars can be visualized on the patient's body in order to support the physician in the real trocar insertion phase.

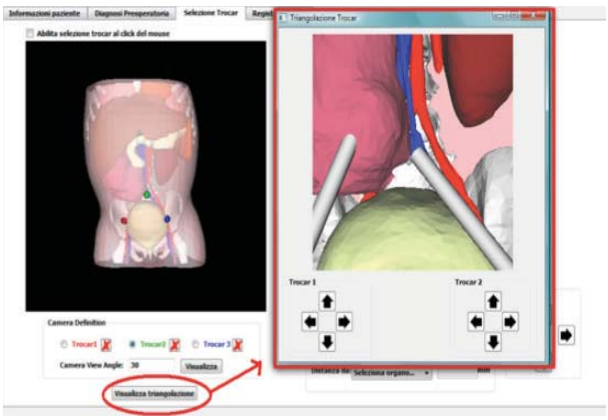

Figure 4: Simulation of the surgical tools interaction

In our application, we have used the Polaris Vicra optical tracker of NDI [10]; the system consists of 2 IR cameras and uses a position sensor to detect retro-reflective markers affixed to the surgical tools or located on the patient's body; based on the information received from these markers, the sensor is able to determine position and orientation of tools within a specific measurement volume. The tracker can calculate the current position of the tool in the space with an accuracy of 0.2 mm and 0.1 tenth of a degree.

Usually the tracking technology is already in the operating

rooms and provides an important help to enhance the performance during the real surgical procedures.

Figure 4 shows the specific section for the simulation of the surgical tools interaction with the possibility to move the trocar entry points using the arrows; Figure 5 shows the augmented visualization of the chosen trocar entry points on the patient's body (a dummy).

Figure 5: Augmented visualization of the entry points

CONCLUSIONS AND FUTURE WORK

The developed application offers a tool to visualize the 3D reconstructions of the patient's organs, obtained by segmentation of a CT slices, and to simulate the placement of the trocars in order to verify the correctness of the insertion sites. A complete user interface allows a simple and efficient utilization of the developed application.

Furthermore the system retains patient and pathology information that the surgeon can insert and includes an Augmented Reality module that supports the placement of the trocars on the patient's body during the real surgery procedure. An accurate integration of the virtual organs in the real scene is obtained by means of an appropriate registration phase based on fiducial points.

The developed platform can support the physician in the diagnosis steps and in the pre-operative planning when a laparoscopic approach will be followed. This support could also lead to a better communication between physicians and patient's parents in order to obtain their informed consent.

The platform has been tested on study cases already operated by the surgeon; the future work will be the validation of the developed application on a new study case by following all the steps from the diagnosis to the pre-operative planning and to the first phase of the real surgical procedure.

The building of a new Augmented Reality system that could also help the surgeon during the other phases of the surgical procedure has been planned as future work.

ACKNOWLEDGMENTS

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Design and Prototypical Development of a Web Based Decision Support System for Early Detection of Sepsis in Hematology

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ABSTRACT
Physicians do not always make optimal decisions. Computer based clinical support systems are intended to provide clinicians with decision aids, but their practical impact remains low. We introduce a software architecture which might overcome key barriers and present the prototypical implementation of a web based knowledge module for early detection a life-threatening medical condition, sepsis.

Keywords
Clinical decision support, Knowledge-based systems in medicine, hematology, sepsis, fever, web-based application, knowledge maintenance, ESGOAB.

INTRODUCTION
The information overload physicians are confronted every day with makes it impossible for them to keep up with all the information and knowledge that would be potentially useful in making optimal clinical judgments. Empirical studies have shown that physicians do not always make optimal decisions [17] [6]. Clinical decisions are often made under time pressure, without having all information and knowledge needed in the right place at the right time. Computer-assisted *clinical decision support systems* (CDSS) are intended to provide *"clinicians, patients or individuals with knowledge and person-specific or population information, intelligently filtered or presented at appropriate times, to foster better health processes, better individual patient care, and better population health. CDS interventions include alerts, reminders, and order sets […]"* [11].
Although research has been done in the field of CDSS for decades, the practical impact remains low for several reasons, e.g. [3]:

- Systems failed to cover an entire medical domain
- Poor practicability and integration into the clinical workflow
- Poor availability of digital patient data
- Poor acceptance

Within the ESGOAB[1] project, which will be described in more detail in the next section, we are trying to overcome the weaknesses mentioned above. In this paper we will briefly describe the ESGOAB software architecture, which provides an electronic health record (EHR) and is designed to provide the base to interact with knowledge modules. We focused on two specific clinical challenges: supporting the physicians' order entry process (CPOE) and supporting early detection of sepsis (a serious and life-threatening medical condition) on patients with hematological underlying diseases. In this paper we will describe the second challenge. We introduce our conceptual design of the sepsis knowledge module and present the currently implemented web-based prototype.

Project Background
The ESGOAB project is a 2-year public funded joined research project between two scientific partners (Heidelberg University Hospital, DFKI) and two industrial partners (COPRA System GmbH, Dosing GmbH).

A survey at the Department of Hematology and Oncology of the Heidelberg University Hospital has shown a range of problems concerning various applications of Information and Communications technologies (ICT) within the hospital (response rate = 70.5 %, 36 of 51 of the medical personnel)

[1] ESGOAB = „**E**ntwicklung einer **S**oftwareumgebung zur **G**enerierung von **o**rganisationsspezifischen **A**nwendungen zum **B**ehandlungs-prozessmanagement"; *english*: Development of a Software Environment for Generation of Organization-Specific Applications for Treatment Process Management

[20]. The study revealed problems concerning e.g., time consuming searches, redundant data entries, use of various software applications to perform the various tasks, different user interfaces, and only marginal decision support. However we found a promising openness towards CDSS [20]. In general the staff was open-minded towards new Information Technology (IT) systems (88 % indicated to be "rather open-minded" or "open-minded"), concerning CDSS, the potential benefit was assessed by the majority (72 %) as "rather high" or "high", as well as prospects of success (53 %). At least 47 % rated *reliability* as well as *acceptance* as "rather high" or "high".

