

chi+med
making medical devices safer



Manifesto for Medical Devices

A research agenda for safe, efficient and effective usage

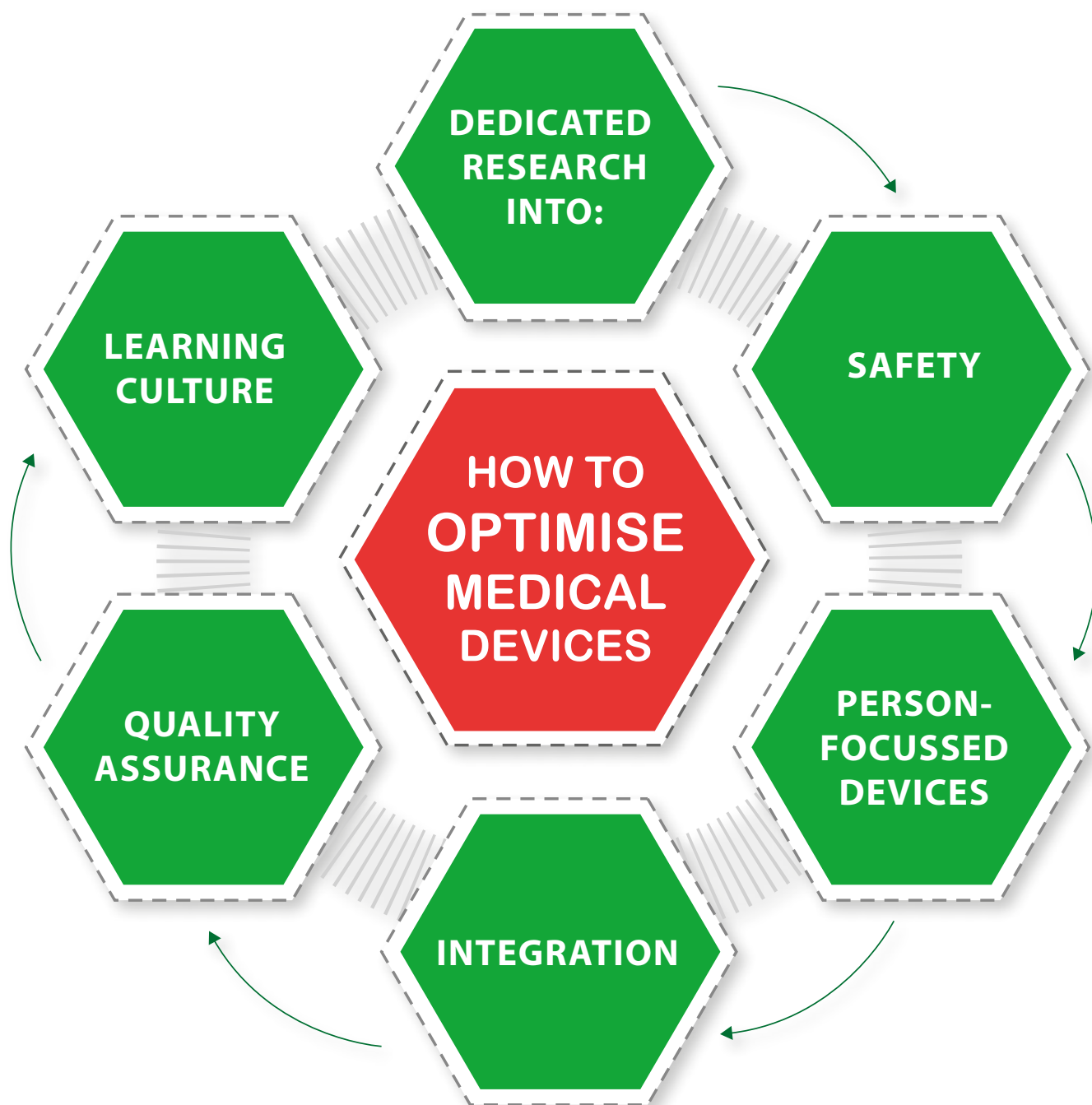
Insights from the **CHI+MED** project

www.chi-med.ac.uk | [@chi_med](https://twitter.com/chi_med)



Contents

> Foreword	5
> Introduction – Further research would improve the quality, efficiency and cost-effectiveness of medical devices – as well as safety.	6
> Designing medical devices that are fit for purpose for the unfolding healthcare revolution Ann Blandford	10
> Solving the ‘deep fat fryer danger’ of data entry in clinical settings Anna Cox	14
> Supporting manufacturers and regulators to eliminate unsafe device design in low cost ways Paul Curzon	18
> Medical devices often have simple, fatal flaws – we could make them as safe as planes Harold Thimbleby	22



Foreword

CHI+MED (Computer-Human Interaction for Medical Devices) was an EPSRC-funded project to improve the safety, efficiency and effectiveness of interactive medical devices, such as infusion pumps.

By understanding more about design and how people use such devices, medical errors can be reduced, saving lives. Efficiency and effectiveness can also be maximised.

