

## Making Medical Devices Safer to Use



## Insights from CHI+MED

[www.chi-med.ac.uk](http://www.chi-med.ac.uk)

CHI+MED (“Computer-Human Interaction for Medical Devices”) was a six year programme that began in 2009 to improve the safety of interactive medical devices. It was a joint project between UCL, Swansea University, Queen Mary University of London and City University, in partnership with a wide range of stakeholders including regulators, manufacturers, hospitals, medical device trainers, procurement staff, clinicians and other medical professionals.

CHI+MED was funded by EPSRC under grant number EP/G059063/1. CHI+MED is pronounced Kye-med.

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Sue Heatherington has also given very valuable support throughout the project. We are grateful to Jack O'Sullivan and the QMUL creative services team for their help and advice preparing this brochure.

# CHI+MED: Making Medical Devices Safer

This booklet presents an overview of CHI+MED, an interdisciplinary research project to improve the safety of interactive medical devices, such as infusion pumps, blood glucose monitors, and haemodialysis machines. Our long term aim is to transform the way medical devices are designed, tested, bought and used, reducing the number of medical errors — and so saving lives.

Our work has blended computer science, engineering, cognitive psychology, the social sciences, and of course healthcare. We have worked with patients, their carers, nurses and other medical practitioners, manufacturers, NHS staff who purchase devices, as well as regulatory bodies who oversee patient safety.

Our first goal was to learn more about how people design, buy and use medical devices in the real world. We examined how people perform device-related tasks in real-world situations, on busy wards and in homes. We then explored how to reduce the likelihood and consequences of human error.

We investigated the designs of devices: focussing on how users have to program them, what can happen when wrong data is entered, and how new technology helps and sometimes hinders. Our laboratory experiments helped understand the causes of human error and how safety can be improved.

Based on the understanding gained from these separate strands, we have created and evaluated design tools and other interventions that can help manufacturers, clinicians, procurement staff and even patients improve safety.

Our work has been recognised internationally.

**Ann Blandford, Harold Thimbleby,  
Paul Curzon, Anna Cox,  
November 2015**



## HAZARDS AND RISKS

[www.chi-med.ac.uk/hazards](http://www.chi-med.ac.uk/hazards)

When designing software, the ways the device could possibly cause harm must be identified, so that the device can be designed to prevent them all occurring.

⚡ We have identified hazards for the use of infusion pumps, conducted risk analyses for novel treatments and developed a new way of thinking about risks that can be used in risk analysis. ⚡

# CHI+MED methods find and highlight otherwise unknown risks to patients

## Our new way to identify hazards uncovers many more problems than traditional approaches

To ensure patients are not harmed, the things that can possibly go wrong when using a new device must be determined.

Working with the US regulator, the Food and Drug Administration (FDA), we have developed a new way to identify such hazards when using medical devices that complements existing methods. It focuses on hazards related to use and possible design flaws that could cause them.

“ We based our method on widely used design principles and models of human cognition to ensure it has a strong focus on hazards related to their use by real people. Our initial experiments suggest that it can detect three times as many use-related hazards as traditional methods. ”

Find out more at: [www.chi-med.ac.uk/hazards/hazardanalysis.php](http://www.chi-med.ac.uk/hazards/hazardanalysis.php)



## We have identified hazards in using infusion pumps, so hospitals, manufacturers and regulators can avoid them

Working with the US regulator, the Food and Drug Administration (FDA), we have identified a substantial set of hazards related to the use of the data entry systems of infusion pumps. We have determined how poor design could lead to these hazards and identified marketed devices where these problems occur.

“ The hazard analysis has been incorporated into the procurement specification of a major hospital trust to ensure newly bought infusion pumps do not have the problems. ”

Find out more at: [www.chi-med.ac.uk/infusionpumps/hazardanalysis.php](http://www.chi-med.ac.uk/infusionpumps/hazardanalysis.php)

# Our recommendations help to make devices safe for children

Swallowing a button battery, such as those used in hearing aids, is a medical emergency. However, the seriousness of the situation is not always understood. Problems can appear only weeks after a battery is swallowed. In younger children it's possible no one sees them being swallowed.

Find out more at: [www.chi-med.ac.uk/hazards/hearingaids.php](http://www.chi-med.ac.uk/hazards/hearingaids.php)

## Hearing aid battery compartments need locks

Battery compartments in hearing aids should be tamper-proof to prevent people swallowing batteries accidentally, or a child choking on them. Greater awareness is needed of the risk. It is a problem that can be avoided with good design. We have raised awareness of the risk and of various solutions.



We have shown that appropriate information should be displayed to remind the clinician to do things such as close a fluid-line clamp before the next phase of the cycle can commence. We have also shown that expected sequences of machine states can only occur in normal and desirable situations when dialysing, washing and so on.

Find out more at: [www.chi-med.ac.uk/hazards/infantdialysis.php](http://www.chi-med.ac.uk/hazards/infantdialysis.php)

## Our analysis of the risks of a novel dialysis system for children will enable it to be used more widely

The Royal Victoria Infirmary in Newcastle has developed a new system for treating babies with kidney problems for which, until now, there has been no suitable treatment. Our risk analysis has shown that its design prevents a series of important and dangerous situations from arising. Our analysis is part of the process employed to convince the regulator to allow the system to be used widely.



## NORMAL USE

[www.chi-med.ac.uk/normalpractice](http://www.chi-med.ac.uk/normalpractice)

Accident investigations and research into healthcare errors only focus on what went wrong, but we have additionally investigated 'normal' practice in healthcare: what actually happens day-in-day-out, getting the job done and making patients better — what happens when things go right. We have studied the everyday use of devices in clinical settings such as on hospital wards but also by patients using devices at home and on the move.

Our work includes understanding how error is avoided on a daily basis. It is important that normal practice is understood so that appropriate design decisions can be made, and as a basis for evaluating whether medical devices appropriately support the tasks being done.

