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Patient Safety

A World Alliance for Safer Health Care

WHO Guidelines for Safe Surgery 2009

Safe Surgery Saves Lives

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Introduction

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Confronted with worldwide evidence of substantial public health harm due to inadequate patient safety, the World Health Assembly (WHA) in 2002 adopted a resolution (WHA55.18) urging countries to strengthen the safety of health care and monitoring systems. The resolution also requested that WHO take a lead in setting global norms and standards and supporting country efforts in preparing patient safety policies and practices. In May 2004, the WHA approved the creation of an international alliance to improve patient safety globally; WHO Patient Safety was launched the following October. For the first time, heads of agencies, policy-makers and patient groups from around the world came together to advance attainment of the goal of "First, do no harm" and to reduce the adverse consequences of unsafe health care. The purpose of WHO Patient Safety is to facilitate patient safety policy and practice. It is concentrating its actions on focused safety campaigns called Global Patient Safety Challenges, coordinating Patients for Patient Safety, developing a standard taxonomy, designing tools for research policy and assessment, identifying solutions for patient safety, and developing reporting and learning initiatives aimed at producing 'best practice' guidelines. Together these efforts could save millions of lives by improving basic health care and halting the diversion of resources from other productive uses.

The Global Patient Safety Challenge, brings together the expertise of specialists to improve the safety of care. The area chosen for the first Challenge in 2005–2006, was infection associated with health care. This campaign established simple, clear standards for hand hygiene, an educational campaign and WHO's first *Guidelines on Hand Hygiene in Health Care* (*1*).

The problem area selected for the second Global Patient Safety Challenge, in 2007–2008, was the safety of surgical care. Preparation of these *Guidelines for Safe Surgery* followed the steps recommended by WHO (Table I.1).

Table I.1 – Development of the WHO Safe Surgery Guidelines (2)

WHO recommended steps in technical guideline development	Action Taken
Define the specific issues to be addressed by the guidelines	Completed
Undertake a systematic search for evidence	Completed
Review the evidence available	Completed
Develop recommendations linked to the strength of the evidence	Completed
Draft guidelines	Completed
Discuss and incorporate, where relevant, comments of external reviewers	Completed
Draft final version of the guidelines	Completed
Make recommendations on dissemination strategy	Completed
Document the process of guideline development	Completed
Test the guidelines through pilot evaluations	Completed

The groundwork for the project began in autumn 2006 and included an international consultation meeting held in January 2007 attended by experts from around the world. Following this meeting, expert working groups were created to systematically review the available scientific evidence, to write the guidelines document and to facilitate discussion among the working group members in order to formulate the recommendations. A steering group consisting of the Programme Lead, project team members and the chairs of the four working groups, signed off on the content and recommendations in the guidelines document. Nearly 100 international experts contributed to the document (see end). The guidelines were pilot tested in each of the six WHO regions—an essential part of the Challenge—to obtain local information on the resources required to comply with the recommendations and information on the feasibility, validity, reliability and cost–effectiveness of the interventions.

The problem: complications of surgical care have become a major cause of death and disability worldwide

Data from 56 countries showed that in 2004 the annual volume of major surgery was an estimated 187–281 million operations, or approximately one operation annually for every 25 human beings alive (3). This is a large and previously unappreciated volume with significant implications for public health. It is almost double the annual volume of childbirths—in 2006, there were approximately 136 million births (*4*)—and is at least an order of magnitude more dangerous. While the rates of death and complications after surgery are difficult to compare since the case mix is so diverse, in industrialized countries the rate of major complications has been documented to occur in 3–22% of inpatient surgical procedures, and the death rate 0.4–0.8% (*5*,*6*). Nearly half the adverse events in these studies were determined to be preventable. Studies in developing countries suggest a death rate of 5–10% associated with major surgery (*7*–*9*), and the rate of mortality during general

anaesthesia is reported to be as high as 1 in 150 in parts of sub-Saharan Africa (*10*). Infections and other postoperative complications are also a serious concern around the world.

Avoidable surgical complications thus account for a large proportion of preventable medical injuries and deaths globally. Adverse events have been estimated to affect 3–16% of all hospitalized patients, and more than half of such events are known to be preventable (11-14). Despite dramatic improvements in surgical safety knowledge, at least half of the events occur during surgical care (*5*,*6*). Assuming a 3% perioperative adverse event rate and a 0.5% mortality rate globally, almost seven million surgical patients suffer significant complications each year, one million of whom die during or immediately after surgery. Surgical safety has therefore emerged as a significant global public health concern. Just as public health interventions and educational projects have dramatically improved maternal and neonatal survival, analogous efforts might improve surgical safety and quality of care (15).

There are at least four underlying challenges to improving surgical safety. First, it has not been recognized as a significant public health concern. Because of the often high expense of surgical care, it is assumed to be of limited relevance in poor- and middle-income countries; however, the WHO *Global burden of disease report* in 2002 showed that a significant proportion of the disability from disease in the world is due to conditions that are treatable by surgical intervention (16). Debas and colleagues estimated that 11% of the 1.5 billion disability-adjusted life years[1] are due to diseases treatable by surgery (17). An estimated 63 million people a year undergo surgical treatment for traumatic injuries, 31 million for malignancies and 10 million for obstetric complications (*17*). Problems associated with surgical safety are well recognized in developed and developing countries alike. In the developing world, the poor state of infrastructure and equipment, unreliable supplies and quality of medications, shortcomings in organizational management and infection control, difficulties in the supply and training of personnel and severe under-financing contribute to the difficulties.

For more than a century, surgery has been an essential component of public health. As longevity increases worldwide, its role is increasing rapidly. Lack of access to basic surgical care remains a major concern in low-income settings, and WHO's Global Initiative on Emergency and Essential Surgical Care has made improved access its central mission (*19*). The parallel requirement for measures to improve the safety and reliability of surgical interventions, however, has gone largely unrecognized.

The second underlying problem in improving surgical safety has been a paucity of basic data. Efforts to reduce maternal and neonatal mortality at childbirth have relied critically on routine surveillance of mortality rates and systems of obstetric care, so that successes and failures could be monitored and recognized. Similar surveillance has been widely lacking for surgical care. The WHO Patient Safety Programme found that data on surgical volume were available for only a minority of WHO Member States. The data that were available were not standardized and varied widely in the types of procedures recorded. Even countries in which data on surgical procedures are collected regularly had significant gaps: few reported outpatient surgical procedures, some did not cover specialty procedures such as gynaecological or orthopaedic operations, and most did not cover private hospitals. Data from low- and middle-income countries were often extrapolated from regional data or studies published for other purposes. Virtually none of the countries had reliable information on inpatient death rates or other measures of adverse outcome.

The third underlying problem in ensuring surgical safety is that existing safety practices do not appear to be used reliably in any country. Lack of resources is an issue in low-income settings, but it is not necessarily the most important one. Surgical site infection, for example, remains one of the most common causes of serious surgical complications, yet evidence indicates that proven measures—such as antibiotic prophylaxis immediately before incision and confirmation of effective sterilization of instruments—are inconsistently followed. This is not because of cost but because of poor systematization. Antibiotics, for example, are given perioperatively in both rich and poor countries, but in both they are often administered too early, too late or erratically.

Complications of anaesthesia also remain a substantial cause of death during surgery globally, despite safety and monitoring standards which have reduced the numbers of unnecessary deaths and disabilities in industrialized countries. Three decades ago, a healthy patient undergoing general anaesthesia had an estimated 1 in 5000 chance of dying from complications of anaesthesia (*20*). With improved knowledge and basic standards of care, the risk has dropped to 1 in 200 000 in the industrialized world—a 40-fold improvement. Unfortunately, the rate of avoidable death associated with anaesthesia in developing countries is 100–1000 times this rate. Published series showing avoidable anaesthesia mortality rates of 1:3000 in Zimbabwe (*21*), 1:1900 in Zambia (*22*), 1:500 in Malawi (*23*) and 1:150 in Togo (*10*) demonstrate a serious, sustained absence of safe anaesthesia for surgery.

The fourth underlying problem in improving surgical safety is its complexity. Even the most straightforward procedures involve dozens of critical steps, each with an opportunity for failure and the potential for injury to patients, from identifying the patient and the operative site correctly, to providing appropriate sterilization of equipment, to following the multiple steps involved in safe administration of anaesthesia, to orchestrating the operation.

The most critical resources of operating teams are the knowledge and experience of the constituent clinicians — the surgeons, anaesthetists, nurses and others. A team that works effectively together to use its knowledge and abilities on behalf of the surgical patient can avert a considerable proportion of life-threatening complications. Yet, operating-room personnel have had little guidance or structure for fostering effective teamwork and thus minimizing the risks to surgical patients.

The aim of the Safe Surgery Saves Lives programme is to remedy these problems.

1 The disability-adjusted life year (DALY) is an indicator of the time lived with a disability and the time lost due to premature mortality. It extends the concept of potential years of life lost due to premature death to include equivalent years of 'healthy' life lost by virtue of being in states of poor health or disability (World Bank working paper, http://www.worldbank.org/html/extdr/hnp/hddflash/workp/wp_00068.html, accessed 12 December 2006; and WHO Health Information Systems and Statistics, http://www.who.int/healthinfo/ boddaly/en/index.html, accessed 12 December 2006).

The safe surgery saves lives challenge: identifying solutions

The goal of the WHO Patient Safety Safe Surgery Saves Lives Challenge is to improve the safety of surgical care around the world by defining a core set of safety standards that can be applied in all countries and settings. Working groups of international experts were created to review the literature and the experiences of clinicians around the world and to achieve consensus on safety practice in four topic areas: teamwork, anaesthesia, prevention of surgical site infection and measurement of surgical services. Contributors with expertise in surgery, anaesthesia, nursing, infectious diseases, epidemiology, biomedical engineering, health systems, quality improvement and other related fields, as well as patients and patient safety groups, were recruited from each of the WHO regions. They then solicited further input from practitioners and other stakeholders worldwide.

At the first consultation in January 2007, difficulties in improving surgical safety were identified and reviewed. Surgery was defined as "any procedure occurring in the operating room involving the incision, excision, manipulation or suturing of tissue that usually requires regional or general anaesthesia or profound sedation to control pain". It was recognized that in surgery, there is no single remedy that would change safety. Safety in surgery requires the reliable execution of multiple necessary steps in care, not just by the surgeon but by a team of health-care professionals working together for the benefit of the patient.

It was recognized that reliability in other medical fields—for example, obstetrics and medication administration—has been improved by identifying the basic components of care to be provided and by standardizing routines with tools such as checklists. Three examples of particular relevance are described below.

Transformation of risk during anaesthesia: No single improvement in the care of surgical patients has had as profound an impact as the advancement of safe practices in anaesthesia. Anaesthesia is dangerous to patients in a number of ways. Respiratory suppression by an anaesthetic leads to hypoxia, while manoeuvres to control the airway can lead to injury. Aspiration is a significant risk for all patients undergoing sedation or anaesthesia. Hypo- and hypertension, cardiac depression or elevation, and medication reactions and interactions are also potential life-threatening problems. Anaesthesia was long considered more dangerous than surgery itself, but a systematic approach to identifying and addressing failures in anaesthesia care has resulted in a sustained, marked reduction in risk in industrialized countries during the past two decades.

Anaesthesia experts reviewed lessons from aviation, nuclear power and other industries known as high-reliability organizations, which have five identifiable qualities that define their performance: preoccupation with failure, reluctance to simplify interpretations, sensitivity to operation, commitment to resilience and deference to expertise (24). Leaders in anaesthesia therefore began by acknowledging the persistence of human error. Researchers studied individual incidents in detail and enumerated a list of contributory factors, which included inadequate experience, inadequate familiarity with equipment, poor communication among team members, haste, inattention, fatigue and poor equipment design (25). Through national professional societies, first in the United States and then across Europe and in other industrialized countries, a system of improved anaesthesia care was designed. The specific standards of practice mandate that anaesthetists never leave a patient unattended and always monitor vital signs in a prescribed minimum regimen. Changes were made in technological and engineering design, and manufacturing standards for anaesthesia equipment were established with fallible human beings in mind. For example, the sequence and size of dials were standardized, as was the direction for turning them on and off; locks were incorporated to prevent accidental administration of more than one anaesthetic gas; controls were changed so that the concentration of oxygen delivered could not be reduced below its concentration in room air. Most recently, pulse oximeters and capnographs have been designated as essential instruments for monitoring anaesthesia.

Since these changes, deaths due to misconnection of the breathing system or intubating the oesophagus rather than the trachea have become virtually unknown instead of being common causes of death during anaesthesia. In a single decade, the overall death rate associated with general anaesthesia in industrialized nations dropped by more than 95%—from one in 5000 cases to one in 200 000 (*26*).

The 'time out' or 'surgical pause': In surgery, there are few examples of systematic improvements in safety; however, over the past several years in the United States and other industrialized countries, a 'time out' or 'surgical pause' has been introduced as a standard component of surgical care (*27*). This is a brief, less than one minute pause in operating-room activity immediately before incision, at which time all members of the operating team—surgeons, anaesthetists, nurses and anyone else involved—verbally confirm the identity of the patient, the operative site and the procedure to be performed. It is a means of ensuring clear communication among team members and avoiding 'wrong-site' or 'wrong-patient' errors. It has been made mandatory in the United States and a few other countries.

Further experiments with this procedure have resulted in what has been called an 'extended pause', during which more protective measures are taken (*28*). This involves confirmation not only the identity of the patient and the surgical site, but also discussion by team members of the critical details of the operation to be performed. Open communication and improved teamwork are encouraged (*29*,*30*). In studies in single institutions, the extended pause has been shown to improve safety and is associated with improved choice and timing of prophylactic antibiotics and appropriate maintenance of intraoperative temperature and glycaemia (*28*,*31*).

Use of a checklist for central line insertion: A research team at Johns Hopkins University in the United States reported remarkable success in reducing complications from a simple invasive procedure—placement of a central intravenous catheter—by implementing a limited

checklist of steps (*32*). The checklist ensured that clinicians washed their hands before inserting the catheter, avoided using the femoral vein when possible, used chlorhexidine soap to clean the insertion site, put on sterile gloves, gown, hat and mask, covered the patient fully with a sterile barrier drape and, after insertion, checked daily to determine if the catheter could be removed. Use of this checklist in 67 hospitals reduced the rate of catheter-related bloodstream infections by two thirds within 3 months. The average intensive care unit reduced its infection rate from 4% to 0. Over 18 months, the programme saved more than 1500 lives and nearly US$200 million.

The checklist approach has several advantages. Checklists help memory recall, especially for mundane matters that are easily overlooked in patients with dramatic and distracting conditions. Checklists clarify the minimum expected steps in a complex process. By helping a team work together, checklists establish a higher standard of baseline performance (*33*). They are particularly applicable to the operating room setting, where checklists have been used successfully around the world, although without clear standards or guidance as to their content.

The safe surgery saves lives approach

The Safe Surgery Saves Lives programme aims to improve surgical safety and reduce the number of surgical deaths and complications in four ways:

(1) by giving clinicians, hospital administrators and public health officials information on the role and patterns of surgical safety in public health;
(2) by defining a minimum set of uniform measures or 'surgical vital statistics', for national and international surveillance of surgical care;
(3) by identifying a simple set of surgical safety standards that can be used in all countries and settings and are compiled in a 'surgical safety check-list' for use in operating rooms; and
(4) by testing the checklist and surveillance tools at pilot sites in all WHO regions and then disseminating the checklist to hospitals worldwide.

The WHO *Guidelines for Safe Surgery* are central to this effort. The working groups of the Safe Surgery programme considered a range of potential standards, systematically evaluated the evidence for their inclusion, estimated their possible impact and designed measures to assess their effects on performance and safety. The programme also designed a checklist that can be used by practitioners interested in promoting safety and improving the quality of surgical services. It reinforces established safety practices and ensures beneficial preoperative, intraoperative and postoperative steps are undertaken in a timely and efficient way. Many of the steps are already accepted as routine practice in facilities around the world. The aim is not to prescribe a single manner of implementation or to create a regulatory tool. Rather, by introducing key safety elements into the operating routine, teams could maximize the likelihood of the best outcome for all surgical patients without placing an undue burden on the system or the providers.

In nearly all settings, the standards will represent changes in some routines. The standards could, however, result in tangible life-saving improvements in care in all environments, from the richest to the poorest. The WHO Patient Safety Second Global Patient Safety Challenge is based on the recognition that every country can improve the safety of its surgical care.

Improvement through the safe surgery saves lives programme

The established framework for safe intraoperative care in hospitals involves a routine sequence of events—preoperative evaluation of patients, surgical intervention and preparation for appropriate postoperative care—each with specific risks that can be mitigated (Table I.2). In the preoperative phase, obtaining informed consent, confirming patient identity and operative site and the procedure to be undertaken, checking the integrity of the anaesthetic machine and the availability of emergency medications, and adequate preparation for intraoperative events are all amenable to intervention. During the operation, appropriate and judicious use of antibiotics, availability of essential imaging, appropriate patient monitoring, efficient teamwork, competent anaesthetic and surgical judgements, meticulous surgical technique and good communication among surgeons, anaesthetists and nurses are all necessary to ensure a good outcome. After the operation, a clear plan of care, an understanding of intraoperative events and a commitment to high-quality monitoring may all improve the surgical system, thereby promoting patient safety and improving outcomes. There is also a recognized need for trained personnel and functioning resources, such as adequate lighting and sterilization equipment. Finally, safe surgery requires ongoing quality assurance and monitoring.