Our goal has been to learn more about how people design, buy, and use medical devices in the real world. We have worked with patients and carers, nurses and other medical practitioners, medical device manufacturers, NHS purchasers and regulatory bodies who oversee patient safety.

This document sets out CHI+MED's achievements and a vision for what should happen next.



Introduction

Further research would improve the quality, efficiency and cost-effectiveness of medical devices – as well as safety.

Further research would offer vital ways to ensure that medical devices support today's need for integrated, person-centred care that is closer to home.

Poor safety is typically a warning flag for wider issues, including underlying inefficiencies, an inadequate learning culture and general under-performance in a system. This observation is certainly true with regard to problems around medical devices, identified by the EPSRC-funded CHI+MED programme (2009-2016) (www.chi-med.ac.uk).

The safety issues we have tackled are important in their own right – they are still claiming lives unnecessarily. Given our findings, there is now, for example, no excuse for devices to employ certain number entry systems that are demonstrably prone to simple human error.

“There is still much to do about safety. But future research must also transform the quality, efficiency and the costs of healthcare delivery that uses medical devices.”

But these problems are the tip of an iceberg. Below the surface lie a host of other connected issues. These often include poor understanding of what people need from interactive medical devices and of how they use them; a need for fresh thinking about how such machines should be integrated with other devices and different forms of care; and the need for more rigorous approaches to developing medical devices, their regulation, adoption and procurement.

As the commentary in this document shows, CHI+MED has highlighted and shown how to tackle some of the safety issues. There remains much to do to apply this learning to all interactive medical devices and ensure that machines already in operation and in development have high standards of safety. However, the goal of research now, beyond completing this safety work, should be to move on to the wider agenda surrounding medical devices. This would not only improve healthcare safety. It could transform the quality, efficiency and costs of healthcare delivery. Achieving this broader success requires a focus on five key research issues that remain largely unexplored.



1 Person-focused technology

Technology development in healthcare should start with the intended beneficiaries – people – not devices.

So we must understand people's needs and how they behave to ensure that we develop technology that's fit for purpose. That includes building in issues such as managing privacy and security, assuring safety and making sure that a design is easy to use.

This is not just a bolt-on to technology development. It goes to the heart of adoption and efficient use. Working, for example, with how people already do things can be extremely productive because innovation can then nudge practices forward in ways that people can master quickly. In contrast, innovation is often technology-led and frequently based on an inadequate understanding of how that technology would be used in practice. It can, therefore, be disruptive of existing practices without offering immediate added value.

2 Supporting the self-care revolution

Healthcare has always been about people and about self-care. That's truer than ever as day-to-day clinical care increasingly shifts from hospital to home and is shared between patients, family members and clinicians. So, it's no good simply designing technology for professionals to use. Or just for patients to use. We need more research into how devices can be user friendly for different groups, be they patients, carers or clinicians, and whether the device is for use at home, in hospital, is mobile or wearable or required to work well in multiple settings and across care boundaries. Catering for use in and out of hospital contexts means understanding and designing for a broad new set of scenarios of use and the associated issues that then arise.

3 Making it easier for devices to work together

People-centred healthcare means an end to silos and to the fragmentation of care delivery that gets in the way of holistic approaches to patient need and people's smooth progress through health systems. This philosophy is at the heart of integrating health and social care. It also underpins today's shift towards shared electronic health and care records.

Likewise, medical devices are not used in isolation and should not be stand-alone. They should operate well with each other (eg a heart monitor and an infusion pump) and with other digital technologies (eg next generation electronic health records). We need research into ways of managing systems to fit and be easy to use with other systems (including those developed by different companies) so that maximum quality, efficiency and cost-effectiveness are achieved. That's a big step from the thinking that currently goes into medical technologies, which are often developed in isolation from broader health ecosystems.

4 Quality assurance

Designers, developers, procurement staff and regulators have, to date, not had access to ways of assuring themselves and others that patient needs, usability and system integration are properly addressed by particular medical devices. CHI+MED started to address these issues, providing, for example, rigorous ways to evaluate user interfaces so that they work well when users are under pressure to perform critical procedures.

We have produced powerful mathematically-based tools, as well as simulations, that allow regulators to check for glitches and help practitioners to explore the usefulness and safety of a device. We have shown that big advances could be made with more research and that regulators are ready to consider such tools. Now these tools need to be further developed so they can support different contexts of use.

This work has laid the foundations for formal approaches that might additionally check whether a medical device really works for a medical system's needs. Our work provides a basis for quality assurance that informs purchasing decisions and compares one device with another.

5 System-level learning

It is essential that the NHS should become a learning culture. Technology design can support this (e.g. logging and learning from device interactions and people's behaviours). Incident reporting and investigation can also be designed to help (or hinder) the development of a learning culture. However, more research is needed on understanding the processes and for developing tools that support investigations in a non-blame focused way.

