

7 Themes for Guiding Situated Ergonomic Assessments of Medical Devices: A case study of an inpatient glucometer

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Abstract

There is relatively little guidance on the situated ergonomic assessment of medical devices, and few case studies that detail this type of evaluation. This paper reports results of a detailed case study that focuses on the design and use of a modern blood glucose meter on an oncology ward. We spent approximately 150 hours in-situ, over 11 days and 4 nights, performing observations and interviews with users. This was complemented by interviews with two staff with oversight and management responsibility related to the device. We identified 19 issues with the design and use of this device. These issues were grouped into 7 themes which can help guide the situated study of medical devices: usability, knowledge gaps and mental models, workarounds, wider tasks and equipment, the patient, connection between services, and policy.

Keywords:

Medical Devices

Human Factors

Usability

Situated studies

1 Introduction

The importance of usability engineering for medical devices has been more widely recognised since the publication of *Medical devices – Application of usability engineering to medical devices* (BS EN 62366, 2008). Both the design and use of medical devices affect patient safety and the quality of care; both issues are a concern and priority internationally (Kohn et al., 1999; Department of Health, 2000, 2001a, 2004). The application of ergonomics continues to contribute to this area by offering frameworks (Vincent et al. 1998; Carayon et al. 2006; Sharples et al., 2012), tools and methods (Buckle et al., 2006), case studies (Martin et al., 2012; Lang et al., 2013) and challenges for researchers and practitioners to overcome (Martin et al., 2008). However, detailed empirical case studies of inpatient medical device evaluations are still needed to test and exemplify possible approaches to studying the use of devices in context; these will provide a firm foundation on which to base better guidance on how to conduct these evaluations. This paper has two main research objectives: 1) to present a detailed case study of a situated ergonomic assessment of an inpatient blood glucose meter; and 2) to identify themes that serve as guidance for design and use reviews of inpatient medical devices.

2 Background

BS EN 62366 raises the profile of human factors and details how to integrate usability with medical device development (Lang et al., 2013). It seeks to ensure that medical devices that are placed on the market are usable and safe. It highlights various activities as part of a usability engineering process to prepare a device for market, including contextual inquiry and observations. These are described as being typically done early in the design process to find out about users and their tasks in context. Observing a working prototype embedded in context is difficult, unless either the clinician using it is a member of the

development team or a clinical trial has been formally approved. Consequently a range of other techniques need to be employed for formative evaluation (BS EN 62366, 2008).

BS EN 62366 gives more detailed guidance, from user research to evaluation, during development than it does on post-market surveillance (PMS) activities. Arguably, this stage in the design lifecycle presents a rich opportunity for learning. It is at this time when a device becomes coupled to the sociotechnical system that unintended consequences emerge that could not be predicted in the design process (Ash et al., 2003).

As Randall (2001) argues, PMS systems should not be thought of as just vigilance systems to monitor for adverse incidents: they should include broader activities that provide manufacturers with knowledge to enhance their product to ensure its long-term viability. PMS should be embedded within a larger quality management system (Schröer, 2012). Li et al. (2011) provide detail about the feedback channels medical device manufacturers exploit to learn about the deployment and use of their devices. Within their work, observations in client hospitals are mentioned in passing but given little attention, so the inference is this is not a widespread or significant activity.

Assessing medical devices in-situ is not new, but neither is there a rich history of detailed case studies that have been published in the literature. Documented assessments are needed not only to learn about the particular device under study (related to research objective 1) but also to reveal broader themes that are useful for other ergonomically informed situated assessments of medical devices (related to research objective 2).