# By understanding people's lives, we help to produce safer designs

## Our picture of how UK hospitals use infusion devices is helping the introduction of safer smart pump software

We have investigated how UK hospitals are using and managing devices that deliver medication to patients in a wide variety of

contexts. Despite their potential benefits for safety, smart pumps, which alert nurses when unusual infusion values are set, are only occasionally used in the UK. We have identified issues preventing their take-up. The Singleton Hospital in Wales is using our research as a driver to introduce smart pump software.

⚡ We have identified important barriers preventing smart pumps being used, including existing contracts, and that those making the decisions must be convinced that the benefit is worth the effort needed to adopt them. ⚡

Find out more at: [www.chi-med.ac.uk/normalpractice/infusionuse.php](http://www.chi-med.ac.uk/normalpractice/infusionuse.php)



## The shift to *home* haemodialysis requires rethinking of technologies to fit people's lives

Complicated processes pose dangers to home users of haemodialysis machines. Designs should be modified to allow more support when something does not work, easy interventions in emergencies, and real-time remote monitoring by technicians. Designers need to understand how the devices are actually used as part of people's lives and to design for these situations.

⚡ One patient set up the machine outside on a veranda because that was a pleasant place to pass the time. They used a heater to maintain the temperature. Such adaptations have safety implications. They can also be seen as design opportunities. ⚡

Find out more at: [www.chi-med.ac.uk/normalpractice/homehaemodialysis.php](http://www.chi-med.ac.uk/normalpractice/homehaemodialysis.php)

# Design devices to fit the way people use them

## There are many uses of infusion devices and different designs *are* needed

In 2004 it was recommended that infusion devices should be standardised as far as possible across each NHS trust. However, we have identified important differences

between the assumptions made during design about how infusion devices will be used and the ways that they are actually used. We have developed resources that illustrate the many variations in the ways that they are used, making visible the real complexities of practice. We have shared them with regulators, clinicians and manufacturers.

There are major differences in the ways that infusion devices are used in different contexts, such as on different wards. For planned care it should be easy to check what has been administered recently. With reactive care, doses are often adjusted in response to vital signs monitors. ¶

Find out more at: [www.chi-med.ac.uk/normalpractice/diverseuse.php](http://www.chi-med.ac.uk/normalpractice/diverseuse.php)



## We have promoted new methods to improve the design of mobile medical devices

Medical devices are increasingly used as part of patients' work and social lives. New methods are needed to ensure they are easy to use in these non-medical contexts. Our research has investigated the real life use of Diabetes technologies in people's everyday lives, using 'qualitative situated methods.' These methods go beyond the scope of the current human factors standards that manufacturers follow.

We have increased the awareness of manufacturers and diabetes charities about these methods. We are now applying them to the design and development of new Type 1 diabetes technologies, through collaborations and a new consultancy set up for the purpose. ¶

Find out more at: [www.chi-med.ac.uk/normalpractice/understandingmobile.php](http://www.chi-med.ac.uk/normalpractice/understandingmobile.php)

# It's also important to understand why mistakes are not made

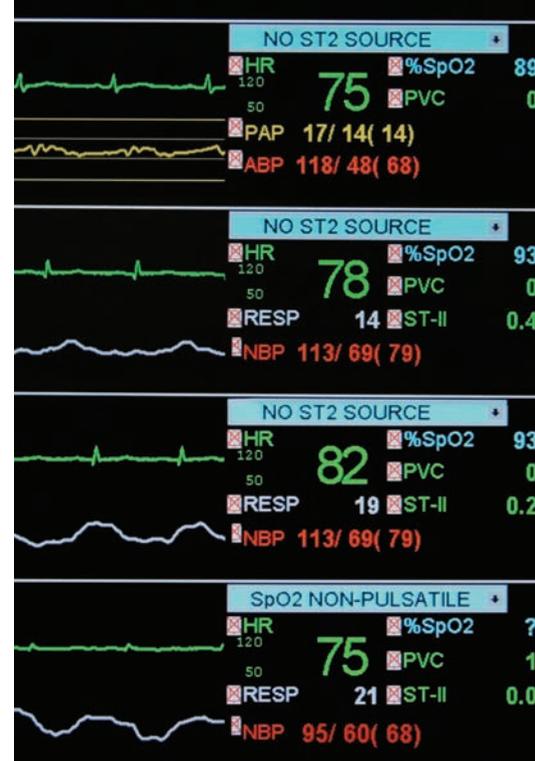
## We have identified the strategies people use to ensure things go right

Most of the time things go right. Understanding why is as important as understanding why they sometimes go wrong, but this is often ignored. We have developed the idea of 'resilience strategies'

One category of resilience strategy is creating new cues or artefacts. When a nurse places a post-it note over the button on a monitor saying 'Do not push', for example, they are following this general strategy. Such strategies highlight design opportunities.

Find out more at: [www.chi-med.ac.uk/normalpractice/resiliencestrategies.php](http://www.chi-med.ac.uk/normalpractice/resiliencestrategies.php)

for the informal and inventive actions people take to avoid making mistakes or to improve performance. We have identified different types of resilience strategy and developed a way to understand how and why they work. We are now using this knowledge to understand how patients and healthcare practitioners maintain safety. Resilience strategies are a powerful and general way to improve the design and use of medical devices making healthcare safer.