“These research challenges lie at the boundaries between funding bodies, and have to date not been a priority for any one of them. They cannot be addressed by short-term, piecemeal support. They need a sustained programme of research that is essential for the future delivery of healthcare that is technology-enabled, and increasingly managed by people with little or no medical training.”

Next steps

In all of these areas – safety; person-focussed technology; use of devices in multiple locations by people with different skills; integration with other technologies and systems; quality assurance and system-level learning – CHI+MED has defined the agenda and offered some initial solutions. We have already made significant advances in the theory and practice of designing interactive medical devices for patient safety.

But the work has only begun. Industry, purchasers and regulators need much more than we have been able to provide so far. These research challenges lie at the boundaries between funding bodies, and have to date not been a priority for any one of them. They cannot be addressed by short-term, piecemeal support. They need a sustained programme of research that is essential for the future delivery of healthcare that is technology-enabled, and increasingly managed by people with little or no medical training.

**The CHI+MED
Management Board**



Designing medical devices that are fit for purpose for the unfolding healthcare revolution

CHI+MED researchers' skills in watching and listening have made visible the once invisible inadequacies of, for example, infusion pumps. We have identified ways to inform regulation and procurement, which are the main forces that shape future design. However, further work is needed to consolidate the findings, in a way that can be immediately taken up in practice, explains **Ann Blandford.**

A key part of our mission has been to understand how safety critical interactive medical devices are used in practice. Our main focus has been infusion pumps. We observe the many different realities of these devices: for a nurse in a hospital, for an anaesthetist in an operating theatre, for a patient or a family member in home. We want to know how their experiences should be taken into account in the design of these devices.

These issues matter because healthcare relies increasingly on digital technologies. Also, particularly with an aging population, more care is outside clinical settings, in non-specialist environments. So technology must be safe, usable and efficient for people who are not necessarily using it all day, every day and where professionals may be at a distance. This requires new ways of thinking about design that involve all users and take account of their situations when designing and deploying new technologies.

Our observations inform important conversations about design, regulation, procurement, training and use. We are outsiders, looking at situations in ways that are difficult for those immersed in the environment to see. They can't immediately see what we see. But they recognise the picture once we describe it. The importance of Human Factors in clinical team working has been widely recognised, but that needs to extend into the design, deployment and use of interactive technologies in healthcare.

+ One size does not fit all

A big lesson is that one size does not fit all. It is not possible to design one infusion device that works equally well for all users. An anaesthetist may need to make rapid changes to critical medications when a patient's condition changes during an operation. Meanwhile, oncology nurses have to prepare a sequence of administrations. They must ensure that a patient attending planned chemotherapy receives all their medication at the right time and that radioactive drugs arrive from the pharmacy at the appropriate moment.

Then there are nurses who occasionally set up pumps to administer fluids, such as saline, to patients, but who don't do this regularly. They need a simple, intuitive device that is quick to set up and easy to run. They might not face the same issues as the anaesthetist or oncology nurse but safety remains important. The danger of free flow, for example, must be avoided. To design the future well, you need to understand the present. There is an urgent need to better understand real user practices and future needs, and ways to regulate, design, procure and train in device use to improve patient safety and user experience.

+ Empowering patients is vital

Our second big lesson is that we must empower patients to manage the technologies they use in their shared care. So transition points between clinical and self-care must be addressed carefully. A typical case might be someone with type 1 diabetes who is admitted to hospital for a condition that is unrelated to their diabetes. They still need to manage diabetes but typically the hospital takes over, using different, more specialist technologies, and that disempowers the patient. We must design technology where that transition is less disruptive. To take a different scenario, it's also not good enough if someone has a device for measuring their blood glucose levels that is too embarrassing to use in public. It may be dangerous if they cannot use the device discreetly, if they cannot for example take measurements when they are stressed at work or on a date with a new partner.



Meanwhile, patients on home haemodialysis may use a machine designed to be operated by a nurse and find that the interface points away from them. Alternatively, where a machine has been designed for single patient use, a patient may be unable to discuss difficulties with a nurse in hospital who is unfamiliar with the machine. There is a need to rethink the design of care processes as well as technology so that they are properly aligned and fit for purpose, empowering clinicians and patients alike.

Solving such problems with interactive medical devices requires the type of thinking that goes into different motor vehicle models. Healthcare needs a fresh approach to medical device design which, for cars, means that specialists can drive a high performance car or a heavy goods vehicle. But they can also drive and understand the family car, which, in turn, is easy for everyone to use.

+ Eliminate compromises through good design

As researchers, we cannot deliver specific solutions for safety critical products. We can highlight user requirements so developers better understand whom they are designing for. Humanity is good at making do, managing with suboptimal situations and poor design. Our work identifies compromises which could be eliminated by better design. We make visible what seems to be invisible, even though it is easy to see once we reveal it.

