Safety Standards for Invasive Procedures

Invasive procedures in medicine have increased in numbers and complexity with the advent of the new technologies and treatment modalities. The entire context of clinical care has changed and many of the invasive techniques being currently administered were not available a few decades ago. These wide ranging interventions have contributed substantially to patient well-being and good clinical outcomes. Previously, invasive procedures were mostly the domain of surgery and anaesthesia, but they now used by many other specialist groups including adult, paediatric and neonatal intensive care, intervention radiology, endoscopists, and cardiologists. It is accepted that all healthcare procedures should conform to a common set of safety guidelines. NHS England has recently published a useful document on the safe execution of invasive procedures. The importance of teamwork is stressed throughout the document. Poor communication and lack of leadership are common factors in the causation of procedural mishaps. The science of patient safety was slow in getting established but is now making a serious attempt to catch up. The Institute of Medicine’s Report in 1999 ‘To Err is Human’ was the catalyst that initiated patient safety programmes. Human factors science, which studies the relationships between humans and systems is central to many of the measures that have been introduced. Many institutions now produce metrics at frequent intervals to note safety issues and document improvements. Pareto charts have proved useful in the drive for quality improvement. The Pareto principle, 20-80 rule, states that for many activities 80% of the effects come from 20% of the causes. When applied to medicine, it indicates that 20% of the hazards will account for 80% of the complications. It has also been called ‘the vital few and trivial many’. The Pareto chart consists of a graph where individual values are represented in descending order by bars and the cumulative total is represented by a line. When interpreting the graph, one can readily identify the most frequent error(s).

The term ‘invasive procedure’ is described in some detail in the NHS report. There are a number of categories. It may involve making a cut or operation to gain access to the inside of the patient’s body. It may refer to the use of endoscopes to obtain access to the gastro-intestinal tract, lungs, or bladder. It may refer to the use of electromagnetic radiation such as laser eye therapy.

It is pointed out that in the last few years there has been increasing emphasis on the safer care of patients. The focus has shifted from understanding procedure adverse events to the introduction of measures that will prevent their occurrence.

The checklist approach should be extended beyond surgery, and it should be applied to all invasive
procedures, irrespective of the specialty involved. The three key headings are, standardize, harmonise, and educate. For every procedure there should be a set of agreed steps, the approach should be the same irrespective of the location, and time and resources should be made available to train staff how to perform it.

The rationale behind ‘Never Events’ is introduced and explained. The term implies that the complication is largely preventable. It was coined in 2001 by Ken Kizer, CEO of the National Quality Forum, to describe medical errors that should never occur such as wrong site surgery. Other examples include electric shock to a patient, the retention of objects following surgery, or injury to a patient following the introduction of a metallic object into the MRI area.

It is a new term for healthcare workers to grasp and comprehend. ‘Never Events’ represent serious harm to the patient and have a number of common features. They are wholly preventable when robust protective barriers are in place and are implemented. They are easily recognized and clearly defined. There is evidence that the event has occurred previously. The role of clinical human risk factors needs to be addressed. Most incidents involve a combination of technical and non-technical issues. The technical components are a poorly constructed workspace, deficiencies in work design, poor understanding of the technical complexity of the task, and inadequate policies and procedures. The non-technical components are lack of situation awareness, poor decision making, poor teamwork, lack of leadership, and an inability to deal with work pressures and stress.

Specific clinical situations can predispose to the occurrence of a ‘Never Event’. A long operation with a large blood loss can lead to the retention of a foreign object. Hurrying, distraction, and confirmation bias, and failure to take account of the patient’s positioning are antecedents to wrong side procedures.

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