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.

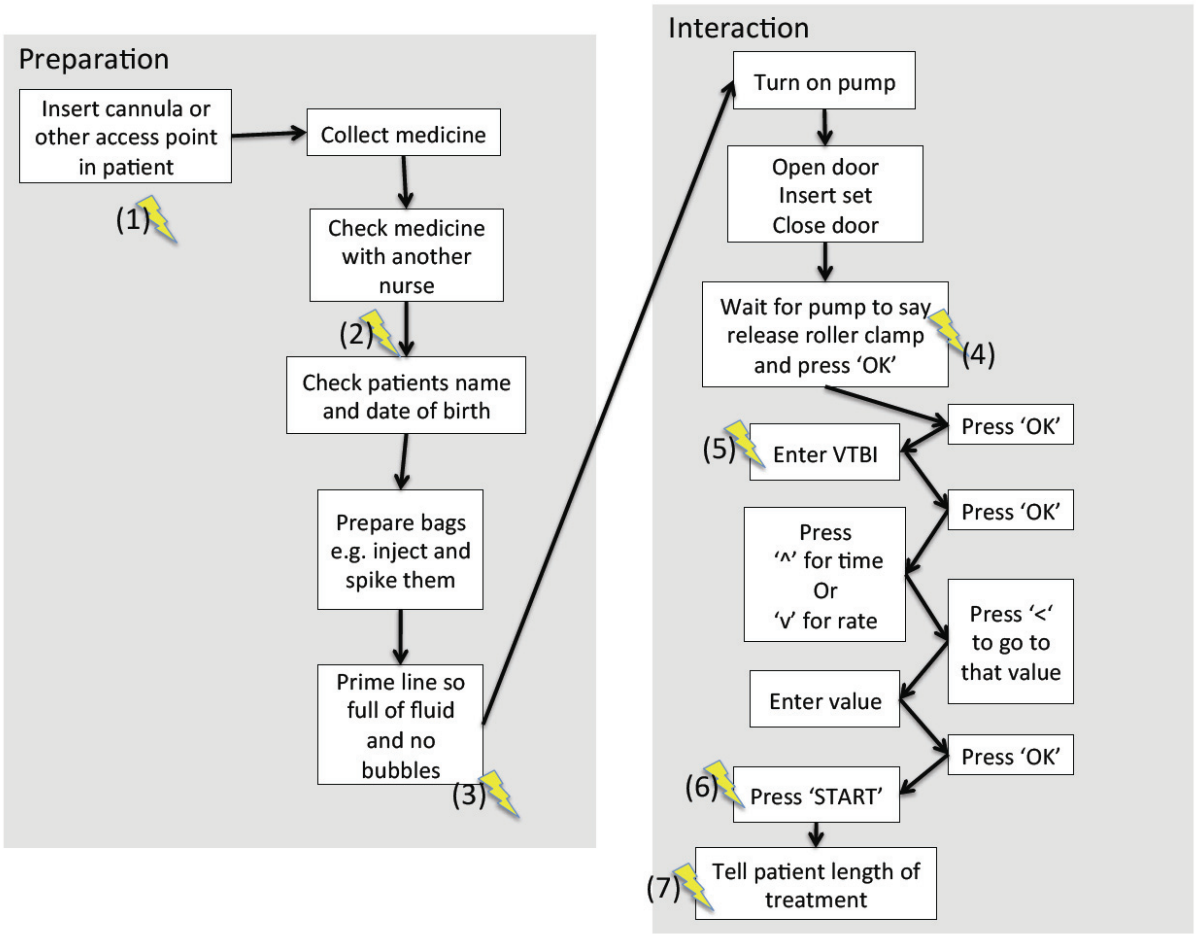

Figure 1: Task steps and disturbances in infusion pump interaction

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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