The ESGOAB project aims at encapsulating various data sources like e.g., hospital information system (HIS), laboratory data or drug information systems (see Figure 1) into one integrated software system which provides one consistent user interface. The second main aim is the development and integration of knowledge bases into the ESGOAB system.

The ESGOAB system is based on a 3-layer software architecture concept. A data collector (layer 1) is responsible to capture and gather data from various existing sub systems which are illustrated below the three layers. Adapters for each of the sub systems are transforming data into defined structures. The knowledge carrier (layer 2) analyzes incoming data from the data collector layer or handles requests triggered by user interactions. The knowledge carrier consists of various knowledge bases (e.g., about drug information) which are connected following a modular concept. If there are e.g., new blood values these will be evaluated by the knowledge carrier and according hints or warnings will be immediately displayed by the visualizer (layer 3) following a defined alerting concept, taking into account the importance, severity etc. of the alert [4].

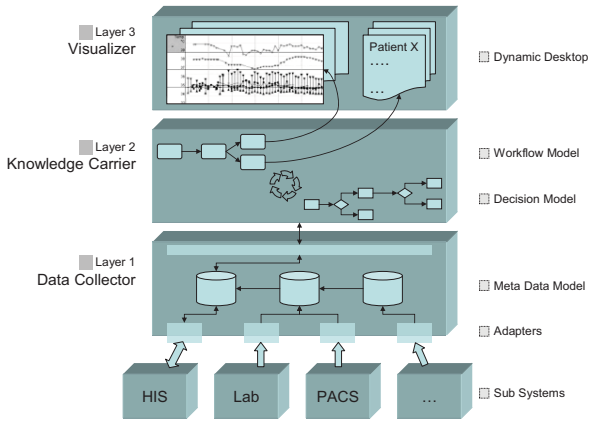

Figure 1: 3-layer architecture of the ESGOAB system

At the end of the ESGOAB project we expect an increase of efficiency of tasks and processes at the Department of Hematology and Oncology at the Heidelberg University Clinic (due to time-savings), a reduction of performance stress, and optimization of clinical decisions, which altogether may improve quality of care.

Related work

Research in the field of medical knowledge-based systems has been done since the early 1960s. Many different research approaches have been explored, but yet the degree of impact of clinical decision support systems still remains low [5]. Only few knowledge-based systems are widely used day-to-day, such as automated electrocardiogram (ECG) interpretation [18]. However, systems utilizing a broad variety of individual patient data had to fail due to poor availability of digital data. Providing an EHR eliminates this obstacle [3].

Research in the field of monitoring and analyzing vital signs in Intensive Care Units (ICU) for early warning of patient deterioration or sepsis were done by [15] and [12]. However, including microbiological findings as well as the accurate handling of the specifics of the hematological patients remained unconsidered.

Clinical Background

The treatment of patients with hematological diseases has advanced enormously in the past years. Nevertheless such infections pose a serious life-threatening risk for these immunocompromised patients. Beside various other clinical and laboratory parameters, fever is an essential factor, which indicates a manifest or beginning infection. Therefore a refined assessment of the body temperature is needed. The responsible physician has to distinguish between innocent fever as immunologic reaction, fever of unknown origin, fever caused by bacteremia or the onset of a severe sepsis. Hereby assists the combination of lab-values, microbiological findings and vital signs. The emphasis and valuation of the combination of single-values and the experience of the doctor partly determine the treatment course and the outcome of the patient. Clinical studies demonstrated that the survival probability of patients with sepsis depends most essentially on the period of time between diagnosis and start of effective antibiotic treatment [7]. Sepsis is not only a problem of hematological patients. It's rather a challenge for the population. Severe sepsis is considered to be the most common cause of death in non-coronary critical care units. Approximately 150.000 persons die annually in Europe and more than 200.000 in the United States [1]. The problematic nature of a timely recognition is not that data is missing, but it is detached from one another, generated at various places and different times. The responsible physician has to link the separated information for the plurality of patients. Ward rounds, printouts with lab values, calls from the microbiologist and signs from monitors serve as instruments for this connection. This work has to be done by the medical personnel even in the future, but the model we present in this article offers the convincing advantage of automated joining of relevant data and usable presentation, resulting in efficient and faster decisions.

APPROACH

Conceptual Requirements

When deploying and operating knowledge-based systems, a weak point is often poor practicability, in particular in terms of maintenance. Either the knowledge model is implemented statically, there is no way experts of the certain domain (in the present case hematologists) can modify the model on their own. This leads to the fact that each adaptation has to be done by a software engineer. Or the user interfaces do not provide intuitive means to modify the knowledge base; thus users have to be instructed and the system becomes error-prone. Between designing and using knowledge-based systems, a long-lasting cyclic process of modeling, testing, adapting, and retesting of the core engine has to be passed through. While operating knowledge-based systems the focus shifts towards maintenance issues. Maintaining the knowledge within the system is critical to successful delivery of decision support [3]. In this context practicability plays an important role. Being aware of this issue, easy knowledge maintenance was an important goal. The clinical expert should be able to modify the underlying knowledge model without extensive training. It has to be simple and intuitive to use. Furthermore it should be possible to test the constructed or adapted model right away. Beyond that, the knowledge model should be generic, so it might be useful for other diagnostic problems.

Knowledge Engineering Process

Knowledge Engineering is the systematic approach for the development of knowledge based systems. The process may be divided into two main phases (Figure 2): *knowledge acquisition* and *knowledge operationalization* [14]. It should be noted, that typically the process of acquisition and operationalization is not a linear process but rather a cyclic process characterized by continuous, iterative refinement.

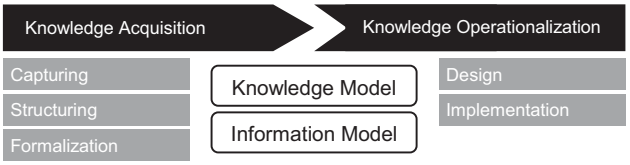

Figure 2: The Knowledge Engineering Process

Knowledge acquisition is the process of capturing, structuring and formalizing knowledge. The result of the acquisition phase is a *knowledge model* and an *information model* which both serve as a base for the system design of an implementation [5]. Sources of knowledge are typically domain experts, medical literature and patient data repositories. Our approach was based on expert opinion and literature research.