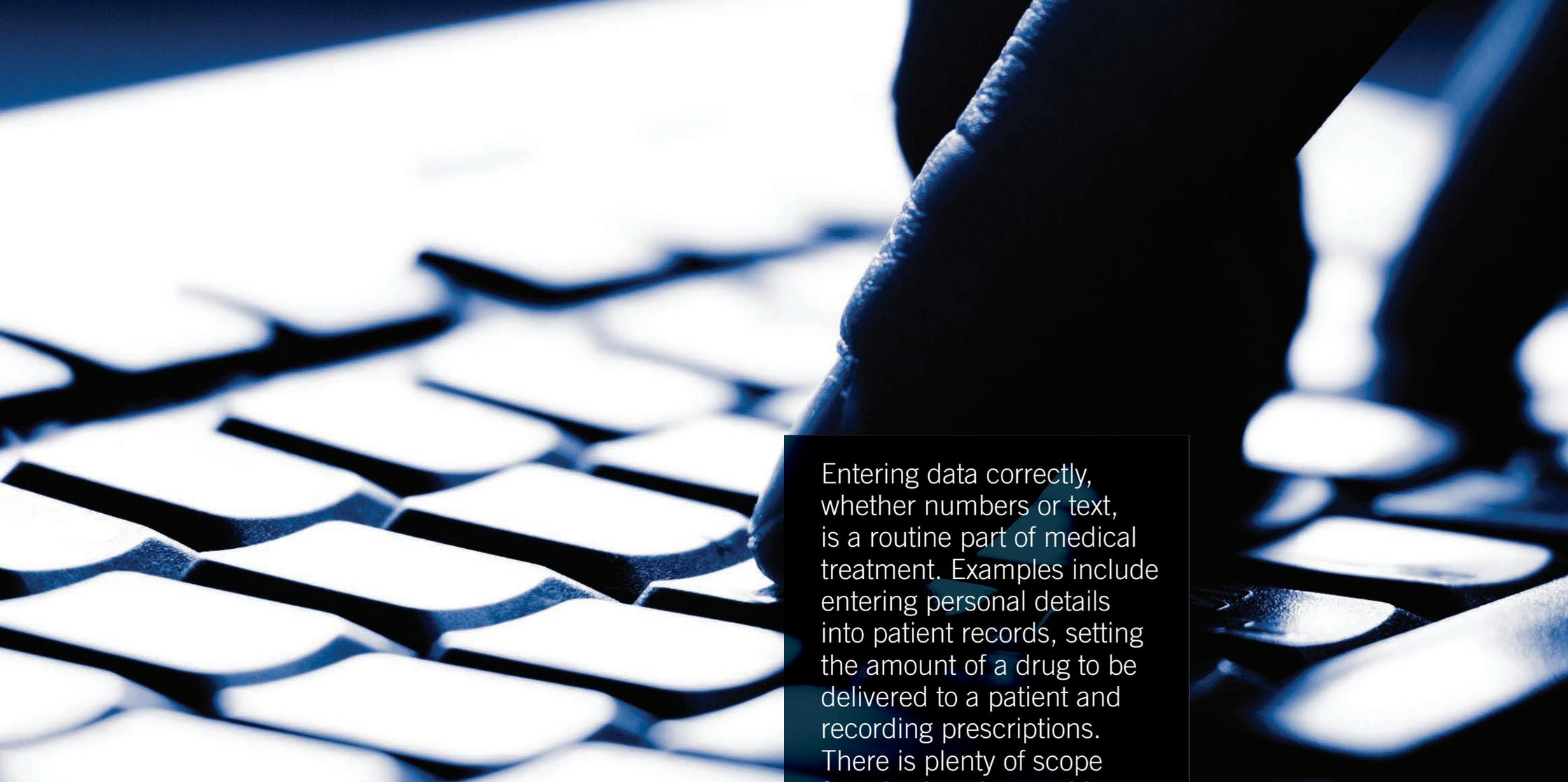


## We have created an easy-to-follow method for understanding the way technology is used in healthcare

Distributed Cognition is a powerful theory about how our mental processes work. It extends cognition from the thoughts in our head to include the way we use objects in the world to represent information. We have developed a method called DiCoT that makes it easier to apply Distributed Cognition to understand the way people work in healthcare teams.

We have shown that DiCoT can give valuable insights in a variety of healthcare contexts, from hospital wards to patients' homes, and for a variety of different devices including infusion pumps, blood glucose meters and haemodialysis machines.

Find out more at: [www.chi-med.ac.uk/normalpractice/dicot.php](http://www.chi-med.ac.uk/normalpractice/dicot.php)



## ENTERING DATA SAFELY

[www.chi-med.ac.uk/dataentry](http://www.chi-med.ac.uk/dataentry)

Entering data correctly, whether numbers or text, is a routine part of medical treatment. Examples include entering personal details into patient records, setting the amount of a drug to be delivered to a patient and recording prescriptions. There is plenty of scope for mistakes that could harm patients. Some mistakes involve the wrong information being entered. Others result in the wrong sequence of steps being followed. We have developed wide-ranging solutions to tackle the problems.

▮ We have explored the underlying reasons why these kinds of mistakes happen and how they can be avoided. We have looked at both the limitations of the way our brains work, and how changes to the design of data entry systems can help prevent errors leading to harm. ▮

# Some ways of entering numbers are safer than others

## We have rated the quality of different number entry interface designs

We have evaluated existing interfaces for entering numbers and shown that the style of interface influences the type of error committed and, thus, the severity of errors.

With existing designs, there is a trade-off between speed of entering a number and doing it safely. Digit-based keypads are fast but likely to lead to errors that are out by 10 or more, whereas 5-key interfaces are slower but less likely to lead to such large and dangerous mistakes. Our research has informed a multi-million pound procurement decision at a UK hospital.

Keying errors, like trying to increase the number beyond the largest possible, should be blocked with a warning that must be acknowledged. It is also easier to enter numbers without making mistakes if the interface is tailored, based on which numbers are most commonly used for the intended task.