These insights are achieved by visiting key settings, such as hospitals and homes, where we watch and listen. Our observations contribute to important conversations about design, regulation, procurement, training and use. We are outsiders, able to look at situations in ways that are difficult for those immersed in the environment to see. They can't immediately see what we see. But they recognise the picture once we describe it. The importance of Human Factors in clinical team working has been widely recognised, but that needs to extend into the design, deployment and use of interactive technologies in healthcare.

Our research brings a perspective based on 'distributed cognition': this looks at how communications between individuals and care technologies can make care work better or can lead it to break down. Our work is also about 'resilience engineering', which examines how to maintain safety and why that sometimes breaks down. We focus on the positive, on human skills that can make suboptimal technology function well and how technology can be adapted so it is fit for purpose.

Latterly, we have focussed particularly on informing the regulatory context in which manufacturers develop medical products. This is an important commercial driver for them and provides leverage for improved design. We have had a big impact on the US Food and Drug Administration and also on the UK's Medicines and Healthcare Regulatory Authority. The MHRA has responded positively to our insights: it recently established a project to investigate how to build human factors more tightly into the regulatory process for medical devices. These initiatives need to be taken further.

+ Supporting procurement

We have also invested in providing resources and tools for procurement, another key factor for manufacturers. That work has begun at a local level, helping hospital trusts to take human factors into account in their procurement of medical devices. Again, it needs to be taken further so as to enable national procurement practices to better line up user needs, care practices, and technology design.

The long term challenge is to design devices for the unfolding healthcare revolution. Care delivery is changing rapidly so that devices are increasingly used at home by people without medical training. The needs and aspirations of these end users must be built into design, regulation, policy, procurement, training and the use of devices long-term. This work has only just begun. There are huge potential benefits for people and for health systems from getting these issues right.



Professor Ann Blandford is Professor of Human-Computer Interaction & Director of the Institute of Digital Health at University College London. She is a member of CHI+MED's Management Board.



Solving the 'deep fat fryer danger' of data entry in clinical settings

Careful observation of how humans interact with computer systems is providing vital insights into designs that reduce mistakes and nudge users to be careful in difficult situations, explains **Anna Cox**.

Safe entry of electronic data in health settings is like using a deep fat fryer properly in the kitchen. No-one wants to start a fire on the cooker. Likewise, no-one wants to harm patients by entering the wrong data and administering the wrong drug dose. These situations share similar safety principles, according to CHI+MED's research.

Safety demands clear focus on the task - not being distracted. It's best to complete the task before beginning something else. But, if someone is distracted, then it's good to pause for thought. That encourages us to remember the task, be it in the kitchen or on a hospital ward. A moment for reflection can prevent a nasty accident.

Computer systems in clinical situations, whether operated by professionals or patients, are increasingly used for frontline care. They allow tasks to be performed quickly and often more accurately, reducing paper use and speeding up the flow of information. But mistakes can occur, not least because data entry systems are created and operated by fallible human beings.

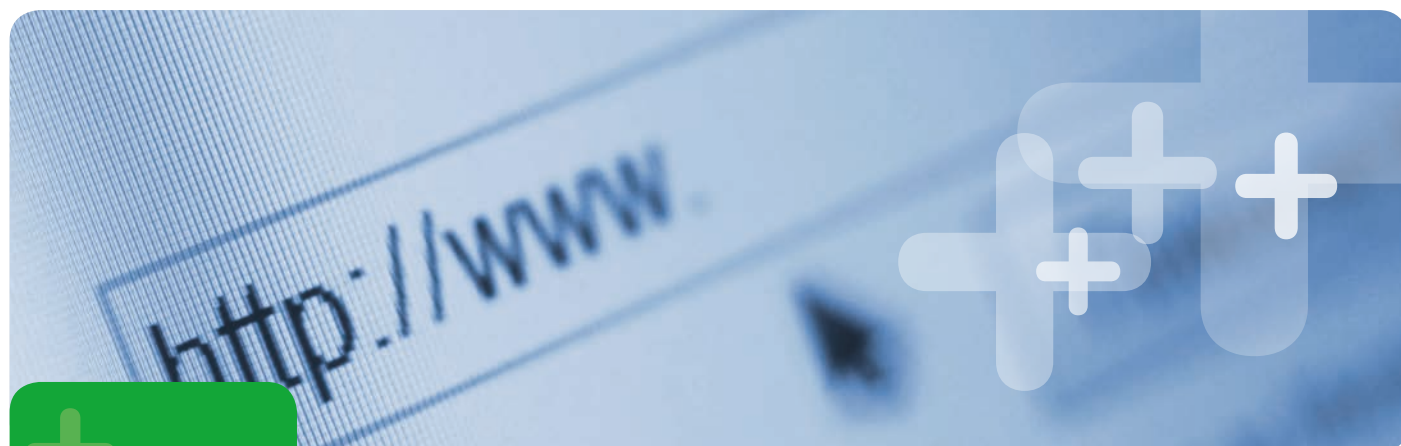
If people input the wrong instructions, the consequences can be fatal. So CHI+MED's research has concentrated on how design can minimise the impact of human fallibility on the patient. Additionally, we have demonstrated how to encourage simple shifts in human behaviour that can reduce mistakes.

