chi+med
making medical devices safer

Update 7

19 February 2013

Welcome to the seventh CHI+MED newsletter. We have now entered the fourth year of our six year project; the team is all on board – indeed, a couple of PhD students are nearing completion – and work is progressing well in many directions. There are too many avenues of investigation to do them all justice in a few sides of text, so in this newsletter we are focusing on the major integrative themes that are being developed across the sites (UCL, Swansea, Queen Mary, City). These are enabling everyone on the project to work with people outside their immediate group and to experience different styles of research (qualitative, quantitative, engineering, etc.) and learn about different perspectives. Integrative work is demanding for everyone, as it requires breadth as well as depth of understanding, but is now starting to pay dividends. So here are our themes for this newsletter: number entry; normal practice; tools and methods; controlled studies; and from a blame culture to a learning culture. Enjoy!

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Upcoming workshops in Paris and London

CHI+MED staff are acting as co-organisers for two workshops at this year's *CHI2013* conference: *CfP: HCI Fieldwork in Healthcare* - creating a graduate guidebook, led by Dominic Furniss [1] on 27 April and *MediCHI 2013*: Safer interaction in medical devices on 28 April, led by Karen Li [2].

Paris, location of the CHI 2013 conference where CHI+MED is running two workshops. Picture credit: Wilhelm Lappe

We are hosting the *DACCHI 2013* workshop (*Dynamic And Continuous Computer-Human Interaction: Human and Computer Around a Loop*) on 24 June 2013 at the EICS 2013 conference.

CHI+MED will also be sponsoring a specialist *Doctoral Consortium* for PhD / EngD students who are researching areas related to human factors for safety-critical systems. The Consortium will take place at UCL on Friday 14 June 2013 the day after the fourth IEHF (Institute of Ergonomics and Human Factors) Early Career Research Symposium (on Thursday 13 June) also at UCL.

Doctoral students are invited to submit a short abstract via the IEHF website, before Monday 11 March, highlighting on which day they'd prefer to present their work.

CHI+MED will also be hosting a dinner (on the Thursday evening) for all PhD students attending either symposium.

New staff – Katarzyna Stawarz (UCL)

Katarzyna Stawarz joins us from Haymarket Media where she was a business intelligence analyst. Before that she did her Masters in Human-Computer Interaction at UCLIC (UCL Interaction Centre) and she's back at UCLIC, studying for a PhD on technology as a medication memory aid – you can read about her research on page three.

Our major integrative research themes

Integrative research themes have been developed across the four sites; these are bringing different groups on the project together to focus on particular challenges.

1. Number entry
2. Understanding normal practice
3. Tools and methods for safe usable devices
4. Investigating interactions in controlled environments
5. Moving from a blame culture to a learning culture

1. Number entry

'Number entry' refers to the methods used for entering numbers (hopefully correctly) into a device. There are a number of ways of doing this including up and down arrows (see picture on the left, below) or numeric keypads (see picture on the right, below) which are also used on telephones.

Entering numbers into a pump that will deliver drugs to a patient is a safety-critical task (where errors can cause injury and death). When an error occurs the temptation is often to retrain, or remove, the person who 'made' the error, assuming that this has fixed the problem. However, it is possible that there are other underlying causes of error and, if nothing is learned about them, these problems will continue to reappear.

Although entering numbers is something done largely by highly trained medical personnel it is increasingly done by patients and carers in a home setting too. We are looking closely at the different interfaces, trying to find ways to uncover the hidden or 'latent' errors (which can be present in the machines themselves) or in the systems in which they're used to see where things can be made safer.

Of our five integrated CHI+MED themes number entry is the most established. Our work has already demonstrated that minor changes in the software that underpins devices such as

chemotherapy pumps can make them less vulnerable to errors that are commonly made when people key in numbers [3].

We have developed a process (called *Differential Formal Analysis, DFA* [3,4]) for determining which features should be present in a number entry interface as well as a method for visualising the trade-offs (eg one type might be easier to enter numbers on, but also easier to enter the wrong numbers) among different types of number entry interface. This information can be used by designers to make informed choices about the interface, depending on the context in which the device will be used.