Find out more at: [www.chi-med.ac.uk/dataentry/safestinterfaces.php](http://www.chi-med.ac.uk/dataentry/safestinterfaces.php)

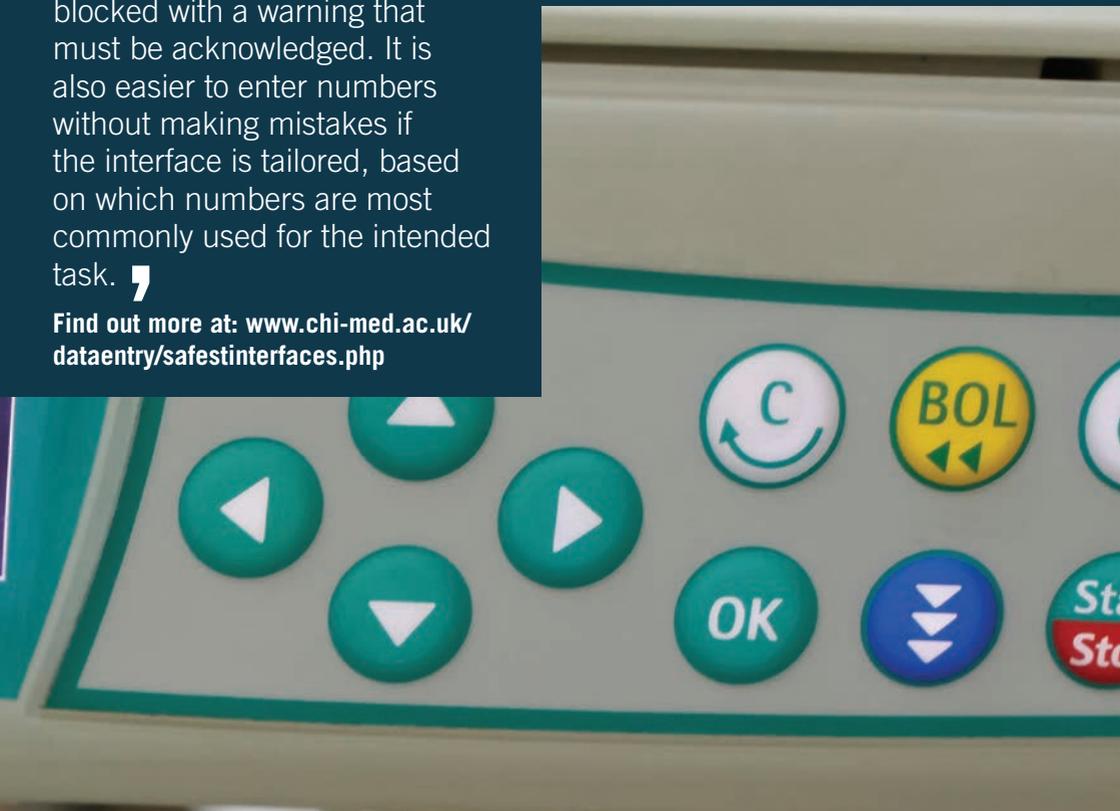


## Devices should give visual reminders after interruptions, to reduce mistakes in busy environments

Interruptions tax people's short-term memory, which makes errors more likely to occur. Our experiments have shown that if you give yourself a few extra moments to recall what you were doing before you are interrupted, your memory is more accurate. Well-designed visual reminders support your short-term memory and make it easier to pick up where you left off and finish the task correctly.

Training staff to pause for a few moments after an interruption also helps to prompt short-term memory and prevent errors. Think of when a word is on the tip-of-your-tongue but momentarily just won't come to mind. Sometimes pausing for a bit of extra mental effort helps you to remember something that a moment ago you couldn't quite recall. The same applies when using medical devices after interruptions.

Find out more at: [www.chi-med.ac.uk/dataentry/interruptions.php](http://www.chi-med.ac.uk/dataentry/interruptions.php)



# Focusing design features on familiar numbers can improve safety

## The number of mistakes people made entering data was reduced when the device asked questions

In experiments, we have shown that prompting people with questions linked to a number they are about to enter makes it more likely that they will enter it correctly. It can also help them correct mistakes when they do make them.

People made far fewer errors after being asked questions about the format of the number, the quantity it refers to, and the context of the number entry task. These are the important factors associated with nurses entering numbers to set up drug delivery devices to prime them not to make mistakes. »

Find out more at: [www.chi-med.ac.uk/dataentry/primingquestions.php](http://www.chi-med.ac.uk/dataentry/primingquestions.php)



We have shown that future experiments on number entry need to be designed in a way that takes account of whether numbers used are familiar to the participants. This includes evaluating number entry interfaces. »

Find out more at: [www.chi-med.ac.uk/dataentry/familiarity.php](http://www.chi-med.ac.uk/dataentry/familiarity.php)

## Evaluation of number entry devices must take account of whether numbers used are familiar to those involved

There are patterns in the numbers that medical workers have to type on hospital wards, which suggests that some numbers could be more familiar than others. Often number entry systems are tested by asking participants to enter sets of random numbers, but this doesn't accurately reflect the real tasks performed in hospitals. The familiarity of a number has a significant effect upon how a user types it: familiar numbers are faster to type than non-familiar numbers.

How much?  
How often?  
When?  
Where?  
How often?  
How much?  
How?  
Where?  
How?  
When?  
Format?  
How much?



# LEARNING FROM INCIDENTS

[www.chi-med.ac.uk/incidents](http://www.chi-med.ac.uk/incidents)

If people fear the consequences of reporting incidents, they are less likely to be open about mistakes. Nothing is improved and similar incidents happen again. If only good will come from it, then they will do so openly and honestly. Future suffering of patients, their families and the professionals involved is reduced and could be avoided.

CHI+MED has looked at the way incidents are reported and investigated, developing models to understand them. Moving to a learning culture will save both lives and money. The NHS currently has set aside £28 billion for medical negligence liability: costs that could go to patient care. **■**

# Better designed reporting forms and training improve learning

## **Our improved reporting form encourages open and honest reporting of mistakes**

We have identified serious flaws in the clinical incident reporting forms that healthcare professionals fill out when they realise someone has made a mistake

that could affect the safety of a patient. Our improved form encourages those filling it out to be more open and honest about mistakes. These improvements are based on our research and the opinion of healthcare professionals combined with the best features of existing forms.