+ Mistakes are easily made

The opportunities for making serious mistakes are many. For example, entering the wrong identification code for a patient might mean that a clinician misses that a patient is allergic to penicillin. A clinician might miscalculate a drug dose because someone previously mistyped the patient's weight. Poor programming of an infusion can cause a drug to be administered too quickly, too slowly or at an incorrect dose. Our research helps manufacturers to create the optimal interaction design to minimise the chances of people making such data entry mistakes.

We have identified four key insights to improve human performance. First, we discovered that human performance is influenced by familiarity with the numbers that are transcribed. This is not surprising, given what is known about text transcription. It is unusual to provide a random selection of letters and expect accurate transcription. Systems are usually designed to require recognised words and proper sentences. Yet, with number transcription, there has been a tendency to use random numbers, which are more prone to mistake. Our research shows that well-known numbers, such as your home telephone number, are easier to type accurately than less familiar ones. Certain numbers are very commonly used for infusion pumps. For example, 500mls is a common volume to infuse, being equivalent to a small bag of fluid. A display setting that provides easy entry for such frequently used numbers can reduce errors. >

“Design should focus attention on the warning signs of error. People tend to ignore the display screen if they use a key pad. However, if they have to adjust values using a chevron, they must look at the display screen to monitor their input. So they make fewer mistakes.”



We showed that even a very small pause – just a few moments – helped reduce mistakes.

+ Focus attention on signs of error

Our second insight is that design should focus attention on the warning signs of error. For example, some infusion pumps use a key pad with a full range of numbers. Others have buttons (chevrons) allowing the person to increase or decrease the volume. We have shown through tests that people tend to ignore the display screen if they use a key pad. However, if they have to adjust the value using a chevron, they must look at the display screen to monitor their input. So they make fewer mistakes.

Third, our research demonstrates the importance of the environment for improving data entry. For example, it is well known that, after an interruption, people are much more likely to make an error. Our work has added further insights. It shows that some interruptions are worse than others depending on their nature and the timing.

So, if someone is programming an infusion pump, and is interrupted by a question about what the patient ate for breakfast, a mistake is more likely. But the risk increases if the question concerns programming of a previous infusion pump. The brain is less likely to become muddled by an unrelated interruption.

+ Reducing transcription errors

Our work has also examined how the layout of a data source – perhaps a printed form – can make transcription more prone to error. If, for example, two items are placed relatively close together on a form, people tend to store them in their memory at the same time. When making entries into a computer system, they may then enter both items at the same time, creating possibilities for confusion.

For example, if a nurse has to programme two infusion pumps for the same patient, the appropriate procedure is to programme one infusion pump and then the other. But the layout of information on a form might encourage the nurse to do the first part of programming for each pump at the same time. So she would be multitasking. She is more likely to forget a critical step in one of the tasks.

These observations all concern improvements in design to provide less scope for mistakes. But we have also researched ways to help people to manage the error prone environment in which they inevitably find themselves.

+ Pause for thought

A vital *aide memoire* is to encourage people to pause for thought. So during tests, at critical moments such as after an interruption, they were prevented from entering data. Imagine a device detecting a break in interaction with the user and inferring that there had been an interruption. When the user returns, it simply does not allow fresh entries for a short period. We showed that even a very small pause – just a few moments – helped reduce mistakes.

This exercise did not ask users to check for errors. We just made them stop, preventing them from entering data for a few moments. It provided an opportunity for checking, for mindfulness, for remembering better what they were doing, before they acted.

This work is making a difference. We created a document for the designers of systems to use, which distils our guidelines for design in a form accessible to lay people. Manufacturers have praised the thoroughness and usefulness of our work and say it is informing their designs. Policy makers recognise better that electronic systems used in medical contexts must be designed with a good understanding of how people interact with them. The regulatory regime faced by manufacturers is changing as a result.

Our methodologies have broadened ways to understand how humans interact with computer systems. Our laboratory-based observation of how people behave in particular contexts is a valuable tool. It should be employed more widely.



Dr Anna L Cox is Reader in Human-Computer Interaction at University College London and is a member of CHI+MED's Management Board.



Supporting manufacturers and regulators to eliminate unsafe device design in low cost ways

CHI+MED has created a pathway for improvements that identifies the dangers, specifies design needs, checks when risks have been removed and offers lay people simple ways to evaluate device safety explains **Paul Curzon.**

We try to identify and eliminate, systematically, accidents with medical devices that are waiting to happen. Training users cannot fix these problems permanently: someone might miss the training, forget what they have learned, have too much to deal with, or be distracted at the wrong moment. So, tragic consequences recur. We can eliminate many of these issues through better design.

“Our work shows that current levels of safety can be greatly improved, often without raising costs. Ignoring what CHI+MED has found will lead to more user-related incidents, further product recalls, more costly investigations after people have lost their lives, more expensive insurance pay outs, more blaming of staff about devices that were inadvertently designed for human error.”

