A review of the top 10 health technology hazards and how to minimise their risks

Exploring key risks associated with the use of medical devices, injuries that can result from their use and how to prevent harm to patients

INTRODUCTION

The Emergency Care Research Institute (now called the ECRI Institute) is an international non-profit organisation dedicated to improving patient safety and care by using applied scientific research to discover which medical procedures, devices, drugs and processes are most effective. It is designated as both a collaborating centre of the World Health Organization and an evidence-based practice centre by the US Agency for Healthcare Research and Quality.

This article reviews the top 10 hazards related to medical devices. The list was compiled by the ECRI Institute (2008) and is based on the experience of its expert technicians, who investigate and consult on device-related incidents, as well as on the institute’s own and other medical device problem-reporting databases.

The hazards are presented in order of importance, based on the collective judgement of ECRI Institute staff.

1. ALARM HAZARDS

Clinical alarms can be vital in preventing patient injury or death. However, if alarm conditions are not effectively communicated, patients are put at risk.

Alarm issues are among the most frequently reported healthcare technology problems. Alarms are used with a wide variety of equipment including patient monitoring equipment, ventilators and dialysis units.

To reduce the frequency of alarm-related adverse incidents, the ECRI Institute makes a number of recommendations:

- Ensure devices handle alarms in a way that is logical, safe and consistent with their facility’s practice, and that they limit false or excessive alarms, which can desensitise staff;
- Ensure that alarm conditions are quickly and consistently conveyed and factors such as speaker volume, floor layout and physical distance do not prevent them from being heard. Ensure that visual alarm indicators can be seen.
- Ensure that staff understand the purpose and significance of alarms and know how to set alarm limits to appropriate, physiologically meaningful values. Low-saturation alarms on pulse oximetry monitors and low minute-volume or high peak-pressure alarms on ventilators are regular subjects of this sort of error.

2. NEEDLESTICKS AND OTHER SHARPS INJURIES

Accidental needlesticks and other sharps-related injuries continue to occur, despite the common use of IV administration sets and other devices that include mechanisms to protect against them. To prevent these injuries, ensure that:

- Staff are trained in operating all protective devices and follow disposal procedures correctly;
- Devices are effective and can be operated easily. If injuries are still happening even with proper training, the problem may be the device rather than those using it – some protective devices offer better protection than others.

3. AIR EMBOLISM FROM CONTRAST MEDIA INJECTORS

Angiography – the X-ray imaging of blood vessels – involves injecting contrast media into a patient’s vasculature.

Power contrast media injectors have begun to replace handheld syringes to improve the control and precision of injection, but the procedure still creates the risk of injecting air, potentially resulting in a fatal embolism.

Most power injectors are equipped with safety features to reduce the risk of air embolism, including systems that detect air in the injection line or the presence of a used media syringe (which contains only air).

However, none of these features is foolproof. There are still reports of air embolism associated with contrast media injectors. For example, in the US, a review of reports submitted to the Food and Drug Administration over the past 10 years revealed 32 such cases – three of them fatal.

To reduce the risk of embolism, facilities using contrast media injectors should:

- Ensure that current safety features are installed and enabled on injectors;
- Alert users to the fact that, while safety features are built in, vigilance is still the best protection;
- Establish standard protocols that define who is responsible for specific tasks – such as tubing checks – so no one mistakenly assumes someone else will perform them;
- Ensure that those preparing injectors are trained on the specific models being used and only disposable items that are labelled as being compatible with those models are used;
- Have a second clinician verify that injection tubing is tight and leak free following air purging, and that there is no contrast medium on the outside of the tubing, since this can interfere with air-detection systems;
- Ensure clinicians inspect tubing and injectors for air bubbles before injection.
**Practice review**

4. RETAINED DEVICES AND UNRETRIEVED FRAGMENTS

Safety agencies frequently receive reports of foreign bodies left inside patients. Typically, these are associated with two adverse events:
- Retained devices, in which an entire device is left behind: this is usually associated with surgery, where objects such as sponges and clamps may become hidden by tissue;
- Unretrieved fragments, where part of a device – such as a catheter tip or forceps jaw – breaks away and remains inside the patient: in some cases, the fragment is left because clinicians fail to notice it, but sometimes the decision is made to leave it because its location makes retrieval too risky.

Accidental retention may lead to serious infection or damage to the surrounding tissue. If a patient subsequently undergoes an MRI scan, retained metal can heat or migrate, resulting in burns or worse.

To reduce the risk of object retention:
- Visually inspect devices just before use and, if a device appears damaged, immediately remove it from service;
- Be alert for resistance during device removal, which could indicate the device is trapped and at risk of breakage. Consider the options – such as repositioning the patient – before continuing;
- Visually inspect devices as soon as they are removed from the patient;
- Adhere to accepted surgical count procedures;
- Use appropriate technology – systems to locate retained surgical sponges before completing a procedure are available, and similar technologies for other devices and fragments may eventually be introduced.