Information Model

A specification of the kinds of information that were required was created, including the data format and the taxonomy. The resulting information model – which will be implemented as an object-oriented data model – provides us the flexibility to use the same implementation (objects) in two kinds of settings:

1. Interactive data retrieval with the user (module execution)
2. Running in background through a web service retrieving data from the EHR

Knowledge Model

Sepsis accompanies with several symptoms, such as fever, increased heart rate, low blood pressure etc. Further important parameters are signs of infections such as specific blood values and microbiological findings. The sequence of appearance and the severity of these manifestations differ from patient to patient. We have to deal with fuzzy and uncertain information. However, some signs are more important than others and certain value ranges are supporting sepsis more than other diagnoses. So the idea was to design a decision model, which balances between a set of differential diagnoses and specifies the one which can be explained best by the observed findings. The *set covering model* is a potentially useful approach, which was introduced by [13], as well as the more abstract view on multiple diagnose problems by [9]. Our approach is based on the set covering model, extended by the possibility to define parameters which contradict certain diagnoses since we experienced a further need for accuracy.

Two sub modules based on a rule engine were required to handle two specific problems:

1. Interpretation of microbiological findings: Presence of an infection or suspected contamination?
2. Interpretation of white blood cell count (leukocytes): May we take this parameter into account?

Implementation

Initially, the basic idea was demonstrated using a prototype realized in Microsoft Excel (Figure 3). Taking advantage of quick implementation possibilities, this prototype helped us to refine our knowledge model.

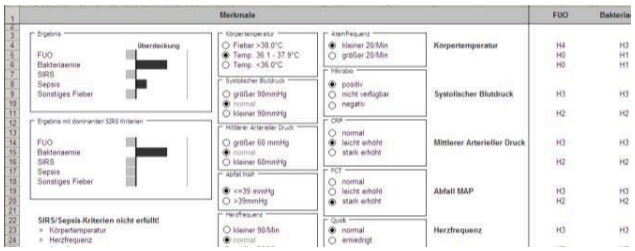

Figure 3: Prototype developed with Microsoft Excel (result presentation in the upper left corner, value selection in the mid-area)

The decision to proceed with the development of a *web-based* application was made due to the following main reasons:

- Easy Accessibility from all clients via the clinic's intranet; no need to install software on clients
- Quick deployment of new versions

We used a *XAMPP* [2] installation on Windows including an *Apache* 2.2.14 web server and a *MySQL* database system. We used the scripting language *PHP* and the Ajax toolkit *xajax* [19].

The application is based on the Model-View-Controller (MVC) design pattern; the PHP code architecture follows an object-oriented approach. The application is implemented using the open source relational database management system MySQL, with use of the *InnoDB* storage engine. An initial database model was designed using the database-modeling tool *MySQL Workbench* [10]. The model was refined iteratively during the implementation of the application.

WEB-BASED PROTOTYPE

Application Structure

The application is composed of three modules: *Sepmod*, *Leukomod* and *Mibimod* (Figure 4). Sepmod represents the generic core model, which implements the weight model as specified before and interacts with the sub modules Leukomod and Mibimod. Leukomod is based on a rule engine, which is responsible for the white blood cells' assessment. Mibimod is also based on a rule engine and performs the assessment of the microbiologic findings.

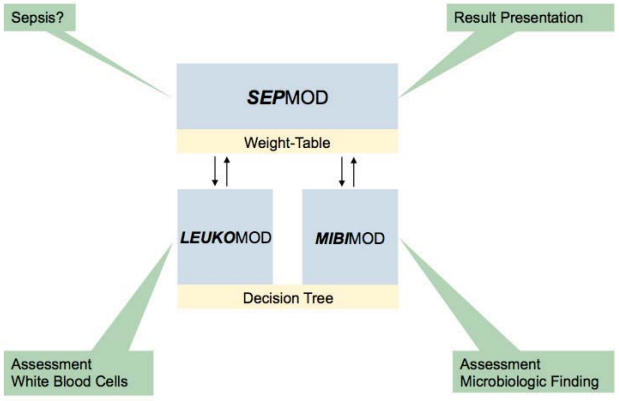

Figure 4: Structure of the application

The web-front-end provides the following two main sections:

- *Maintenance*: Provides editors for each module for construction and modification of the knowledge base.
- *Module-Execution*: Interactive tool, which requests for data or selection of options by the user and presents the results.

The interactive tool is basically designed for testing purposes. The impact of adaptions of the knowledge base can be explored right away.

Knowledge Maintenance Section

Sepmod

In this section the user can create a new and edit existing knowledge models. Created models can be loaded, saved, and deleted. The core element is the weight table (Figure 5).

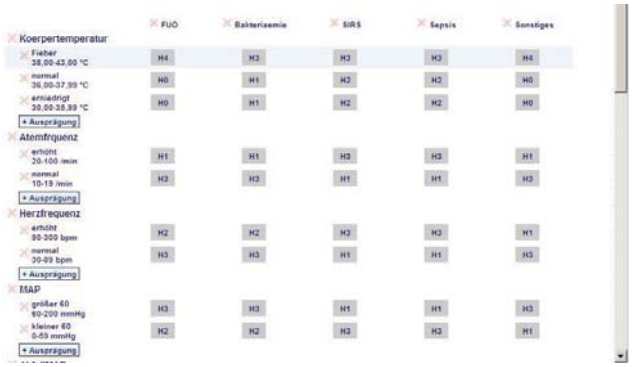

Figure 5: Screenshot of a weight table (columns: diagnoses, rows: parameters and values)

The process of creating a new model facilitates the following steps:

1. Add *diagnoses*
2. Add *parameters*
3. Add *value* ranges for each parameter
4. Create *weight relations* between value and diagnosis
5. Define *Equivalencesets*
6. Define *Minimalsets*

These steps are described in more detail below.

Step 1: Firstly we need to add diagnoses, by providing its *name* and optionally a *description*. For each diagnose added, the table will be expanded by one column.