Consider the magician’s art. Even though you know they are going to misdirect you, you are still misdirected. You can’t stop yourself being fooled. It’s because the magician has designed a system precisely with properties that can fool you. It’s nothing to do with negligence. It is all about the limitations of the human brain. The same phenomenon plagues medical devices – they are often designed in ways that mean someone can easily make a mistake when they use them.

+ Hazard analysis

‘Hazard analysis’ lies at the heart of CHI+MED’s approach. We examine a procedure that uses a medical device and imagine everything that could possibly go wrong. So we can specify potential safety issues that manufacturers should address. This analysis can be undertaken before a device is ever designed. It provides key material for the design drawing board.

Take, for example, hazard analysis related to infusion pumps. Clearly, the top level hazard is administering an over- or under-infusion. How could this occur? A nurse might misread a prescription or mistype the dose on a pump’s key pad. Alternatively, they could type in the right data but the entry might be rejected by the device in favour of a default setting. Perhaps a nurse might be interrupted while setting a dosage, forget what stage they had reached and not finish setting it (so the machine uses the last reading instead of a new one). Perhaps, the battery runs out in the middle of an infusion, a patient switches the device off accidentally, or someone inadvertently changes the settings. All could lead to the top level hazard.

Typically, manufacturers of medical devices undertake hazard analysis on software bugs or hardware faults but they rarely look at how people might make mistakes, so they do not design to prevent it happening. CHI+MED has demonstrated the importance of undertaking such ‘user analysis’. As a result, CHI+MED has worked closely with the US Food and Drug Administration to support development of this field and UK regulators have employed CHI+MED staff to review devices from the user point of view.



Our approach is based on human factors theory about people's limitations. User analysis recognises what magicians know - that people, for example, have a single focus of attention at any particular time. So, if you direct them somewhere else, they can miss crucial information. Likewise, people have limited working memory. So a device designed to reduce human error should give feedback on what has been done, what needs to be done next and where they are in the process. These factors can all be built into the hazard analysis of devices.

+ How hazards occur in real life

We identify not only hazards, but how they may be encouraged by design. For example, over-infusion is a top level hazard. The immediate cause might be that a person entered a number that was too large. We've shown that this might be caused by accidentally entering two decimal points, deleting one, and not being alerted that both decimal points had been deleted, meaning that the final number entered is 10 times larger than intended. A mistake could occur because of an inconsistency in the device, such that, when someone presses the 'up' chevron key, they can get a larger number than they expect. Alternatively, perhaps, the nurse is interrupted while typing, the machine resets itself in the nurse's absence but the nurse does not realise. Perhaps the device beeps to alert staff to a resetting, but that doesn't help if no-one can hear it.

We go beyond the theoretical. Having demonstrated potential design problems that could cause hazards, we have highlighted them in actual devices. So, these issues are not simply hypothetical. Some have led to product recalls. We can also demonstrate these problems using a simulator - this provides both feedback to manufacturers and material for our training videos.

We have made it easy to specify user-based design needs – and to check on compliance. The secret lies in mathematics. We have developed a way to create mathematically-defined versions of such requirements so there is no scope for misunderstanding. Formal descriptions written in this logic-based language ensure that there is a precise mathematical meaning for manufacturers. It might be a requirement of predictability, namely that pressing a button will always have the same effect. That can be stated in mathematical language.

Giving manufacturers examples of what can go wrong helps them to see the serious nature of the issues and to create better design which is cheaper and less risky to reputation than a product recall. Examples also encourage regulators. They know what they are looking for and can recognise the dangers.

+ Describing designs mathematically

Similarly the designs of devices can be described mathematically. Expressing both designs and requirements mathematically allows mathematical checks on the design – by regulators and by manufacturers who are keen to show their compliance. We have also created a maths-based, prototype tool, applicable to multiple devices, which runs rapidly through all the options to make sure that every possibility has been covered. This reduces human error in checking and regulating devices. It has potential to greatly reduce regulatory workload. It also prevents faulty design ever reaching the regulator because the manufacturer can see where faults lie and that regulators will spot them.

We have also worked with the FDA on 'reference architecture' – mathematically based versions of outline designs that cover the features of real designs, highlighting potential hazards that should be avoided. They help to show that design is possible without these problems.

It's also vital for devices to work safely together, such as when the infusion rates are dictated by variations in heart monitor readings. Safe 'interoperability' means that devices are as safe when connected as apart. We have built prototype mathematical toolkits and simulators for connected devices.

Because the urgency of safe design is so great, we have studied those devices that are most prone to hazard and solved some of the inherent design problems ourselves, creating mathematical descriptions of a range of real devices, exploring problems and finding solutions. For example, CHI+MED has created a tool kit that automatically generates data entry interfaces for safe number entry and so prevents faulty inputting of numbers. We have also created software to ensure that key number entry errors in infusion pumps are eliminated.