Not all these factors can be addressed within the context of the Safe Surgery programme. The financial and physical resources of national health systems are limited by many factors, including economic development status. The Safe Surgery Saves Lives Challenge is a two-year initiative, and, early in the investigative phase, the programme team determined that it would be unable to address the issues of resources and infrastructure shortfalls given the budget and time frame of this project. Similarly, although human resources are vital for

Table I.2 – The nature of the challenge: *Teamwork, safe anaesthesia and prevention of surgical site infection are fundamental to improving the safety of surgery and saving lives. Basic issues of infrastructure must be considered and of the ability to monitor and evaluate any instituted changes must be addressed.*

Surgical Resources and Environment: Trained personnel, clean water, consistent light source, consistent suction, supplemental oxygen, functioning surgical equipment and sterile instruments		
Prevention of Surgical Site Infection Hand washing Appropriate and judicious use of antibiotics Antiseptic skin preparation Atraumatic wound care Instrument decontamination and sterility	Safe Anaesthesia Presence of a trained anaesthetist Anaesthesia machine and medication safety check Pulse oximetry Heart rate monitoring Blood pressure monitoring Temperature monitoring	Safe Surgical Teams Improved communication Correct patient, site, and procedure Informed consent Availability of all team members Adequate team preparation and planning for the procedure Confirmation of patient allergies
Measurement of Surgical Services: quality assurance, peer review and monitoring of outcomes		

health delivery and for safe care, improvement will require so much investment in education, infrastructure and training that success is unlikely in the near future. In addition, the significant work performed by many health-care workers who lack credentials but fill an important, even vital need, particularly in resource-limited settings, should not be minimized; but there is no clear consensus on what constitutes appropriate training, how much training is enough and how to measure competence. The absence of such basic information makes it exceedingly difficult to set standards for training and credentialing and ultimately leaves it to governments and professional societies to determine how best to approach these issues, given their resources and needs.

In view of the limitations for addressing infrastructure and human resources, the expert working groups determined that the most effective initial intervention would be to establish universal standards for safety for existing surgical teams and their work in the operating room. These standards would be operationalized by wide implementation of a checklist and the creation of basic, standardized measures of surgical services. Universal features, strategies and workflow patterns of the perioperative period are critical for care, prone to failure and amenable to simple improvements.

The aim of the working groups was to identify potential standards for improvements in four areas: **safe surgical teams**, by promoting communication among team members to ensure that each preparatory step is accomplished in a timely and adequate fashion with an emphasis on teamwork; **safe anaesthesia**, by appropriate patient monitoring and advance preparation to identify potentially lethal anaesthetic or resuscitation problems before they cause irreversible harm; **prevention of surgical site infection**, through antisepsis and control of contamination at all levels of patient care; and **measurement of surgical services**, by creating public health metrics to measure provision and basic outcomes of surgical care.

The Safe Surgery Saves Lives Challenge was further guided by three principles. The first is **simplicity**. An exhaustive list of standards and guidelines might create a package that would improve patient safety, but such comprehensiveness would be difficult to implement and convey, and would probably face significant resistance. The appeal of simplicity in this setting cannot be overstated. Uncomplicated measures will be the easiest to institute and can have profound effects in a variety of settings.

The second principle is **wide applicability**. Focusing on a specific resource milieu would reduce the number of issues (e.g. minimum equipment standards for resource-poor settings), but the goal of the challenge is to reach all environments and settings, from resource rich to resource poor, so that all WHO Member States can be involved. Furthermore, regular failures occur in every setting and environment and are amenable to common solutions.

The third is **measurability**. Measurement of impact is a key component of the Second Challenge. Meaningful metrics must be identified, even if they relate only to surrogate processes, and they must be reasonable and quantifiable by practitioners in all contexts.

If the three principles of simplicity, wide applicability and measurability are followed, the goal of successful implementation will be feasible.

Organization of the guidelines

The guidelines are designed to meet these principles and are organized in three steps.

First, the specific objectives for safe surgical care are enumerated. Second, the findings from reviews of evidence on and experience with approaches to meeting each of the objectives are described. Lastly, potentially beneficial practices are classified into three categories on the basis of clinical evidence or expert opinion as to their ability to reduce the likelihood of serious, avoidable surgical harm and whether adherence is unlikely to introduce injury or unmanageable cost:

- **'highly recommended': a practice that should be in place in every operation;**
- **'recommended': a practice that is encouraged for every operation; and**
- **'suggested': a practice that should be considered for any operation**

While the review was relatively comprehensive, it did not make clear how the findings were to be operationalized. Therefore, at the end of the review for each objective and in order to provide simple means for practitioners to ensure and improve standards of safety, we focused on the 'highly recommended' practices and used them to construct two products: the WHO Safe Surgery Checklist and a set of recommended 'surgical vital statistics' for measurement.

These guidelines have undergone final review and testing at pilot sites around the world (see Appendix A). There is wide recognition that every country can improve the safety of its surgical care and that this is a critical matter of public health, affecting hundreds of millions of people worldwide each year. By creating a culture of safety, WHO Patient Safety is seeking to promote practice standards that reduce injuries and save lives.

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Section II.

Ten essential objectives for safe surgery: review of the evidence and recommendations

Surgical care is complex and involves dozens of steps which must be optimized for individual patients. In order to minimize unnecessary loss of life and serious complications, operating teams have 10 basic, essential objectives in any surgical case, which the WHO safe surgery guidelines support.

(1) The team will operate on the correct patient at the correct site.
(2) The team will use methods known to prevent harm from administration of anaesthetics, while protecting the patient from pain.
(3) The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
(4) The team will recognize and effectively prepare for risk of high blood loss.
(5) The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk.
(6) The team will consistently use methods known to minimize the risk for surgical site infection.
(7) The team will prevent inadvertent retention of instruments and sponges in surgical wounds.
(8) The team will secure and accurately identify all surgical specimens.
(9) The team will effectively communicate and exchange critical information for the safe conduct of the operation.
(10) Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results.

Objective 1

The team will operate on the correct patient at the correct site

While wrong-site or wrong-patient surgery is rare, even a single incident can result in considerable harm to the patient. There are recurrent and persistent reports of wrong site operations on limbs and the brain and of patients who have had the wrong kidney, adrenal gland, breast or other organ removed. The attention that such events invariably attract in the media undermines public confidence in health-care systems and in the physicians who provide care.

It has been estimated that wrong-site and wrong-patient surgery occurs in about one in 50 000–100 000 procedures in the United States, equivalent to 1500–2500 incidents each year (*1*,*2*). In an analysis of sentinel events reported between 1995 and 2006, the Joint Commission for Accreditation of Health Organizations found that just over 13% of reported adverse events were due to wrong-site surgery (*3*). An analysis of 126 cases of wrong-site or wrong-patient surgery in 2005 revealed that 76% were performed on the wrong site, 13% on the wrong patient and 11% involved the wrong procedure. The literature supports the supposition that wrong-site surgery is more common in certain fields, particularly orthopaedic surgery. In a survey of 1050 hand surgeons, 21% reported having performed wrong-site surgery at least once in their careers (*4*). An analysis of malpractice insurance claims following orthopaedic surgery showed that 68% were for wrong-site surgery (*5*).

Wrong-site surgery is more likely to occur in procedures associated with bilaterality. Failures in communication between team members and problems with leadership were the major contributory factors in the report of the Joint Commission for Accreditation of Health Organizations (*3*). In a separate analysis of 13 non-spine wrong-site procedures, Kwaan et al. showed that four cases were due to errors in the operating schedule, and in 66% of cases in which the consent form was reviewed, the site or side was not specified *(1)*. Factors such as the

absence of radiographic images and wrong site labelling on the images play a causative role in faulty orthopaedic and spinal procedures (*1*,*2*). Organizational culture, interpersonal dynamics and steep hierarchical structures in the operating room contribute to error by creating an environment in which persons who could prevent an error are reluctant to speak up (*6*). Thus, systems failures account for a large number of wrong-site events. Accurate patient identification and labelling, patient involvement in preoperative planning, informed consent, better communication among team members and improved teamwork and protocols could all reduce these types of error. Elimination of wrong site, wrong patient and wrong procedure errors has been a goal of the Joint Commission since 2000 (*7*).

Wrong-site surgery received prominent attention in the early 1990s, and surgeons (in particular orthopaedists) and professional organizations made attempts to address the issue. The Canadian Orthopaedic Association recommended 'marking the incision site with a permanent marker' in 1994 (*8*). Professional orthopaedic organizations took this up as a matter of policy, and in 1998 the American Academy of Orthopaedic Surgeons started a campaign called 'Sign Your Site'. That same year the Joint Commission gathered information on sentinel events of wrong-site surgery and sought strategies to address the issue. In 2003, the Joint Commission formulated and mandated use of a universal protocol for the prevention of wrong-site, wrong-patient and wrong-procedure errors; this has been adopted by many professional organizations, including the American College of Surgeons and was updated in 2009 to extend identification checks to procedures performed outside the operating room (*9*, *10*).

The universal protocol

The Universal Protocol is a three-step process in which each step is complementary and adds redundancy to the practice of confirming the correct patient, site and procedure.

Step 1. Verification: This consists of verifying the correct patient, site and procedure at every stage from the time a decision is made to operate to the time the patient undergoes the operation. This should be done:

- when the procedure is scheduled;
- at the time of admission or entry to the operating theatre;
- any time the responsibility for care of the patient is transferred to another person; and
- before the patient leaves the preoperative area or enters the procedure or surgical room.

The step is undertaken insofar as possible with the patient involved, awake and aware. Verification is done by labelling and identifying the patient and during the consent process; the site, laterality and procedure are confirmed by checking the patient's records and radiographs. This is an active process that must include all members of the team involved in the patient's care. When many team members are involved in verification, each check should be performed independently. Team members must also be aware, however, that the involvement of multiple caregivers in verification can make the task appear onerous and could lead to violations of the protocol. Adherence to the verification procedure can be facilitated by the use of reminders in the form of checklists or systematic protocols (*11*).

Step 2. Marking: The Universal Protocol states that the site or sites to be operated on must be marked. This is particularly important in case of laterality, multiple structures (e.g. fingers, toes, ribs) and multiple levels (e.g. vertebral column). The protocol stipulates that marking must be:

- at or next to the operative site; non-operative sites should not be marked;
- unambiguous, clearly visible and made with a permanent marker so that the mark is not removed during site preparation (Health-care organizations may choose different methods of marking, but the protocol should be consistent in order to prevent any ambiguity. The guidelines of the National Patient Safety Agency in England recommend use of an arrow drawn on the skin and pointing to the site, as a cross could denote a site that should not be operated and introduces an element of ambiguity (*12*). The American Academy of Orthopaedic Surgeons endorses a 'sign your site' protocol in which surgeons write their initials or name on the operative site (*13*).);
- made by the surgeon performing the procedure (To make the recommendations practicable, however, this task may be delegated, as long as the person doing the marking is also present during surgery, particularly at the time of incision (*14*).); and
- completed, to the extent possible, while the patient is alert and awake, as the patient's involvement is important.

The verification and marking processes are complementary. They are intended to introduce redundancy into the system, which is an important aspect of safety. Either one used alone is unlikely to reduce the incidence of wrong-site surgery.

Patients or their caregivers should participate actively in verification. The Joint Commission views failure to engage the patient (or his or her caregiver) as one of the causes of wrong-site surgery. The Joint Commission has published information leaflets for patients to inform them of their important role in preventing wrong-site surgery (*15*); patient awareness initiatives have also been adopted by the National Patient Safety Agency in the United Kingdom (*16*) and the Australian Commission of Safety and Quality in Healthcare (*17*).

Step 3. 'Time out': The 'time out or 'surgical pause' is a brief pause before the incision to confirm the patient, the procedure and the site of operation. It is also an opportunity to ensure that the patient is correctly positioned and that any necessary implants or special equipment are available. The Joint Commission stipulates that all team members be actively involved in this process. Any concerns or inconsistencies must be clarified at this stage. The checks during the 'time out' must be documented, potentially in the form of a checklist, but the Universal Protocol leaves the design and delivery to individual organizations. The 'time out' also serves to foster communication among team members.

The Australian Commission on Safety and Quality in Healthcare uses a five-step process similar to the Universal Protocol to prevent wrong-site surgery (*17*):

Step 1: Check that the consent form or procedure request form is correct.
Step 2: Mark the site for the surgery or other invasive procedure.
Step 3: Confirm identification with the patient.
Step 4: Take a 'team time out' in the operating theatre, treatment or examination area.
Step 5: Ensure appropriate and available diagnostic images.

Consent is part of both protocols. It is the first step in the Australian protocol and is included as critical documentation in the Universal Protocol in the United States. While consent is being obtained, the patient must be awake and alert and have the capacity to understand the details and implications of the procedure. Consent must be obtained in a language that the patient understands or through an interpreter. It should include a clear statement of the procedure to be performed and the site of operation, including laterality or level (*18*). The consent protocol can, however, be waived in emergency cases with threat to life or limb.

Preoperative verification protocols have only recently been introduced in many parts of the world. Evidence of their efficacy in reducing the incidence of wrong-site surgery is lacking, although preliminary data suggest that such actions are effective. The Orange County Kaiser Permanente organization in the United States found a reduction in the incidence of wrong-site surgery after the introduction of a checklist (*19*). Similarly, there has been a reduction in wrong-site surgery in Western Australia, from 10 reported cases in 2004–2005 to four in 2005–2006 (*20*). A study by Makary et al. at Johns Hopkins hospital in the United States showed that team awareness of the correct site of operation increased with use of a checklist and briefing (*21*). While evidence is still being gathered, protocols for ensuring correct patient and procedure are well established, inexpensive, recommended by many professional societies and, if followed with care and consideration, promote safe surgical practice.

Recommendations

Highly recommended:

- Before induction of anaesthesia, a member of the team should confirm that the patient is correctly identified, usually verbally with the patient or family member and with an identity bracelet or other appropriate means of physical identification. Identity should be confirmed from not just the name but also a second identifier (e.g. date of birth, address, hospital number).

- A team member should confirm that the patient has given informed consent for the procedure and should confirm the correct site and procedure with the patient.

- The surgeon performing the operation should mark the site of surgery in cases involving laterality or multiple structures or levels (e.g. a finger, toe, skin lesion, vertebra). Both the anaesthetist and the nurse should check the site to confirm that it has been marked by the surgeon performing the operation and reconcile the mark with the information in the patient's records. The mark should be unambiguous, clearly visible and usually made with a permanent marker so that it does not come off during site preparation. The type of mark can be determined locally (signing, initialling or placing an arrow at the site). A cross or 'X' should be avoided, however, as this has been misinterpreted to mean that the site is the one *not* to be operated on.

- As a final safety check, the operating team should collectively verify the correct patient, site and procedure during a 'time out' or pause immediately before skin incision. The surgeon should state out loud the patient's name, the operation to be performed, and the side and site of surgery. The nurse and anaesthetist should confirm that the information is correct.

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Objective 2

The team will use methods known to prevent harm from administration of anaesthetics, while protecting the patient from pain

In developed countries, anaesthesia is associated with low risks for serious morbidity and mortality. Current estimates of avoidable mortality associated with anaesthesia in Australia and Europe vary from about 1:10,000 to about 1:185, 000 (*1–4*). The rate of mortality attributable solely to anaesthesia in healthy patients undergoing minor surgical procedures is likely to be at the lower end of this range. The higher estimates tend to reflect mortality to which anaesthesia is thought to have contributed, often in patients with significant comorbidity who are undergoing major surgery. There are, however, few reliable data to determine the true rate of mortality associated with anaesthesia. A rate of 1 in 79,509 was reported in a review in Australia between 1997 and 1999 (*5*). In a subsequent review from the same source covering the years 2000–2002, the reported rate was 1 in 56,000, the revised estimate being based on improved data for the denominator attributable to the introduction of anaesthesia-specific coding (*6*). These Australian reports probably provide the best estimates of mortality associated with anaesthesia available for any nation in the world; however, the discrepancy between the rates in the two reports indicates that the mortality rate for the 1990s was unclear, and it remains so for most of the world. Lagasse (*7*) reviewed data on mortality during the last four decades of the twentieth century and attributed the wide variation in rates to lack of standardization of definitions. His contention that mortality had not improved was strongly challenged by Cooper and Gaba (*8*), who argued that there is credible evidence that mortality has decreased substantially among relatively healthy patients undergoing elective procedures, which was the initial aim of patient safety efforts in anaesthesia.

Estimation of mortality due to anaesthesia is problematic: most reporting is voluntary, the denominator is seldom a reliable figure, sedation is not routinely captured, the case mix to which the figures are applied is usually unknown, and there is no agreed definition of anaesthetic mortality. Even when clearly defined, it may be difficult to separate it from causes related to the operation and the patient's underlying condition. Nevertheless, there is good reason to believe that anaesthesia-related risks in the developed world have decreased significantly over the past two decades due to improvements in training, equipment and medications and the introduction of standards and protocols. Mandatory monitoring standards, in particular pulse oximetry and capnography, are considered particularly important (*9,10*).

Unfortunately, the avoidable anaesthesia-associated mortality in developing countries has been estimated at 100–1000 times the rate reported in developed countries. In published series, avoidable mortality associated with anaesthesia was as high as 1:3000 in Zimbabwe (*11*), 1:1900 in Zambia (*12*), 1:500 in Malawi (13) and 1:150 in Togo (14). The methods used in these studies are comparable, and they demonstrate a serious, sustained lack of safe anaesthesia for surgery.

Patterns of avoidable morbidity and mortality during anaesthesia

Mortality associated with anaesthesia, particularly in the developing world, is primarily related to two causes: airway problems and anaesthesia in the presence of hypovolaemia. A substantial proportion of anaesthesia-related deaths in the developed world occur in obstetric patients (*15–17*). Reports from Nigeria (*18*) and Malawi (*19*) demonstrate that these patients account for 50% of the anaesthesia-related deaths in developing countries. These studies also indicate that poor technique and lack of training, supervision and monitoring contribute to the high mortality. The potential for professionals to learn lessons about avoidable deaths is limited in many hospitals, as few such events are recorded or formally discussed.

These unacceptably high figures are indicative of a deteriorating situation. Information from Uganda in 2006 illustrates the constraints anaesthesia providers face, including shortages of the most basic facilities, equipment and medications and few physician anaesthetists (13 for 27 million people, compared with 12,000 for 64 million in the United Kingdom) *(20)*; most anaesthesia is thus performed by non-physicians. This situation is similar to that in other parts of Africa (*21–23*). Although the situation varies widely throughout the world, anaesthesia services in many countries are extremely poor, particularly in rural areas (*24,25*). For the most part, deficiencies go unrecorded, as there are few systematic reviews of anaesthetic conditions and practice.