“ The forms currently used in the NHS do not allow easy and quick reporting at the point of care nor do they support learning from incidents. ”

Find out more at: [www.chi-med.ac.uk/incidents/incidentreportforms.php](http://www.chi-med.ac.uk/incidents/incidentreportforms.php)



“ It would help the NHS become more of a learning organisation if there were a style guide. ”

Find out more at: [www.chi-med.ac.uk/incidents/writingincidentreports.php](http://www.chi-med.ac.uk/incidents/writingincidentreports.php)

## **Incident reports would be more useful if staff were trained in report writing**

Working with NHS England, we have reviewed over 8,500 incident reports about the use of medical devices. We have demonstrated the limitations of the reports for learning about design, training and practice about infusion pumps: the free-form boxes for entering text are used inconsistently, often giving too little information about who was involved in an incident, what actually happened, what devices were involved, or what the circumstances were. Our research also

found that incident reports with device user errors were written differently from other types of errors – including other types of errors with medical devices. This demonstrates that the quality of incident reports is affected by multiple factors. This has led to our making recommendations to NHS England about training in writing incident reports.



# Logged data must be forensically robust to prevent patient harm

## We have shown how forensic analysis of logs can uncover problems with infusion pump design

We studied the logs recording the use of infusion pumps from hospitals across the UK, concentrating on alarms and number entry errors. This highlighted problems with the pumps' designs. The results have been used to alert hospitals to the issues so they can raise awareness of the problems amongst clinicians who use the pumps. Our work also shows how manufacturers can improve the data loggers to better

support the investigation of safety issues and other incidents by providing stronger evidence of what happened. The approach is now being used by one hospital as a basis for evidence-based evaluation of pumps over their lifetime, in order to help future procurement decisions.

“ Our results are useful for hospital procurement staff, suggesting what they should look for in the logging software when buying new pumps to help improve safety. ”

Find out more at: [www.chi-med.ac.uk/infusionpumps/dataloggersforensic.php](http://www.chi-med.ac.uk/infusionpumps/dataloggersforensic.php)

## Hospital devices and systems are sometimes too unreliable for use in evidence

Two innocent nurses might have gone to prison, but they are now free after a three year battle. They had got caught up in a complex medical device issue where the computer records of the use of the device were to be presented in court as evidence against them. A CHI+MED expert witness was able to show that the computer evidence was unreliable. The problems were wide-ranging including in ways that were unrelated to what the nurses had actually done. The case thus collapsed: the prosecution presented no evidence, and

“ This was but one device in one hospital. We wonder how many other incidents across the country are turned into unfortunate legal action. Had CHI+MED knowledge been used earlier, the problems might have been avoided in the first place. The key learning from this is that unthinking reliance on hospital computer systems can lead to inappropriate prosecutions. ”

Find out more at: [www.chi-med.ac.uk/incidents/evidence.php](http://www.chi-med.ac.uk/incidents/evidence.php)

the jury was directed by the judge to enter a verdict of not guilty. The judge heavily criticised the amount of wasted time, and the failure of the process to help anyone, whether patients, families or nurses.

# Working with the media could raise the quality of devices

## Hospitals can encourage the media to give balanced reporting that supports learning from incidents

The way the media report an incident can affect whether the underlying problem is corrected. Before investigations (such as coroner's reports or criminal investigations) are closed, balanced reporting is key. Hospitals need to be open and honest if they are to encourage reasoned reporting.

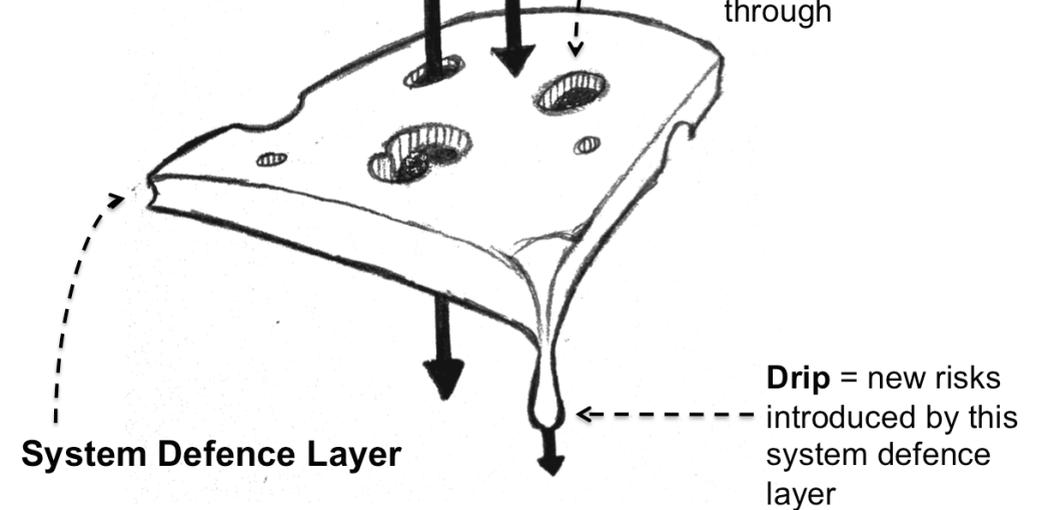
🗨️ Hospitals should make clear recommendations of how the hospital as a whole can change to prevent similar incidents occurring in the future, rather than suggesting there isn't a problem or that it is restricted to a single "bad apple". 🗨️

Find out more at: [www.chi-med.ac.uk/incidents/mediareporting.php](http://www.chi-med.ac.uk/incidents/mediareporting.php)



**Force** = errors allowed forward or risks introduced by previous system defence mechanisms

**Loophole** = badly designed or overlooked elements that may allow errors and risks to fall through



## Our 'Hot Cheese' model helps understand the impact of bad design on incidents

Poor design of medical devices has contributed to many incidents where patients have been harmed. However, design is not prominent in existing models of accident causation, particularly James Reason's widely-used Swiss Cheese Model. Our new 'Hot Cheese' model highlights the impact of bad design on incidents in a simple, flexible and memorable way.

🗨️ Our model supports risk analysis and risk management in safety critical fields, such as aviation, as well as healthcare. If it were adopted widely, it has potential to help prevent and (if they happen) understand incidents, saving both lives and money for the healthcare system. 🗨️

Find out more at: [www.chi-med.ac.uk/incidents/hotcheesemodel.php](http://www.chi-med.ac.uk/incidents/hotcheesemodel.php)

# TOOLS

[www.chi-med.ac.uk/tools](http://www.chi-med.ac.uk/tools)

CHI+MED aimed not just to undertake scientific research but also to develop tool support for professionals based on that research. This support comes in a variety of forms such as guidance documents, practical techniques and computer-based tools.