+ Next steps

Our work is highly innovative and remains in its infancy. Our hazard analysis methods should be trialed on a wider range of devices including heart monitors, diabetes diagnostics and radiation therapy machines. Any device that uses number entry could lead to the most dangerous hazards of the kind we have focused on, but any device that people interact with falls within the scope of our user centred hazard analysis.

The next step would be to create full mathematical versions of safety requirements and designs for various devices. We also need a suite of easy-to-use tools for the separate steps – hazard analysis, design specification and safety checking - that everyone involved – including designers, manufacturers, regulators and users – can access.

We want to support and educate manufacturers and regulators about risks and find ways to support procurement, so that lay people can easily judge the strengths and weaknesses of any device. In all of this work, there are trade-offs. It may be impossible to meet all the safety requirements so then our input would be into training, limiting the risks.

Our work shows that current levels of safety can be greatly improved, often without raising costs. Ignoring what CHI+MED has found will lead to further user-related incidents, more product recalls, more costly investigations after people have lost their lives, more expensive insurance pay outs, more blaming of staff about devices that were inadvertently designed for human error. CHI+MED has identified a way forward that is good for everyone.



Professor Paul Curzon is Professor in Computer Science at Queen Mary University of London and is a member of CHI+MED's Management Board.



Medical devices often have simple, fatal flaws — we could make them as safe as planes

CHI+MED's research demonstrates safety weaknesses in medical devices that could be eliminated. If equipment was safety rated in the way household goods are now rated for their energy efficiency, this would stimulate the transformation, explains **Harold Thimbleby.**

One of CHI+MED's most significant insights shows how policy makers could make medical devices much safer. A safety culture already exists for many products such as cars and aircraft, but there isn't one for medical devices — yet. For medical devices, some simple measures would drive such a culture and thus expose and fix today's hidden dangers. These moves would save lives.

CHI+MED has a key recommendation: all devices should be safety rated. An analogy is electronic, household goods, such as fridges and washing machines, which are already rated for their energy efficiency. Energy efficiency has dramatically improved because of informed market pressure. Likewise, for medical devices, healthcare providers and individuals must see safety ratings on devices. This would nudge demand towards safer products, just as households have increasingly opted for more energy efficient consumer goods. This is not fast, but is very effective. We have done enough research already to put evidence-based safety ratings on a wide range of medical devices.

“Medical devices are not rated for safety. Yet they vary a great deal. And it is practical to make them safer: in the laboratory, we can design devices that are up to 20 times safer than some available commercially.”

Some may think that safety is already paramount in medical devices such as infusion pumps. In fact, many still include dangers that could be avoided relatively easily. We should not be surprised by the numerous, sometimes fatal, incidents that occur because patients are wrongly treated. We should be slow to blame individuals. Human error is often identified as the cause, but the faults frequently lie in a device's or system's design, which make it unnecessarily vulnerable to error.

+ Risks of data entry

For example, with one infusion pump, if a person enters a decimal point for a high number, the machine ignores it. So if you type in 100.0, the pump will treat the figure as 1,000 – ten times higher than the intended number. That may harm a patient.

Nurses are often busy and use calculators to work out dosages. On some calculators in use the delete key produces confusion when it is used to correct an entry error, because it does not handle decimal points well. So, for example, a nurse might accidentally input 2.5 when they meant to enter 25. So they press delete-delete and retype the 5. The nurse thinks that 25 has been entered. But the calculator only actually records 5 because the two deletes deleted not only the .5, but also the 2, resulting in zero (then the retyped 5 makes the final number 5)! As a result, the number is now a fifth of the nurse's intended number. This error may be concealed inside a larger calculation, and make the final answer unknowingly harmful.





There is little incentive for medical device manufacturers to improve safety.



In some devices, if a user accidentally inputs two decimal points, the machine will ignore the error. However, it would be much safer if the user was alerted to having made this (or any other) mistake. This is a moment when the machine should be alerting the user, making them pause and recognise that they are making mistakes — not ignoring their obvious mistakes!

CHI+MED colleagues have elsewhere highlighted the dangers of number keypads, instead of using chevron buttons, to raise or lower doses. Users tend to look at the keypads and relatively ignore the screen display. Chevrons are twice as safe, according to our research, because the user's eye is fixated more on the screen. Yet many devices continue to provide keypads.

+ Manufacturers slow to face safety issues

Why is more not being done to eliminate poor design features? An interaction I had with a manufacturer demonstrates one problem. CHI+MED spotted some risks with a particular device. We met the manufacturer's Chief Technology Officer, who said he had never thought of how their device might actually encourage human error. He asked us to meet him the next day. When we arrived, we were told the company did not wish to work with us. The reason was obvious. If they knew officially there were problems with their devices, they would have to fix them. As long as the manufacturer didn't officially know about problems they didn't have to fix them. The same is true for hospitals. If they don't know about problems, they don't understand the risks — and they will continue to buy unsafe equipment.