Perioperative mortality is usually due to a combination of factors related to patients (and their underlying medical condition), surgery, anaesthesia and management. In order to improve the safety of patients undergoing surgery, anaesthesia services must be made safer, especially in developing countries. This will require investment in the form of improved training of anaesthetists, safer facilities, functioning equipment, adequate drug supplies and mandatory pulse oximetry. International standards play an important role in guiding the development of anaesthesia services and should be adopted by ministries of health and local professional societies.

In order that no patient be harmed by anaesthesia, several goals must be met:

- Anaesthesia services should be made safer.
- Training and facilities for anaesthesia should be improved in many parts of the world.
- Safety in obstetric anaesthesia should be a priority, as obstetric patients are at particularly high risk from anaesthesia.
- Standardized global definitions of anaesthesia mortality should be developed.
- Every avoidable death is a tragedy, and lessons should be learnt from each instance of death during anaesthesia in order to reduce the risk of recurrence.

Approaches to improving the safety of anaesthesia

Anaesthesiology has played a pioneering role in the patient safety movement and in the establishment of standards for safe practice. Anaesthesiologists first codified the concept of 'patient safety' in 1984 at the inaugural meeting in Boston (United States) of the International Committee on Preventable Anesthesia Mortality and Morbidity. The first organization devoted to the concept of patient safety was the Anesthesia Patient Safety Foundation, created in the United States in 1985. This independent organization was the result of considerable effort on the part of the medical professionals involved, with the support of related industries and government regulators. The original 'Harvard monitoring standards' for intraoperative anaesthesia care were the first formally published, detailed medical standards of practice (*26*). They stimulated the American Society of Anesthesiologists to adopt their 'Standards for Basic Intraoperative Monitoring' in 1986. This initiative encouraged a cascade of standards, guidelines and protocols by professional anaesthesiology groups and societies around the world.

In 1989, the International Task Force on Anaesthesia Safety was established, comprising leaders in anaesthesia patient safety in nine countries (*27*). After two years of extensive work, the Task Force published the first *International standards for a safe practice of anaesthesia* (*28*). The document consisted of four printed pages and contained an outline of both general standards for the profession and practice of anaesthesiology and specific standards for peri-anaesthetic care and monitoring. Because of the variation in resources available in different locations around the world, the standards for equipment required for peri-anaesthetic care and monitoring were classified into three levels: basic, intermediate and optimal, to correlate realistically with available local resources. The essential care and monitoring concepts were universal and applicable everywhere, from the most isolated, resource-challenged locations in the developing world to the most economically and technologically advanced capitals. Ability to implement the concepts differed greatly, however. One focus was to help provide more anaesthetists in disadvantaged areas and to secure resources for improving anaesthesia quality and safety. The World Federation of Societies of Anesthesiologists formally adopted these international standards at its congress in The Hague in June 1992 and recommended them to all its member societies. The *International standards for a safe practice of anaesthesia* and 10 supporting documents were published as Supplement 7 to the *European Journal of Anaesthesiology* in January 1993 (*28*).

The work of the International Task Force underpins much of the current work in anaesthesia safety. At the most recent meeting of the World Federation of Societies of Anaesthesiologists, the 1992 standards were revised and updated and subsequently endorsed by the General Assembly during the 14th World Congress of Anaesthesiologists in Cape Town, South Africa, on 7 March, 2008 (*29*). The older standards had not, however, been actively promoted or endorsed globally. If the safety of anaesthetic services is to be improved, wide adoption of the standards is imperative. The main addition to the previous international standards is the requirement for pulse oximetry as an essential component of patient monitoring. Pulse oximetry is used almost universally in industrialized countries during the administration of anaesthesia. While strong, unequivocal evidence from a randomized clinical trial is lacking, few anaesthesia providers would willingly do without this device. As this represents a departure from the previous standards and imposes a potentially substantial cost on facilities, a full review of the evidence for this recommendation is warranted.

Evidence on monitoring with pulse oximetry and capnography

There is no evidence from randomized controlled trials that pulse oximetry or capnography has had an important effect on the outcome of anaesthesia (*30*). Evaluation of any safety intervention, however, requires consideration not only of the frequency of the adverse events that might be prevented but also of their potential severity. The prevention of an event may warrant considerable investment if it is serious, even if it is infrequent. Furthermore, prevention is more readily justified if the risks associated with the preventive measures are low. The death of, or brain damage to, an otherwise healthy person due to an entirely preventable anaesthetic mishap, such as ventilator disconnection or oesophageal intubation, is catastrophic; the risks associated with pulse oximetry and capnography are exceedingly low.

expert opinion: The anaesthesia community has led health care in the pursuit of patient safety (*8*). A prime example of systems improvement is the adoption of pulse oximetry and capnography as standard care in anaesthesia. In many countries today, there is a generation of anaesthetists who have never practised without pulse oximetry or capnography, and routine use of these techniques is mandated in the standards or guidelines of professional anaesthesia organizations in a number of countries (e.g. the Australian and New Zealand College of Anaesthetists, the Hong Kong College of Anaesthetists, the Malaysian Society of Anaesthesiologists, the Nigerian Society of Anaesthetists, the Association of Anaesthetists of Great Britain and Ireland, the American Society of Anesthesiologists in the United States and the Uruguay Society of Anaesthesiologists). It is likely that pulse oximetry and capnography are used in over 99% of general and regional anaesthetics in the United States and Canada, much of Europe, Australia, New Zealand and many other countries. This level of adoption reflects an almost universal conviction on the part of anaesthesia providers that these techniques contribute substantially to the safe provision of anaesthesia. The fact that the standards in many different countries are almost identical amounts to an extended 'Delphi process' for establishing consensus among experts. The weight of international expert opinion overwhelmingly supports use of these techniques for the safety of anaesthesia.

Compliance with best-practice guidelines for health care in general is sporadic and inconsistent, even in highly developed systems of health delivery (*31*); however, compliance with standards, guidelines and recommendations for the use of pulse oximetry and capnography in the developed world is virtually 100%. They have not only been mandated by authorities in the anaesthetic profession, they have also been embraced whole-heartedly and unequivocally by virtually every practising anaesthetist who has access to them (*32*). Informal surveys indicate that anaesthetists in many parts of the world cancel elective cases rather than proceed in the absence of either of these monitors. Widespread use of pulse oximetry is the primary goal of the Global Oximetry project, a collaboration among several professional societies of anaesthesiology and industry to promote widespread adoption of pulse oximetry, with particular emphasis in developing countries. The project includes evaluation of current oximeter design and cost, the educational requirements for effective use of pulse oximeters and barriers to their widespread adoption in appropriate settings (*33*). The adoption of pulse oximetry by anaesthetists has been an unusual, strikingly successful example of standardization of practice in health care.

controlled trials: A recent Cochrane review addressed the value of pulse oximetry in anaesthesia (*30*). The authors identified six studies of oximetry, two of which were deemed ineligible for inclusion because they lacked a control group or information on relevant postoperative outcomes. They concluded:

"The studies confirmed that pulse oximetry can detect hypoxaemia and related events. However, we have found no evidence that pulse oximetry affects the outcome of anaesthesia. The conflicting subjective and objective results of the studies, despite an intense, methodical collection of data from a relatively large population, indicate that the value of perioperative monitoring with pulse oximetry is questionable in relation to improved reliable outcomes, effectiveness and efficiency."

The authors, however, went on to explain that, "Due to the variety of outcome variables used in the four studies, there are no two groups which could be compared directly by formal meta-analysis."

Thus, the conclusions of this review were not based on a synthesis of a substantial body of comparable data but rather on the only large randomized controlled trial in which pulse oximetry has been evaluated, with some reference to three much smaller studies. This trial, conducted by Moller et al. (*34*), involved 20,802 patients and is impressive in concept, the detail of the data collected and the care with which the findings were presented. The study, however, lacked power to show differences in mortality associated with anaesthesia between groups. Given the observed rate of one death partially associated with anaesthesia per 335 patients, 1.9 million patients would have been needed to show a significant difference in outcome. Even for myocardial infarction, 500,000 patients would have been needed to show a difference in events, on the basis of the observed rate of 1 in 650 patients. Thus, the negative findings of the Moller study—revealing no change in overall rates of respiratory, cardiovascular or neurological complications—were related to outcomes that would have required much larger numbers of participants to be detected. It did, however, demonstrate a 19-fold increase in the detection of hypoxaemia in the group monitored by oximetry ($p = 0.00001$) as well as a significant increase in the detection of endobronchial intubation and hypoventilation. In addition, myocardial ischaemia occurred in half as many patients when oximetry was used.

The theoretical value of pulse oximetry lies in its ability to provide earlier, clearer warning of hypoxaemia than that provided by clinical signs alone. This may well reduce mortality rates and catastrophic hypoxic events, but these proved too infrequent to be evaluated in a study of only 20,000 patients. While anaesthesiologists still

disagree about the implications of the Moller et al. study, it confirmed unequivocally that pulse oximetry facilitates early detection of hypoxaemia. Analysis of the data strongly suggested that oximetry improves outcomes as well. In addition, all the other identified studies demonstrated at least some benefit of the use of oximetry (Table II.2.1).

The results of trials of capnography are less clear, partly because its value is too obvious to require a randomized trial. Oesophageal intubation and hypoventilation are potentially disastrous if not identified early, and they can be detected reliably and promptly by the use of capnography (*9*,*42*). This is not the case with clinical signs alone. Capnography can also facilitate the detection of endobronchial intubation and airway circuit disconnections (*43*). No reasonable ethics board is likely to permit a randomized trial of capnography.

Table II.2.1 – Other studies of pulse oximetry and its demonstrated benefits

Study	Benefit
Bierman et al. (*35*): Blinded randomized controlled trial of 35 patients undergoing cardiac surgery	Clinically undetected episodes of arterial desaturation were observed in 7/15 patients in the control group and none in the pulse oximetry group.
Moller et al. (*36*): Blinded randomized clinical trial of 200 adult patients undergoing general surgery under general or regional anaesthesia, allocated randomly to pulse oximeter and alarms 'available' vs 'unavailable' to the anaesthesia team and recovery room staff	The incidence of hypoxaemia was reduced significantly in the 'available' group in both the operating theatre and the recovery room.
Moller et al. (*37*): Blinded randomized clinical trial of 736 patients undergoing elective procedures under general or regional anaesthesia; oximetry used during anaesthesia and in the post-anaesthesia care unit vs not at all	No difference in cognitive function between groups
Coté et al. (*38*): Controlled study (alternating patients) in 152 children undergoing surgery allocated to pulse oximeter data and alarms 'available' vs 'unavailable' to the anaesthesia team	Hypoxic events diagnosed by the oximeter but not the anaesthetist were more common in the non-oximetry group (13 vs 5: $p = 0.05$).
Coté et al. (*39*): Blinded randomized clinical trial of 402 paediatric patients in four groups: (1) oximeter and capnography, (2) only oximeter, (3) only capnography and (4) neither	Blinding the oximeter data increased the number of patients experiencing 'major desaturation events' (31 vs 12: $p = 0.003$). Blinding the capnographic data increased the number of patients with minor capnographic events (47 vs 22: $p = 0.003$) but not the number with major capnographic events or desaturation events. More patients experienced multiple problems when neither capnographic nor oximeter data were available (23 vs 11: $p = 0.04$). The authors concluded that oximetry was superior to capnography or clinical observation in providing early warning of potentially life-threatening problems, and that use of both monitors together significantly reduced the number of problems observed in their patients.
Cullen et al. (*40*): Non-randomized study of 17 093 surgical patients	After introduction of pulse oximetry in all anaesthetizing locations (not including the recovery room), the overall rate of unanticipated admission to an intensive care unit and, specifically, the rate of admission to rule out myocardial infarction, decreased significantly.
Mateer et al. (*41*): Non-randomized study of 191 consecutive adult patients undergoing emergency endotracheal intubation	Hypoxaemia (O2 saturation less than 90%) occurred during an intubation attempt in 30 of 111 unmonitored versus 15 of 100 monitored attempts ($p < 0.05$), and the duration of severe hypoxaemia (O2 saturation less than 85%) was significantly greater for unmonitored attempts ($p < 0.05$).

Incident reporting: In the seminal work of Cooper and his group, reporting of incidents identified failure to deliver oxygen to patients as the leading cause of mortality during anaesthesia (*44*). Over a decade ago, qualitative analysis of 2000 incidents showed a reduction in cardiac arrest when pulse oximetry was used, 9% of which were first detected by pulse oximetery (*45*). A theoretical analysis of the subset of 1256 incidents involving general anaesthesia showed that pulse oximetry on its own would have detected 82% of them. Of these, 60% would have been detected before any potential for organ damage occurred. Capnography alone would have detected 55% of these 1256 incidents. If both oximetry and capnography had been used in combination, 88% of the adverse events would have been detected, 65% before potential permanent damage (*46*). A recent review of 4000 incidents and over 1200 medico-legal notifications reported by anaesthetists in Australia and New Zealand revealed no cases of hypoxic brain damage or death due to inadequate ventilation or misplaced tubes since the introduction of oximetry and capnography (*10*).

Inferences from data on anaesthesia mortality: An analysis of the effects of oximetry and capnography over time in the Closed Claim Project[2] of the American Society of Anesthesiologists showed that although the number of damaging events due to respiratory failure decreased, the number of cardiovascular damaging effects increased (*47*). A separate analysis based on changes in the patterns of incident reporting indicated, however, that catastrophic hypoxic events are much less common today than they were before the introduction of these monitors (*10*). Anaesthesia is safer today than it was before these techniques were introduced, particularly in the developed world, where oximetry and capnography are used with nearly 100% compliance.

Other considerations on oximetry and capnography: A key element of pulse oximetry and capnography is their safety. While either type of monitor could provide misleading information because of technical problems, this is uncommon. In the study by Moller et al., for example, it occurred in 2% of cases. Experience and training allow most problems of this type to be identified and corrected.

Use of these devices requires an understanding of the relevant physiology and pathological processes leading to the changes they indicate. Their limitations and the possibility of incorrect or artefactual readings must also be appreciated. For example, in the United Kingdom, many doctors and nurses are inadequately prepared to interpret oximetry readings accurately (*48*). Users must also know how to respond effectively if oxygen saturation falls, by, for example, administering supplemental oxygen. Any clinician trained to give anaesthetics safely, including those not medically licensed, should, however, be able to incorporate either or both techniques into their practice within a short time.

While the cost of pulse oximetry has fallen dramatically over the past 20 years, concern about capital outlay and resource constraints is germane. Oximeters are relatively inexpensive (e.g. less than US$1000) and may be much cheaper in many places, such as China, where they are available at a fraction of this price. When calculated over the life of the machine and the number of patients on whom it can be used, this simple monitoring device becomes exceedingly cost–effective. In addition, harm due to anaesthetic mishaps is not cost-free, and a single error averted with pulse oximetry justifies its initial cost.
The devices themselves have excellent visual and auditory outputs, are reliable and robust and do not require much maintenance. The probes are, however, readily damaged and their replacement represents a relatively high proportion of the overall cost of oximetry. It is not easy to calculate the cost per patient of use of pulse oximetry, but the cost of probes over time is likely to equal or exceed that of the actual device. Reliable, resistant probes are needed. The cost of capnography is somewhat higher, and maintenance is a little more challenging than for oximetry.

Conclusion: Mandated use of pulse oximetry and capnography in the developed world has stood the test of time. In settings with limited resources, the issue is somewhat less clear because of arguments about priorities for health-care funds. The overwhelming weight of evidence is that these techniques together improve safety, but it seems likely that much of the gain can be obtained from oximetry alone. Oximetry appears to provide early warning in a greater variety of situations than capnography (46). It will alert clinicians to problems in every situation that would be detected by capnography, perhaps later but certainly in time for action to be taken. Conversely, there are many situations in which oximetry is potentially life-saving and in which capnography alone might not be as helpful. Finally, oximetry is less expensive and less difficult to maintain than capnography.

2 The American Society of Anesthesiologists Closed Claims Project is an in-depth investigation of closed anesthesia malpractice claims designed to identify major areas of loss, patterns of injury, and strategies for prevention (http://depts.washington.edu/asaccp/ASA/index.shtml accessed 3 June 2008).

Preparation for and delivery of anaesthesia

The provision of safe anaesthesia depends on careful preparation, which is facilitated by a systematic approach to reviewing the patient, machine, equipment and medications. This is ideally based on a formal check of the anaesthesia system. In addition to the personnel involved in delivering anaesthetic, the anaesthesia system includes:

- any machine or apparatus that supplies gases, vapours, local anaesthesia or intravenous anaesthetic agents to induce and maintain anaesthesia;
- any equipment necessary for securing the airway;
- any monitoring devices necessary for maintaining continuous evaluation of the patient; and
- the patient himself or herself, correctly identified, consensual and evaluated preoperatively.

In preparing for anaesthesia, the anaesthesia system should be checked before each anaesthetic, before the start of each operating day and after any repairs or maintenance to equipment or the introduction of new equipment. Figure 2.1 shows a universally applicable list of the checks to be made before anaesthetizing any patient. If the items on this list are available and functioning correctly before every anaesthetic, many mishaps can be prevented and lives will be saved. Additional checks to be undertaken before the first case of the day will depend on the level of resources available and should be decided locally.

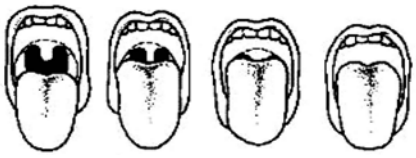
Anaesthesia is usually administered in the operating room but may be required in intensive care units, emergency departments or other locations, such as radiology suites. There are clear requirements for the provision of safe anaesthesia services and recommended approaches for purchasing equipment. Even if there are financial constraints, it is the responsibility of the hospital management to maintain operating rooms and equipment and to provide an appropriate supply of medications and other consumables.