⚡ We have developed tools and methods for different purposes including: to support the design and procurement of new medical devices; to help in arguing that a device satisfies regulatory requirements, as well as to check such claims; and to document and to analyse medical incidents. ⚡

# Our maths-based tools can help create better, safer designs

## **We can make medical devices user-friendly, saving lives and money, by identifying dangerous, latent flaws rigorously and cheaply**

Our tools supporting the design and simulation of infusion pumps and other medical devices are underpinned by sophisticated mathematics that could help cut many of the hundreds of unnecessary deaths caused by design-linked human error as well as save millions of pounds.

⚡ This tool is able to spot design flaws that can be fixed so the problems will never happen again. If, instead, something goes wrong and you just sack the doctor or nurse who made the mistake, you have not prevented that mistake from happening again. ⚡

Find out more at: [www.chi-med.ac.uk/tools/pvsiowebforprototyping.php](http://www.chi-med.ac.uk/tools/pvsiowebforprototyping.php)

## **Our tool automatically creates data entry user interfaces that are safer to use than those created in *ad hoc* ways**

Our data entry development tool helps ensure that programmers cover all eventualities and the user interface responds to errors in a sensible way. Programmers have at best *ad hoc* solutions as to what to do when people enter data incorrectly, like when they include a second decimal point or put a leading 0 in a number, but often programmers just

⚡ One approach the tool uses is 'traffic lights,' so both user interface and user know when a mistake has been made. A red traffic light — perhaps with added sound or vibration — alerts the user that a problem must be solved. The tool implements traffic lights flexibly, efficiently and dependably. ⚡

Find out more at: [www.chi-med.ac.uk/tools/programmingsafedevices.php](http://www.chi-med.ac.uk/tools/programmingsafedevices.php)

ignore these seemingly simple problems. Failing to manage user error well causes even worse problems, and this is what our tool helps prevent. Crucially, the programmer does not need to worry about dealing with these kinds of user errors, as the tool has done that already.



# Simulating how users behave gives fast ways to compare designs

## We have developed a fast, and effective, way of seeing how usable and safe designs are

Many different user interfaces for entering numbers could be made much safer without affecting their normal use. Our technique for seeing how safe a design is, called stochastic evaluation, involves computer simulation of users pressing buttons. It is automatic and works best

when there is an objective measure of how significant an error is. For example, 'drug doses that are out by a factor of ten or more' is easy to quantify and hence easy to evaluate automatically.

“ We have identified ways to make common designs much safer, quickly identifying bugs or defective design choices. Our approach also allows choices to be compared by putting a value on the size of a problem's impact on safety. ”

Find out more at: [www.chi-med.ac.uk/tools/stochasticevaluation.php](http://www.chi-med.ac.uk/tools/stochasticevaluation.php)



“ Careful design decisions need to be taken to ensure safety of operation when medical devices are connected. For example, what happens if a patient monitor is configured incorrectly, operated incorrectly, or malfunctioning? It is certainly desirable that an infusion pump it is passing information to operates as safely as in a situation when they are not connected. ”

Find out more at: [www.chi-med.ac.uk/tools/modellinginteroperativedevices.php](http://www.chi-med.ac.uk/tools/modellinginteroperativedevices.php)

## Our development tools help ensure medical devices work together safely

We have developed new tools for verification and validation of interoperable medical systems as part of our PVSio-web prototyping environment. They have been successfully used to develop a realistic interoperable medical system prototype based on commercial products and application scenarios described by the US regulator, the Food and Drug Administration (FDA). With international collaborators we are using them to validate the FDA requirements for interoperable medical systems.

# Our tools help regulators to check the safety of devices

## Regulators can use our methods to check that requirements are satisfied

Safety requirements set out the acceptable safety of medical devices; they are typically described precisely, but in natural languages like English. An important issue is how the regulator can be sure that the given requirements are satisfied by a new device.

Our refinement-based approach involves gradually transforming a requirement into a form that can be coded, underpinned by mathematics to ensure mistakes aren't made. It complements the pre-market review process promoted by the US regulator, the FDA, to provide the necessary safety assurances.

Our approach helps to both design and clarify high level safety requirements that relate to user interfaces of medical devices. It also supports the development of models that describe different interaction methods and their verification against safety requirements.

Find out more at: [www.chi-med.ac.uk/tools/refinement.php](http://www.chi-med.ac.uk/tools/refinement.php)

