Cutting-edge design

Maryanne Mariyaselvam describes some of the latest solutions being developed to protect patients and clinicians from potential errors

The foundations that keep clinical practice as safe as possible and that have improved over time include education, standards, professional organisations, personal diligence and commitment. However, the environment in which clinicians work has a profound impact on patient outcomes and the inevitability of errors occurring despite our best efforts.

Frontline clinicians are acutely aware of the impact of resource limitations and the organisation of healthcare systems within which we work. This includes the team structures, patient pathways and the limitations of medications and devices that are available to us. Sometimes we are clearly set up to fail.

However, if failure occurs, the clinician at the head of the team can be held personally responsible at a local, regulatory or even criminal level[1-3], potentially leading to more defensive medicine from the profession and resulting in incalculable patient harm.

Investigation is not supposed to apportion blame[4]. However, there tends to be a focus on the acts or omissions of individuals rather than the context in which errors have occurred. The high-reliability industries have led the way in safety improvement and optimisation. They came to understand over decades that the culture of blame can be both individually unfair and counterproductive in improving outcomes when dealing with highly motivated groups. Professional organisations should call this out and support members when they are under individual scrutiny in this way.

The hierarchy of intervention effectiveness (Figure 1) was first described within high-reliability industries and is now increasingly used in healthcare and patient safety[5]. Traditionally, at the top of the hierarchy is "elimination and substitution"; that is, can you achieve the goals by not doing the risky task at all or by doing something else – for example, one could eliminate air crashes by grounding all planes.

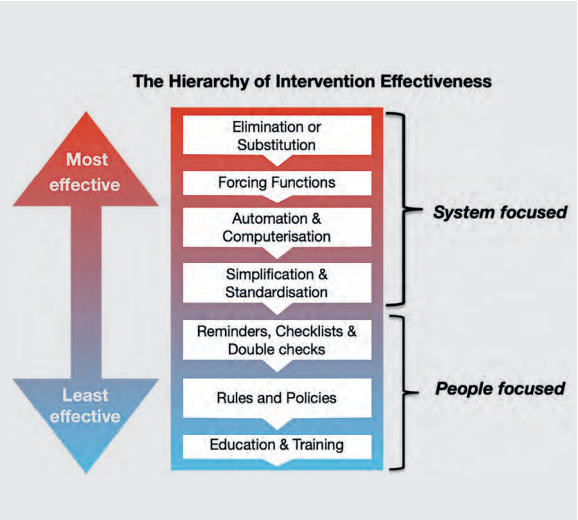


Figure 1: The hierarchy of intervention effectiveness, a risk-management theory describing the effectiveness of interventions used in the workplace. Image created and adapted from data published by Cafazzo and St-Cyr, 2012

In many situations, this may be impractical or impossible. So for a specific task, although the lower elements of the hierarchy, such as education and training, are laudable and absolutely necessary, designing risks out of the system is the most effective control.

In daily life, we see design solutions that prevent error. A classic example is the microwave oven – its combined off-switch/door latch ensures a level of safety where education and diligence would be ultimately ineffective. However, at UK petrol pumps, despite it being impossible to put a diesel nozzle into a petrol tank – and this error being extremely rare – the error of putting petrol into a diesel tank occurs every three minutes[6] because, to avoid this, we rely on colour-coding, haptics, education, warning signs, individual diligence and punishment – it is very costly to make this error!

> **"If failure occurs, the clinician at the head of the team can be held personally responsible"**

A type of design solution that is helpful but less 'hard' is described as a nudge – for example, the embossed picture of a fly placed centrally on the porcelain of a urinal, designed to reduce spillage in public toilets[7].

There are many examples in medicine. Specifically, in the operating theatre, the medical gases that we use have Schrader connectors that are unique for each gas at the wall and have non-interchangeable screw threads at the other end, making misconnection all but impossible. One can only imagine the deaths that would have occurred if we were relying on diligence and checking alone. Although more than 99% effective, error can still occur with any design, as shown in multiple extraordinary events, such as the Westminster Hospital tragedy when the gas pipes were connected to the wrong outlets during servicing[8].