Figure 2.1* – Proposed *list of anaesthesia safety checks before any anaesthetic

Patient name _____ **Number** _____

Date of birth _____ **Procedure** _____

Site _____

Check patient risk factors *(if yes – circle and annotate)*		**Check resources**	Present and functioning
ASA 1 2 3 4 5 E		***Airway***	
		– Masks	☐
		– Airways	☐
		– Laryngoscopes (working)	☐
		– Tubes	☐
		– Bougies	☐
Airway *(Mallampati classification)*  Class 1 Class 2 Class 3 Class 4		***Breathing***	
		– Leaks (a fresh gas flow of 300 ml/min maintains a pressure of >30 cm H_2O)	☐
		– Soda lime (colour, if present)	☐
		– Circle system (two-bag test, if present)	☐
Aspiration risk?	No	***suCtion***	☐
Allergies	No	***Drugs and devices***	
		– Oxygen cylinder (full and off)	☐
Abnormal investigations?	No	– Vaporizers (full and seated)	☐
		– Drips (intravenous secure)	☐
		– Drugs (labelled, total intravenous anaesthesia connected)	☐
		– Blood and fluids available	☐
		– Monitors: alarms on	☐
		– Humidifiers, warmers and thermometers	☐
Medications?	No	***Emergency***	
		– Assistant	☐
co-Morbidities?	No	– Adrenaline	☐
		– Suxamethonium	☐
		– Self-inflating bag	☐
		Tilting table	☐

Facilities: The operating room should be of an appropriate size, well lit, conform to relevant electrical safety codes and meet design requirements that minimize hazards from fire, explosion and electrocution. Electricity and fresh water should always be supplied, and a back-up electrical generator should be immediately available.

A maintenance programme must be established in each hospital. All anaesthetic and ancillary equipment should be inspected regularly by qualified personnel and a maintenance record kept. Ideally, routine maintenance should not interrupt clinical services.

Secure storage is required for medications, particularly opioid drugs, and anaesthetic equipment. A refrigerator is required for storing drugs such as suxamethonium. Infection control measures are required to ensure that potentially infectious materials or agents are not transferred between patients or personnel. These should include respiratory equipment (e.g. disposable filters to protect patients and circuits), syringes, infusion pump administration sets and multi-dose drug vials. Sterile practice must be followed for clinical procedures such as spinal anaesthesia or insertion of central venous lines.

Wherever obstetric anaesthesia is performed, a separate area for assessment and resuscitation of newborns, including designated oxygen, suction apparatus, electrical outlets, a source of radiant heat and equipment for neonatal airway management and resuscitation, should be provided.

Policies about the running of operating rooms should be agreed. These should include details on the composition and organization of operating schedules. A recordkeeping system (paper or electronic) for anaesthesia and surgery is essential.

Anaesthesia equipment: An anaesthesia delivery system or machine is a vital part of the system but cannot function safely on its own. A professionally trained anaesthesia provider and patient monitoring devices are also mandatory for the delivery of safe care. Anaesthesia equipment should be suitable for the full range of patients treated at the facility. In addition, it should function effectively in the local environment.

Anaesthesia can be given intravenously, using agents such as ketamine, or as inhaled mixtures of volatile gases, such as halothane or isoflurane. Anaesthesia gases can be delivered through continuous flow equipment (e.g. a Boyles machine), which depends on supplies of compressed gases, or by drawover equipment (e.g. an Epstein Macintosh Oxford [EMO] system), which uses ambient air with added oxygen. In both systems, a vaporizer is needed to deliver an accurate concentration of the volatile agent.

In hospitals with unreliable compressed gas supplies, continuous-flow anaesthesia machines cannot function safely; in this situation, drawover equipment or machines based on oxygen concentrators have considerable advantages. When anaesthesia machines are purchased, the local environment must be taken into account to ensure that the machine will function correctly and can be maintained or repaired.

Gas Supplies in anaesthesia: Oxygen is essential for almost all anaesthesia and must be readily available during induction, maintenance and recovery. Many patients require additional oxygen postoperatively as well. Oxygen may be supplied to operating rooms in cylinders or via pipelines from a central oxygen distribution point. Hospital oxygen systems may be based on liquid oxygen plants, large cylinders in central banks or oxygen concentrators. Whichever system is used, there must be a method for confirming that the oxygen supplies are adequate before starting anaesthesia. There should always be a back-up source of oxygen, such as a reserve cylinder.

Medical gas pipeline systems, connectors, pressure regulators and terminal units should meet national standards for identification, construction and installation. All safety regulations for the preparation, storage, identification and use of medical gases, anaesthetic drugs and related materials must be met. Wherever anaesthetic gases are used, scavenging systems within the airway circuit should be in place to reduce the risk for long-term exposure.

When oxygen concentrators are installed, users must be aware that the fraction of inspired oxygen (FiO2) delivered can vary between 0.93 and 0.99. Concentrators differ in size: some are capable of supplying an entire hospital, while others are designed to be used as the oxygen source for a single machine.

Air is commonly used during anaesthesia. Medical air is normally supplied by pipeline from a central compressed supply and is often used for a number of other purposes in operating rooms (e.g. for power tools and tourniquets) in addition to anaesthesia. Ambient air is used in draw-over anaesthesia.

Nitrous oxide is an analgesic gas often used in anaesthesia. It is supplied as a liquid in high-pressure cylinders and vaporizes to form the gas breathed during anaesthesia. Nitrous oxide is always used with oxygen. Anaesthesia machines should be designed so that it is impossible to administer a hypoxic mixture of nitrous oxide. In many countries, nitrous oxide is expensive. It is not often used in modern anaesthesia and is not classified as an essential gas. In situations of limited resources, it is safer to dispose with nitrous oxide altogether.

Monitoring: Equipment for monitoring may be integrated within the anaesthesia machine or be provided as separate modules. One monitor can display a number of parameters or have a single function. Monitors are complex, with delicate electronic components that are sensitive to heat, dust, vibration, sudden movement and rough handling.

The most important component of monitoring is the continuous presence of a trained anaesthetist, whose expertise is augmented by the physiological information displayed on the monitoring devices. In addition to monitoring, careful continuous clinical observation is required, because the equipment may not detect clinical deterioration as rapidly as a skilled professional.

Supplemental oxygen is also essential for all patients undergoing general anaesthesia, and the anaesthetist should verify the integrity of that supply. Ideally, the inspired oxygen concentration is monitored throughout anaesthesia with an instrument fitted with an alarm set off by a low oxygen concentration. This ensures that the patient is protected against oxygen supply failure or the delivery of a hypoxic gas mixture. Integrated and fail-safe systems, for example tank yokes and hose connections, should be used to prevent misconnection of gas sources. As an added measure, tissue oxygenation should also be monitored continuously by a quantitative monitor of blood oxygenation (e.g. pulse oximetry). This provides a secondary system to ensure that the patient does not become hypoxic during surgery. A redundant system such as this is essential, as the consequence of hypoxia can be

catastrophic. Hypoxia is highly preventable with careful planning and monitoring. Adequate illumination and exposure of the patient can also provide visual clues to hypoxia by allowing observation of the lips or nail beds.

As the adequacy of the airway, breathing and circulation is essential for safe delivery of anaesthesia, continuous monitoring is extremely important. For the first two, this can be accomplished by observation and auscultation at the very least, or by using a precordial, pretracheal or oesophageal stethoscope. When a breathing circuit is used, the reservoir bag can also be observed. The correct placement of an endotracheal tube can be confirmed, as can the adequacy of ventilation, by displaying the expired carbon dioxide waveform and concentration by capnography. When mechanical ventilation is used, disconnect alarms are essential to prevent catastrophic disconnection of the patient from the ventilator. Circulation is easily monitored by palpation, auscultation, a display of the pulse waveform or electrocardiograph trace. Pulse oximetry has the added benefit of continuous monitoring of both tissue perfusion and heart rate. Arterial blood pressure provides a measure of the adequacy of the peripheral circulation. It can be measured simply with a blood pressure cuff at appropriate intervals (usually at least every 5 minutes, and more frequently if indicated by clinical circumstances). Continuous measurement and display of arterial pressure using invasive monitoring may also be necessary in certain circumstances.

Homeostatic mechanisms for maintaining body temperature are frequently undermined during anaesthesia. Hypothermia can increase the risk for infection and cause problems of hypocoagulation. Hyperthermia can be one of the first signs of a medication or anaesthetic reaction. A means of measuring body temperature is an important component of patient monitoring and should be used at frequent intervals where clinically indicated, such as in a prolonged operation or in young children.

Finally, the depth of anaesthesia must be assessed regularly throughout the operation to ensure appropriate levels of pain control and sedation. This includes an assessment of the state of paralysis when neuromuscular blocking agents are used.

Ancillary equipment and medications: In addition to anaesthesia apparatus, ancillary equipment and medications are required to manage emergencies such as trauma, eclampsia, cardiac arrest and malignant hyperthermia. Patient warming devices, intravenous fluid warmers and special padding to support patients during surgery improve the quality of care. A self-inflating breathing bag is necessary in case of gas flow failure. Units for the care of children should have special paediatric equipment, including X-ray and ultrasound facilities.

Hospitals should ensure that adequate supplies of anaesthetic drugs are maintained. Table II.2.2 provides guidance for such materials and equipment, but each national society should have guidelines relevant to their environment. Drugs should be correctly stored, labelled in the local language and used before their expiration date. Safe methods of drug administration should be practised by all staff (see Objective 5).

Table II.2.2 – Guide to infrastructure, supplies and anaesthesia standards at three levels of health-care facilities

Level 1 - Small hospital or health centre (Should meet at least 'highly recommended' anaesthesia standards)	**Level 2 - District or provincial hospital (Should meet at least 'highly recommended' and 'recommended' anaesthesia standards)**	**Level 3 - Referral hospital (Should meet at least 'highly recommended', 'recommended' and 'suggested' anaesthesia standards)**
• Rural hospital or health centre with a small number of beds (or urban location in an extremely disadvantaged area); sparsely equipped operating room for 'minor' procedures • Provides emergency measures in the treatment of 90–95% of trauma and obstetrics cases (excluding caesarean section) • Referral of other patients (for example, obstructed labor, bowel obstruction) for further management at a higher level	• District or provincial hospital (e.g. with 100–300 beds) and adequately equipped major and minor operating rooms • Short-term treatment of 95–99% of major lifethreatening conditions	• A referral hospital with 300–1000 or more beds and basic intensive care facilities. Treatment aims are the same as for level 2, with the addition of: • Ventilation in operating room and intensive care unit • Prolonged endotracheal intubation • Thoracic trauma care • Homodynamic and inotropic treatment • Basic intensive care unit patient management and monitoring for up to 1 week: all types of cases, but possibly with limited provision for: – Multi-organ system failure – Haemodialysis – Complex neurological and – cardiac surgery – Prolonged respiratory failure – Metabolic care or monitoring

Table II.2.2 – Guide to infrastructure, supplies and anaesthesia standards at three levels of health-care facilities - continued

Essential procedures	Essential procedures	Essential procedures
• Normal delivery • Uterine evacuation • Circumcision • Hydrocoele reduction, incision and drainage • Wound suturing • Control of haemorrhage with pressure dressings • Debridement and dressing of wounds • Temporary reduction of fractures • Cleaning or stabilization of open and closed fractures • Chest drainage (possibly) • Abscess drainage	• Same as level 1 with the following additions: • Caesarean section • Laparotomy (usually not for bowel obstruction) • Amputation • Hernia repair • Tubal ligation • Closed fracture treatment and application of plaster of Paris • Acute open orthopaedic surgery: e.g. internal fixation of fractures • Eye operations, including cataract extraction • Removal of foreign bodies: e.g. in the airways • Emergency ventilation and airway management for referred patients such as those with chest and head injuries	• Same as level 2 with the following additions: • Facial and intracranial surgery • Bowel surgery • Paediatric and neonatal surgery • Thoracic surgery • Major eye surgery • Major gynaecological surgery, e.g. vesico-vaginal repair
Personnel	**Personnel**	**Personnel**
• Paramedical staff or anaesthetic officer (including on-the-job training) who may have other duties as well • Nurse–midwife	• One or more trained anaesthetists • District medical officers, senior clinical officers, nurses, midwives • Visiting specialists, resident surgeon, obstetrician or gynaecologist	• Clinical officers and specialists in anaesthesia and surgery

Table II.2.2 – Guide to infrastructure, supplies and anaesthesia standards at three levels of health-care facilities - continued

Drugs	Drugs	Drugs
• Ketamine 50 mg/ml injection • Lidocaine 1% or 2% • Diazepam 5 mg/ml injection, 2 ml or midazolam 1 mg/ ml injection, 5 ml • Pethidine 50 mg/ ml injection, 2 ml • Morphine 10 mg/ml, 1 ml • Epinephrine (adrenaline) 1 mg • Atropine 0.6 mg/ml • Appropriate inhalation anaesthetic if vaporizer available	• Same as level 1, but also: • Thiopental 500 mg/g powder or propofol • Suxamethonium bromide 500 mg powder • Pancuronium • Neostigmine 2.5 mg injection • Ether, halothane or other inhalation anaesthetics • Lidocaine 5% heavy spinal solution, 2 ml • Bupivacaine 0.5% heavy or plain, 4 ml • Hydralazine 20 mg injection • Frusemide 20 mg injection • Dextrose 50% 20 ml injection • Aminophylline 250 mg injection • Ephedrine 30/50 mg ampoules • Hydrocortisone • (?) Nitrous oxide	• Same as level 2 with the following additions: • Propofol • Nitrous oxide • Various modern neuromuscular blocking agents • Various modern inhalation anaesthetics • Various inotropic agents • Various intravenous antiarrhythmic agents • Nitroglycerine for infusion • Calcium chloride 10% 10 ml injection • Potassium chloride 20% 10 ml injection for infusion

Table II.2.2 – Guide to infrastructure, supplies and anaesthesia standards at three levels of health-care facilities - continued

Equipment: capital outlay	Equipment: capital outlay	Equipment: capital outlay
• Adult and paediatric self-inflating breathing bags with masks • Foot-powered suction • Stethoscope, sphygmomanometer, thermometer • Pulse oximeter • Oxygen concentrator or tank oxygen and a drawover vaporizer with hoses • Laryngoscopes, bougies	Complete anaesthesia, resuscitation and airway management systems including: • Reliable oxygen sources • Vaporizer(s) • Hoses and valves • Bellows or bag to inflate lungs • Face masks (sizes 00–5) • Work surface and storage • Paediatric anaesthesia system • Oxygen supply failure alarm; oxygen analyser • Adult and paediatric resuscitator sets • Pulse oximeter, spare probes, adult and paediatric* • Capnograph* • Defibrillator (one per operating suite or intensive care unit)* • Electrocardiograph monitor* • Laryngoscope, Macintosh blades 1–3(4) • Oxygen concentrator(s) (cylinder) • Foot or electric suction • Intravenous pressure infusor bag • Adult and paediatric resuscitator sets • Magill forceps (adult and child), intubation stylet or bougie • Spinal needles 25G • Nerve stimulator • Automatic non-invasive blood pressure monitor	Same as level 2 with these additions (per each per operating room or intensive care unit bed, except where stated): • Electrocardiograph monitor* • Anaesthesia ventilator, reliable electric power source with manual override • Infusion pumps (two per bed) • Pressure bag for intravenous infusion • Electric or pneumatic suction • Oxygen analyser* • Thermometer (temperature probe*) • Electric warming blanket • Electric overhead heater • Infant incubator • Laryngeal mask, airways sizes 2, 3, 4 (three sets per operating room) • Intubating bougies, adult and child (one set per operating room) • Anaesthetic agent (gas and vapour) analyser • Depth of anaesthesia monitors are being increasingly recommended for cases at high risk of awareness but are not standard in many countries.

** It is preferable to combine these monitoring modalities in one unit.*

Table II.2.2 – Guide to infrastructure, supplies and anaesthesia standards at three levels of health-care facilities - continued

Equipment: disposable	Equipment: disposable	Equipment: disposable
• Examination gloves • Intravenous infusion and drug injection equipment • Suction catheters size 16 FG • Airway support equipment, including airways and tracheal tubes • Oral and nasal airways	• Electrocardiograph electrodes • Intravenous equipment (minimum fluids: normal saline, Ringer lactate and dextrose 5%) • Paediatric giving sets • Suction catheters size 16 FG • Sterile gloves sizes 6–8 • Nasogastric tubes sizes 10–16 FG • Oral airways sizes 000–4 • Tracheal tubes sizes 3–8.5 mm • Spinal needles sizes 22 G and 25G Batteries size C	• Same as level 2 with these additions: • Ventilator circuits • Yankauer suckers • Giving sets for intravenous infusion pumps • Disposables for suction machines • Disposables for capnography, oxygen analyser, in accordance with manufacturers' specifications: • Sampling lines • Water traps • Connectors • Filters and fuel cells

Adapted in part from (28,49)

Infrastructure, supplies and care standards: WHO has established a list of necessary equipment for resuscitation, acute care and emergency surgery and anaesthesia in countries with limited health budgets. This is updated in Table II.2.2. The three-level model takes into account the fact that the provision of staff and equipment to meet the needs of the population served by the type of hospital considered must be within the constraints of available resources and that not all facilities can provide every service.

In the smallest units, many basic surgical procedures are undertaken with local anaesthesia. Emergency operations (notably caesarean sections and other obstetric procedures) are often performed under ketamine or regional anaesthesia without access to proper facilities or anaesthetic equipment. At times, anaesthesia is provided under the supervision of the surgeon as the most highly qualified health professional available. Despite the fundamental issue of resources, all health units should strive to meet the 'highly recommended' WHO standards listed below. They should also work to meet as many of the 'recommended' standards as possible.

In considering the formulation of standards and the requirement to balance resources against requirements, health authorities and administrators should align the standards of 'highly recommended', 'recommended' and 'suggested' with the three levels of facilities outlined in Table II.2.2. For each level of facility, it is desirable to exceed the applicable anaesthesia standard. In well-resourced locations with well-functioning facilities, professionals should be able to exceed the 'recommended' anaesthesia standard.