Example definition:

Name: `SIRS`
Range: `Systemic Inflammatory Response Syndrome`

Step 2: In the second step, symptoms or "parameter" can be defined, specifying its *name*, *type, unit*, *value range*, *validity*, *importance*. The *type* tells us, which kind of data we deal with, e.g. integer, float or special medical classifications like the *anatomic therapeutic classification* (ATC) code. The *value range* defines the valid value range for the parameter and is used to perform plausibility checks. Regarding the process of diagnosis, an important and relevant issue is always the time context. *How long can I rely on a measured value?* The answer depends on each parameter. In the present model we therefore define for each parameter a time frame (*validity*), entering a numerical value for the absolute time (minutes, hours or days) within this parameter remains valid or in other words we can assume that the measured value may be used for the diagnostic assessment. If a parameter exceeds the defined time frame, it will be ignored and treated, as it would be not available. Alternatively we can define a relative time frame such like "Valid until next measurement". Some parameters may have a more significant importance than other. Thus for each parameter the importance can be defined, choosing from given weights "very important", "fairly important", "important".

Example definition:

Name:	*bodytemperature*
Type:	*float*
Unit:	*°C*
Range:	*30.0 to 43.0*
Validity:	*6 hours*
Importance:	*very important*

Step 3: In the next step, for each parameter, several *values* have to be defined. The values are specified by its name and its value range.

Example definition:

Name:	*fever*
Range:	*38.0 to 43.0*

Step 4: Adding diagnoses, parameter and its values results in a *count(diagnoses) x count(values)* matrix. For each pair of a value and a diagnosis we can now define a weight relation between a specific value and a diagnosis by clicking on the corresponding button. A weight relation is the symbol for the strength a specific value supports a diagnosis. The currently implemented model supports five different weights, ranging from H0 (value does not support the diagnosis or even contradicts) to H4 (value strongly supports the diagnosis or is even essential) depending on the currently used weight model which can be defined in a separate section. For each weight symbol the value can be selected through a slide control.

Step 5: In the section called *equivalencesets* we define sets of previously defined parameters, which are clinically equivalent (Figure 6). In other words all of these parameters support a specific context diagnosis, such as *low blood pressure*.

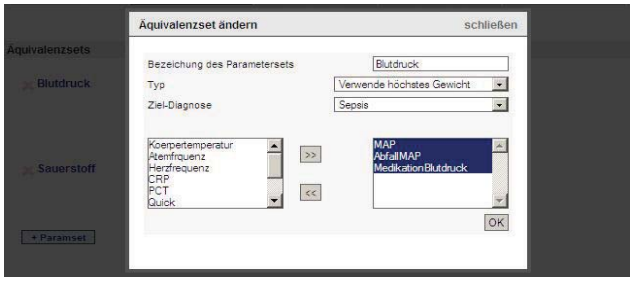

Figure 6: Screenshot of the equivalenceset dialog

In this case we would define that low blood pressure exists if at least one of these blood pressure parameters takes a specific value (and a corresponding high weight) or in this special case we also assume low blood pressure if vasopressors (substances which result in an increase in blood pressure) are given what we can specify through a list of ATC codes.

Step 6: A decision model might be sophisticated but its accuracy highly depends on the available parameters. So it only makes sense to perform a diagnostic assessment if at least a certain set of parameters is available. In the section minimalset the clinical experts can define, which parameters they consider as being essential for performing a profound assessment. It is possible to define more then one set.

Leukomod

Leukomod is based on a rule engine. The rules were defined by clinical experts. In the current version they are implemented statically and can be activated or deactivated through the web-front-end in the section leukomod/rules. Further we can adapt various parameters (like thresholds) of the rules. For the assessment, if the white blood cells may be included, the underlying disease is of high importance. A dynamic list of diagnosis codes (*ICD*, *International Statistical Classification of Diseases and Related Health Problems*) can be maintained in the section diagnoses.

Mibimod

Mibimod is based on a rule engine. A dynamic list of germs which support the suspicion of a contamination can be maintained in this section. The rules of this module are currently implemented statically.

Module Execution Section

For testing purposes the web-front-end provides a section to run the modules. The current version has one section to run each of the modules separately and one, which encapsulates all three of them. These execution modules are implemented as interactive tools, requesting each parameter step-by-step.

For each input field a check for plausibility is performed while entering data, considering two main issues

- Valid characters (depending on the data type)
- Valid value range (as defined in the model).

To keep track of entered values, we show breadcrumbs horizontally across the top of the input form (Figure 7).

Figure 7: Entering values using the interactive mode

The user can easily go back to previously entered values and change them if necessary. Each breadcrumb item shows the name of the parameters as well as the entered value and unit. Once all values are entered, the system performs the assessment and presents the results, giving explanations and a visualization of the results (Figure 8). Presenting results in an appropriate way means finding a balance between (1) simple, clear and aggregated representations, supporting e.g. quick task completion and (2) comprehensive and detailed representations, which are needed for making comprehensible decisions.

Figure 8: Result presentation (diagram and textual explanation)

DISCUSSION & FUTURE WORK

We identified two important and promising factors that will help overcome key barriers limiting more widespread use of CDSS: Firstly we did not experience the "physician resistance" using decision support systems; they are rather convinced of their usefulness as described in the introduction. Secondly we can take advantage of the software infrastructure we presented which has the potential to improve clinical processes and to integrate and interact with sharable knowledge modules conceived to support the physicians in their decisions. We also introduced a web based prototype of a knowledge module for early detection of sepsis. We believe to contribute important elements to lift computer-aided decision support into widespread practice.

However, our approach still needs to be refined and evaluated. It has to be shown that our knowledge modules are able to provide accurate and traceable support, characterized by high sensitivity. A test concept as well as test scenarios will be defined. Further alerting concepts will be tested in practice since empirical studies have shown that too many generated alerts could lead to "alert fatigue", whereas "non-interruptive" alerts only have low impact and are not effective [8].

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User-Centered Design for Citizens' Empowerment through the Portal of the Italian Ministry of Health

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ABSTRACT
In this paper we report on a study concerning the redesign of the Web portal of the Italian Ministry of Health, jointly conducted by the ministry and Sapienza Università di Roma. In this project, a multidisciplinary team consisting of computer scientists and engineers, sociologists and experts in communication, doctors and experts in public health was involved, in order to fully identify and understand citizens' needs in terms of health information, on the one hand, and to apply the most innovative methodologies and techniques for user-centered design and interfaces, on the other. Guidelines for on-line communication on protection and promotion of the health, and a mock-up for the future Web portal of the Italian Ministry of Health have been realized during the project.