5. SURGICAL FIRES

Surgical fires do not happen often, but patients can be seriously injured or killed when they do. Most can be avoided if surgical staff are trained to recognise and control the elements that combine to cause fires:
- **Ignition source**: ensure devices that could serve as ignition sources – most commonly electrosurgical units, electrocautery devices and lasers – are in good condition and being used properly, and that disposable components, which can stay hot for some time after use, are discarded safely;
- **Oxygen**: fires are more likely in the presence of supplemental oxygen. To reduce oxygen enrichment:
  - arrange surgical drapes to prevent the pooling of oxygen;
  - keep the amount of oxygen used to the minimum necessary;
  - begin limiting the administration of oxygen at least 30 seconds before using an ignition source.
- **Fuel**: potential fuel sources such as fenestration towels and gowns must be kept as far as possible from the ignition source. If an item cannot be moved, find another way to limit risk posed by it. For example, allow alcohol-based preparations to evaporate fully before electrosurgery is started, and moisten sponges to reduce their flammability.

In addition, surgical booms housing electrical cables and oxygen hoses should be inspected regularly.

6. ANAESTHESIA HAZARDS DUE TO INADEQUATE INSPECTION

Each year, there are reports of staff discovering serious problems with anaesthesia equipment just before it was to be used, including disconnected breathing circuits, ventilator leaks and empty gas cylinders. More rarely, problems going unnoticed until the patient was seriously – or sometimes fatally – injured have been reported.

To help ensure anaesthesia systems and their accessories are safe for patient use, make sure:
- Anaesthesia systems are inspected using only the procedure designed by the manufacturer for that model;
- Inspections involve not only the anaesthesia unit but also other devices and accessories that may not be specified in the procedure for the unit, such as scavenging equipment and manual resuscitators;
- Documentation is easily accessible – if a checklist is required, ensure it is physically attached to the anaesthesia unit;
- People responsible for performing the inspection are familiar with the procedure and understand its importance.

7. MISLEADING DISPLAYS

Displays are built into many medical devices to convey a wide range of sometimes critical data. However, some displays are ambiguous or counterintuitive. This introduces a particularly insidious problem, since treatment decisions will be based on this information – these decisions could be reasonable and yet wrong.

To reduce this risk:
- Device displays should be assessed during pre-purchase trials, and an eye kept open for those that pose a real risk of confusion;
- Manufacturers should be alerted if problems are detected after the device has been put in to use;
- Users must understand how to interpret the misleading display if the manufacturer cannot provide an immediate solution and the device cannot be removed from service.

8. CT RADIATION DOSES

Computed tomography (CT) is fast and reliable but its comparatively high X-ray dose has only just begun to attract attention.

In the US, it has been estimated that CT radiation could be responsible for about 6,000 additional cancers a year, roughly half of them fatal (ECRI Institute, 2008).

To ensure patients are not unnecessarily exposed to high dose levels:
- The expected benefits of a CT need to outweigh the radiation risks and CT referral guidelines should be regularly reviewed, particularly where children are concerned;
- Scanning protocols should be optimised to minimise doses;
- Those performing CT exams should be specifically trained and maintain their training;
- Monitoring CT use and dose should be part of quality control and equipment maintenance;
- Referring clinicians should have easy access to information regarding the dose and the cancer risk associated with CT.

9. MRI BURNS

When people hear about accidents involving magnetic resonance imaging (MRI), they usually think of the projectile hazards: oxygen
cylinders, medical devices and – in one well-publicised incident from the US – even a handgun flying into the bore of a magnet.

Burns are a much more common hazard. To prevent them:

- Ensure conductive cables are not looped and that cables do not cross each other;
- Place sensors – such as those for pulse oximetry – as far as possible from the radio-frequency (RF) coils;
- Use manufacturer-supplied padding, rather than blankets or sheets, to prevent patients from contacting the magnet bore;
- Regularly check all sensors, cables and MR accessories such as RF coils and cables for any breaks in insulation;
- Regularly inspect items provided for patient comfort, such as headphones and video goggles, for signs of damage.

Even when steps such as these are taken, heating can occur during an MR scan, so MR technicians must ask patients to signal if they feel undue heat during the scan.

10. BURNS FROM FIBRE-OPTIC LIGHTS

Fibre-optic light sources – used in devices such as endoscopes, retractors and headlamps – are often referred to as ‘cold’ light sources. This can be misleading.

There are two main sources of burns from fibre-optic lights:

- **The light itself:** usually caused when a clinician places the endoscope or the distal end of the fibre-optic cable on the patient without shutting off the light source;
- **Heated cable connections:** typically caused when the diameter of the light cable is too large for the light post on the connected device. The light then contacts the metal portion of the light post, rather than the fibres within, heating the connection. If the connection contacts skin, a burn may result.

To reduce the risk of burns:

- Never place the endoscope or the end of the light cable on a patient or on flammable objects;
- Turn off the light source or place it in standby before removing the cable from the light source or the instrument from the cable;
- Use only the minimum output needed to perform the procedure;
- Only use light sources that incorporate safety features, such as those that power up in standby mode or at very low output settings.

CONCLUSION

Patient safety is the responsibility of all healthcare professionals, and all need to be alert to the risks posed by medical devices. By establishing clear protocols and guidelines and ensuring they are followed, healthcare providers can drastically reduce the risk of patients being harmed during healthcare interventions.

REFERENCE