Recommendations

Highly Recommended:

- The first and most important component of peri-anaesthetic care is the continuous presence of a vigilant, professionally trained anaesthesia provider. If an emergency requires the brief temporary absence of the primary anaesthetist, judgement must be exercised in comparing the threat of an emergency to the risk of the anaesthetized patient's condition and in selecting the clinician left responsible for anaesthesia during the temporary absence.
- Supplemental oxygen should be supplied for all patients undergoing general anaesthesia. Tissue oxygenation and perfusion should be monitored continuously using a pulse oximeter with a variable-pitch pulse tone loud enough to be heard throughout the operating room.
- The adequacy of the airways and of ventilation should be monitored continuously by observation and auscultation. Whenever mechanical ventilation is employed, a disconnect alarm should be used.
- Circulation should be monitored continuously by auscultation or palpation of the heart beat or by a display of the heart rate on a cardiac monitor or pulse oximeter.
- Arterial blood pressure should be determined at least every 5 minutes and more frequently if indicated by clinical circumstances.
- A means of measuring body temperature should be available and used at frequent intervals where clinically indicated (e.g. prolonged or complex anaesthesia, children).
- The depth of anaesthesia (degree of unconsciousness) should be assessed regularly by clinical observation.

Recommended:

- Inspired oxygen concentration should be monitored throughout anaesthesia with an instrument fitted with a low-oxygen concentration alarm. In addition, a device to protect against the delivery of a hypoxic gas mixture and an oxygen supply failure alarm should be used.
- Continuous measurement and display of the expired carbon dioxide waveform and concentration (capnography) should be used to confirm the correct placement of an endotracheal tube and also the adequacy of ventilation.
- The concentrations of volatile agents should be measured continuously, as should inspiratory or expired gas volumes.
- An electrocardiograph should be used to monitor heart rate and rhythm.
- A cardiac defibrillator should be available.
- Body temperature should be measured continuously in patients in whom a change is anticipated, intended or suspected. This can be done by continuous electronic temperature measurement, if available.
- A peripheral nerve stimulator should be used to assess the state of paralysis when neuromuscular blocking drugs are given.

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Objective 3

The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function

Securing the airway of a patient undergoing general anaesthesia is the single most critical event during induction. Reduced tone in the upper airway results in airway collapse and diminished protective reflexes expose the patient to the risk of aspiration. In addition, most anaesthetics reduce respiratory drive, and administration of muscle relaxants at clinical doses causes complete paralysis, preventing patients from breathing on their own. In this situation, the anaesthetized patient is extremely vulnerable to hypoxia and completely dependent on the anaesthetist for airway maintenance and ventilation. In the past, adverse outcomes associated with respiratory events were the largest class of injury in the American Society of Anesthesiologists Closed Claims Project (*1*). Inadequate ventilation, oesophageal intubation, difficult tracheal intubation and aspiration were the most common mechanisms of respiratory-related adverse outcomes (*2–4*). Inability to maintain oxygenation in a patient is one of the most feared situations in anaesthesia. Inadequate management of a failed airway, including inadequate identification of its risk, continues to contribute to preventable mortality associated with anaesthesia around the world.

Incidence of difficult and failed airway management

A failed airway has been defined as three unsuccessful attempts at orotracheal intubation by a skilled practitioner or failure to maintain acceptable oxygen saturation (usually ≥ 90%) in an otherwise normal patient (*5*). While failure to secure an airway is infrequent in much of the developed world, it can have catastrophic consequences for the patient. Mortality from anaesthesia-related procedures frequently can be due to failure to recognize and address airway and ventilation problems that compromise the patient's oxygenation. While many strategies can be used to manage a difficult airway—such as mask ventilation, insertion of a laryngeal mask airway, endotracheal intubation, fibre-optic intubation and, in the most extreme cases, creation of a surgical airway—simultaneous failure of these approaches is fatal.

Difficulties can arise with any of the strategies described above, and while the incidence of these difficulties has been estimated, it varies with the skill of the anaesthetist and the case mix. Table II.3.1 presents the reported incidence rates of failure with various techniques for airway management. Apart from failure of these techniques, some situations are particularly risky and can result in airway loss. Airway difficulties during emergency intubation can occur in up to 20% of emergency cases, and the incidence of failed intubation and ventilation is 10-fold higher in obstetric anaesthesia than in other settings *(6,7)*.

A number of reviews show that airway loss continues to plague anaesthesia delivery. The ninth report of the Victorian Consultative Council on Anaesthetic Mortality and Morbidity in Australia listed 41 anaesthesia-related events between 2000 and 2002, giving an estimated mortality rate associated with anaesthesia of 1 in 47,000 (*11*). Airway difficulties were the cause of two deaths and 11 morbid events; aspiration was the cause of a further five deaths and two major morbid events; and 12 cases of acute negative pressure pulmonary oedema were attributed to airway obstruction during emergence from anaesthesia. In addition, failures in airway management or ventilation contributed to 16 deaths reported throughout Australia over the same period (*12*). The Australian Incident Monitoring Study (AIMS) reported 160 difficult intubations; lack of an adequate preoperative assessment and preparation contributed to the failure to predict difficulties in over half of these cases (*13*). Difficulty with face-mask ventilation occurred in 23 incidents, and 12 patients required emergency airway procedures. While deaths were rare, the report concluded that problems with airway management remain a challenge.

Table II.3.1 – Failure of airway management, by technique

Technique	Failure rate (%)
Bag mask ventilation (*8*)	0.16
Supraglottic airway insertion (*9*)	2-6
Intubation (*10*)	0.05–0.35
Intubation requiring multiple attempts or blades with optimal external laryngeal manipulation occurs in 1-18% of intubations	
Intubation requiring multiple attempts or blades with optimal external laryngeal manipulation and also requiring multiple laryngoscopists occurs in 1-4% of intubations	
Intubation and ventilation (*10*)	0.0001–0.02

Similar problems are reported from other developed countries. In the United States, 179 claims arising from difficulties in airway management were identified in the American Society of Anesthesiologists Closed Claims Project database between 1985 and 1999 (*14*). Most (87%) occurred during perioperative care, while the remainder occurred at locations other than the operating room. Death resulted from these airway crises 58% of the time and brain damage 100% of the time, and persistent attempts at intubation were associated with an increased likelihood of death or brain damage. A study of mortality associated with anaesthesia in the Netherlands showed a mortality rate of 1.4 per 10,000 anaesthesias; of the 119 anaesthesiarelated deaths, 12 (10%) were associated with ventilatory management (*15*).

Much higher avoidable mortality associated with anaesthesia has been reported in developing countries. In Zimbabwe, a rate of 1:3000 was reported, with airway catastrophe being a major cause of death (*16*). In Zambia, the death rate attributable to anaesthesia was 1:1900, half of which was a direct result of failed airway management (*17*). In Malawi, the anaesthesia-attributable death rate was 1:500, nearly all of which stemmed from failure to secure the airways or prevent aspiration (*18*). In Togo, the mortality rate associated with anaesthesia was 1:150, and eight of the 11 deaths (out of 1464 anaesthesias) were due to compromised airways (*19*). These studies illustrate the hazards that surgical patients face due to the pervasive absence of safe anaesthetic practice.

Taken collectively, these results show that failure to maintain an airway and to ventilate and oxygenate patients adequately continues to pose a serious risk during anaesthesia throughout the world. While there are few data from countries with limited resources, the risk for harm is even greater when optimal assistance, expertise and equipment are not available.

Airways assessment

Preoperative recognition of a difficult airway allows for appropriate preparation and planning (*20–23*). Failure to evaluate the airway and anticipate problems is widely accepted as the most important factor in ventilation and oxygenation failure (*1*). Therefore, every patient's airway should be thoroughly assessed before anaesthesia and the results of the assessment recorded.

A complete airway assessment includes the patient's history, medical conditions (including components of airway compromise, such as sleep apnoea and asthma), prior surgery and anaesthesia and previous difficulties with anaesthesia. It also includes a thorough physical examination, with particular attention to body habitus and obesity, characteristics of the neck including shortness or lack of mobility, and characteristics of the jaw including a receding jaw or limited ability to open the mouth. Dentition is also an important component of assessment: loose or protruding teeth and dentures or implants should be noted. Several tests or investigations can be used in evaluating a questionably difficult airway, including airway tests (discussed below) and radiographs (including computed tomography if tracheal compression is suspected).

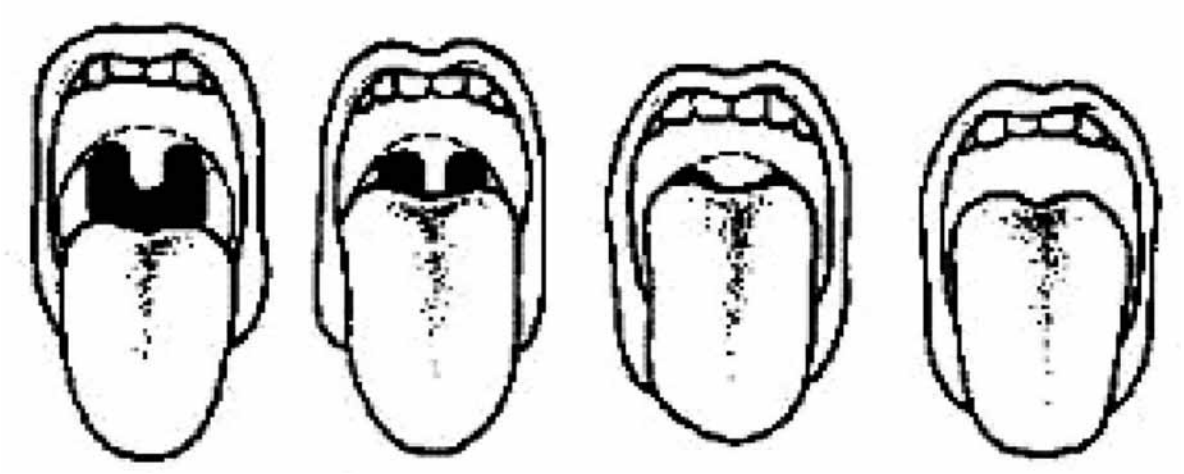
A number of bedside screening tests have been proposed for identifying difficult airways, but no single test or combination of tests can always predict a difficult airway (*8*,*24*). As difficult intubation is rare, even highly specific and sensitive tests have low positive predictive value (*25*,*26*). Diagnostic reliability is increased by combining tests and using clinical judgement in evaluating characteristics that might predispose the patient to difficulty, such as obesity or a short, immobile neck (*24*). The most useful bedside test for predicting a difficult intubation in an apparently normal patient is a combination of the Mallampati classification and thyromental distance.

Thyromental distance: Patil and Zauder first described measurement of the thyromental distance in 1983 (*27*). This objective test is based on a measurement taken with a ruler or thyromental gauge from the thyroid notch to the undersurface of the mandible with the head fully extended. In an adult, laryngoscopy and intubation should be straightforward if the thyromental distance is > 6.5 cm, challenging if it is 6.0–6.5 cm (especially if associated with prominent teeth, receding jaw, temporomandibular joint problems or cervical spine abnormalities), and often impossible if the thyromental distance is < 6.0. In fact, difficult intubation can occur with both extremes of the distance (*28*).

Mallampati classification: The Mallampati test is a subjective evaluation of the ratio of oral cavity volume to tongue volume (*29*). Mallampati et al. originally proposed three oropharyngeal classes, but modified this to comprise four classes on the basis of experience with the technique (*30*,*31*). The test is performed on a sitting patient with the head in a neutral position, mouth fully opened and tongue fully extended and involves evaluating the visibility of anatomical structures, as shown in Figure 3.1. The difficulty of intubation is then classified, a Class 1 airway being the easiest to manage and control by intubation, and a Class 4 airway being potentially the most difficult.

These screening tests are designed to help clinicians predict the potential difficulty of intubation during airway control and management. They are therefore useful for assessment and their use can prevent problems (*32*). They cannot be used to predict potential difficulty with perfect accuracy, however, and it would be dangerous to assume that an evaluation indicating an easy intubation will necessarily always be a simple intubation. A patient whose airway defies accurate prediction has the highest likelihood of catastrophe during induction.

Fig.3.1 - Mallampati classificationof the airway



Class 1
soft palate, fauces, uvula, anterior and posterior pillars visible

Class 2
soft palate, fauces, uvula visible

Class 3
soft palate, base of uvula visible

Class 4
soft palate not visible at all

Management of the airway

Guidelines for managing a difficult airway are numerous, and many strategies exist to manage the airway during induction (*22*,*33*–*38*). The general themes of all the guidelines and recommendations are similar: avoid hypoxia; prevent trauma; use pre-planned strategies; attempt to identify a difficult airway preoperatively; be prepared with equipment, assistance and skill; be practised in a range of techniques; have back-up plans; confirm endotracheal intubation; prepare a clear extubation strategy; and, if the airway is difficult, consider managing patients while they are awake. The essential requirement for managing a difficult airway is a skilled practitioner with adequate assistance, a clear plan of action and suitable equipment.

Several techniques can be considered in planning the management of an airway, each of which can be used according to the circumstances, or a combination can be used if one is inadequate for maintaining a patent airway.

Face-Mask ventilation: Ventilation with a face mask is a fundamental skill in anaesthesia. Success depends on the ability to maintain a patient airway while holding an airtight seal with a bag-mask. It requires proficiency acquired with practice. The advent of the laryngeal mask airway reduced the need to use face-mask ventilation in the maintenance of anaesthesia. In countries with a ready supply of laryngeal mask airways, this skill may be less widespread than formerly.

Face-mask ventilation, while the most basic of skills necessary to maintain an airway, can be difficult. Problems occur when the practitioner cannot provide sufficient gas exchange because of inadequate mask seal, large volume leaks or excessive resistance to the ingress or egress of gas (*22*). The incidence of difficult mask ventilation in adults is estimated to be 1.4–5%, and ventilation is impossible to achieve in 0.16% of anaesthetized patients (*8*,*39*). Independent risk factors for difficult mask ventilation include age > 55 years, body mass index > 26 kg/m^2, presence of a beard, lack of teeth, history of snoring, severely limited jaw protrusion and a thyromental distance < 6 cm. Of these, only a beard is easy to modify.

Supraglottic airway ventilation: The laryngeal mask airway has become the device of choice for supraglottic airway ventilation. Its growing popularity, where it is available, is testament to its superiority to manual face-mask ventilation. Again, skill and practice are required to appropriately insert it and safely maintain it in position, and inadequate supraglottic airway ventilation occurs after 2–6% of insertions (*9*). Appropriate patient selection is also essential to avoid problems and complications (*40*,*41*). Factors associated with difficult supraglottic airway use include restricted mouth opening, upper airway obstruction at or below the level of the larynx, a disrupted or distorted airway, stiff lungs and a stiff cervical spine (*42*).

Endotracheal intubation: Endotracheal tubes have become fundamental to the practice of anaesthesia, particularly since the advent of neuromuscular blockade (*43*). Its usefulness for maintaining the patency of the airway in anaesthetized patients is undisputed. The skill required to accurately insert and properly maintain an endotracheal tube comes from substantial practice, as well as thorough knowledge of the anatomy of the upper airways and comfort with its many physiologic variations. Difficult endotracheal intubation occurs when multiple attempts are required, either in the presence or absence of disease (*22*).
A four–grade scoring system has been devised to define the difficulty of direct laryngoscopy on the basis of the appearance of the larynx (*6*): Grade I, full view; Grade II, partial view; Grade III, epiglottis only; and Grade IV, no epiglottis visualized. Recording and transmitting

this information among care providers when a difficult airway is encountered is fundamental to safe practice. The incidence of difficult intubation depends on the skill of the laryngoscopist. Techniques and devices to facilitate successful intubation of the trachea include optimum external laryngeal manipulation, appropriate patient positioning, purpose-designed laryngoscope blades, appropriate stylets or bougies and fibre-optic laryngoscopes. True expertise in endotracheal intubation comes from extensive training and experience, which should be incorporated into the wider expertise associated with overall management of a difficult airway. It is clearly unsafe practice to expect safe management of difficult airways from relatively untrained personnel with inadequate resources.

Fibre-optic intubation: The ability to cannulate the airways by flexible bronchoscopy is a skill required of all anaesthetists. It is considered the gold standard for managing an airway expected to be difficult (*44*). The indications for its use are numerous: endotracheal intubation of normal and difficult airways, placing selective segmental blockers and tubes such as for thoracic cases, assessing airway function and diagnosing pathology, monitoring during tracheostomy, changing the endotracheal tube, confirming tube placement, broncho-alveolar lavage, placing nasogastric tubes, facilitating other airway management techniques such as retrograde intubation and laryngeal mask airway placement in difficult patients, avoiding extension of the neck or dental damage, performing intubation with topical anaesthesia and improving experience and teaching (*45–48*). Relative contraindications are important to recognize however, and include an acute life-threatening airway obstruction, an uncooperative conscious patient, copious secretions or blood in the airway, an airway-obstructing abscess or friable tumour and distortion of anatomy that limits the airway space (*49*,*50*).

While clearly useful in patients with difficult airways, fibre-optic intubation can have a number of important adverse consequences, such as hypoxia, bacteraemia, trauma to the airway and laryngeal cords and alterations in blood pressure and heart rate (*51–54*). In addition, the apparatus can be expensive to acquire and requires several other functioning pieces of equipment, including endoscopic masks and airways, oxygen, suction, bite blocks and a topical anaesthetic spray or atomizer to allow comfortable passage of the bronchoscope.

The success rate of flexible bronchoscopy can be very high, but it depends on case selection and the skill of the operator. A review of a series of fibre-optic intubations showed a 98.8% success rate (*55*). Yet lack of training and experience in flexible bronchoscopy are major problems, even where this equipment is routinely available. A survey of 386 anaesthesiologists in New Zealand revealed that the mean number of fibre-optic intubations performed per year was three for consultants and four for trainees, and confidence in the technique varied widely (*44*).

Fibre-optic intubation requires skill and resources, but it is useful for establishing the status of the airway in patients who are at high risk for airway failure. The technique should be reserved for carefully selected cases and used by anaesthetists experienced with it and familiar with the equipment and manoeuvres required.

Below are provisional lists of the ideal equipment for managing a difficult airway drawn up by the Australian and New Zealand College of Anaesthetists (*56*).

