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## Safe surgery: time for a paradigm shift

Surgery, by its very nature of invasiveness, carries a risk of unintended harm unless the overall plan is executed with due care. The management strategy includes correct diagnosis and a considered balance between the decision to proceed with surgery and the potential harm associated with non-performance. This clinical skill has a significant impact on the outcome. Equally important are the procedural skills which include technical dexterity and decision making at every stage of an operation. A surgical procedure is a set of sequential steps that is initially reversible; at this stage the surgeon is in a position to abandon the operation if the operative findings indicate that the originally intended procedure is not in the best interests of the patient. When operating on a physiologically compromised patient with major trauma or sepsis, the surgeon should follow the principles of damage control surgery which means performing the minimum procedure to save life and then withdrawing without compromising patient safety. The mindset of the surgeon tuned towards the safety of the patient is essential for a good outcome.

In the pre anaesthetic pre-antiseptic era, a successful outcome of an operation, then considered rare, depended almost wholly on the surgeon's speed and hand skills. Patients consented for surgery as the last resort, in the face of impending death. They were not 'prepared' for surgery and many died of shock due to extreme pain or bleeding. The discovery of anaesthesia and antiseptics in the nineteenth century had a major impact on outcome and uplifted the status of the surgeon. During this era of the 'autonomous clinician' undesirable outcomes were just considered to be surgical misadventures. As a result of easy access to information, modern society has developed high expectations of surgical outcomes. Undesirable outcomes arising from surgical errors due to ignorance, inaptitude and risk taking are no longer acceptable; quality of care and accountability have become key issues, and patient safety is increasingly recognized as a matter of global importance.

### Magnitude of the problem

The global volume of surgery is estimated to be 187-281 million procedures annually [1]. Complication rates vary in different settings from 3-22%. Half of these complications are considered to be preventable. The death rate varies from 0.4-0.8% in developed countries to 5-10% in the developing countries. It is estimated that over one million patients die annually as direct consequences of surgery [2]. In 1999, a report by the Institute of Medicine in the United States of America (USA), based on two major studies, revealed that as many as 98,000 people die in hospitals each year in the USA as a result of medical errors that could have been prevented. Preventable medical errors in hospitals exceeded deaths due to road traffic accidents, breast cancer, and AIDS [3].

According to an estimate in 2013, 440,000 preventable hospital deaths occur each year in the USA, 4.5 times higher than the 1999 estimate. This makes medical errors the third-leading cause of death in the USA, after heart disease and cancer [4]. There is paucity of such data from developing countries, especially South East Asia. Health Care Associated Infection (HCAI) is 2-20 times higher in developing countries, but data are mostly anecdotal [5].

### **Surgical risks and errors**

There are 4 major risks from any surgical procedure: bleeding, infection, anaesthetic risk and unexpected events, such as, bowel perforation, finding an unexpected pathology or retaining surgical instruments. Two other factors that increase surgical risk and occurrence of errors are poor communication and team work. Although studies have shown the importance of cognitive skills and social behaviour, including risk taking behaviour, of the members of the surgical team, this is regarded as a desirable, rather than an important skill that needs to be acquired and applied cautiously [6,7]. Surgical errors may occur due to many factors. These are the complexity of the task, involvement of many individuals in the process, poor interpersonal relationships, risk taking behaviour, undue speed, urge to learn complex surgical techniques, problems regarding delegating responsibility, difficulty in remembering to carry out all activities relying on memory alone, rigid adherence to guidelines, stress and work fatigue. There is evidence that the degree of cognitive function is compromised by stress and fatigue [8]. However among all these factors, two stand out; the complexity of the procedure and difficulty in remembering to carry out all activities when relying on memory alone. Therefore, it is logical to assume that a surgical safety check-list will help to minimise surgical errors.

### **Surgical safety check-lists**

Previous studies have shown the beneficial effects of guidelines in operation room settings. In 2001, the Johns Hopkins Hospital, USA, introduced a simple five item check list to reduce morbidity associated with placement of central lines, which included washing hands prior to the procedure, skin cleaning with antiseptic, using sterile drapes, wearing gloves, masks and sterile gowns during the procedure and placing a sterile dressing over the site after completion. These measures reduced the infection rate from 11% to zero [9]. In 1998, responding to the global problem of safe patient care the WHO appointed a team of experts led by Atul Gawande of Harvard University to study the issue of surgical safety. The team identified three major areas which needed urgent attention: establishing safety of anaesthesia, establishing safe surgical teams (to minimise excessive bleeding and unexpected events) and prevention of surgical site

infection (SSI) (to minimise post surgical sepsis). A 19 item checklist was designed. The design was of the 'do confirm type' and not the 'read type'. The check list is in three parts and has to be completed in three steps, before the patient is anaesthetised, before the skin incision is made and before patient leaves the operating room after completion of the procedure following recovery from anaesthesia [10]. A pilot study on the use of the check list was performed in eight hospitals, four from high income and four from mid and low income countries. Six outcome measures were used by direct observation. These were airway evaluation, pulse oximeter, venous access, prophylactic antibiotics, patient identity and site marking and sponge count. Significant improvement was noted in all measures except obtaining venous access in patients with anticipated high blood loss. Five parameters were used to assess improvement in outcomes when using the checklist. There was a significant difference in surgical site infection and complication rate. The other three parameters (incidence of pneumonia, unplanned return to operating theatre and mortality) also showed a non-significant trend towards improvement [11]. In June 2008, the WHO Surgical Safety Checklist was released globally. Two controlled studies tested the checklist and both confirmed that a thoughtfully constructed surgical safety checklist can achieve significant reductions in complications and death [11].

### **Progress made in the WHO South East Asian Region (SEAR)**

Recognizing the magnitude of the problem the WHO in its resolution of May 2002 called upon member states to pay the closest possible attention to the problem of patient safety [12]. This was endorsed by the regional committee for the South East Asian Region (SEAR) through resolution SEA/RC59 on Promoting Safety in Health Care in August 2006. In 2004, WHO launched the World Alliance for Patient Safety [13]. One of the first initiatives of the Alliance was the Global Patient Safety Challenge. The first challenge in 2005 focused on health care associated infection with the theme 'Clean Care is Safer Care' [14]. Five countries in SEAR, including Sri Lanka, were committed to the challenge. The second challenge 'Safe Surgery Saves Lives' was about the application of standards of care for patients undergoing surgery, and implementation of the WHO Surgical Safety Check List to minimise errors.

In 2012, the Sri Lanka Ministry of Health responded to the need for patient safety by establishing the Healthcare Quality and Safety Directorate. Several papers related to errors and complications of surgery from Sri Lanka have also been presented and published [15, 16, 17], highlighting the need for a major paradigm shift in the systems and processes of surgical care and the mindsets of surgeons.

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