Our group[9] specialises in the conceptualisation, development, implementation and evaluation of design solutions for errors that occur in the operating theatre. The concept is perhaps the easiest part, but the realisation of an approved marketable product and the implementation across healthcare systems is the challenge.

This article shows some examples of these solutions, which have been fully developed and marketed in the UK or have reached late-stage development.

Solutions for the operating theatre

FULLY DEVELOPED AND MARKETED IN THE UK

1. Non-injectable arterial connector (NIC)
Wrong-route drug administration into an arterial line causes limb ischemia hours after the insult and so causation is not always overt. The NIC is a hub with a one-way valve that prevents this and also protects the transducer set from bacterial contamination[10]. It now protects patients in around a third of NHS hospitals and has won the AAGBI innovation award as well as the National Patient Safety Award.

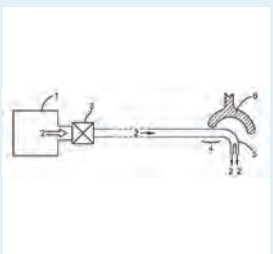
2. WireSafe
Retained central venous catheter guidewires are the most common 'never events' in emergency medicine. The WireSafe makes this impossible by rendering the equipment required to complete the procedure inaccessible until the wire is removed[11]. Crucially, the WireSafe also improves the speed and safety of procedures for the clinician and has been well received by the hospitals that have implemented it[12]. It received the President's Award for outstanding achievement from the Royal College of Anaesthetists and was highly commended at the National Patient Safety Award.

3. High-flow nasal safety cannulae
Transnasal humidified respiratory insufflation and ventilatory exchange (THRIVE) is now commonly used for preoxygenation at induction of anaesthesia or during procedural sedation. A common error – placing a facemask over the nasal interface in an emergency – can lead to rapid stomach insufflation due to the high flow rates of oxygen used (>60 l/min). By using a collapsible nasal interface at the malar region and proximal relief valve, we found that we could divert and vent the high-flow oxygen when the facemask compressed the tubing that supplies nasal prongs[13]. An example of this technology is now marketed by Fisher & Paykel under the brand name Optiflow Switch.

4. SAFIRA
Injecting local anaesthetic into nerves at high pressure causes temporary or permanent injury and is a leading cause of claims in the UK[14]. It is impossible to accurately determine injection pressure by feel alone. The Safe Injection of Regional Anaesthesia (SAFIRA) system is a single operator, automated injection system that limits the pressure to safe levels[15]. It protects the patient from injury and the clinician from litigation. SAFIRA, which is now marketed worldwide, has been highly successful and received the National Patient safety award in 2021.

1. NIC: Protects an arterial line from mis-injection error and bacterial contamination. Amdel Medical (www.amdelmedical.com)

2. WireSafe: prevents guidewire retention. Venner Medical International. (www.vennermedical.com/venner-wiresafe)



3. A prototype high-flow nasal oxygen safety device to divert oxygen from the patient when a face mask is applied (from patent WO2016203211A1, with permission)

4. SAFIRA: Protects against nerve injury during regional local anaesthesia infiltration. Medovate (www.medovate.co.uk)

AT LATE-STAGE DEVELOPMENT

Arterial Glucosave
The Health Service Investigation Branch (HSIB) is currently investigating the problem of patient harm and death from neuroglycopenia-based brain injury following the wrong flush solution being used with arterial transducer sets and a resultant sampling error[16]. The Arterial Glucosave is in development and utilises the glucose oxidase colour-change technology used in glucose test strips for diabetics. This gives a dramatic warning to clinicians at point of care before the error causes harm[17].

Humidicare
There are different types of filters in breathing circuits that must be placed at specific locations depending on type and whether active humidification is used or not[18]. This complexity causes confusion and they are commonly misplaced by staff. This has caused a recent spate of avoidable deaths in the UK[19]. The Humidicare is a breathing circuit filter under development[20] with a heat-dependent colour-change technology embedded in the plastic to alert staff if an error of placement has occurred before patient harm has ensued.

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