This has led to our development of a tool for generating software prototypes that incorporate pump user interfaces and this also feeds into the work being done on the 'tools and methods theme' [5], see also Section 3.

We have also created a number entry game – Save the Patients [6] – which simulates the different types of number entry interfaces and lets us collect data about how well each interface works as the player plays the game.

2. Understanding normal practice

Accident investigations and research into healthcare errors both typically focus on what went wrong. In studying normal practice we are learning about everyday hospital activities in healthcare and how potential errors are already being avoided on a daily basis and where else they can be avoided.

An understanding of normal practice is important for (a) the appropriate design and evaluation of medical devices (so that they are suitable for the environment in which they'll be used), (b) learning where errors might emerge from and (c) understanding issues that are broader than just 'error' and 'safety', such as how a device's user experience (the way a user feels about using a product or device) can influence how it is used.

We are investigating and experimenting with various methods in order to capture this information to help us understand normal practice in context. We are also investigating how these methods, when used in the area of medical device usability, can be useful for the future design and evaluation of medical devices.

We have focused on normal practice in clinical settings (on an oncology ward, haematology ward and in an intensive care unit [7, 8] and non-clinical settings (at home and on-the-move [9, 10, 11]). In addition, we are adapting our work on the methods used by incident investigators, in the context of moving away from a blame culture, to explore how they can also be used to investigate normal practice (see section 5 on blame and learning culture).

Our work has helped us develop a broad picture of the design and use of devices across the different contexts that we have studied, going into greater depth in certain clinical, and non-clinical, areas such as chemotherapy infusion pumps and the way in which blood glucose meters are used by people with diabetes, and how they manage their condition. Focusing on infusion devices, we have developed a set of personas and scenarios of use as tools for future design and for people making procurement decisions (see section 4).

One researcher has undertaken an autoethnography (self-study) on their own use and experience of a mobile medical device to better understand how people who have to use such devices routinely might experience them.

Based on interviews with people in several hospital trusts, who manage medical devices and train staff in using them, we are also developing an understanding of how people acquire mental models of infusion pumps from training and practice.

We have also reviewed and reported on the strategies and experiences of conducting 'in the wild' studies in a healthcare setting. This also enabled us to work with researchers from outside CHI+MED (Rebecca Randell, Leeds; Helena Mentis, Harvard Medical School; Ken Catchpole, Cedars Sinai Medical Centre, LA) [12].

3. Tools and methods for safe usable devices

We are investigating the relationship between medical device regulators and manufacturers in the context of the development and supply of medical devices. In particular we are exploring how best to ensure that issues that users experience are not neglected.

There are a number of ways in which we're investigating this, including holding workshops with manufacturers, analysing existing regulation and developing a model that regulators can use both to communicate design requirements to manufacturers and to check that devices satisfy regulatory requirements.

The same models allow manufacturers to generate working prototypes that are safety-assured with respect to given requirements [5]. Ongoing work involves engaging with regulators and manufacturers to refine these into something that supports them in practice.

We have analysed guidance and regulatory documents from the NPSA and FDA relating to infusion pumps. Our study with manufacturers has highlighted some strengths but important limitations of these resources, including that some recommendations need stronger evidence to back them up, some are too narrowly-focused and need to be more generalisable, and some actually conflict with other standards or guidance [13]. Future studies will assess our own resources against these criteria.

4. Investigating interactions in controlled environments

Disruptions are a normal part of any healthcare environment and can arise because of the external environment (if an alarm goes off or a patient needs urgent attention) or internally (eg when doing several tasks at once). If our procedures and routines are disrupted then errors are more likely to occur and when they happen in a safety-critical then the errors can have very serious consequences.

Studying people (under controlled conditions) while they are experiencing disruptions can help us understand the effects of

these disruptions on human performance and cognition. We are investigating the mental processes involved in dealing with disruptions and also developing mathematical models to explain them.

Information about how people respond to a disruption can be used to design an interactive device so that it helps the user be more resilient to such disruptions. For example what cues are available to the user when they resume a task after being called away to deal with something else?

If people know an interruption is likely then they can create a cue to remind them to do something later (eg adding 'buy milk' to a shopping list) but the device itself can also generate cues to prompt the user. We have investigated the role of these cues where people are resuming after a disrupted task. Our research has shown that these system-generated cues can reduce error rates [14] and we will look at the effect of user-generated cues too.