Currently, medical devices are not rated for safety. Yet they vary a great deal. And it is practical to make them safer: in our laboratory, we have designed devices that are up to 20 times safer than those available commercially. The safety culture around medical devices is different, for example, than for aviation or even car tyres. Planes become safer over time because, when an aircraft crashes, it is very high-profile and manufacturers want to make sure that they are not at fault and, if they are, they really want to fix any problems. In contrast, there is little incentive for medical device manufacturers to improve safety. Once they have a CE mark, indicating the device 'works', there are few further expectations, and a lot of pressure to avoid admitting any possible liability.

+ Scapegoating of staff

This failure to develop the right incentives to promote safety puts patients at risk. It also leads to the demoralisation – often scapegoating – of staff when problems arise with medical devices. I was recently an expert witness in a case involving problems with a device. Many nurses were suspended and five were arrested over accusations of falsifying patient data in an investigation lasting three years. Eventually the case collapsed when it became evident that the devices and IT systems had design flaws leading to chronic difficulties. The human cost in this process was huge.

The good news is that CHI+MED's insights are beginning to transform practice. We have supported change in one hospital where a patient experienced a fatal infusion overdose. As a result, the hospital has changed its practices: staff are now increasingly reporting faulty equipment and systems before things go wrong rather than making do and hoping that they don't get blamed after something goes wrong. It would be useful to combine these and other incident reports with device safety ratings.

+ Medical devices should be safety-rated

We recommend more systematic change around safety-rating medical devices. Hospitals do want to buy safer equipment, and it will produce an instant impact. Manufacturers would then focus on producing safer products that would sell better. This does not happen at the moment, because it is difficult for a purchaser to choose wisely, even if they want to pay extra if the additional cost will reduce harm or save lives. Patients would also demand safer equipment. Nurses would spot poorly-rated equipment they might have to use and highlight its faults. Everyone would realise that, like cars, hospital devices and systems vary according to safety.

This is a practical, realistic solution to a hidden crisis. Currently, ignorance is bliss – except when a tragedy occurs. At that point, there is a knee-jerk urge to blame the last person who pushed a button. Typically, manufacturers and procurement walk away without sharing blame. The hospital may believe that disciplining or sacking a staff member has solved the problem. In fact, the problem is usually still there, in the equipment, waiting to damage the next patient.

Everyone – patients, nurses, hospitals and the best manufacturers – wants safer, better medical devices. CHI+MED has identified a workable way to achieve this breakthrough.



Professor Harold Thimbleby is Professor of Computer Science at Swansea University, Wales and a visiting professor at UCL and at Middlesex University. He is also a member of CHI+MED's Management Board.

The CHI+MED team were: Chitra Acharya, Carlos Monroy Aceves, Jonathan Back, Erik Berndt, Ann Blandford, Jo Brodie, Duncan Brumby, George Buchanan, José Campos, Abigail Cauchi, Shauna Concannon, Anna Cox, Paul Curzon, Jonathan Day, Enrico D'Urso, Parisa Eslambolchilar, David Ford, Dominic Furniss, Andy Gimblett, Sandy Gould, Sinan Halilbeyoglu, Michael Harrison, Huayi Huang, Victoria Hurst, Jo Iacovides, Matt Jones, Alexis Lewis, Karen Li, Paolo Masci, Piergiuseppe Mallozzi, Astrid Mayer, Peter McOwan, Chrystie Mykietiak, Gerrit Niezen, Paul Noble, Aisling O'Kane, Patrick Oladimeji, Tom Owen, Abigail Parisaca-Vargas, Atish Rajkomar, Rimvydas Rukšenas, Katarzyna Stawarz, Harold Thimbleby, Huawei Tu, Chris Vincent, Julie Webster, Graham White, John Williams, Sarah Wiseman, Richard Young.

Our steering committee comprised: Gregory D Abowd, John Clarkson, David Gerrett, Laura Meagher, Lisa Coles.

Our advisory team comprised: James G Barlow, Chris Johnson, Nicholas Komaromy, Paul T Lee, Ed Matthews, Frankie Thompson, John Trow, Oliver Wells, Terry Young. Sue Heatherington has also given very valuable support throughout the project.



Writer / Editor - Jack O'Sullivan / www.think-osullivan.com
Design - Jonathan Sivyer / www.linkedin.com/in/jonathansivyer

Manifesto for Medical Devices

A research agenda for safe, efficient and effective usage



CHI+MED (Computer-Human Interaction for Medical Devices) is an EPSRC-funded project to improve the safety, efficiency and effectiveness of interactive medical devices, such as infusion pumps.

“We need a sustained programme of research for the delivery of healthcare that is technology enabled, and increasingly managed by people with little or no medical training.”

Further information:

Professor Ann Blandford

a.blandford@ucl.ac.uk

Dr Anna Cox

anna.cox@ucl.ac.uk

Professor Paul Curzon

p.curzon@qmul.ac.uk

Professor Harold Thimbleby

harold.thimbleby@gmail.com



www.chi-med.ac.uk | [@chi_med](https://twitter.com/chi_med)