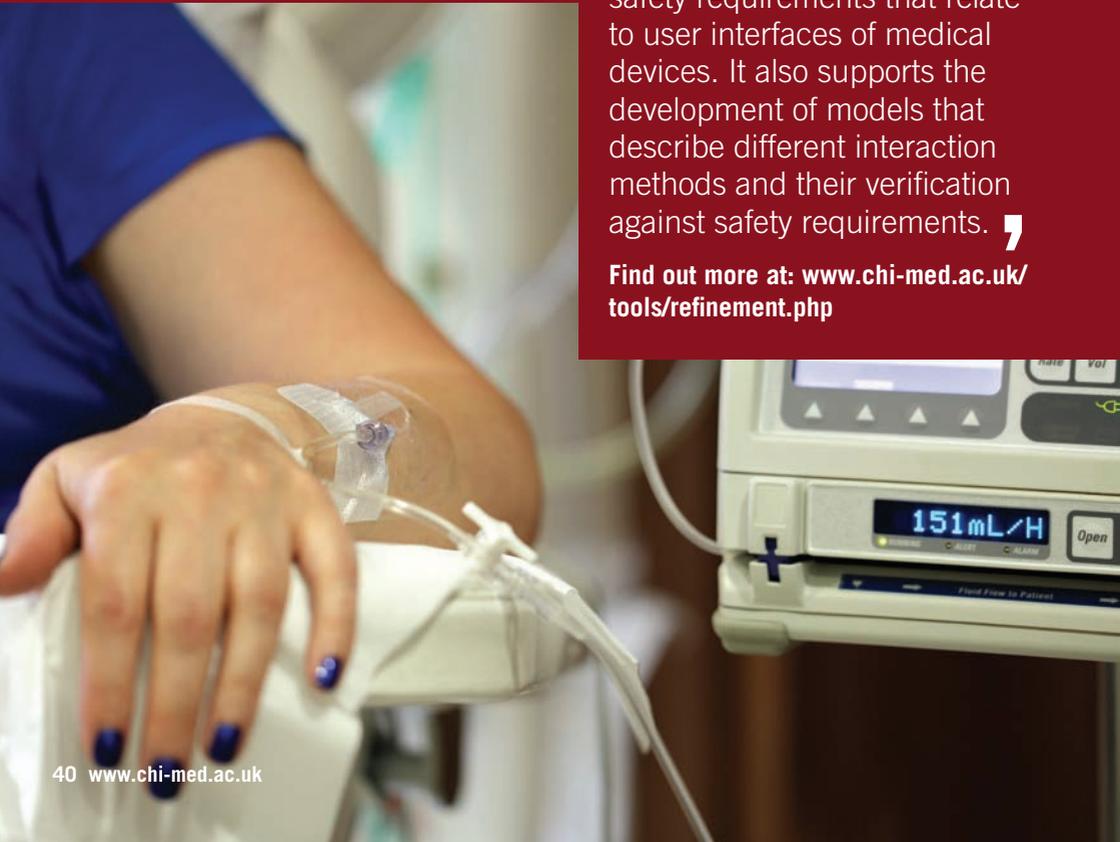
## We can identify design flaws that would lead to a large overshoot when adjusting numbers

We have developed a new approach for evaluating the user interfaces of medical devices by combining existing techniques from aerospace engineering and robotics. We can model both individual actions of human operators like pressing a button but also a person doing things that have an effect over a period of time. This gives

We have integrated our technique into our analysis toolset, PVSio-web, and have demonstrated it can be useful by simulating a person entering values on an infusion pump using up and down buttons.

Find out more at: [www.chi-med.ac.uk/tools/controltheory.php](http://www.chi-med.ac.uk/tools/controltheory.php)

a novel way to describe precisely, and so simulate and reason about, a person using a medical device with buttons that behave differently when pressed and when held down.





## We have raised awareness with key stakeholders

### **Our user interface architecture has supported the FDA's programme to improve the safety of infusion pumps**

Concerned about the number of incidents and recalls of devices, the US regulator, the FDA, initiated a programme to improve the safety of infusion pumps. One strand of this, called the 'Generic Infusion Pump Project' was to develop a set of reference specifications for infusion pumps that describe the key elements. The aim is for them to be used by manufacturers to check safety properties of their own devices. CHI+MED provided the expertise to add a missing element of this work: a reference architecture for the user interface software that could be used to ensure its safety.

“ We demonstrated the usefulness of our reference model by using it to help find hazards in commercial infusion pump software and identify user interface design issues that explain common problems reported in infusion pump incidents. ”

**Find out more at: [www.chi-med.ac.uk/tools/architecture.php](http://www.chi-med.ac.uk/tools/architecture.php)**



“ As a result of their work on CHI+MED, regulators in the UK have appointed several CHI+MED researchers as expert reviewers checking new devices are safe to be marketed. ”

**Find out more at: [www.chi-med.ac.uk/impact/regulators.php](http://www.chi-med.ac.uk/impact/regulators.php)**

### **Regulators are using our research as the basis for checking that medical devices are safe to be marketed**

Before medical devices can be marketed they must go through a 'pre-market review' approval process to ensure that they are safe. In the past issues related to interaction design, that is, how the device responds to user input, has not been a major concern. In direct response

to our work, the US and UK regulators for medical devices (the FDA and MHRA) have now established a programme of work on interaction design. Working with them, we have found previously undetected safety issues in marketed medical devices. Together with them, we are developing theories and tools that will form the basis of a new safety standard on interaction design in medical devices.



# EDUCATION, GUIDANCE AND PUBLIC ENGAGEMENT

[www.chi-med.ac.uk/education](http://www.chi-med.ac.uk/education)

**chi+med**  
making medical devices safer

CHI+MED has prepared practical guidance for professionals based on our research, as well as for people needing to conduct fieldwork studies. CHI+MED's long term aim is to be transformational and that requires everyone to understand issues around human error and blame culture. Our education programme aims to support this transformation through inspiring, memorable and fun activities for school children too.

Our guidance documents have supported regulators, manufacturers and advisory bodies as well as procurement and training staff. We have also worked with school children. Change their understanding and in the long term transformational change is much more likely. ▸

# CHI+MED has changed how key stakeholders see these issues

At the request of one hospital, we created a video demonstrating issues we had uncovered while working with the US regulator. The video demonstrates design problems in a wide range of marketed devices that nurses need to be aware of. This video has now been downloaded over 3000 times in less than 18 months.

Find out more at: [www.chi-med.ac.uk/impact/training.php](http://www.chi-med.ac.uk/impact/training.php)

## Hospitals in both the UK and the USA are training their staff using our tools and results

Nurses are often unaware of design issues with the devices they use. Some such problems could lead to them making mistakes without knowing, and through no fault of their own. We have worked with several hospitals to support the training of their staff, to raise awareness of the problems of poor design, and to promote learning culture.

## Our guidance has raised awareness of relevant standards for Usability Engineering in medical device design

We prepared a summary guidance document to signpost relevant standards for manufacturers on usability engineering. This led to raised awareness of the need for usability engineering standards in the design of medical devices by manufacturers, regulators and advisory committees. This also led to our acting as an expert reviewer on a white paper on Usability Engineering standards for the British Standards Institute.

Both the UK regulator (MHRA) and the organisation most responsible for international consensus standards for the medical device industry (AAMI) asked us to share our guidance.

