Article by AfPP President, Mona Guckian Fisher

The long journey of the surgical instrument

Mona Guckian Fisher, President of the Association for Perioperative Practice, looks at the before, during and after of surgical equipment safety.

'Primum non nocere' is a latin phrase that means 'first, do no harm' and is a mantra that is often heard within healthcare settings.It reminds the health care staff that they must consider the possible harm that any intervention might cause to patients in their care. There is nowhere that this is more appropriately stated than within the environs of perioperative practice.

Perioperative practice covers the period before, during and after a patient has undergone a surgical procedure in the operating theatre. It is well documented that the operating theatre is an area that is fraught with risk, and there is therefore a legal, moral, ethical and professional duty on organisations and individual healthcare workers to minimise risk for each single aspect of the care that is delivered.

It is unimaginable to most people who work outside of the operating theatre to visualise the amount of equipment necessary to care for one patient at a time within this specific environment. This is aside from the vast quantities of individual instruments which are the tools of surgical trade and without which the actual procedure could not be undertaken.

Instruments of integrity

The importance of providing surgical instruments and equipment which are unimpaired, of a standard quality, appropriateness and integrity to enable the surgeon to perform his role cannot be overestimated on any level. There are other additional factors directly at the point of use which need consideration such as availability, integrity, cleanliness, functionality, appropriateness, sterility and decontamination status.
The science of decontamination is a world apart from most people working within the operating theatre, who have an expectation that instruments will arrive in time for procedures and will be prepared and sterilised to the required standard.

Surgical instruments have a medical purpose and are considered as medical devices defined within the terms of the Medical Devices Directive (MDD) 93/42/EEC (MHRA 2014). As far back as 1999 the Department of Health launched the National Decontamination Programme to support the NHS in England in improving and maintaining standards relating to the reprocessing of medical devices. The aim of the programme was to review working practices, to assess the condition of facilities and equipment and to agree local action plans to improve standards where necessary.

A snapshot survey in England (NHS Estates 2000) investigated the application of decontamination standards and found instances where decontamination processes fell short of current standards, and in some cases practice was poor. It identified that substantial improvement could be achieved by ensuring effective management of decontamination services and improving staff training and development. At the time, many of the buildings and much of the equipment used in sterile services departments (SSDs) needed refurbishment or replacement. Analysis of the findings of this initial survey highlighted the need for a comprehensive review of decontamination services across the whole of the NHS. As an outcome of this work a considerable amount of surgical equipment was replaced, and many units upgraded or newly built to provide the service and the required quality standard.

As a nurse who can clearly recall this initiative, the changes that have been introduced and embedded in practice throughout the NHS and independent sector hospitals are today extraordinary by comparison, and certainly more in keeping with 21st century healthcare provision. In 2006 the National Institute for Health and Care Excellence (NICE) published the guidance 196: Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob Disease (CJD) via interventional procedures (NICE 2006). Whilst the guidance relates to high risk surgical procedures (intradural operations on the brain and operations on the retina or optic nerve) many of the principles in the guidance are recognised as best practice and multi-professional groups continue to explore how issues such as migration of instruments, instrument tracking systems, and the quality of single use instruments can be adopted in everyday decontamination practice.

In February 2007 the chief medical officer (CMO) reiterated that NHS trusts were required to implement the NICE guidance to minimise the risk of vCJD transmission from medical devices during certain procedures (DH 2007). Concerns that vCJD could be transmitted during surgical procedures led to the publication of updated guidance (DH 2015a, b, NICE 2006). The guidance recommended changes in practice which could be achieved and delivered within a short time frame.

Safe standards

As perioperative nurses and practitioners we rely on the decontamination experts to provide a consistent safe standard in the provision and availability of surgical instruments which are in all aspects and at all times fit for purpose. Decontamination involves a considerable number of processes and there are several methods which can be used to achieve the required outcome. The process is determined by factors such as the instrument itself, its integrity and most suitable procedure to provide sterility working in consensus with the experts and the manufacturers' guidance. This is a process which all reusable medical devices must undergo before they can be used safely on a patient.

The various cycles that form part of this process are defined and validated according to the standards that are set by the industry. The basic principle of decontamination is to remove microorganisms that might harm a patient if introduced into their body. The process for decontamination can be broken down into many elements all of which are important as part of the overall process.

Cleaning is obviously the first stage of this process and whilst we each have an understanding of what 'clean' means to us as individuals; as part of the decontamination process cleaning of surgical instruments requires to be undertaken by mechanical, thermal or chemical means and there are strict principles to adhere to in relation to each task within the process. The cleaning process itself is monitored during routine production to ensure that each established part can be validated and that the intended outcome has been achieved.