2.1 Situated studies of medical devices and glucometers

Field studies of medical device design and use to elicit requirements are less common than one might expect given their importance (e.g. see Martin et al., 2012). Collating case studies can also be challenging because they are published across ergonomic, human factors, HCI, clinical and informatics domains. There is a need to bring these different literatures together, but this is most effectively done around particular topics. For example, Schraagen and Verhoeven (2013) provide an extensive review of methods used to investigate user-interface issues with infusion pumps across domains. In their review, 47 empirical studies of infusion pumps were identified, 9 of which were categorised as observational studies. These nine studies ranged from observing usability issues (e.g. Obradovich & Woods, 1996), to counting different frequencies and types of error (Husch et al., 2005). Within this nine, only Liljegren et al. (2000) use field studies to elicit requirements for an infusion pump in ICU and redesign the interface based on these.

Blood glucose meters, or glucometers, are an important medical device where one would expect a wealth of ergonomic case studies. They are important because they play a central role in modern inpatient diabetes management: they allow the measurement of blood glucose levels at the patient's bedside in minutes, compared to what could be hours for laboratory tests (Perry & Wears, 2009). Ross et al. (2013) highlight the significance of inpatient diabetes

management including that poor glycemic control is associated with longer time in hospital and associated costs (Smith et al., 2009); the need for quality improvement in inpatient diabetes care (Daultry et al., 2011); and that good diabetes management is a priority for healthcare organisations (Department of Health, 2001b). These issues are significant, for example, in the UK, diabetes patients account for 9% of hospital expenditure (Diabetes in the NHS report, 2007). Modern inpatient diabetes management requires more frequent measurement of blood glucose levels to check whether patient's are within narrow limits (Perry & Wears, 2009). Furthermore, there have been relatively recent developments in these devices in terms of more complex functionality like scanning patient identification wristbands; and developments in their capability like the uploading of data to a central hospital database so data can be monitored remotely. These changes are not just technical but could impact work and patient care across the hospital.

Despite the importance of glucometers there is not a wealth of case studies that assess them in the literature. Rogers et al. (2001) perform a usability analysis on glucometers used at home and find they are not as 'simple' as the manufacturers suggest. They have over 50 procedural steps to take a reading and a number of issues that could be improved, e.g. modifying test strips, the meter's design, their features, the blood sampling procedure, instructional material and with the introduction of innovative larger system changes. Price (2009) describes an interesting case that involved the repeated hospitalisation of a 28-year-old patient who had sporadic low glucose readings and hyperglycaemia complicating her dosing decisions. After extensive investigations her puzzling condition was routed in user issues with her glucometer. McDonald (2006) report a more serious case of modern inpatient diabetes care that nearly led to a patient receiving a fatal dose of insulin. The fatal error nearly occurred because two patients had the wrong patient identification wristbands on, so one nearly received insulin for the other's high glucose level. It was averted because the medics treated the patient's data with suspicion. This active role of the human element interpreting data from modern glucometer systems and avoiding error is also recognised as part of the resilience of the system by Perry and Wears (2009). Despite the issues listed above a situated ergonomic assessment of an inpatient glucometer could not be found.

2.2 Broader themes, models and frameworks

Case studies become more powerful tools for learning if we can extrapolate from the details towards more general learning, e.g. by proposing broader themes and frameworks. A recent demonstration of extrapolating out themes is by Lang et al. (2013) who identify five factors that may improve the effectiveness of a physiotherapy device for use by adolescents with Cystic Fibrosis: engagement, information, confidence, aesthetics and compatibility with lifestyle. A recent example of a framework is by Sharples et al. (2012) who use five case studies, with existing human factors theories and approaches, as the basis for proposing a model to describe the link between device design, user, context and consequences. SEIPS (Systems Engineering Initiative for Patient Safety) is a similar model in that it focuses on details of the work system, processes and outcomes (Carayon et al., 2006). However, Sharples et al. (2012) differentiate their model by focusing it on "the role of the device with the aim of supporting

future device designers in understanding the potential influences on the impact of medical device design.” For studies that take a socio-technical view of the world there will always be a link between the device and the system of work that surrounds it, and a view of the system of the work in which the device is embedded. We take a socio-technical perspective in our glucose meter analysis and focus on the device and the system of work that surrounds it.