Immediately available (for the management of adult patients without upper airway obstruction):

- Oxygen
- CO_2 Detector
- Self-inflating bag
- Pulse oximeter
- Suction
- Means for calling for help
- Face masks #3, 4 and 5 suitable for artificial ventilation
- Oropharyngeal airways #3, 4, 5 and 6
- Nasopharyngeal airways #6, 7 and 8
- Laryngeal masks #3, 4 and 5
- Endotracheal tubes, cuffed, #6, 7, and 8
- Laryngoscope handles x 2
- Compatible blades #3 and 4
- Angled blade (e.g. Kessel blade)
- Tracheal tube introducer able to hold its shape or with a coudé tip
- Malleable stylet
- Water-soluble lubricant
- Magill introducing forceps
- Difficult airway algorithm flowchart

Readily available 'difficult airway container' (should ideally be sealed, available within 60 seconds, all equipment within it compatible, restocked promptly after each use and all staff oriented to its location)

- Short laryngoscope handle
- At least one alternative blade (straight)
- Intubating laryngeal mask airway #3, 4 and 5, with fast-track dedicated tubes and stabilizing rod or C-track
- Specialized tracheal tubes: reinforced #5 and 6, cuffed; microlaryngoscope 5- and 6-mm
- Aintree intubating catheter
- Flexible intubating bronchoscope with portable battery light source
- Fibre-optic equipment with spare battery or light source, intubating airways, local anaesthetic (sprays, jelly, atomisers), bite block
- Easy-tube: small and adult, or Combi-tube
- Airway exchange catheter
- Supreme laryngeal mask airway (or equivalent) # 3, 4 and 5
- Surgical cricothyroidotomy kit (scalpel with #20 blade, tracheal hook, Trousseau dilator, 6- or 7-mm tracheal and tracheostomy tubes)
- Cricothyroidotomy cannula with high-pressure jet ventilation system oxygen flow modulator
- Large-bore cricothyroidotomy cannula
- Oesophageal intubation detector device such as a capnograph
- Pulse oximeter

Aspiration of gastric contents

The incidence of aspiration during general anaesthesia has been estimated at 2.6 per 10,000 in patients undergoing elective surgery and 11 per 10,000 in patients undergoing emergency procedures (*57*). The overall incidence of aspiration with a laryngeal mask airway is 2 per 10,000 (*58*). Aspiration remains a significant risk for patients undergoing anaesthesia, even in the most technologically advanced settings, and can result in substantial morbidity (*2*,*3*). Predisposing factors for aspiration include emergency surgery in a nonfasting patient, obesity, a difficult airway or difficulty with intubation, steep Trendelenburg position with an inflated abdomen, pregnancy and previous gastric surgery. The risk for aspiration can be reduced by recognizing these risk factors, decompressing the stomach before induction and induction and intubation in rapid succession with pre-oxygenation and cricoid pressure. If mask ventilation is necessary, low pressure and slow inflation times are important. The risk for aspiration can also be reduced by appropriate selection of both patients and the method of airway control, correct insertion of airway devices and appropriate depth of anaesthesia.

It is widely accepted that application of cricoid pressure is important for preventing passive regurgitation of stomach contents, predicated on the assumption that cricoid pressure will be applied correctly (*59*). In fact, the efficacy of cricoid pressure is largely unproven, and most clinicians and their assistants do not apply it correctly (*60*,*61*). Aggressive cricoid pressure can cause tracheal compression and prevent ventilation or require high bag pressures; it can also distort the airways during intubation and can create a worse view at laryngoscopy (*62*,*63*). Thus, unskilled application of cricoid pressure might actually increase the risks for failed intubation and regurgitation (*60*).

Aspiration of gastric contents may produce harm either by blockage of the airway with solid material resulting in immediate hypoxia or by gastric acid causing a pneumonitis. Pneumonitis, which may progress to acute respiratory distress syndrome, is worsened by low pH of the aspirate. An appropriate period of fasting is recommended prior to elective surgery to minimize gastric contents and the likelihood of aspiration; this is not usually feasible in emergency surgery, however. Patients at risk of aspiration can be treated prior to elective surgery by either a proton pump inhibitor (e.g. omeprazole, lansoprazole) or an H2 antagonist (e.g. ranitidine, cimetidine) and prior to emergency surgery with oral sodium citrate.

Airway disasters, while uncommon, are lethal and entirely preventable with appropriate planning, adequate pre-induction airway evaluation and careful preparation of the patient and equipment. The skill, experience and judgement of a practised anaesthetist and the timely and appropriate support of assistants can avert airway catastrophes and prevent death from anaesthetic administration. All anaesthetists should have a strategy for intubation of the difficult airway.

Recommendations

Highly recommended:

- All patients should undergo an objective evaluation of their airway before induction of anaesthesia, even when intubation is not anticipated, in order to identify potential difficulties in airway management.
- The anaesthetist should have a planned strategy for managing the airways and be prepared to execute it, even if airway loss is not anticipated.
- When the anaesthetist suspects a difficult airway, assistance during induction should be immediately available and a back-up plan for airway management should be clearly identified.
- When a patient is known to have a difficult airway, alternative methods of anaesthesia should be considered, including regional anaesthesia or awake intubation under local anaesthetic.
- All anaesthetists should maintain their airway management skills and be familiar with and proficient in the multiple strategies for dealing with difficult airways.
- After intubation, the anaesthetist should always confirm endotracheal placement by listening for breath sounds as well as gastric ventilation and monitoring the patient's oxygenation with a pulse oximeter.
- Patients undergoing elective surgery should be fasting prior to anaesthesia. Those at risk of aspiration should be pre-treated to reduce gastric secretion and increase pH.

Recommended:

- The anaesthetist should confirm endotracheal placement after intubation by use of capnography.
- The results of the airway evaluation and a description of the ease or difficulty of intubation, if performed, should be recorded in the anaesthesia record.

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Objective 4

The team will recognize and effectively prepare for risk of high blood loss

Loss of a large volume of blood, especially when associated with haemodynamic instability, has been clearly associated with poor surgical outcome (*1*). Controlling haemorrhage and mitigating its clinical effects by appropriate fluid resuscitation are important components of intraoperative care. Clinical knowledge of resuscitation in the setting of haemorrhagic hypovolaemia was initially based on field observations of soldiers injured in battle (*2*). Rapid accumulation of scientific knowledge of the physiology of shock came during the twentieth century with controlled experiments in animal models (*3*). This work conclusively demonstrated that fluid resuscitation is essential to reverse the signs and symptoms of shock from hypovolaemia (*4*).

In advanced trauma care systems, standard practice dictates early initiation of intravenous access and fluid administration to victims of trauma. In epidemiological studies, haemorrhage has been shown to be the major cause of death of trauma victims (*5*). The Advanced Trauma Life Support course directed by the American College of Surgeons mandates the insertion of two large-bore intravenous lines for all traumatically injured patients as soon as possible, including before hospitalization (*6*). This allows the administration of fluid and medications before arrival at the hospital and minimizes delays once the patients have arrived at a facility capable of delivering care. Early attempts at manual pressure control of external haemorrhage are also important.

Table II.4.1 – Classification of hypovolaemic shock associated with acute blood loss (in adults)

	Class I	**Class II**	**Class III**	**Class IV**
Blood loss	≤ 750 ml	750–1500 ml	1500–2000 ml	> 2000 ml
% of blood volume lost	15%	15–30%	30–40%	> 40%
Pulse rate	< 100	> 100	> 120	> 140
Blood pressure	Normal	Normal to decreased	Decreased	Markedly decreased
Mental status	Normal to slightly anxious	Mildly anxious	Anxious and confused	Confused or lethargic
Urine output	Normal	Reduced	Minimal	Nil
Fluid replacement	Crystalloid	Crystalloid	Crystalloid and blood	Crystalloid and blood

From American College of Surgeons Advanced Trauma Life Support manual (6)

Shock can be categorized clinically by the magnitude of blood loss (Table II.4.1). Up to 15% of the circulating volume can be lost without obvious clinical symptoms, particularly in healthy individuals. By the time 30% of the circulating volume is lost, however, patients usually begin to display the early signs of shock: tachycardia, hypotension and anxiety. With a volume loss greater than 30%, hypotension, sustained increases in heart rate and confusion are clearly present. Blood loss exceeding 40% of the total body circulating volume is immediately life-threatening and manifests as a mentally altered, hypotensive and oliguric patient. While the changes in pulse rate listed for the different classes of shock usually hold true, massive rapid uncompensated blood loss can paradoxically result in relative bradycardia (*7*,*8*). In addition, the absence of tachycardia does not reliably rule out severe blood loss (*9–12*). Other important caveats to the characteristics of different classes of shock are that the blood pressure of young patients (particularly children) can remain fairly high even after profound haemorrhage and that blood pressure and heart rate can be unreliable indicators in patients receiving beta-blockers or other medications with cardiovascular effects. Therefore, the clinical picture of shock might not manifest exactly as depicted in text books. Nonetheless, severe haemorrhage is an immediate threat to life and must be managed immediately.

The aggressiveness of fluid resuscitation during prehospital management is still the subject of much debate. Conflicting reports of increased mortality associated with fluid resuscitation during uncontrolled and ongoing blood loss has led some to advocate fluid restriction until definitive care begins (*13*,*14*). The type of fluid is also the subject of discussion, and the usefulness of various types of crystalloid solutions in prehospital management continues to be

evaluated (*15*). Nevertheless, there is no debate on the mandatory need for fluid support during definitive intervention for hypovolaemic patients.

Hypovolaemia can have disastrous consequences for surgical patients and has been recognized as a major contributor to avoidable mortality and morbidity. Identifying current or potential hypovolaemia and instituting a resuscitation plan are essential for reducing surgical morbidity and mortality. Preparation for instability in a patient with hypovolaemia includes understanding the degree of and reason for the hypovolaemia, establishing appropriate intravenous access, ensuring adequate supplies of fluids for resuscitation, confirming the availability of blood products where appropriate, and coordinating resuscitation with the operating team. As blood loss is a major contributor to hypovolaemia, control of haemorrhage must be coupled with a well-thought-out plan for resuscitation to optimize the patient's outcome. Dehydration also contributes to preoperative hypovolaemia. It can be due to inadequate fluid intake by an ill patient, excess fluid loss (through e.g. diarrhoea or vomiting) or redistribution of fluid volume out of the circulation (as in e.g. bowel obstruction or peritonitis). Additionally, vasodilation due to sepsis or spinal cord injury can result in a relative hypovolaemic state. Accurate identification of these situations allows timely, targeted therapy and can reduce mortality (*16*). Intra-operative care differs from pre-hospital resuscitation in that intra-operative manoeuvres can be both the cause and the treatment of continuing blood loss. Therefore, adequate preoperative preparation is essential to mitigate or avoid the physiological derangements of intra-operative hypovolaemia caused by excessive blood loss or other physiological events, such as decreased sympathetic tone due to anaesthetic agents or third spacing of fluids. When loss of a large volume of blood is either expected or a major risk, placement of adequate intravenous access before skin incision will help the team to keep the volume status adequate.

Resuscitation of hypovolaemic patients

Patients who present for surgery in a volume-depleted state should be resuscitated before surgery whenever possible. Intravenous access should be obtained promptly and resuscitation begun in an efficient fashion to minimize delays in performing the operation. Fluid deficits should be remedied by infusion of crystalloid solutions. In certain circumstances, some of the fluid deficit can be replaced by oral intake; however, this is often undesirable in gastrointestinal conditions, impending general anaesthetic or other clinical concerns.

Monitoring of fluid status should be instituted wherever feasible, tailored to the specific clinical situation and include regular evaluation of haemodynamic parameters, such as pulse rate and blood pressure (see Objective 2). It may also include urinary catheterization, central venous cannulation and other invasive monitoring. Communication among the clinicians caring for the patient in the pre-, intra- and postoperative periods will improve resuscitation and allow for appropriate timing of the operation.

Prevention of blood loss

Some procedures, such as caesarean section or major vascular surgery, inevitably involve heavy blood loss. Other circumstances can also predispose a patient to unusually heavy bleeding during an operation, such as reoperation or dissections known to be difficult. The first step in mitigating blood loss during an operation is prevention. Known coagulation deficits should be corrected before surgery whenever clinically possible. The surgical, anaesthetic and nursing personnel involved in an operation should all be aware of the potential for major blood loss before the procedure and be prepared for it.

Ensuring appropriate intravenous access is a critical step and allows the anaesthetist to respond to fluctuations in blood pressure (*17*).

Access may take the form of large-bore peripheral lines, central venous catheters or some combination of the two. If the expected blood loss is greater than 500 ml for an adult or 7 ml/kg in children, the observed standard of practice dictates the insertion of two wide-bore intravenous lines or a central venous catheter (also preferably large-bore) to allow for adequate resuscitation. When the need for a blood transfusion is anticipated, operating teams should communicate early with the blood bank to ensure prompt availability of cross-matched blood products. When the patient is bleeding before surgery, it is imperative that all members of the operating team be aware of the source and estimated volume of blood loss.

Management of blood loss

If surgery is undertaken in an emergency or urgently for haemorrhage, complete preoperative resuscitation is often neither practical nor desirable, and resuscitation must be coupled with surgery to stem the haemorrhage. Again, large-bore intravenous access must be obtained and resuscitative measures instituted as soon as possible before operation. Volume resuscitation includes infusion

of crystalloid solutions and transfusion of blood products or other volume expanders. Evidence is accumulating for the effectiveness of transfusing fresh-frozen plasma, when available, for each one or two units of packed red blood cells to combat coagulopathy (*18–21*). While increasing the amount of fresh-frozen plasma used, this may decrease the overall use of blood products by decreasing the amount of packed red blood cells required. Where appropriate and available, mechanisms to collect and re-transfuse shed blood may be used. In some situations, temporizing measures should be taken to control bleeding in order to allow fluid resuscitation to catch up with accumulated blood loss before definitive surgical management. In other situations, intra-abdominal packing to temporize bleeding is prudent and may allow for correction of coagulopathy, hypothermia and acidosis. In such 'damage control' surgery, abdominal re-exploration follows 24–72 hours after the initial surgical exploration (*22–24*). The team of anaesthetists, surgeons and nurses must all be aware of the plan for resuscitation so that they can take appropriate measures to reduce the morbidity of haemorrhage.

Hypovolaemia represents a situation in which clear, unhindered communication is essential to optimize patient care. Coordination of care during resuscitation and the operation combined with an anaesthetic plan based on the patient's physiological state can make a profound difference in intra-operative management.

Recommendations

Highly recommended:

- Before inducing anaesthesia, the anaesthetist should consider the possibility of large-volume blood loss, and, if it is a significant risk, should prepare appropriately. If the risk is unknown, the anaesthetist should communicate with the surgeon regarding its potential occurrence.
- Before skin incision, the team should discuss the risk for large-volume blood loss and, if it is significant, ensure that appropriate intravenous access is established.

Recommended:

- A member of the team should confirm the availability of blood products if needed for the operation.

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Objective 5

The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk

A medication error can be defined as an error in prescription, dispensing or administration of a drug (*1*). Medication errors are a major problem in every health system and every country and have featured prominently in studies of iatrogenic injury conducted in the United States and many other countries (*2*). In the United States, at least 1.5 million people are injured annually from medication errors, and the costs to the health system exceed US$3.5 billion each year (*3*). Perioperative errors in drug administration contribute to this problem. In the Closed Claims Project of the American Society of Anesthesiologists, drug administration errors were found to result in serious problems, including death in 24% and major morbidity in 34% of the cases reviewed (*4*).

Human error contributes substantially to injuries due to medication errors. In an early analysis of critical incidents in anaesthesia, Cooper et al. found that a common cause of such incidents was inadvertent substitution of one drug-filled syringe for another (*5*). A further analysis published by Cooper's team identified syringe swapping, ampoule switches and drug overdose (via syringe and vaporizer) as frequent problems in anaesthesia (*6*). More recent studies show that the problem is more widespread than previously thought (Table II.5.1). Surveys in Canada and New Zealand suggest that the vast majority of anaesthetists have made a medication error at some time during their careers (*7*,*8*). Major morbidity or death were complications in 1.4% of the reported errors. Traditional incident reporting has been shown to identify only a minority of medication errors (*9*). Improved incident monitoring substantially increases the number of identified errors, but many medication errors are never recognized or reported, and most studies probably underestimate the extent of the problem (*10*).

Table II.5.1 – Prospective estimates of rates of drug administration error in anaesthesia from 1978 to the present

Study (reference)	Period	No. of anaesthesias	No. of drug errors	Drug error rate (%)
Craig, Wilson (*11*)	6 months	8 312	12	0.14
Kumar et al. (*12*)	April 1984–January 1985; April 1985–January 1986	28 965	31	0.11
Short et al. (*13*)	1990	16 739	26	0.16
Fasting, Gisvold (*14*)	September 1996–October 1999	55 426	63	0.11
Webster et al. (*10*)	February 1998–October 1999	10 806	81	0.75
Bowdle et al. (*15*)	21 weeks	6 709	41	0.61
Merry et al. (*16*)	February 1998–November 2003	74 478	364	0.49

Modified from (17)

Perioperative administration of medication is particularly complex. In a report from MEDMARX®, the United States Pharmacopeia programme for the reporting of medication errors and adverse drug reactions, 5% of more than 11,000 perioperative medication errors resulted in harm, including four deaths (*18*). This rate is more than three times higher than the percentage of harm in all MEDMARX® records. Children were found to be at higher risk than adults: nearly 12% of paediatric medication errors resulted in harm. Data from a general paediatric ward in New Zealand showed a rate as high as one event per four medication orders, and over 1% of medication orders for children resulted in preventable harm (*9*).

Drug infusions are another area of potential risk, as errors can occur during the mixing of solutions, in calculating concentration and infusion rates and from co-administration of incompatible drugs through in the same intravenous cannula (*19*). As with all drug errors,

the consequences of these mistakes are sometimes serious; even infusions of common opioids have resulted in fatal errors (*1*).

While it is difficult to provide a precise overall estimate of the extent of harm attributable to perioperative medication error, it is almost certain that harmful errors are grossly underreported. The barriers to reporting are significant. Often, the only person aware of an error is the one who made it, and motivation to report the incident may therefore not be high. Given the large number of surgical procedures performed globally every year, it is likely that the burden of patient harm from medication errors is substantial. With appropriate safety practices, many incidents are entirely preventable.

