SAFER BY DESIGN

Thousands of patients each year are harmed by medical errors, many of which could be prevented. **Alison Tonks** reports on steps to make the NHS mistake-proof

While a badly designed chair might be a little uncomfortable, and a badly designed oven might test your ability to turn out evenly browned cakes, a badly designed piece of hospital equipment can kill you. In 2001, Wayne Jowett, a leukaemia patient in a UK hospital, died from an intrathecal injection of the intravenous drug vincristine. Intravenous and intraspinal connections were, and still are, interchangeable—a fundamental design flaw according to the chairman of the subsequent external inquiry.¹ A similar design flaw contributed to the death in 2004 of a new mother who was given a bolus of bupivacaine intravenously instead of into her epidural catheter.²

In 2003, 16 year old Natalie Dibden died of a head injury soon after falling out of a badly designed ambulance.^{3 4} These tragedies and many others would never

have happened in a world where hospitals, equipment, drug packaging and information, computer systems, and patient transport were specifically designed to prevent them—to protect patients from every conceivable harm, and particularly from human error. Cars, nuclear power stations, and aeroplanes are designed to be safe. They have to be. Rather belatedly, healthcare authorities all over the world are starting to learn from these indus-

tries and to think seriously about how good design can save lives.

Starting from scratch

It could be a long hard slog, according to a 2003 joint report by the Department of Health and the Design Council.⁵ The report concluded that the NHS was complex, chaotic, and clueless about design.

“The NHS is seriously out of step with modern thinking and practice with regard to design. A consequence of this has been a significant incidence of avoidable risk and error,” it says.⁵ Part of the problem is that “The NHS does not appear to see itself as a high risk industry,” according to experts from industries that do.

Since then, however, patient safety has moved up the political agenda. In the United Kingdom and elsewhere there is

new enthusiasm for invention, innovation, and redesign. A new connector to prevent intravenous drugs being injected through the spinal route is typical of current projects. “The new connector is similar to the traditional and ubiquitous Luer connector but has a different locking mechanism that makes it incompatible with existing devices such as syringes for intravenous injections,” says Rebecca Lawton, who is leading the team testing the new

connector at the University of Leeds. The prototype has passed extensive usability tests, including a prospective hazard analysis to make sure the new connector won’t replace one hazard with another. Doctors in Leeds are already using it, and the developers hope it will be on the market soon.

Meanwhile, the NHS ambulance fleet is under scrutiny at the start of a long term project to redesign and standardise vehicles to make them safer.³ Remarkably, ambulance trusts set their own specifications, so there are over 40 different variations in the internal layout and equipment carried by UK ambulances. A recent report concluded this inconsistency was unsafe, and listed nine key areas for redesign, including how to “effectively secure people and equipment in transit.”³

Whole hospitals can also be designed to minimise the risk of harm to those working or being cared for inside.⁶ The new University College Hospital in London, which opened in 2005, is packed with features to help prevent the spread of infections such as methicillin resistant *Staphylococcus aureus* (MRSA). The hospital has a separate floor in the middle of the building for patients with infections, sloping surfaces that don’t accumulate dust, red and green ping pong balls over the doors to indicate the direction of air flow, and 1200 sinks placed strategically so health professionals can’t ignore them.⁷ Earlier this year, infection control chiefs introduced new computer

keyboards that flash when they get dirty and don't stop until someone wipes them down with alcohol or detergent.

Other smaller scale ideas from working professionals who have spotted a problem and designed a solution include an apron in layers that can be torn off after each patient; an antimicrobial gown with fastenings designed to minimise skin contact (and infection transfer) between doctor and patient; and reusable bags for the safe transfer of patients' medicines and drug information during hospital stays, the bags, developed by a team at Nottingham City Hospital, are already for sale and helping to reduce drug errors on discharge.

So you have an idea

Health systems are complex and confusing. It's hard to know whose door to knock on with an idea for a new product or design that might make health care safer. For people working in the English NHS, one such door is called an innovation hub. There is one in each region of the country, thanks to a collaboration between the Department of Health and the Department of Trade and Industry.

"The innovation hubs grew out of a recognition that most good ideas come from staff," says Maire Smith, director of the National Innovation Centre, which oversees their work. "They specialise in giving legal, financial, and

intellectual property advice to anyone with new ideas in the NHS. Your local hub can tell you if your proposal is genuinely new, and whether it has potential commercial value. Most importantly, the staff can help you protect intellectual property and prevent good ideas leeching out of the NHS." Ultimately, the hubs have the expertise to broker deals, negotiate with potential manufacturers, apply for patents, and secure commercial returns for the inventor and for the NHS. Similar local networks operate in Wales, Scotland, and Northern Ireland.

In the hubs' last annual report, David Gleaves, chief executive of NHS Innovations West Midlands, described his hub as "The interface between the NHS and the commercial world. Our insight is unique. Whether your idea is complex or simple, we are interested—it could well make a difference. And

NHS innovation hubs in England

East (www.hee.org.uk)
 North (www.nhsinnovationsnorth.org.uk)
 East Midlands (www.em-nhs-hub.org)
 South East (www.nhsinnovations-southeast.com)
 West Midlands (www.midtech.org.uk)
 North West (www.trustech.org.uk)
 Yorkshire and Humber (www.medipex.co.uk)
 London (www.nhsinnovationslondon.com)
 South West (www.nisw.co.uk)

when we think an idea can be developed, we always pass the baton to the best runner."⁸

That runner must, of course, clear the necessary regulatory hurdles. For new devices, such as an endotracheal tube, the manufacturers must convince the regulatory authorities that it is safe, says Susanne Ludgate, clinical director of the UK's Medicines and Healthcare Products Regulatory Agency. "The level of evaluation required depends on how potentially risky a new product might be. It could be extensive bench testing, or it could be clinical trials. But it's up to the manufacturer to provide data to back up any claims. They also have to tell us when something goes wrong after marketing."