3 Method

Ethical clearance was granted by an NHS REC (National Health Service Research Ethics Committee) to perform an investigation into medical device design and use on a busy Oncology Ward in a London teaching hospital. Observations and interviews were done for 11 days (approx. 7.30am – 7.00pm) and 4 nights (approx. 7.30pm – 7.00am) over a 5 month period, totalling about 150 hours of fieldwork. The glucometer presented itself as an interesting device to study because it had only just been introduced on the ward. Around 26 episodes of blood glucose monitoring were directly observed over 6 days, i.e. where the researcher accompanied the user of the glucometer. The majority of observations were just prior to patient lunchtimes. Not every observation day resulted in glucometer observations because staff were too busy to notify the field researcher or other activities conflicted with these observations. These direct observations were embedded within more general and indirect observations and complemented by contextual interviews with staff at opportune times.

The data gathering and analysis was informed by Distributed Cognition (DC), which looks at how information is transformed and propagated across people and artefacts over time (Hutchins, 1995; Hollan et al., 2000). DC has been used in the study of different contexts in healthcare (Nemeth et al., 2004; Hazlehurst et al., 2007; Hazlehurst et al., 2008). However, its application to the situated assessment of specific medical devices is less common (Rajkomar & Blandford, 2012). To facilitate the application of DC we use the DiCoT method (Blandford & Furniss, 2006; Furniss & Blandford, 2006). This was complemented by a logic-based analysis that helped identify device design and use issues systematically, described in (Masci et al., 2012). DiCoT essentially divides the contextual data into five interdependent models: the information flow model, artefact model, physical model, social structures model and evolutionary model. This method has been successfully applied in different healthcare contexts and other socio-technical systems more broadly (e.g. Sharp et al., 2006; Sharp & Robinson 2008; McKnight & Doherty 2008; Rajkomar & Blandford, 2012; Werth & Furniss 2012).

Detailed field notes were kept throughout data gathering and analysis. Like Grounded Theory techniques (e.g. Furniss et al., 2011b), data gathering and analysis were iterative so analysis could feed further data gathering and understanding was built from the bottom-up, i.e. from users and their use rather than from instruction manuals and management. Meetings between the first and second author facilitated the logic-based approach, which interrogated the emerging data in a finer grained way. The DiCoT models, described in Section 4.1, were developed. Disturbances and issues were recognised either by users directly self-reporting issues or researchers gaining insight from observations

and analysis; these are reported in Section 4.2. By reflecting on these issues and patterns, we identified broader themes that can be used to guide future analyses. These themes were linked to the literature and are presented and discussed in Section 5.

4 Results

We first report a description of the device and its use, which was built from empirical data grounded in users' perspectives. This understanding provides a foundation for the issues we raise.

4.1 Description of the device and its use

We briefly describe the basic workings of the system with relation to DiCoT's five models (Furniss & Blandford, 2010).

4.1.1 Results from The Evolutionary Model

Findings from this model include significant developments over time. The introduction of this glucometer to the ward marks an evolutionary change to inpatient diabetes management, and introduces staff and patient barcode scanning technology that is new to the ward. The glucometer has the ability to upload its results to a central network so patient glucose readings can be monitored remotely and electronically.

4.1.2 Results from The Artefact Model

Findings from this model include the most significant artefacts around the new device's use: the glucometer and docking station, the case and the trolley set-up, and staff and patient barcodes.

The blood glucose monitor has one physical button to turn it on and off, which is centrally located below the screen. It has a touchscreen to allow input, e.g. via an onscreen number pad for patient and operator ID. It has a test strip port at its top to allow test strips to be inserted for blood readings and a beam from the top enables barcode scanning. When not in use staff put the handheld devices into their docking stations to charge them and to upload patient results to a central server (see Figure 1). The device has wireless capability.