Author Keywords
Web portal, taxonomies, guidelines, mock-up

ACM Classification Keywords
H.5.2 User Interfaces: User-centered design; J.3 Life and Medical Sciences: Health

INTRODUCTION
Current Web portals of ministries of Health, in Europe and all over the world, are evolving from simple information sites, mostly oriented to offer institutional and administrative information, to really interactive e-health systems, providing citizens and operators with various services related to health promotion and prevention, as well as facilitating the access to services of the National Health Systems (NHSs) (cf. `http://www.dh.gov.uk` and `http://www.nhs.uk` in the UK, and `http://www.bmg.bund.de` in Germany).

In this paper we report on a study concerning the redesign of the Web portal of the Italian Ministry of Health[1], jointly conducted by the ministry and Sapienza Università di Roma, from February 2010 to January 2011. Sapienza participated in the project with a multidisciplinary team involving computer scientists and engineers, sociologists and experts in communication, doctors and experts in public health, in order to fully identify and understand citizens' needs in terms of health information, on the one hand, and to apply the most innovative methodologies and techniques for user-centered design and interfaces, on the other. The main products realized within this investigation have been:

- Guidelines for online communication on protection and promotion of the health and access to the Italian NHS [5], targeted mainly to Italian local (i.e., at the regional and municipal level) health administrations; such guidelines are focused on communication issues ("how to talk to citizens?") and on Web design suggestions;
- a mock-up for the future Web portal of the Italian Ministry of Health, together with its design specifications [8].

This work is part of the process of renewing the relationship between health organizations and citizens, in order to improve the condition of *empowered citizens*, repeatedly emphasized by the WHO (1978, 1986, 1998, 2005)[2]. The empowered citizen is able to understand and choose, to define her own life-style, and to take an active role in managing her well-being, and is thus able to interact rationally and responsibly with those to whom she refer, i.e., the NHS. Empowerment means "giving power" to citizen. A citizen who has control over her state of health is a citizen able to participate in her own diagnostic, therapeutic, and rehabilitative processes, but she can act in this way only because she is informed. Even if a citizen is not yet a patient, provided health information could play a double role: on the one hand, it could prevent the onset of specific diseases, and, on the other hand, it could play an educational role that makes the citizen more aware of her rights and duties towards the NHS.

The aim of this experience paper is to present both the particular methodology adopted to produce the guidelines and the

[1] `http://www.salute.gov.it`
[2] cf. the Alma Ata Declaration (1978), the Ottawa Charter (1986), the Jakarta Declaration (1998), the Bangkok Charter (2005).

mock-up, and the main technical innovations of the portal, in terms of interactivity and user interface. We therefore structure the paper as follows: Section 2 outlines the methodology and the activities carried out in the project; Sections 3–5 describe such activities and the related outcomes; Section 6 presents the redesign of the portal and describe the mechanisms used in the portal for semantic classification of contents to empower information retrieval; finally, Section 7 concludes the paper.

THE METHODOLOGY ADOPTED IN THE PROJECT

To devise the mock-up and the guidelines, we adopted a User-Centered Design (UCD) approach, which, as standardized in the ISO 13407, identifies four principal activities: *(i)* understand and specify the context of use, *(ii)* understand and specify the user and business requirements, *(iii)* design the product, in particular by creating a prototype, and *(iv)* evaluate the design.

In this project, we focused on *(i)* – *(iii)*, whereas activity *(iv)* is currently on progress. In the initial activities, the main challenge has been to understand the context and the requirements of a portal which potentially could be visited and used by millions of citizens. In particular, we had the need to obtain useful insights on the following questions:

- which are the health needs of the Italian population, i.e., what is the epidemiological situation of the main diseases and risk factors for diseases in Italy?
- who searches the Internet/Web for health information, which forms she adopts to surf the Web, and which kind of health information is actually looked for?
- what are other information needs in terms of protection and promotion of health that could be satisfied through online communication?
- what works on Internet/Web, i.e., which types of Internet/Web health interventions are actually efficacious and effective for improving health?

To this aim, we carried out our analysis in three main stages: *(i)* design and administration, for several months, of an online questionnaire, aimed at identifying the needs of the citizens using (also) Internet/Web to access health information and health services; *(ii)* systematic study of the literature concerning health needs and what has been discussed and demonstrated about the effectiveness of Internet-based interventions on public health; *(iii)* systematic analysis of a significative number of sites/portals of local health administrations, in order to derive possible best practices and to identify the critical points to be addressed.

Then, on the basis of the outcomes, a mock-up of the portal has been devised. The following sections provides some insights on the various activities. For the full details (including all the collected data) the reader is referred to [5].

THE ON-LINE QUESTIONNAIRE

In order to collect data concerning the online information needs of users of the Italian NHS, we have run a survey in the period ranging from April 14 to September 21, 2010, through the definition and the online administration of a questionnaire. The questionnaire considered the following aspects:

- socio-demographic characteristics of the interviewees (age, sex, geographic area, education level, employment status);
- how they access Italian NHS Web sites;
- frequency of consultation of the Web, reasons for their consultations and main diseases included in their searches;
- which health promotion campaigns and which data on quality of the healthcare performances they would like to see advertised on NHS sites;
- how they evaluate the quality (i.e., completeness and usefulness) of online information currently available on the portals of the Ministry of Health and of other NHS organizations.

The questionnaire has been advertised on various sites, including the current portal of the Ministry of Health, the sites of some local health organizations, and on Facebook. We collected 2381 responses, 2324 of which have been analyzed, after checking the quality. 866 respondents were male (27%) and 1458 (63%) were female. 62% of the surveyed citizens use the Web especially for finding general information. Only around 30% use the Web in the first instance to search about an health problem, percentage that is relatively homogenous in different age groups; it varies from 23% for those who are 65 years old or more to 28% for those who are under 30. Around 58% of respondents prefer to search online information about the protection of the health rather than apply directly to a doctor. This is primarily due to the fact that through the Web they can immediately get some information. The information mainly searched includes: *(i)* specific diseases, therapies/treatments, side effects of therapies; *(ii)* hospitals or other medical facilities, booking systems for medical examinations, doctors or specialists; *(iii)* lifestyle. People look for information about the following diseases or health conditions: cardiovascular and/or lung diseases (23%); rheumatic and musculoskeletal diseases (16%); gastrointestinal diseases (gastritis, colitis, etc.) (12%); infectious and/or sexually transmitted diseases (9%); cancer (7%).