It is imperative that the highest standard of care must be taken to ensure that all medical devices and equipment used within the perioperative environment and during surgical procedures are not a source of microbial contamination thereby presenting high risk for the patient. It is accepted that instruments which are used in invasive procedures present significant risks for healthcare associated infection. The Healthy Technical Memorandum HTM 01-01 issued by the Department of Health in 2013 provides guidance about the management and decontamination of reusable surgical instruments and medical devices used in acute care. The Choice Framework for local Policies and Procedures (CFPP) CFPP guidelines (DH 013b) stipulate that in commissioning decontamination services for medical devices used in acute care, organisations should aim to ensure that staff are trained throughout the reusable surgical instrument cycle.

Training should be of a standard recognised by the Institute of Decontamination Sciences (IDSc) recommended by the MHRA (2014) and quality controlled by external organisations such as the Care Quality Commission (CQC 2014). The CQC monitors organisations to ensure that they have met the requirements stipulated for the NHS on the prevention of healthcare associated infections (DH2009a). The CQC assesses healthcare organisations on their compliance with the requirements of section 20(5) of the Health and Social Care Act 2008 (DH 2009a)(AfPP 2016).

In order to meet the requirements of the directive organisations need to implement a quality management system. This quality system must focus on measuring all aspects of the decontamination work from staff, processes, products and equipment. The code of practice provides details for healthcare organisations on how they can meet the requirements and sets nine compliance criteria (DH 2009a).

Some of the criteria states that a provider must designate a lead manager for decontamination of equipment used in treatment. This individual has responsibility for ensuring that a decontamination programme demonstrates that appropriate and dedicated facilities are provided for the decontamination of reusable medical devices, that staff are trained and can show evidence of competencies within their role, that the systems and processes are fit for purpose and there is a system of audit in place to support that the required standard is met. (DH 2009a) (AfPP 2016).

An interventional environment

There are several individuals involved in the process of providing surgical instruments to the surgeon or interventional professional and numerous checks to undertake prior to handing these instruments to be used on a patient. This is in addition to all the checks and processes already referred to as part of the actual decontamination process. The national perioperative standards (AfPP 2016) are in place to protect patients, staff and others who may be at risk of acquiring a healthcare associated infection (HCAI), and states that healthcare organisations should ensure that there are effective arrangements in place for the appropriate decontamination of reusable invasive medical devices and other equipment. These should be incorporated within appropriate disinfection and decontamination policies (The Health and Social Care Act 2008 criterion 2 DH 2010).

Theatre staff inspect instrument sets on receipt to ensure that packaging is undamaged and sterility is not compromised. The 'scrub' practitioner who assists the surgeon by providing the instruments directly during the surgical procedure, will check immediately prior to the surgery to ensure that all instruments are sterile and available to use. Only then can the operation be performed. The theatre team take responsibility for tracking the instrument tray details to the patient postoperatively. Theatre staff return sets of instruments to SSD for reprocessing using a method set out and agreed in local policy, ensuring that they are appropriately containerised or packaged and addressed for collection by supplier at the agreed time.

All instruments must be handled with care throughout their entire use since any scratches and roughened surfaces will harbour dirt and bacteria. Healthcare professionals who hold responsibilities for decontamination are required to meet the requirements of the core standards (DH 2009a) and personnel working in the perioperative setting understand their legal and ethical requirement with regards to their duty of care, and the principles of professional accountability with respect to their employer and appropriate regulatory body. This responsibility also extends to the purchasing, deployment, maintenance, repair and disposal of medical devices (MHRA 2006), and providing a safe system for instrument storage and transportation.

Effective decontamination

Perioperative practitioners working within the operating theatre department have a responsibility to ensure that patients are protected from the risk of cross infection from reusable medical devices. Decontamination of instruments and equipment is of vital process in ensuring this. It is imperative that any decontamination practices which are undertaken within the operating theatre department are carried out by appropriately trained personnel, and that a consistent and reliable service is provided from the central sterilising supply unit to enable the operating theatre efficiency and patient satisfaction.

Effective decontamination of reusable medical devices is critical in the management of healthcare acquired infections (HCAI) and patient safety. Local practice is led by a local risk assessment group to ensure that current evidence and best practice determines local processes. There are policies detailing the processing of reusable instrumentation, including decontamination, tracking and traceability, maintenance and repair that conform to national guidance. Reusable medical devices are decontaminated to national standards and provide a consistent and reliable service to users. Where instruments are on loan from medical device companies or elsewhere there must be a policy which details that they are appropriately sourced, decontaminated and used safely with support, education and guidance from appropriate persons.

The hospitals infection prevention and control (DIPC) specialist is responsible for the infection control aspects of decontamination, and is responsible for the departmental risk assessments and provision of support to the theatre team. Part of this process establishes the instrument management of identified high risk patients; and where reusable invasive medical devices have been used in high-risk procedures.

The ability to be able to track patients to instruments used is a critical part of the process of protecting individual patients and providing assurance to the public that the long journey from manufacture to the operating table is a well-considered, methodical safe and regulated process; and one that is under scrutiny at all times.

Article taken from Health Business Magazine August 2016
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