[Figure 1 about here]

Figure 2 shows: (1) the glucometer, (2) the swabs, (3) lances, (4) the vials that contain strips used to collect the patient's blood, and (5) two small plastic bottles of fluid that are used in quality control procedures. One plastic bottle has a grey top and the other a white top to distinguish the HI and LO fluid needed for quality control tests. The HI and LO fluid provide a high and low range so the device can be tested. The test strips are kept in closable vials to maintain their integrity for accurate readings. The lances are used to prick the finger of the patient and are designed to be single use so they cannot spike again once they have been used once. The swabs are needed to absorb any blood after the skin has been broken and enough blood has been used for the reading. Figure 3 shows that the typical set-up of the trolley has two levels for clean apparatus and waste. The top level is the clean level that has the glucometer case and (6) a box of disposable gloves. The bottom level has (7) a portable sharps bin required to

put in 'sharps' (e.g. the lances) after they have been used by the bedside and (8) cardboard trays for the temporary location for other waste like used swabs and used test strips before they are transferred to a bin.

[Figure 2 about here]

[Figure 3 about here]

4.1.3 Results from The Physical Model

The oncology ward had 24 beds; 16 are in four 4-bed bays and the remaining 8 are single bedrooms. Trolleys would not typically be wheeled to the patient's bedside in single rooms, e.g. due to infection control measures, and so there would be more preparation outside of the room, including manually typing the patient's ID rather than scanning it. Figure 4 shows the layout of the ward. When doing a blood glucose reading round, the healthcare assistant typically makes a note of all the bed numbers that need to be seen on their handover sheet, a cardboard tray or a piece of tissue paper to help them remember.

[Figure 4 about here]

4.1.4 Results from The Social Model

Different individuals were involved in blood glucose monitoring. The patients had more interaction compared to the glucometer's predecessor, as they had the added requirement to wear and offer their patient wristband for identification purposes. The healthcare assistants were the main users of the device as they did the blood glucose reading rounds and used the device. If the readings were too high or too low then the healthcare assistant would need to notify the nurse assigned to that patient immediately. Sometimes the nurses would use the device if the healthcare assistants were busy or they needed more urgent readings. To understand the wider aspects of the system we also interviewed a diabetes specialist nurse and a biochemist who monitor the data that the system collects. The diabetes specialist nurse monitors the data for clinical reasons and the biochemist monitors the data for quality control purposes, e.g. errors reported in the database might signify that training is required or that a glucometer needs to be replaced.

4.1.5 Results from The Information Flow Model

The main process for using the device to take a glucose reading is summarised in Figure 5. However, extra details about the steps in the process are needed for accuracy. For example, Step 3 is normally only needed for the first patient because the member of staff stays signed-in for a length of time. This length of time is normally adequate to get from one patient to another. This time period might expire if the member of staff is distracted by another task (e.g. an urgent request by a patient) or if part of the task takes too long (e.g. we observed instances where the healthcare assistant needed to notify the nurse looking after a particular patient that the reading was too high or too low but they were difficult to locate).

[Figure 5 about here]

4.2 Issues in the table

Table 1 lists 19 issues that emerged from the analysis. The last column relates these issues to more general themes concerning the situated assessment of the design and use of inpatient medical devices, which are discussed in the discussion section.

[Table 1 to go about here]

5 Discussion

Seven broader themes for medical device evaluation emerge from the issues in Table 1. We describe each in turn below, expand on our results and relate these themes to the broader medical device literature:

5.1 Usability of the device

It is unsurprising that the usability of the device should emerge as a strong theme given the focus of the study. Six issues are associated with it in Table 1: 3, 9, 14, 15, 16, 19. Issue 3 (Emergency lockout) provides an interesting case as staff did not know what to do if someone had to use the blood glucose meter who did not have a patient ID. The diabetes specialist nurse and biochemist said staff should know to enter 2222 or 9999. This is known by staff who use this feature more frequently, e.g. accident and emergency staff, but proved more of an issue where this feature is rarely used. Entering 2222 or 9999 seems like an official workaround, as it is contained in the instruction manual. One potential design change is to have a specific option so the user can select 'Emergency use' or 'Patient has no ID' rather than try to recall an arbitrary sequence of numbers. We learnt that issue 9 (Failing to display patient details) occurs because of delays between synchronising the glucometer database with the main patient database; however, perhaps extra checks could be enforced by the device for safety. Issue 14 (Too much blood) puzzled the diabetes specialist nurse and biochemist as they were not aware of this issue. By their understanding the test strips were designed not to take too much blood so this should not be a problem. For Issue 15 (Premature blood) the device's feedback did not seem very salient, e.g. a small drop is added to the screen to indicate the device's readiness to receive blood (see Figure 6). This could be replaced by a much more salient display so users are more likely to notice it and wait, e.g. a count down could be displayed until the device is ready (see Figure 7). Issue 16 (Not taking notes) refers to the note taking feature being underutilised, which could have something to do with the ease of data entry. Issue 19 (Device freeze) indicates that there is no feedback for staff on what to do when the device freezes, or the reasons for this error.

[Figure 6 about here]

[Figure 7 about here]

This is a well-established theme that is strongly supported in the literature. For example, from their early study on infusion devices Obradovich and Woods (1996) report "several classic HCI deficiencies" including complex and arbitrary sequences of operation and ambiguous alarms. Lin et al. (1998, 2001) assess a commercial available PCA device and compare its performance with a prototype

through user testing. Usability testing has also been performed to develop medical devices (e.g. Garmer et al., 2002) and heuristics have been developed and applied to infusion pumps (e.g. Zhang et al., 2003; Graham et al., 2004). This is only a sample of work that has been done to evaluate devices, recognise requirements and improve the usability of devices.

5.2 Gaps in user's knowledge / Mental models of device use

Gaps in users knowledge and mental models of how things worked had three issues associated with it in Table 1: 1, 2, 3. The diabetes specialist nurse and biochemist were surprised that staff did not know who was monitoring the data and why (Issue 1: Data monitoring), and said staff should know to press 2222 or 9999 if the patient did not have an ID (Issue 3: Emergency lockout). The biochemist confirmed that all data was transmitted to a central database via the dock as its wireless capability was not activated (Issue 2: Information transmission). These gaps in user's knowledge might not impact their normal routine but could impact problem solving situations, e.g. if a visitor collapses and needs a reading or if the wireless network goes down their behaviour will be influenced by gaps and misunderstandings in their knowledge.

This theme seems less well established in the medical device assessment literature. The traditional focus on the usability of the device will typically bias evaluation toward interface issues and miss where there are gaps in users' knowledge and conflicts between user's mental models and the way the device works. BS EN 62366 (P27) explicitly draws our attention to the importance of mental models for effective device design and use, and for problem solving. However, it is less clear whether this work has been explicitly used for medical device design and assessment. Sharples et al. (2012) express the importance of work on users' mental models (e.g. Wilson & Rutherford, 1989) but it is less clear how this has been incorporated in their framework or case studies. This is an area that needs further research effort, that will recognise device and training needs, and could be most relevant for conceptually challenging issues e.g. multi-line intravenous infusion set-up (Cassano-Piche et al., 2012).

5.3 Workarounds, Adaptations, Resilience and Tailoring

This theme had six issues associated with it in Table 1: 3, 4, 5, 6, 10, 19. As stated above Issue 3 (Emergency lockout) provides an interesting case of a workaround. Workarounds are normally considered informal or unofficial practices that staff use, but here entering 2222 or 9999 is formalised in the manual. We class it as a workaround because the device does not directly support the avoidance of entering a patient ID when it is not known.

A different example of an adaptation included a member of staff who took to remembering his ID because he had stuck it in an inconvenient place after he received it (Issue 6: Staff ID stickers). This manual entry could erode some of the safety and efficiency gains from scanning because it takes longer and there is more potential to mistype digits. Continuous manual input of this kind could be monitored from the central database and remedial action taken, e.g. issuing a new sticker.