Can you design mistakes out of medicine?

Jim Reason, emeritus professor of psychology at Manchester University, thinks it's possible to eliminate mistakes but not easy. "Murphy's law says that if it's possible to do something wrong, people will. That's why at least 50 patients worldwide have died such a horrible death from intrathecal vincristine. These deaths were certainly preventable, and design safeguards such as the new spinal only connector will help. But safeguards do have a way of biting back, partly because new equipment tends to add to the complexity, opacity, and unfamiliarity of a situation."

Computerised aids to prescribing are a good example. Designed, among other things, to reduce drug errors, some systems have been found to do just the opposite. A recent study of one leading computerised physician order entry system in the US found potentially dangerous deficiencies that could cause 22 different kinds of drug error.⁹ The screen was too small and hard to read. Information was fragmented and not always labelled with the patient's name, increasing the risk of selecting the wrong patient or the wrong drug. The system often crashed. It told doctors about patients' allergies only after a drug had been ordered.

Computer systems used by general practitioners in the UK have also been criticised for prescribing deficiencies.^{10 11} These systems are not foolproof. Doctors are adaptable, intelligent, and can easily work round the design flaws. But they don't always do it right, and the technology doesn't always stop them getting it wrong. The patient safety jargon for foolproof is mistake-proof. It means

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equipment should be designed to prevent mistakes or at least to detect and remedy mistakes before they cause any harm. Equipment should also be designed to fail safely.¹²

The concept of mistake-proofing can be applied to almost anything from drug trolleys to surgical swabs. But it rarely is—possibly because of the lingering notion that people, not things, make mistakes and that if we all just tried a bit harder we could stop. Professor Reason abandoned this way of thinking decades ago. In an interview last year he remarked that we all make mistakes because most of the time we are on autopilot. We have to be. If we thought carefully about everything we would never make it out of bed in the morning.¹³ He told the *BMJ* that health professionals often make mistakes because of a “conspiracy of benevolence.” They bend rules, break protocols, and force functions to try to make patients' lives easier. Human error can't be prevented, but good design can help to manage it.

The task is urgent. Two years ago, Glyn Elwyn wrote in the *BMJ* that mistakes in health care are on a different scale from the level of error tolerated in other industries.¹⁴ Solutions are beginning to filter through from unfamiliar territories such as systems

engineering, psychology, and human factors research and from unfamiliar professionals such as designers and architects. Liam Donaldson, chief medical officer for England and Wales, would like things to improve faster. “Design skills play a major part in safety in other sectors that healthcare has been slow to embrace,” he said. “Seemingly simple applications, such as medicine packaging and labelling, have hardly been exploited while patients continue to be harmed from look-alike, sound-alike medication errors. Design experts should be part of every team that seeks to find an effective solution to a major source of risk in patient care. This should embrace both technological areas but also so called soft systems. The power of design has a potential to make health care of tomorrow safer than it is today. It should be used, and used with open mindedness and imagination.”

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My most informative mistake

Medicine will always come down to one thing: a doctor or two puzzling out what might be wrong with a patient. Experience, common assumptions, and human nature can guide them but can just as easily lead them astray.

One of the errors that greatly influenced my clinical practice concerned a middle aged man admitted with acute paraplegia. His symptoms had started only 12 hours before admission and included lower back pain, paralysis, and urinary retention. Clinical examination revealed leg weakness, diminished sensation below the T8 level, and bladder distension, for which the patient was catheterised.

Spinal magnetic resonance imaging showed an inflammatory lesion within the cord at the T6 level. As the rest of the work-up was unremarkable, a diagnosis of acute transverse myelitis was made. Treatment with methylprednisolone (750 mg/day) and omeprazole (40 mg/day) was started.

Four days later, I noticed marked abdominal distension. This was attributed to autonomic dysfunction, a common occurrence in such cases, causing retention of urine and faeces. However, I examined the patient and ordered a full blood count. No signs of abdominal irritation or tenderness were present, and blood tests revealed no increase in white blood cell count. There was, however, neutrophilia (90%), which was presumed to be caused by the corticosteroid treatment.

The next day the patient went into shock. Abdominal computed

tomography revealed a perforated colonic diverticulum. The patient required sigmoidectomy and a long stay in the intensive care unit.

This incident was a series of mistakes, resulting from predictable mental traps. Corticosteroids can cause sigmoid diverticular perforation in about 0.7% of patients. However, typical signs of peritonitis may be masked by the suppression of the inflammatory process caused by the steroid treatment itself. For the same reason, white cell count may be normal. At the same time, the presence of severe sensory disturbance caused by the transverse myelitis—for which the patient was receiving cortisone in the first place—did not allow the emergence of pain, even after diffuse peritoneal inflammation. What's more, it made me believe that the marked abdominal distension and silence on auscultation were a result of paralytic ileus due to “spinal shock” rather than peritonitis.

Although I can give myself many excuses for this mistake, it did alter my medical thinking. It taught me that experience without vigilance and confidence without diffidence can be fatal. Medical mistakes are the result of cognitive errors, which bedevil all humans. As such, they are inescapable. However, sharper, broader, and less stereotyped thinking can raise the odds that the doctor will not get detoured from the truth.

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