Another aspect of this strand of work is on the visual salience of the different areas that people are looking at on an interactive device. Which are more likely to be seen first by a user? We are exploring ways to identify the areas mostly likely to become the focal point when a user interacts with the system.

5. Moving from a blame culture to a learning culture

Despite the widespread organisational emphasis on learning from incidents, there is a perception that the so-called 'blame culture' is still a significant factor that may prevent effective organisational learning from taking place, and it is often believed that this is reinforced by a sensationalist media.

Our preliminary work, on an analysis of three case studies (of infants who died after being administered an overdose) presented in the news media [15], on and offline, suggests that the assumptions about blame are often much more nuanced and guided by the tone of official reports.

The reporting process itself may then be an important driver of people's resulting perceptions of medical accidents and we are looking at incident reporting and incident investigation processes to see what aspects can lead to better learning.

We have developed a new standardised report form to address the issue of under-reporting of adverse events based on the literature and expert opinion [16, 17]. We have also developed two 'systems' perspectives that may help to facilitate more effective learning.

The first, called '*Hot Cheese*', is a model of how incidents are caused, and extends James Reason's *Swiss Cheese* model. Our model encourages incident investigators to focus on the dynamic aspects of the systems that are put in place to defend against error, but which can actually contribute to other errors getting through – an example might be closing off part of a supermarket aisle after a spillage forcing customers to move through a narrower area resulting in them knocking items off the shelf, causing further problems [18].

The second, called a 'Safety Functions' framework, focuses attention on how embedded safety checks may support the system in enabling the error-free movement of critical information throughout the process of investigation [19, 20].

We are also thinking big and looking at how our practical public engagement work, and research, can change the general public's perceptions about blame.

My PhD – Katarzyna (Kathy) Stawarz, UCL

Have you ever forgotten to take your medication? Most of us have, because forgetting is easy. With drugs and medication regimens there are many things that could be forgotten: you may forget to take your pills on time, or how you should take them (with food? in the morning?), or whether you've taken them already a few minutes ago. You may even forget to pack your medication when you're going away and realise the next day that they are missing.

Picture credit: Noel C. Hankamer

My PhD research focuses on forgetting and I will be investigating how technology could help people remember their medication. I'm planning to find out in what circumstances people – especially women taking contraception, busy parents with sick children or carers in general – forget about medication, how they develop habits when starting a new treatment, how important those habits are, and what strategies they employ to prevent forgetting. I also want to investigate what technologies people use at the moment and how they could be improved in the future.

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Our full list of publications is also available.

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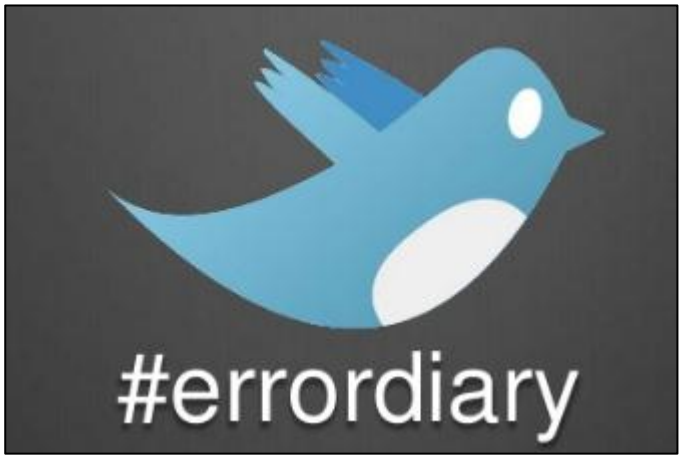

http://www.errordiary.org

To err is human… To understand why we err and to try to reduce our erring is human too!

Errordiary uses Twitter to share everyday errors so people can think about human error in a new way. We already know that the same psychological principles lie behind everyday errors and those errors of a more serious nature. Whether they are funny, frustrating or fatal depends on the context.

We are using Errordiary to learn about human error and we're developing teaching practices and materials around this theme. By understanding and raising awareness of human error we can make life easier and save others too.