Staff were resilient to forgetting who needed a blood glucose check because they used different external artefacts to remember which beds needed to be attended to at the start of the blood glucose reading round (Issue 10: Blood glucose round). One design consideration is whether the device could play a role in supporting the round rather than single readings.

An example of a different workaround for Issue 19 (Device freeze) included staff working out that docking the device unfroze it as they could not even turn it off and on.

This theme incorporates different areas in the literature that use related terms. We see this class of behaviours as derivations of what Rasmussen (1986) calls “finishing off the design”. For example, Obradovich and Woods (1996) call this sort of behaviour tailoring e.g. nurses writing their own device guide for patients because manuals provided by the manufacturer were inadequate to help patients use the device. Koppel et al. (2008) provide an analysis of workarounds to do with barcode medication administration; Randell (2003, 2004a) has looked at appropriation and customisation of technology in ICU; and Furniss et al. (2011a) look at resilience practices around infusion pump use. These forms of adaptive behaviour towards technology need to be consolidated and developed in further research. It should be noted that these adaptations can have positive and negatives elements to them.

5.4 Fit with wider tasks and adjacent equipment

Fit with wider tasks and adjacent equipment had nine issues associated with it in Table 1: 4, 6, 7, 10, 11, 12, 13, 17, 18. The strength of this theme has really emerged from our approach that has sought to understand how the device is designed and used in its wider environment and practice. This theme highlights the strengths and weaknesses of integration, which can lead to improvement and innovation. An example of an improvement is Issue 11 (Hidden test strips) where the test strips are hidden from view in closed vials – could these vials have a window to allow users to quickly access the needed information? An example of an innovation is thinking not only about individual glucose readings but instead the blood glucose reading round, e.g. the informal practice of scribbling bed numbers to attend to on bits of card and tissue paper could be formally listed on the device and ticked off as the blood glucose monitoring round is completed, see Issue 10 (Blood glucose rounds).

This theme of fitting with wider tasks and adjacent equipment is hard to discern from the literature beyond it being a normal part of situated studies. A good example is Tang and Carpendale (2008) who look at how nurses cope with mismatches between mobile computer units and fit with practice – mismatches to physical space, the timings of lock-out features and the virtual coverage of the wireless network all contribute to the device’s poor performance. Rajkomar and Blandford (2012) report on infusion administration in ICU and conclude that it is a distributed activity across different artefacts, people and within other tasks. Situated and socio-technical studies understand device performance as part of the wider system of practice. Recognising strengths and weaknesses of this fit can provide data for improvement and innovation.

5.5 Putting the patient in the loop: Interactions and Implications

Putting the patient in the loop had 2 issues associated with it in Table 1: 8, 13. The main change for patients is that they now should wear a wristband that needs to be scanned in the process (Issue 8: Patient barcodes). We observed the following issues:

- Patient wristband not present as it has fallen off, e.g. in the shower
- Patient wristband not present as the patient has removed it
- Patient wristband kept outside the room as they refused to wear it
- Patient barcode doesn't scan as it has been printed badly or is incomplete
- Patient barcode doesn't scan as the wristband has been put on awkwardly
- Patient slept on the arm with the wristband so they were disturbed and needed to move so staff could access it
- Patients sometimes manipulate their arm awkwardly so the barcode and scanner can be aligned

In terms of the patient experience the last two were most noticeably, and the third issue suggests that at least some patients do not like wearing the wristband. For Issue 13 (Extra patient information) we suggest that the device could help record why patients refuse readings, e.g. one member of staff might not be as persuasive as others or refusals might take place because the patient has started eating – both issues that could lead to organisational learning and improvement.

