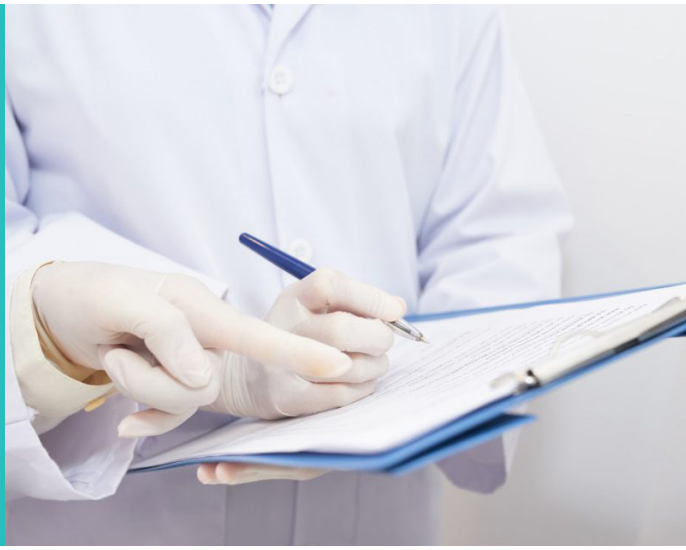
The importance of traceability in the high-level disinfection (HLD) of ultrasound probes

Critical Summary

- Traceability is the process of linking reprocessing cycle information and medical device identifiers to a patient record.
- Guidelines in the UK and Ireland require medical devices classified as semi-critical and critical to have full traceability to the patient.
- In the event of an outbreak or infection prevention breach, a reliable traceability system becomes instrumental for a facility in investigating, identifying and notifying affected patients.
- Digitisation of traceability records can help reduce manual administrative burden, the risk of operator error and incomplete record keeping.



Guidelines in the United Kingdom and Ireland require facilities to collect reprocessing cycle information and medical device identifiers and then link this to the patient record.[1-3] This is referred to as tracking, or traceability.

Examples of traceability in healthcare

Traceability applies to all medical devices and broadly refers to the ability to trace the movement, use and condition of a device during its life cycle.

For medical device manufacturers, the EU Medical Devices Regulation (MDR) requires total lifecycle traceability between all stages of medical device development and post-market activities.[4]

Surgical devices used in healthcare facilities are also required to have traceability, with current guidance for hospitals to track instruments to at least tray level.[5] A record of the decontamination equipment and cycle used is required as part of this traceability. NHS guidelines also require that healthcare organisations operate a tracking and traceability system to track endoscopes through the decontamination process.[6]

Traceability in ultrasound probe reprocessing

Ultrasound presents unique challenges as its versatility and portability have resulted in its expanded use across healthcare.[7] Traceability is minimally required for ultrasound probes that undergo high level disinfection or sterilisation, which depends on the probe Spaulding classification.

Semi-critical ultrasound probes contact non-intact skin or mucous membranes and require a minimum of HLD (e.g. transvaginal and transrectal ultrasound, scanning across non-intact skin).[1-3] Critical probes enter or contact sterile tissue, and require sterilisation (e.g. surgical probes).[1-3] If critical probes cannot be sterilised, they can undergo HLD and require use with a sterile sheath.[1]

For semi-critical and critical probes, the patient record must be linked with a record of previous sterilisation or HLD of the device.[1-3]

Why is traceability required?

Traceability is essential to identify the remedial action undertaken following failure of any part of the decontamination process.[2]

For example, in an outbreak investigation traceability is used to determine the extent of patient notifications and device recalls. In an outbreak of *Serratia marcescens* attributed to an ultrasound probe used in a digestive surgery ward, 8 out of 9 patients who came into contact with the contaminated probe were infected.[8] Traceability records were instrumental in identifying previously missed cases. A recurrent outbreak of postoperative infections in cardiac patients was sourced to trans-oesophageal echocardiogram (TOE) probes.[9] These probes are semi-critical devices that require HLD, and human errors in manual reprocessing were identified as contributing to the outbreak. A full traceability system was promptly implemented at this institute following the outbreaks, to prevent similar events in the future.[9]

In non-outbreak settings, traceability allows facilities to demonstrate that they have met their duty of care to patients.

Implementing traceability for high-level disinfection

Traceability involves linking both a reprocessing record and a procedure record to the medical device. The minimum dataset for a procedure record includes patient name or identifier, medical record number, procedure type, and operator for the procedure.[1] For reprocessing, the minimum dataset required by guidelines is transducer and serial number, cleaning product serial number, date and time, and staff member undertaking cleaning.[1]

In addition to these parameters, users should collect information that demonstrates the cycle critical parameters were met. This will depend on the HLD process used. According to UK Health Technical Memorandums for the decontamination of flexible endoscopes, the following additional reprocessing data should be recorded and linked to the patient the device is used upon:[6]

- Person responsible for release of the product and assurance that the device is fit for purpose
- Visual inspection (separate operator preferred)
- Reprocessing machine and cycle number
- Reprocessing cycle result (pass/fail)
- Evidence that the probe is operating satisfactorily (there is a duty of care on the clinical operator to ensure this is the case)

A similar dataset for ultrasound reprocessing is recommended to meet traceability requirements. Figure 1 lists a suggested level of data to be capture for every semi-critical and critical probe use.

Figure 1. A traceability system links the information from the reprocessing cycle to the patient. The above information is a suggested dataset to be collected and linked to the patient for every HLD cycle.

Benefits of digitisation to traceability in ultrasound

Traceability can be completed manually (e.g. logbooks) or by incorporating digitisation (e.g. RFID scanning and electronic records). Digitisation ensure standardised information across the entire workflow and can reduce manual administrative burden, the risk of operator error, and incomplete record keeping.

Records should be retained for a period of time specified by local regulations and guidelines. For example, Health Service Executive Ireland guidelines require the maintenance of validation records and traceability records for the lifetime of the equipment plus 11 years.[2] If not specified, record retention should be determined in conjunction with the facility's risk management and infection prevention and control committees.

Conclusion

In healthcare, a robust traceability system can be used as a tool for investigating and identifying affected patients in the event of an outbreak or infection prevention breach. Implementing digitisation into traceability workflows can ensure record security, accuracy and efficiency across the ultrasound infection prevention workflow.

Contact us today for your specific educational needs on traceability or understanding when to HLD at your facility.

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