According to those who filled out the questionnaire, the health campaigns that should be promoted through the web sites of the Ministry of Health and other NHS organizations, as first option, should concern blood donation (20%), organ donation/transplantation (16%), workplace safety (13%), and responsible use of medicines (12%). If we consider more than one answer option for each respondent, preferences also include issues concerning the responsible use of drugs, screening cancers (breast, cervical and colorectal), proper nutrition/obesity. About half of the respondents consider important to find on institutional sites information on attitudes and actions necessary to maintain good health (49%), and indications concerning the levels of quality of health services provided by the local health organizations and hospitals (50%). For the 78% of respondents, the data on levels of quality should be published on the portal of the Ministry of Health. For what concerns the quality[3] of health

[3]The quality of information is expressed in term of usefulness, accuracy, level of update.

information currently available on the Web, the best overall score has been obtained by the sites of associations of patients with specific diseases. Interestingly, the most useful information currently available on the portal of the Ministry of Health has been considered the one on transplantation, statistical data and materials on contests, announcements and legislation.

THE REVIEW OF THE LITERATURE

The epidemiological analysis of the health status of the Italian population was made through consultation of official data and reports of the Italian Ministry of Health, the National Observatory of Health of the Italian Regions and the National Institute of Statistics [4, 2, 3, 10].

To understand the Internet health information needs of the population, also in order to validate the online questionnaire, a systematic review of the literature was performed. A total of 52 cross-sectional surveys were retrieved, carried out mainly in the USA and Europe. The analysis of the three main surveys performed in USA, Europe and Italy [9, 7, 1] allowed us to identify the main determinants of Internet use for health purposes, the type of health information most frequently searched on the Web and other useful information. Gender, age and socioeconomic status are the major determinants of Internet use for health purposes. Women search the Internet for information about health more than men, even if they are penalized by the fact that they sometimes have less access to the Web. Younger people and people with high socio-economic level search more frequently the Internet for obtaining health information, but the quote of elderly and disadvantaged people using Internet for health is increasing. Specific diseases and specific treatments are the most popular topics searched through Internet. However, it is important to note that people searching the Internet for having information about health promotion activities and interventions for disease prevention are increasing, as well as people seeking information about access to health services and the performance of health care organizations. Although the main health related activity on the Internet is information seeking, a considerably increasing number of people use the Internet as a communication channel, participating in forums, self-help groups, etc. The increasing use of Internet to tackle isolation, to access experiential knowledge and for gaining social support should definitively taken in proper consideration when defining the Internet health information needs of the population.

The evaluation of the effectiveness of health interventions delivered through Internet is a difficult task. The field has suffered from a lack of clarity and consistency. The absence of professional leadership and of accepting governing approaches, terminology, professional standards, and methodologies has caused the field of the evaluation of these intervention to be diffused and unstructured. Only recently some categorizations have been proposed, as the classification proposed by Strecher [14], considering the ways that Internet can interact with the user: *(i)* user navigation; *(ii)* collaborative filters; *(iii)* applications; *(iv)* human-to-human interactions. Given the number of original studies evaluating the effectiveness of Internet health intervention, in this case the systematic search of the literature was limited to systematic reviews and/or meta-analysis published in the literature. A total of 52 systematic reviews/meta-analyses fulfilled our predetermined inclusion criteria and were included for analysis. The methodological quality of the studies evaluating the effectiveness of Internet health intervention is not high, and the possibility of some conflict of interests cannot be ruled out in some situations. Despite these limitations, considering the most comprehensive reviews on the topic [14, 12, 11], it is possible to draw different conclusions: (i) the most effective Internet health interventions are the tailored interventions, with adaptation to the user, personalization and feedback; (ii) the sizes of these interventions could be categorized as small to medium for population-based interventions; (iii) however, the potential impact of these interventions on population health is high, and the cost-effectiveness ratio potentially highly favorable compared to other health interventions; (iv) however, common sense advices to implement hybrid models, which could combine applications or tailored interventions, user navigation, collaborative filtering, as well as human-to-human interactions, considering the high popularity of the latter ones among the Internet users.

The results of the review of the literature allow us to draw a set of recommendations for the construction of a national evidence-based health website. In summary it should:

1. contain information concerning the physiopathology of the human body, the most frequent diseases, risk behaviors, and health interventions of proven effectiveness, in order to improve the health literacy of citizens (cf. *Salute A–Z* in Figure 1);
2. include tailored interventions, with adaptation, personalization and feedback, aimed to promote healthy behaviors for disease prevention and compliance to secondary prevention programs of proven effectiveness (cf. the availability of applications on the portal, see Section 6);
3. give accurate information on the organizational structure of the national NHS, in order to facilitate the access to the health care organizations and, at the same time, to promote the appropriate use of them (cf. *Esplora SSN* in Figure 1);
4. contain information about the performance of the different health care organizations (hospitals, etc.) and, possibly, of physicians;
5. include systems and tools able to endorse the participation of citizens, as well as the human-to-human interactions (cf. the use of Web 2.0 tools, as discussed in Section 6).

AN ANALYSIS OF ITALIAN HEALTH WEBSITES

An analysis of Italian health organizations' websites has been carried out in order to obtain useful indications in planning for an effective online communication strategy. Its objective was to respond to the following questions:

- what kind of health information is available on the websites of such organizations (aims, logical information structure, content, online services, technologies, etc.)?
- do the websites satisfy the health information needs of the population concerning the available healthcare services, the promotion of public health and the prevention of diseases?

(a) Homepage

(b) Menu

Figure 1. The mock-up

- do they observe the standards set by the Italian e-government policy?