In most of the traditional usability studies of inpatient devices we have reviewed, the patient is treated as a passive element, almost ignored, because it is the clinician that is taken as the typical user. For example, Lin et al. (1998, 2001)'s study of setting up PCA devices focus on the clinicians use of the device even where there is opportunity to investigate interaction with the patient. This focus was not the case where the user is the patient e.g. in home use of glucometers (Rogers et al., 2001), and outpatient use of a physiotherapy device (Lang et al., 2013). Carayon et al. (2006) highlight the two different roles for the patient: 1) being the recipient of good and bad outcomes; 2) being active in using the device. There should be more effort to put the patient in the loop even when their role is informal and peripheral, but still important, because they are the ultimate recipients of this service. A case in point is where patients, and their friends and family, are disturbed by device alarms (Randell, 2004b). These can be unremarkable to clinical staff but remarkable and unpleasant for those who are not used to them (Furniss et al., 2011c)

5.6 Connection between local and hospital-wide services

This theme had three issues associated with it in Table 1: 1, 13, 16. The new capability of this device, to allow the uploading of glucometer data to a central database, allows the possibility for new interactions, new information needs and design potential. For example, many staff did not know who might be monitoring the collected data and why (Issue 1: Data monitoring); this might impact their perception of the purpose and usefulness of the notes feature that was underutilised (Issue 16: Not taking notes). New design potential could also lie in developing the notes feature for two-way communication between members of staff and oversight groups, data might also be useful on why readings are not

taken, e.g. if a patient frequently refuses a reading then perhaps a diabetes specialist nurse could attend and help.

The new functionality of uploading glucometer data to a central database has brought this theme into focus. Older studies are unlikely to have encountered this theme because devices and their data have worked under a model of more isolated use. It is likely that more devices will be interconnected, share data with central services, and open up new possibilities for monitoring and interaction in the future. At the crux of this theme is the connection between different groups of specialists and their contribution to the quality of care. A sociological approach to investigate the formal and informal contributions of technology, roles and expertise to patient care has been successful elsewhere and could be used here too (Swinglehurst et al., 2011). Ross et al. (2012) report on the coordination of diabetes care between specialist and non-specialist nurses. Their focus is on the complexity, resilience and quality of care rather than technology. We suggest that the role of modern devices and interconnected data could play a larger role in such studies in the future.

5.7 Impact of policy

This theme had three issues associated with it in Table 1: 3, 4, 5. Issues with policy are highlighted where staff perform workarounds or where they have concerns that policy does not fit practice. Examples of the former include not taking the sharps bin to the bedside (Issue 4: Sharps bin) and lending staff ID access to colleagues who do not have their own barcodes (Issue 5: Staff sharing barcodes). An example of the latter includes management decisions that configure the device to behave in a certain way that could potentially cause friction with practice. For example, management could have enabled a function that allowed the emergency use of the device even when it had not had a quality control check (Issue 3: Emergency lockout). Instead management took the view that these were not needed as staff should ensure that quality control checks are performed routinely and promptly. Staff expressed concern about being locked out in these circumstances but did not understand enough about the device to know it was a configurable option rather than the way the device was designed from source.

Traditional focus on the usability of devices has assumed that devices work 'as is'. However, we suggest that more attention needs to be paid to policy and configuration decisions at the blunt-end before they reach the sharp-end of practice. Modern devices, like infusion pumps, are complex and contain configuration decisions that are set by management long before they reach the user. Users may complain about how the device operates but this might be a more local management configuration issue rather than a design issue for manufacturers. The closest engagement we have found with these issues is by Perry and Wears (2009) who discuss how tighter controls and stricter adherence to agreed procedures can erode the resilience of the system. They contrast different views of system performance, e.g.: rigid safety and flexible resilience. The former presumes a predictable system whereas the latter emphasizes responses to disturbances within and outside the system. These perspectives could have a tangible impact on device configuration decisions and

the subsequent behaviour of the system. More research is needed in this area and the impact of policy on device design and use more broadly.