Find out more at: [www.chi-med.ac.uk/tools/standards.php](http://www.chi-med.ac.uk/tools/standards.php)



# Our stories are helping people understand the problems

## Telling stories about people, and the situations they find themselves in, gives a powerful way to improve technology

Technology is not always used in the ways that those who designed it expected and this can both lead to frustration for those involved and raise safety issues. We have

“ An elderly patient has been brought into A&E. A car travelling at about 40mph hit him...

Sam opens the pump door and then aligns the plastic guides ... the first two go in easily, but the third seems to be stuck. Something is not right and he feels like he is forcing the clip into the pump mechanism ... ”

Find out more at: [www.chi-med.ac.uk/tools/personas.php](http://www.chi-med.ac.uk/tools/personas.php)

shown how a simple but powerful approach can help avoid the problem. It is based on giving fictional but realistic accounts of the people who use the technology, and of the situations they find themselves in (such as the quote on the left). These accounts are based on interviews and observation of the actual work of real people. They give a powerful way to communicate to designers the day-to-day reality they are designing for, as well as forming the basis of a training activity based on role playing that is helping nurses understand how poor design can cause incidents.



## We have made healthcare fieldwork studies easier to do

Fieldwork for healthcare is a very challenging research area, for which there was little support: a gap we have filled. We have made it easier for new researchers and practitioners to do healthcare fieldwork studies by collecting case studies and experiences from international experts, sharing them through a published graduate guidebook. We have also identified guidance and strategies for overcoming the problems of doing fieldwork for healthcare, writing a second graduate guidebook on this.

“ We have fostered a supportive international research community in fieldwork for healthcare, providing a range of guidance to help people get started doing fieldwork and do it better. ”

Find out more at: [www.chi-med.ac.uk/normalpractice/fieldworkforhealthcare.php](http://www.chi-med.ac.uk/normalpractice/fieldworkforhealthcare.php)

# Magic and mayhem lead to a deeper understanding of mistakes

## **Our fun education programme, based on magic tricks, is an inspiring way to introduce issues around engineering safer medical devices**

Our educational activities based on magic tricks have been highly popular, engaging school students and their teachers about important themes and issues drawn from CHI+MED research. Magic systematically brings human error dramatically alive! We have created a book, shows, science festival activities, school activity sheets and workshops for teachers, all based on

magic as a way to introduce CHI+MED themes. Through our websites and invited keynote talks at education conferences, this approach has been taken up internationally.

Our use of magic tricks is based on two key ideas: Magicians show we can engineer systems that lead to people consistently making mistakes however hard they try not to (programmers must do the opposite). Magic and software both combine an algorithm with a presentation and the two ingredients must both be right. ¶

**Find out more at: [www.chi-med.ac.uk/education/engagingthroughmagic.php](http://www.chi-med.ac.uk/education/engagingthroughmagic.php)**



## **Our citizen science project, Errordiary, engages people with issues about human error and blame culture**

Our Errordiary website juxtaposes funny, frustrating and fatal examples of error from both the media and the public's own experiences. In doing so, it provokes people to think about human error, resilience and blame culture. It raises awareness about the issues with healthcare professionals, people with health conditions (in particular diabetes) and the public. It has also provided us with the basis for building a vocabulary of different kinds of strategy people use to avoid making mistakes.

Errordiary is being used in universities to teach human error in psychology, computer science and human factors, as well as to train researchers and practitioners to identify resilience strategies. ¶

**Find out more at: [www.chi-med.ac.uk/education/errordiary.php](http://www.chi-med.ac.uk/education/errordiary.php)**



# We have given teachers practical ways to teach CHI+MED topics

## **Safer medical device design provides a rich context for teaching computing in school**

By running workshops and developing teaching resources, we have given school teachers both deeper understanding and practical ways to teach the new English computing curriculum. We have shown them how to include themes of safer design, and how to make technology easy to use, in their teaching of computing. Our research focus allows teaching to be embedded in inspiring and rich stories. Combined with activities that teach

computing away from computers, such as role-playing the way software works, this makes learning fun and engaging. The workshops have been given to around a thousand teachers so far with highly positive feedback. In 18 months, tens of thousands of copies of resources have been downloaded from the related Teaching London Computing website that are either directly CHI+MED based or include its themes.

“ In every session I am in, people are gripped. You can see them thinking “I am going to get that into my class”. ”

Find out more at: [www.chi-med.ac.uk/education/teachers.php](http://www.chi-med.ac.uk/education/teachers.php)



## **Our persuasive games raise awareness about human error and blame culture in healthcare**

Well-designed persuasive games can be powerful awareness raising tools. We organised a game design competition challenging university students to create a persuasive game that raised awareness about human error in healthcare. We judged the games based on the reflection that they led to. All the games are freely available from our Errordriary Discovery Zone.

“ Our Nurse’s Dilemma game puts the player in the role of a nurse who is trying to get to the drug cabinet to get her patient his medication. On her way she is constantly interrupted by others who really need her help. Should she stop and help the man who has fallen in the corridor or keep going to the drug cabinet so that her patient does not have to wait any longer? ”

Find out more at: [www.chi-med.ac.uk/education/persuasivegames.php](http://www.chi-med.ac.uk/education/persuasivegames.php)



# Making Medical Devices Safer to Use: The Future

CHI+MED has shown we can transform healthcare by better design of medical devices, and that we can start immediately by improving incident reporting. We have shown how to engage with, and get useful, practical information from, healthcare and find out what is going on so that information can be used. We have shown we can save hospitals money, we could save lives, and we can even prevent unsafe convictions. Our world-leading research collaborating with UK and international regulators and others has shown the power of multi-institution, multidisciplinary teams — and the huge value of EPSRC Programme Grants.

Although a very serious topic, we managed to have some fun too, and we hope others will be inspired by the questions and issues we have raised. Preventable harm in healthcare is one of the big killers, comparable in lost life with cancer and heart disease. Now we know we can do a lot about it.

This booklet highlights some of the many success stories from CHI+MED.

Much more information and many useful resources are available from CHI+MED's website: [www.chi-med.ac.uk](http://www.chi-med.ac.uk)



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