We have identified a set of indices and organised them in 4 dimensions, that explain the concept of "quality of online health information supply":

1. institutional identity and networking attitude: the possibility to easily identify the site with a specific authority, and also its attitude towards the development of thematic and operative networks with other public health administrations or professional associations or patients' associations working in the health service;
2. administrative transparency, based on the availability of online information regarding the organizational structure of the NHS, tasks and performance, and the availability of citizen protection mechanisms/tools;
3. availability and quality of the online services, concerning not only the quality of the website content and the use of Internet healthcare interventions, but also the quality (interactivity) of electronic forms and of facilities for on line booking of such services
4. accessibility and ICT quality, referring to the different solutions for presenting and organising the website content, regarding both accessibility for Internet users and technological criteria.

The analysis has considered the websites of all the Regional Governments (in fact, 19 regions and 2 autonomous provinces) and the websites of a sample of 84 Local Health Authorities (out of 195 in total). The main results of the analysis highlight that Regional Government health websites show:

- a strong institutional identity, because they present the local health policy as an outcome of the approach taken by Regional Governments and have a low international perspective;
- a weak attitude to networking with other public health administrations or private associations working in the local health service;
- a satisfactory level of administrative transparency, even though citizen protection mechanisms/tools are mainly normative statements;
- an high level of attention to the promotion of public health, even though they rarely make use of the communication campaigns offered by the Ministry of Health;
- a good level of ICT quality.

Instead, the websites of the Local Health Authorities are characterized by:

- a significant institutional identity, with frequent references to their respective Regional Government rather than to the Ministry;
- a good level of administrative transparency, even though the citizen protection mechanisms are mainly normative statements;
- a satisfactory level of availability of information regarding online services, even though electronic forms and facilities for online booking of health services are not very frequent;
- a good level of ICT quality.

Therefore, analyzing the websites of the Regional Governments and of the Local Health Authorities we can see a scenario revealing different online health communication strategies, with a strong local identity and with weak coordination by and towards the central institutional level (Ministry). In order to improve on line health communication, we suggested the following strategies:

- to recognize the centrality of citizens/patients, both in the phase of identifying and structuring the content of websites, and during the editing of the website and the organization of health services via the Internet;
- to strengthen the orientation and coordination role that the Ministry of Health should play in respect of other healthcare administrations as regards information and commu-

nication activities;
- to view online health information as the result of cooperative networking between the Ministry of Health and the other healthcare administrations (at national and local level);
- to build a network of health public administrations and professional associations and patients' associations working in the health services, aimed at exchanging information and strengthening mutual legitimacy, in order to reduce the fragmentation of information and to promote wider communication.

THE PORTAL

Figure 1 shows the homepage of the proposed mock-up. The four main pillars of the proposal are *(i)* a navigation interface, on the top of the page, based on "buttons" instead of the classical links, *(ii)* a large number of interactive applications, either accessible on the portal or downloadable on mobile devices, *(iii)* the possibility to customize the home page through the *MyPage* application (a-la iGoogle) and *(iv)* advanced search functionalities and page-to-page correlations based on taxonomies. In terms of contents, the (mock-up of the) portal respects the suggestions previously described.

The navigation menu based on buttons has the twofold aim of being aesthetically more catchy than the classical one, and ready for visualization on touch devices (e.g., iPads, touchpads, etc.), which represent the future of Web surfing. In order to enforce the citizen-oriented vocation of promoting good life habits, a lot of applications will be made available, e.g., for dietary calculation, alcohol abuse control, pregnancy check schedule, etc.; such applications, which enhance the level of interactivity of the portal and therefore attract users, can be mobile apps to be downloaded on devices, or Web applications accessible through the portal.

The possibility of customizing the page of the portal is an absolute novelty wrt existing public administrations/agencies, not only in Italy but, at the best of our knowledge, all over Europe. This has been obtained by including a MyPage application, which allows each registered user to personalize the information she wants to access.

The portal provides four main "channels", i.e., sections specifically tailored to particular categories of information and possible interested users: citizens (corresponding to *La nostra salute*), health and administrative operators (*Attività e professioni*), users interested in institutional and organizational information (*Ministro e Ministero*), and users interested in *News e Media*. Each section, which is managed by a specific editorial board, has its own space in the home page, even if, in compliance with the user-centered approach previously described, the section dedicated to citizens is predominant.

Moreover, in order to satisfy the suggestion 4 of Section 4, a specific information system, collecting quality and performance data of healthcare organizations, will be developed and made accessible through the portal. It is also worth remarking that Web 2.0 tools are used throughout the portal (e.g., tag clouds, wiki and blogs, correlations with Facebook, Twitter, etc.), in order to promote user interaction.

To provide users with powerful and effective means to retrieve the information they are looking for on the portal, its contents are being classified according to a *taxonomy*, i.e., a classification scheme which organizes in a hierarchical structure the main categories of interest in the domain. By virtue of this classification, the user can query the portal by referring to the categories of the taxonomy, and get as reply those documents that belong to the same or related categories. Notably, the reference to the categories does not need to be explicit, i.e., the user is not required to a priori know the taxonomy to pose queries to the portal (see also below).

In order to simplify the process of definition, validation, and maintenance of the taxonomy, and to ease the possible integration in the portal of contents coming from external information sources, to realize our taxonomy we analyzed existing (de-facto) standards. Among various proposals for content classification and terminological representation in the biomedical domain (e.g., UMLS[4], ICD[5], SNOMED CT[6], GALEN[7]), in our project we referred to `MeSH` (Medical Subject Headings)[8] a taxonomy developed by the National Library of Medicine (NLM) of the United States. This choice has been motivated by the fact that `MeSH` is specifically tailored to information retrieval (and thus suited to our aims), contains also non-biomedical or clinical categories, and with respect to other proposals has more compact dimensions (it includes around 22000 terms), which makes it simpler to use.

In fact, to make easier the process of content classification, we operated a simplification of the `MeSH`, aimed at both reducing the number of categories and eliminating the most technical ones. However, to not loose the advantages of adopting a (de-facto) standard, we simply "cut" some branches of the "`MeSH` tree" so as to exclude too detailed categories. In this process, we have been helped by domain experts. The resulting taxonomy contains around 3500 `MeSH` terms.