5.8 Strengths and limitations

The strength of any situated study can be found in the specifics of how devices interact with the circumstances of a particular context, i.e. we look at the device and the context holistically (Sittig & Singh, 2010). This means that results may also be specific to that context, i.e. results and components cannot be taken from one context to another without accounting for context (Chisholm et al. 2001). There are limits to the generalizability of findings. The results of this study are focused on one device in one context. Other glucometers in other contexts may have similar but different issues. Taking this further, even the time of the study has an impact: because we conducted the study shortly after the device had been deployed the diabetes specialist nurse and the biochemist remarked that issues that we had observed would resolve themselves over time. The implication is that some issues were teething problems rather than persistent issues. We have evidence from on-going studies that at least one issue, the sharing of staff barcodes, persists, which shows that the story is more complicated than just teething problems. But even 'teething problems' are barriers to effective working, and ideally will be anticipated and addressed quickly.

Fitzpatrick and Ellingsen (2013) highlight that a balance should be struck between investigating the specifics of a situation and other contexts for generalizability. This will come from further studies, particularly on the generalizability of the seven themes that are the more general contribution of this paper. Confidence is strengthened in the generalizability of these themes because of the supporting literature that has been reviewed. This literature review highlights well evidenced themes, e.g. usability and workarounds, and themes that need to be better established through more research, e.g. putting the patient in the loop and the impact of policy. Fitzpatrick and Ellingsen (2013) highlight these latter themes as challenges for CSCW research in healthcare. Our themes show good coverage both within our results, and in relation to the literature, but it may be that other themes are found important for other devices in other contexts (e.g. see Lang et al. 2013). Future studies could look across themes or focus more deeply on one theme, e.g. there is great potential for further investigating the theme of putting the patient in the loop.

Koppel et al. (2008) is an example of focusing on one issue, i.e. that of workarounds for barcode medication administration. They use themes from the work system model in SEIPS (Carayon et al., 2006) in classify their workarounds, including technology, task, organisational, environment and people related workarounds. Our themes specifically focus on device design and use rather than the work system more generally.

Data gathering and analysis are necessarily time limited for projects. As the study progressed we were discovering fewer new issues and reaching a point where we understood those we had discovered, i.e. we were reaching a point of saturation (Furniss et al., 2011b). However, this was not the case for all issues. For example, some nurses reported that too much blood on the test strip could cause problems with the glucometer reading. This confused the diabetes

specialist nurse and biochemist because the test strip is designed not to take too much blood. This issue would need further investigation, and may be one of understanding or use if it is not a design problem.

A strength of this study is that it focuses on process details and not just outcomes, which is recognised as a positive aspect of studies in computing and collaborative work (Fitzpatrick & Ellingsen, 2013). Furthermore, Halverson (2002) highlights that DC provides a description of process at a level of detail that facilitates moving from assessment to design considerations. These aspects make case studies richer and more amenable to different design considerations.

There is a need for more research and assessment of medical devices in practice. These relate to the objectives of this study, i.e. 1) to provide case studies and learning about the design and use of different medical devices; and 2) to identify broader themes to serve as guidance for reviews of other studies. The relatively recent implementation of BS EN 62366 places greater emphasis on the role of usability and ergonomics in medical device design and assessment, and makes this need timely.

6 Conclusion

This paper offers the first case study of a critical ergonomic assessment of a modern inpatient blood glucose meter. From the issues discovered with the device's design and use emerge seven themes that can help guide medical device assessment more broadly. Some of these themes are more established in the medical device literature than others. Where these themes are less well established there is research opportunity. This list of themes is not meant to be comprehensive and complete across all medical devices. Indeed, different medical devices will highlight the importance of different themes (e.g. Lang et al., 2013). However, these themes do provide a starting point for further application and development, particularly for inpatient situated studies of devices, where there seems to be a lack of guidance in what to attend to. Similarly, this case study could inform manufacturers and researchers who want to explore situated ergonomic studies as part of medical device post-market review processes (BS EN 62366). The identification of these themes is already contributing to our ongoing work in infusion pump design and use, and future work includes applying them to this more formally.

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