Types of adverse reactions

Adverse drug reactions include allergic reactions, side-effects (e.g. severe asthmatic response to nonsteroidal anti-inflammatory drugs in susceptible patients), effects from overdosage or underdosage and harm attributable to omission of important drugs (such as heparin for cardiopulmonary bypass or timely antibiotics to prevent infections, as outlined in Objective 6). Administration of a drug to which the patient is hypersensitive or otherwise at known risk for an adverse reaction is especially dangerous. This may occur when the correct drug is given to a patient who has no previous history or allergy; in such cases, an adverse drug reaction is usually unavoidable. It can also involve errors of commission despite known hypersensitivity. This can be prevented by taking a proper history from all patients, adequate documentation and record-keeping, good communication among members of the clinical care team and the use of checklists to ensure that the appropriate safety steps are accomplished efficiently.

Anaphylactic reactions to anaesthetics are estimated to occur in 1:10,000–1:20,000 cases (*20*). Common causes of anaphylaxis include neuromuscular blocking drugs, latex, antibiotics, colloids, hypnotics and opioids (*21*). Cross-reactions to drugs may also occur. Patients who have had an anaphylactic reaction to penicillin are at risk of reacting in the same way to cephalosporins or imipenem, and a reaction to one type of neuromuscular blocking drug significantly increases the chances of a reaction to another drug in this class. Anaphylactic reactions present with a range of signs, including cardiovascular collapse, bronchospasm, angio-oedema and rash. Most anaphylactic reactions are immediately evident upon introduction of the offending drug intravenously, although a full reaction may take 5–10 min to develop. Management of this life-threatening emergency includes supportive measures to address cardiovascular collapse, airway occlusion and bronchospasm. Oxygen, ventilation, intravenous fluids and antihistamines are all recommended in published protocols (*22*,*23*). After elimination of the suspected allergen, treatment should include epinephrine (adrenaline) to reverse vasodilation and hypotension. Epinephrine can be titrated intravenously while cardiovascular status is monitored, although intramuscular administration is possible in a patient without venous access.

The positive outcome of an anaphylactic reaction depends on prompt and effective treatment. Training of anaesthetists in the management of these crises is an important aspect of medication safety. A major anaphylactic reaction in an operating room staffed with trained clinicians and with ready access to perioperative nursing and technical support is unlikely to result in death nowadays; the same reaction in an isolated setting with limited resources and less well trained personnel might result in death.

Most medication errors in anaesthesia involve intravenous bolus administration, infusion or the administration of gases or vapours, but any route of administration can be involved. Most fit into the following categories (*1*,*10*):

- omission: the intended drug was not administered;
- repetition: an unintended extra dose of the intended drug was administered;
- substitution: the wrong drug was administered;
- incorrect dose or rate of infusion;
- incorrect route: the drug was administered by the wrong route; and
- incorrect patient: the drug was administered to the wrong patient.

Causes of error in delivery of perioperative medications

With respect to drug administration, the clinical practice of anaesthesia is unusual, as providers both prescribe and administer the medications they use. This removes some of the systematic checks commonly built into drug administration and places a special onus on anaesthetists to use safe practices. Compliance with widely accepted principles of safe medication administration could be improved. In the Closed Claims Project of the American Society of Anesthesiologists, reviewers of legal claims against anaesthesiologists judged the standard of care to be ‘less than appropriate’ in 84% of drug error claims (*4*).

There is wide agreement among international experts on the safety steps needed to improve intravenous administration of medication. Jensen et al. (*24*) undertook a systematic review of publications on drug administration in anaesthesia, identified a number of practices for which there was strong international evidence, tested these against incidents collected by a facilitated incident reporting approach and made recommendations for medication labelling and clinician communication on the basis of their findings. Other authors and professional societies have published similar guidelines, but

changing established practice patterns is problematic. In a survey of practising clinicians in Canada, 86% of the respondents were aware of the Canadian Standards Association labelling standards, and 87% agreed or strongly agreed that these labels reduced the incidence of drug errors, yet only 72% actually used them (*7*). Furthermore, fewer than half the respondents 'always' read the labels of medications they were administering. In a survey of 210 delegates at an anaesthesiology conference in New Zealand, most of the participating anaesthesiologists indicated that drug error in anaesthesia was an important problem, but most considered that this was more a problem with the practices of other anaesthesiologists than with their own (*25*).

The idiosyncratic nature of the system of medication acquisition, labelling, storage and administration can contribute to medication errors. Inconsistent colour coding, 'look-alike' and 'sound-alike' labelling of different medications and illegible markings on syringes and ampoules are common problems in hospitals throughout the world (*26*). To complicate matters, ampoules of similar appearance containing different drugs are often stored close together, increasing the chance of error.

One approach to improving patient safety is to structure a system of medication delivery that allows clinicians to manage errors rather than focusing on their elimination. In such a system, practices must be established to reduce the likelihood of drug error and also to identify errors when they occur, allowing appropriate steps to be taken to mitigate their consequences. The chance of dangerous errors can be reduced by simple changes. Colour-coding by class of drug, for example, can diminish the likelihood of administering a medication with a similar-sounding name but which has a different effect and mechanism of action; within-class errors are less likely to cause serious harm than between-class errors. Attention should also be focused on particularly dangerous types of error, such as wrong route of administration or the concentration of a medication in a solution.

Safe medication delivery implies the consistent administration of the correct drug to the correct patient in the correct dose at the correct time by the correct route. Studies evaluating medication errors demonstrate that clinicians frequently fail to achieve this. In addition to careful practice and conscientious attention to detail, a systems-based approach to the processes of drug administration is therefore required.

Recommendations

Highly recommended:

- Anaesthetists should fully understand the pharmacology of the medication they prescribe and administer, including its toxicity.
- Every patient to whom any drug is administered must first be identified clearly and explicitly by the person administering the drug.
- A complete drug history, including information on allergies and other hypersensitivity reactions, should be obtained before administration of any medication.
- Medications should be appropriately labelled, confirmed and rechecked before administration, particularly if they are drawn into syringes.
- Before any drug is administered on behalf of another health provider, explicit communication should take place to ensure that the two have a shared understanding of the indications, potential contraindications and any other relevant information.

Recommended:

- Medication drawers and workspaces should be organized systematically to ensure consistent positions of medication ampoules and syringes, tidiness and separation of dangerous drugs or drugs with similar-sounding names.
- Labels on ampoules and syringes should be legible and include standardized information (e.g. concentration, expiration date).
- Similar packaging and presentation of different medications should be avoided when possible.
- Errors in intravenous drug administration during anaesthesia should be reported and reviewed.
- Drugs should be drawn up and labelled by the anaesthetist who will administer them.

Suggested:

- Medications in a similar class should be colour-coded according to an agreed system that is understood by all members of the operating team.

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Objective 6

The team will consistently use methods known to minimize the risk for surgical site infection

An infection that occurs in surgical patients at the site of operation is known as surgical site infection. These infections occur after invasive procedures in the superficial or deep layers of the incision or in the organ or space that was manipulated or traumatized, such as the peritoneal space, pleural space, mediastinum or joint space. These problems are serious and costly, and are associated with increased morbidity and mortality as well as with prolonged hospitalization (*1–3*). Recently, their prevalence has been used as a marker for the quality of surgeons and hospitals (*4–7*).

Surgical site infection accounts for about 15% of all health-care-associated infections and about 37% of the hospital-acquired infections of surgical patients (*8*,*9*). Two thirds of surgical site infections are incisional and one third confined to the organ space (*9*). In western countries, the frequency of such infections is 15–20% of all cases, with an incidence of 2–15% in general surgery (*3*,*10–12*). Surgical site infections lead to an average increase in the length of hospital stay of 4–7 days. Infected patients are twice as likely to die, twice as likely to spend time in an intensive care unit and five times more likely to be readmitted after discharge (*11*,*13–15*).

Health-care costs increase substantially for patients with surgical site infections. The severity of the effects depends on the extent of the surgical procedure, the country and the method used to calculate costs (*3*,*12*,*16–18*). In the United States, at least 780,000 surgical site infections occur each year, with rates as high as 13% for high-risk colon surgery (*19*,*20*). Such infections resulted in 3.7 million excess hospital days and US$1.6–3 billion in excess hospital costs per year (*15*,*21*). In the United Kingdom, the excess cost has been calculated to be about £1594 per infection (*3*). In the European Union, surgical site infections exact an economic toll of €1.5–19.1 billion per year (*12*). The prevalence and consequences of surgical site infections are illustrated in Tables II.6.1 and II.6.2.

Table II.6.1 – Prevalence of surgical site infections in certain countries

Country *(Reference)*	**Setting (Number of centers involved)**	**Study period**	**Study design**	Surgical site infections	
				No.	%
Australia (*26*)	Hospitals (28)	1992	Retrospective	5 432	7.9
Brazil (*27*)	University hospital (1)	1993–1998	Retrospective	9 322	6.8
France (*24*)	Hospital network (67 surgical wards)	1998–2000	Prospective	26 904	3.3
Italy (*23*)	Public hospitals (31)	1 month (date not given)	Prospective	6 167	3.3
Spain (*25*)	Tertiary-care hospital (1)	1992–1994	Prospective	1 483	10.5
Thailand (*29*)	General and regional hospitals (33)	1992	Prevalence	15 319	2.7
Thailand (*30*)	University hospitals (9)	2003–2004	Prospective	4 764	1.4
United States (*20*)	NNIS hospitals (225)	1992–1998	Prospective	738 398	2.6
Viet Nam (*28*)	Tertiary-care hospitals (2)	1999	Prospective	697	10.9

NNIS, National Nosocomical Surveillance System

Table II.6.2 – Consequences of surgical site infections

Reference	Type of operation	Consequence studied	Excess stay, cost or mortality
Asensio, Torres (31)	Heart	Length of postoperative stay	21 days
Kasatpibal et al. (18)	General surgery, neurosurgery	Length of postoperative stay; cost	14 days; bhat 31 140
Astagneau et al. (13)	Gastrointestinal, orthopaedic, gynaecology	Length of postoperative stay	8.5 days
Coello et al. (32)	General surgery, orthopaedic, gynaecology	Length of postoperative stay; cost	8.2 days; UK£ 1798
Poulsen et al. (33)	All surgery	Length of postoperative stay	6 days
Kirkland et al. (15)	All surgery	Length of postoperative stay; mortality	5 days; 4.3%
Whitehouse et al. (2)	All surgery	Length of postoperative stay	1 day
Plowman et al. (34)	General surgery, orthopaedic, obstetrics and gynaecology	Cost	UK£ 1618
Whitehouse et al. (2)	Orthopaedic	Cost	US$ 17 708

Pathogenesis and microbiology

Microbial contamination during a surgical procedure is a precursor of surgical site infection. Most surgical wounds are contaminated by bacteria, but only a minority progress to clinical infection (*35*). Infection does not occur in most patients because their innate host defences eliminate contaminants at the surgical site efficiently (*36*). There are at least three important determinants of whether contamination will lead to surgical site infection: the dose of bacterial contamination, the virulence of the bacteria and the resistance of the patient (*37*). This is demonstrated in the following formula (*38*):

$$\frac{\text{Dose of bacterial contamination} \times \text{Virulence of bacteria}}{\text{Resistance of host}} = \text{Risk of surgical site infection}$$

Other factors that affect the probability of infection are depicted in the following hypothetical equation (36):

$$\frac{\text{Inoculum of bacteria} + \text{Virulence of bacteria} + \text{Adjuvant effects}}{\text{Innate and adoptive host defence} - \text{Acute and chronic host liabilities}} = \text{Probability of infection}$$

The probability of infection increases proportionally as the number and virulence of the bacteria increase. Local characteristics of the wound, such as residual dead tissue, sutures or other foreign material or the presence of drains, will amplify the consequence of the bacterial inoculum.

Bacterial contamination is a necessary precursor to surgical site infection. Skin bacteria are always present, despite thorough skin preparation. In addition, numerous bacteria contaminate any operation involving a body structure ordinarily colonized by bacteria, such as the bowel. Quantitatively, the risk for surgical site infection is markedly increased if the surgical site is contaminated with > 10^5 microorganisms per gram of tissue (*38*); however, the dose of contaminating microorganisms required to produce infection might be much lower when foreign material is present at the surgical site (e.g. 100 staphylococci per gram of tissue introduced on silk sutures).

The aggressiveness of many invasive micro-organisms is often a function of their biology. Many bacteria that cause surgical site infections contain or produce toxins and other substances that increase their ability to survive on or in host tissue and invade and damage the host. The more virulent the bacterial contaminant, the greater the probability of infection.

Some bacterial surface components, notably polysaccharide capsules, inhibit phagocytosis, a critical and early host defence response to microbial contamination. Certain strains of clostridia and streptococci produce potent exotoxins that disrupt cell membranes or alter cellular metabolism (*39*). A variety of microorganisms, including Gram-positive bacteria such as coagulase-negative staphylococci, produce glycocalyx and an associated component called slime, which physically shields bacteria from phagocytes or inhibits the binding or penetration of antimicrobial agents (*40*). Although these and other virulence factors are well defined, their mechanistic relationship to surgical site infection has not been fully determined.

The source of the pathogens that cause most surgical site infections is the endogenous flora of the patient's skin, mucous membranes or hollow viscera. When a mucous membrane or skin is incised, the exposed tissues are at risk for contamination. The organisms are usually aerobic Gram-positive cocci (e.g. staphylococci) but may include faecal flora (e.g. anaerobic bacteria and Gram-negative aerobes) when the incision is made near the perineum or groin. When a gastrointestinal organ is opened during an operation and is the source of pathogens, Gram-negative bacilli (e.g. *Escherichia coli*), Gram-positive organisms (e.g. enterococci) and sometimes anaerobes (e.g. *Bacteroides fragilis*) are the typical isolates.

Bacterial contaminants may also enter the wound from exogenous sources, including the air in the operating room, instruments, prostheses or other implants, or the surgical team that comes into contact with the wound (*41–44*). The exogenous flora are primarily aerobes, especially Gram-positive organisms (e.g. staphylococci and streptococci). Fungi from endogenous and exogenous sources rarely cause surgical site infections, and their pathogenesis is not well understood (*45*,*46*).

Pathogens isolated from the surgical site vary according to the type of surgery as well as the organ and location. The distribution of pathogens isolated from the surgical site in the National Nosocomial Infections Surveillance (NNIS) system in the United States between 1986 and 1996 is shown in Table II.6.3. The pathogen most frequently isolated was *Staphylococcus aureus*, followed by coagulase-negative staphylococci, *Enterococcus* spp., *E. coli* and *Pseudomonas aeruginosa*. There was a notable increase over this time period in antimicrobial-resistant pathogens, such as methicillin-resistant *S. aureus* and fungal pathogens, especially *Candida albicans* (*46*,*47*). This increase might reflect inappropriate use of antimicrobial medication. Because not all specimens can be sent to laboratories for isolation of pathogens, and some pathogens are difficult to identify in the laboratory, some surgeons prefer to use broad-spectrum antibiotics instead of drugs with a narrower susceptibility profile (*48*). The increase in fungal pathogens might also reflect an increase in the number of immunocompromised surgical patients.

Table II.6.3 – Distribution of pathogens isolated from surgical-site infections in the National Nosocomial Infections Surveillance system (9,49)

Pathogen	**Percentage of isolates**	
	1986–1989	**1990–1996**
	(n = 16 727)	**(n = 17 671)**
Staphylococcus aureus	17	20
Coagulase-negative staphylococci	12	14
Enterococcus spp.	13	12
Escherichia coli	10	8
Pseudomonas aeruginosa	8	8
Enterobacter spp.	8	7
Proteus mirabilis	4	3
Klebsiella pneumonia	3	3
Other *Streptococcus* spp.	3	3
Candida albicans	2	3
Group D streptococci, other (non-enterococci)	–	2
Other Gram-positive aerobes	–	2
Bacteroides fragilis	–	2

The distribution of pathogens that cause surgical site infections is similar in many countries. In a study of these infections in the European Union, 27–40% were due to S. aureus, 6–11% to coagulase-negative staphylococci, 3–15% to E. coli and 7–10% to Pseudomonas (12). A study in Turkey showed that S. aureus accounted for 50% of 621 pathogens isolated from surgical site infections, E. coli for 8%, S. pyogenes and Ps. aeruginosa each for 7% and coagulase-negative staphylococci for 6% (50). In Thailand, the most common causative pathogens identified in surgical site infections were E. coli (15.3%), S. aureus (8.5%), Ps. aeruginosa (6.8%), K. pneumoniae (6.8%) and Acinetobacter baumannii (3.4%) (30).

Prevention and surveillance of surgical site infections

The Study on the Efficacy of Nosocomial Infection Control (SENIC) showed that about 6% of all nosocomial infections can be prevented with minimum intervention (*51*,*52*). Simple methods that can be used to limit risk include:

- complete assessment of all surgical patients preoperatively;
- reduced preoperative hospitalization;
- evaluation and treatment of remote infections;
- weight reduction (for obese patients);
- cessation of tobacco use;
- control of hyperglycaemia;
- restoration of host defences;
- decreased endogenous bacterial contamination;
- appropriate methods of hair removal;
- administration of appropriate and timely antimicrobial prophylaxis;
- confirmation of proper asepsis and antisepsis of skin and instruments;
- maintenance of meticulous surgical technique and minimization of tissue trauma;
- maintenance of normothermia during surgery;
- shortened operating time; and
- effective wound surveillance.

Effective surveillance systems and feedback to surgeons on their infection rates have been shown to improve the prevention of surgical site infection (*53–55*). The rates can be reduced by one third or more with programmes and personnel trained in infection control and surveillance (*51*). In studies in Brazil, the Netherlands, the United Kingdom and the United States, surgical site infection rates were reduced by 33–88% when a surgeon-specific feedback system was used, with strategies such as organized surveillance and control, an adequately trained staff, education and standardized infection control policies (*56–60*). In many of these studies, the follow-up period was more than two years. Surgeon-specific infection rates could be calculated and reported not only to the surgeons but also to the head of the department of surgery (*52*,*59*). Collaboration by surgeons in research projects as the principal or co-investigator was instrumental in their success (*52*). A study in Thailand showed that feedback on surgical site infection rates to surgeons alone did not affect the rate but could give rise to self-assessment and rigorous prevention practices *(55)*. To ensure acceptance by staff, infection prevention measures should be designed and implemented by a multidisciplinary team, as sustainable changes in procedure and behaviour require commitment from all the disciplines involved.