Despite `MeSH` includes general purpose categories (e.g., the ones of the *Disciplines and Occupations* or *Phenomena and Processes* branches), we found out cases in which `MeSH` results insufficient in order to satisfactory classify some documents included in the portal. To overcome this problem, we decided to include in our taxonomy some of the categories used for article classification in (the Italian version of) Wikipedia[9], and in particular we selected the categories included in the *Human Activities* branch of the Wikipedia classification schema[10], which in fact substitutes in our taxonomy the (more limited) *Humanities* branch of `MeSH`. We choose the Wikipedia classification for two main reasons:

[4] `http://www.nlm.nih.gov/research/umls/index.html`
[5] `http://www.who.int/classifications/icd/en/`
[6] `http://www.ihtsdo.org/snomed-ct/`
[7] `http://www.opengalen.org`
[8] `http://www.nlm.nih.gov/mesh/meshhome.html`
[9] `http://www.wikipedia.org/`
[10] `http://it.wikipedia.org/w/index.php?title=Speciale:AlberoCategorie&target=attivitá+umane&mode=categories&dotree=Vai`

(i) Wikipedia is one of the most popular portal on the Internet, and its contents are widely shared among several millions of users; (ii) its category tree is designed through a collaborative process aiming at including categories proposed by the users, and therefore particularly suited for information retrieval activities.

We finally observe that, to further support the process of content classification in the portal, we foreseen the development of tools helping the research of the categories in the taxonomy. In this respect several directions can be followed: (i) realization of keyword-based search mechanisms to directly access the categories of interest in the taxonomy (thus avoiding to manually navigate the taxonomy); (ii) use of a dictionary (extending the one already available with MeSH) to include in the taxonomy also synonyms of categories, thus both expanding the lexicon of the taxonomy and including more terms in it, in a way transparent to the user; (iii) definition of techniques for automatic keyword extraction from text documents, in such a way that document classification could be done according to extracted terms, in the spirit of [6, 13]. More details on the taxonomy and the classification process in the portal of the Italian Ministry of Health can be found in [8].

CONCLUSIONS

In this experience paper we have presented a project, carried out during 2010, focused on the definition of guidelines for online communication on protection and promotion of the health in the Italian NHS (including regional health web portals, local health authorities websites, hospital websites, etc.), and the realization of a mock-up to serve as input for a redesign of the web portal of the Ministry of Health. The guidelines, as well as the mock-up, were successfully presented in a workshop on February 17, 2011. They are published online and are currently in the process of being formally adopted by all the interested administrations.

In a scenario in which all websites of the NHS organizations are realized in accordance with the guidelines, the portal of the Ministry of Health can be also able to act as a broker, in order to offer a centralized access to information and services of the NHS. An interesting future issue will be to consider how users will react, with respect to trust and privacy concerns, about the personalization features of the portal offered through the MyPage, as they may feel as their information access requests on the portal might be logged and analysed for potential medical information.

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The biggest challenges are the social ones: workshop report from EICS4Med 2011

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ABSTRACT
EICS4Med was held in conjunction with EICS2011 in Pisa. Many challenges to designing innovative healthcare applications where identified, including the tendency to design conservatively to avoid patient harm and the difficulties of establishing rich communications between clinicians and engineers. In considering the timescales for developments, the group concluded that technical developments are more easily achieved than the equally essential cultural changes, such that which errors are accepted and regarded as learning opportunities, and investment is directed toward the design of safer, more usable systems.

INTRODUCTION
First the statistics: the workshop was attended by 23 participants from 6 countries, and 14 papers were presented. These covered a variety of medical systems:

- Visualisation, simulation and VR systems (e.g. for training or surgery);
- Systems to support cooperation, coordination and planning;
- Clinical information systems; and
- Medical devices.

Presentations were kept brief so as to maximise the time for discussion.

CRITERIA FOR SUCCESS
In discussing criteria for success, it became apparent that our research is motivated by many different aims, including:

- Avoiding harm to patients;
- Improving the reliability of systems;
- Delivering better training for clinicians; and
- Improving patient treatment through innovation.

Workshop report from EICS4Med 2011 workshop.

The aims of delivering innovative technologies that may improve patient outcomes and of avoiding harm can sometimes be in conflict with each other, as avoiding harm may imply a conservative approach to development, focusing on reliable engineering rather than innovation. Other challenges that were identified included:

- How to balance the need for consistency (as nurses and patients move from one context to another) with the need for specialisation (to optimise for local needs);
- When systems should be context-aware, adapting to the context of use, and when design should be tailored to specific needs;
- To what extent clinicians (and other users) should be expected to be trained in the use of particular systems, and to what extent systems should be "walk up and use" tools that require minimal training;
- How to improve communications between clinicians and engineers, who bring complementary skills sets to design, but may also bring incompatible understandings and conflicting values; and
- How to identify and meet the real needs of medicine, and avoid "tilting at windmills", addressing imagined but low priority issues.

Although participants came with different interests and priorities, there was nevertheless a consensus that the ultimate aim of research on the engineering of interactive computer systems for medicine should be on developing systems that work for the people (clinicians, patients and others) who use them, and who are dependent on them for effective treatment.

PRIORITISING FUTURE RESEARCH
The afternoon activity built on the theme of challenges by considering what the priorities for future research and development should be. This was done with the aid of post-it notes and a time-line, considering not just what the priorities are, but also the timescale on which they might be achieved (see Figure 1).

The latter proved to be the subject of much discussion, as the question of what it means to "have achieved" something in this area is often unclear: unlike challenges such as mapping the human genome or putting a person on the moon, most of the challenges we identified cannot be easily classified as "done" or "not done", as typically something has already been achieved, but it is always possible to do better.

Figure 1: constructing and voting on a timeline

Priorities were voted on by the group with the use of coloured dots, and proposals were grouped into larger themes to produce a summary timeline (Figure 2). A common thread of these themes was that technology developments were typically judged to be achievable on a shorter timescale than social and cultural changes. This may be because the technologies that we can envisage are ones that – by definition – we have already made some progress on, and for which we can envision what further developments are needed, whereas we recognise the magnitude of the challenge in effecting social change.

Figure 2: the summarised timeline and issues

So, for example, the development of inspectable safety assessments for devices, and the introduction of a "near miss" button for incident reporting were considered to be achievable within a few years, whereas the creation of a culture in which errors are accepted and regarded as learning opportunities, and where the healthcare system invests heavily in the design of safer, more usable systems, were regarded as much longer term objectives.

These challenges help define a future research agenda in engineering interactive computer systems for medicine.

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