The methods of surveillance include chart review, medication review, laboratory-based ward surveillance, laboratory-based telephone surveillance, ward liaison surveillance, treatment and temperature chart surveillance, risk factor surveillance, antimicrobial use monitoring and microbiology reports (*8*). While the details of these methods are beyond the scope of this document, the principles of an effective surveillance system are:

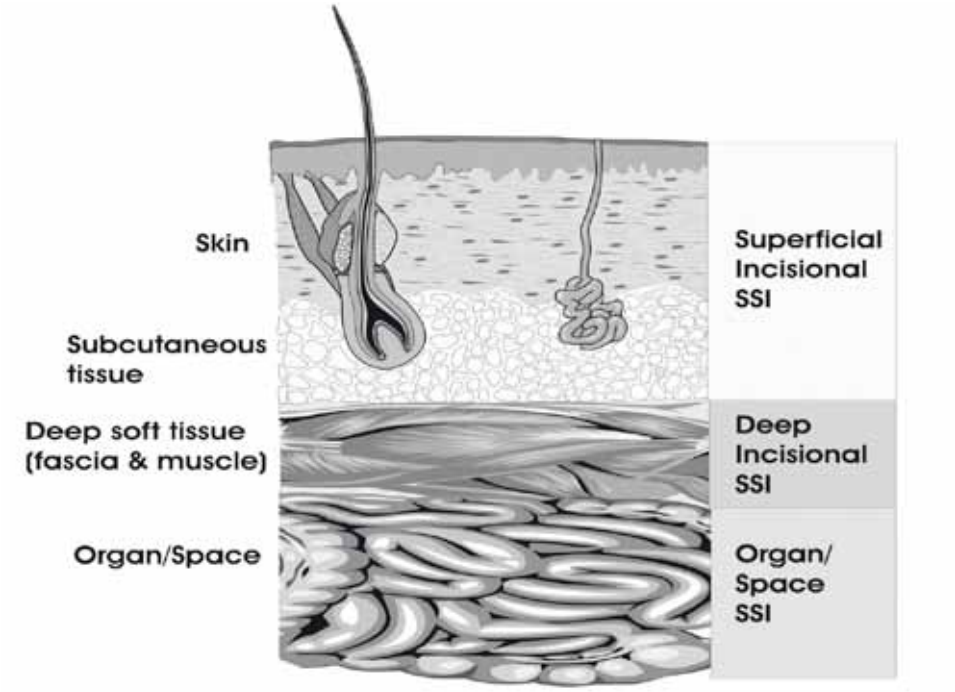
- to maintain accurate, efficient, confidential data collection;
- to provide data on final infection rates stratified by multivariate risk for each surgeon and patient;
- to use clear, consistent definitions of infection; and
- to use standardized post-discharge follow-up protocols and proper maintenance of data.

Not all studies, however, show a reduction in surgical site infection rates after continuous surveillance. Standardized definitions of infection and objective criteria should be used whenever possible. The most widely used definition is that of the NNIS system of the Centers for Disease Control and Prevention in the United States (*61*).

Definitions of surgical site infection

A precise definition of surgical site infection is vital for personnel measuring infection rates. It should be simple and accepted by nurses and surgeons. Use of a standard definition allows comparison of rates across surgeons and hospitals. In the NNIS definition, surgical site infection is divided into two main groups, incisional and organ–space. Incisional infections are further subdivided into superficial (skin and subcutaneous tissue) and deep (deep soft tissue such as fascia and muscle layers). Organ–space surgical site infection involves any part of the anatomy other than the incision that is opened or manipulated during an operation (Figure 6.1). The criteria for the different sites of infection are given below.

Figure 6.1 – Cross-section of abdomen depicting classification of surgical site infection according to the Centers for Disease Control and Prevention (United States)



SSI, surgical-site infection

Superficial incisional surgical site infection: Infection occurs at the incision site within 30 days of surgery and involves only skin or subcutaneous tissue at the incision and at least one of the following:

- purulent drainage from the superficial incision;
- an organism isolated by culturing fluid or tissue from the superficial incision;
- deliberate opening of the wound by the surgeon because of the presence of at least one sign or symptom of infection (pain, tenderness, localized swelling, redness or heat), unless the wound culture is negative; or
- diagnosis of superficial incisional surgical site infection by the surgeon or attending physician.

The following conditions are generally not reported as surgical site infection:

- stitch abscess with minimal inflammation and discharge confined to the points of suture penetration;
- infection of an episiotomy site;
- infection of a neonatal circumcision site; or
- infected burn wound.

Deep incisional surgical site infection: Infection occurs at the site of operation within 30 days of surgery if no implant (non-human-derived foreign body permanently placed in the patient during surgery) is left in place and within 1 year of surgery if an implant is left in place. In addition, infection appears to be related to surgery and involves deep soft tissue (muscle and fascia layers) and at least one of the following:

- purulent drainage from deep incision but not from the organ–space component of the surgical site;
- wound dehiscence or deliberate opening by the surgeon when the patient has fever (> 38 °C) or localized pain or tenderness, unless the wound culture is negative;
- an abscess or other evidence of infection involving the deep incision seen on direct examination during surgery, by histopathological examination or by radiological examination; or
- diagnosis of deep incisional surgical site infection by the surgeon or attending physician.

Organ–space surgical site infection: Infection occurs within 30 days of surgery if no implant (non-human-derived foreign body permanently placed in the patient during surgery) is left in place and within 1 year of surgery if an implant is left in place. In addition, infection appears to be related to surgery and involves any part of the anatomy other than the incision that is opened or manipulated during an operation and at least one of the following:

- purulent drainage from a drain placed through a stab wound into the organ–space;
- an organism isolated from an aseptically obtained culture of fluid or tissue in the organ or space;
- an abscess or other evidence of infection involving the organ or space seen on direct examination during surgery, by histopathological examination or by radiological examination; or
- diagnosis of an organ–space surgical site infection by the surgeon or attending physician.

Methods of scoring infection

Several different scoring systems have been described that objectively evaluate wound status or risk of infection. The ASEPSIS (Additional treatment, Serous discharge, Erythema, Purulent exudates, Separation of deep tissues, Isolation of bacteria and Stay duration as inpatient) scoring system was devised in 1986 by Wilson and co-workers in England (*62*). This scale can be used to monitor and record the rate and severity of surgical site infections. It was initially designed for evaluating the effectiveness of antibiotic prophylaxis before cardiac surgery but has been proposed for comparing outcomes at different institutes (*63–65*). The surgical site is inspected on five of the first seven days after surgery, and the wound scored is based on the findings of serous exudates, erythema, purulent exudate and separation of deep tissue. The findings are scored as shown in Table II.6.4.

Table II.6.4 – Point scale for daily wound inspection for ASEPSIS scoring of surgical site infections

Wound characteristic	Proportion of wound affected (%)					
	0	< 20	20–39	40–59	60–79	≥ 80
Serous exudates	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissue	0	2	4	6	8	10

The point scales for additional information on wound treatment, culture findings and delayed discharge are:
a) *antibiotic therapy for wound infection (additional treatment): not given = 0, given = 10*
b) *drainage of pus under local anesthesia (additional treatment): not done = 0, done = 5*
c) *debridement of wound under general anesthesia (additional treatment): not done = 0, done = 10*
d) *isolation of pathogenic bacteria: none = 0, present = 10*
e) *stay as inpatient: not prolonged = 0, prolonged = 5*

ASEPSIS scores range from 0 to 70, with the following interpretation: 0–10, satisfactory healing; 11–20, disturbance of healing; 21–30, minor wound infection; 31– 40; moderate wound infection; > 40, severe wound infection.

The risk index in the Study on the Efficacy of Nosocomial Infection Control (SENIC) is based on four clinical findings: abdominal operation, operation lasting more than 2 hours, surgical wound classed as contaminated, dirty or infected, and patient with three or more major pre-existing diagnoses (*66*). Each clinical finding adds one point to the total score, the minimum index value being 0 and the maximum 4; 0 denotes a low risk for surgical site infection, 1 point implies an intermediate risk, and 2–4 points indicate a high risk. While the SENIC risk index is valid as a scoring system, it has not been popular because of the constant 2-hour cut-off point for the duration of the operation.

The NNIS risk index was based on the SENIC index (*66*), with three parameters: the American Society of Anesthesiologists (ASA) preoperative assessment classification, reflecting the patient's preoperative physical status; the duration of the procedure; and the surgical wound class. One point is scored for each finding: an ASA preoperative assessment classification of 3, 4 or 5; duration of surgery longer than 75% of similar cases; and a surgical wound classed as contaminated, dirty or infected. If a procedure is performed endoscopically, the NNIS risk index score is modified by subtracting one point; therefore, the NNIS risk index ranges from –1 to 3. An index of 0 is interpreted as a low risk for surgical site infection, an index of 1 means an intermediate risk, and an index of 2 or 3 equates to a high risk. The NNIS risk index is popular because it includes the specific duration of the operation being performed and replaces the severity of underlying disease in the SENIC risk index by the ASA classification. Moreover, it shows a linear trend with both crude and adjusted rates of surgical site infection. The NNIS risk index has therefore been applied to benchmarked surgical site infection rates by indirect standardization and reported in terms of a standardized infection ratio (*24*,*67–70*). This ratio can be a useful tool for comparing surgical site infection rates between institutions (*30*). The NNIS risk index has been shown to be more accurate than the simple preoperative wound classification of 'clean', 'clean–contaminated', 'contaminated' and 'dirty' described by the Centers for Disease Control and Prevention in the United States (see 'Antibiotic prophylaxis' below).

Surveillance of surgical site infections

Surveillance has been described as the on-going systematic collection, analysis, evaluation and dissemination of data. Monitoring systems use assessment criteria based on standard definitions, extent of coverage, adjustment for risk, ability to collect and validate data, ability to analyse data and provide feedback to clinicians, and wider dissemination to academic and clinical personnel (*65*,*71*). An active surveillance programme is necessary for accurate identification of surgical site infections (*72*).

The methods used for surveillance of surgical site infections were originally designed for monitoring inpatients only. Over the past decade, the shift from inpatient to outpatient surgical care has been dramatic, making traditional surveillance methods considerably more difficult to employ *(73)*. Most hospitals do not have the resources to monitor all surgical patients all the time; therefore, they should target their efforts to high-risk procedures and combine computer-assisted, laboratory-based screening with case confirmation by surgeons (*10*,*30*,*53*,*67*,*68*,*70*,*74*). When the necessary technology is available, these methods can be reliable, accurate and less time-consuming than conventional methods of chart review.

Inpatients: Several methods have been used to identify inpatients with surgical site infections. Direct observation of the surgical site by the surgeon, a trained nurse or infection control personnel, and indirect detection by infection control personnel who review laboratory reports, patient records and hold discussions with primary care providers are two of the most common strategies (*38*). Direct observation of surgical sites is the most precise and accurate method for detecting surgical site infections (*10*), but several studies have utilized indirect methods (*75*,*76*). Because the hospital stay is often very short, post-discharge surveillance has become increasingly important to obtain precise infection rates.

Post-discharge: As 96% of postoperative superficial surgical site infections occur within 28 days of surgery (*77*), 30 days has become the accepted length of surveillance for infections after operations that do not involve prosthetic implantation (*61*). Surgical site infections are frequently detected after patients have been discharged from hospital (*17*,*78–82*). Post-discharge surveillance methods have been used with varying degrees of success for different procedures and hospitals. The methods include direct examination of patients' wounds during follow-up visits, review of medical records and mail or telephone surveys with patients or surgeons (*82*). As integrated health information systems expand, tracking surgical patients throughout care may become easier and more practical and effective. There is currently no consensus on which post-discharge surveillance methods are the most sensitive, specific and practical. The method chosen will necessarily reflect the hospital's mix of operations, personnel resources and data needs.

Risk factors

Patient characteristics and comorbidity play an important role in determining the likelihood of infection after surgery. Coincident remote-site infections, colonization (in particular, nares colonization with *S. aureus*), diabetes, cigarette smoking, use of systemic steroids, obesity (body mass index ≥ 30 kg/m^2), extremes of age, poor nutritional status, perioperative blood transfusion and prolonged preoperative stay have all been shown to increase the risk of surgical site infection (*42*,*43*,*83–102*). Prolonged postoperative hospital stay has also been frequently associated with increased surgical site infection risk (*52*,*103*,*104*). Length of stay is, however, probably a surrogate for severity of illness and comorbid conditions requiring inpatient work-up or therapy before or after the operation.

The characteristics of the operation can also affect the likelihood of surgical site infection. Preoperative preparation has a demonstrable role in preventing infection. Antiseptic showering, clipping (as opposed to shaving) for hair removal, skin preparation and hand and forearm scrub antisepsis are steps that can reduce infection rates. Several studies have shown that preoperative hair removal by any means is associated with increased surgical site infection rates and have suggested that no hair be removed (*38*,*105*,*106*). Appropriate antiseptic agents, scrubbing technique and duration of the scrub (both of the patient's skin and of the hands and forearms of the surgical team) result in decreased bacterial colony counts (*107–111*), although these practices have not been shown definitively to reduce surgical site infection rates (*112*,*113*).

Intraoperative factors such as the operating room environment (appropriate ventilation and cleanliness of environmental surfaces), sterilization of instruments, designated surgical attire (including masks, caps and shoe covers) and sterile drapes and scrub suits (including sterile gloves and gowns) also increase the likelihood of reducing contamination of the surgical wound. Antibiotic prophylaxis has the most evidence to support its use in the prevention of surgical site infection. When used appropriately, infection rates can be significantly reduced (see 'Antibiotic prophylaxis' below).

The two most important principles of infection prevention, however, are related to the duration of the operation and the surgical aseptic technique (*114,115*). Minimizing the amount of time required for surgery is considered to be one of the principle means of preventing infections. Lack of adherence to the principles of asepsis during procedures has been associated with outbreaks of postoperative infections (*116*). Meticulous surgical technique is widely considered to reduce

the risk for surgical site infection and includes maintaining effective haemostasis while preserving an adequate blood supply, preventing hypothermia, handling tissues gently, avoiding inadvertent entries into a hollow viscus, removing devitalized tissue, using drains and suture material appropriately and eradicating dead space (*117–119*).

Appropriate postoperative management of the incision can reduce surgical site infection. The type of care is determined by whether the incision is closed or left open to heal by secondary intention. The evidence is inconclusive as to whether an incision should be covered with a dressing or whether showering or bathing is detrimental to healing. However, when a surgical incision is left open at the skin level for a few days before it is closed (delayed primary closure), the incision should be packed with sterile moist gauze and covered with a sterile dressing (*110*) or a hydrofibre dressing (*120,121*).

Blood glucose and risk of infection: Patients with diabetes have long been recognized as being at increased risk for infectious complications of all types, with surgical site infection rates two to three times higher than those of patients without diabetes after cardiac operations. The occurrence of hyperglycaemia (glucose > 200 mg/dl) among patients undergoing gastrointestinal or cardiac operations has been correlated with a significant increase in surgical site infection rates (*122,123*). A recent report on patients with and without diabetes undergoing cardiac surgery showed that the risk for surgical site infection doubled when the postoperative glucose level was > 200 mg/dl in the first 48 hours. Half of all hyperglycaemic episodes occurred in patients without diabetes (*124,125*). Other surveys showed that hyperglycaemia is common in hospitalized patients (*126*). Furnary et al. demonstrated significant reductions in deep sternal wound infection and in mortality when perioperative insulin management was changed from subcutaneous administration on a sliding scale to continuous infusion (*127,128*). While the strongest evidence of benefit exists for patients undergoing cardiac surgery, it is likely that all surgical patients could benefit from perioperative screening of glucose level and continuous insulin infusion in the perioperative period when glucose levels are elevated (*129*). The American College of Endocrinology recently issued a position statement emphasizing the importance of glucose control in all hospitalized patients, including perioperatively (*130*).

Oxygen tension and temperature in the perioperative period: All surgical wounds contain at least some bacteria at the end of the procedure (*35*). The balance between the number and virulence of bacteria and the resilience of host defences determines whether a surgical site infection will result. One of the key host defences is the action of leukocytes in the wound. White cells use activated oxygen to kill bacteria, and a number of studies in vitro and in experimental animals have shown the importance of oxygen tension in supporting this process (*131–135*). Subsequent studies of postoperative patients showed that the risk for surgical site infection was associated with subcutaneous oxygen tension at the wound (*136*). Tissue warming improves tissue perfusion and tissue oxygen tension (*137*).

A multicentre trial in Europe of patients who had undergone colectomy showed that maintaining normothermia during the operation reduced the rate of infection (*138*), while a trial in the United Kingdom of smaller operations (on the breast, hernias and varicose veins) showed a lower infection rate when patients were warmed before the operation (*139*). Perioperative morbid cardiac events are also reduced by maintaining normothermia during major operations (*140*).

The benefit of increasing the level of inspired oxygen during surgery in order to increase tissue oxygen tension is less clear cut than that of maintaining normothermia. Three prospective randomized trials of patients undergoing colectomy or other major intra-abdominal procedures compared administration of an 80% or 30–35% fraction of inspired oxygen during the operation and for 2–6 hours afterwards (*141–143*). The first and third trials showed a benefit and the other trial showed an increased infection rate with a higher fraction of inspired oxygen. The two trials showing benefit were better designed and had more patients, but no conclusion can yet be drawn (*144,145*). Yet increasing the fraction of inspired oxygen might be beneficial and is almost certainly not harmful. Risk factors associated with surgical site infection are listed in Table II.6.5.

Table II.6.5 – Patient and operation characteristics that may be associated with surgical-site infection

Patient characteristic	Operation characteristic
• Advanced age • Poor nutritional status • Diabetes • Smoking • Obesity • Colonization with microorganisms • Coexisting infection at a remote body site • Altered immune response • Preoperative hospitalization	• Inadequate preoperative skin preparation • Inappropriate preoperative shaving • Inadequate surgical team preoperative hand and forearm antisepsis • Contaminated operating room environment • Inappropriate surgical attire and drapes • Inadequate sterilization of instruments • Excessive duration of operation • Poor surgical technique: excessive blood loss, hypothermia, tissue trauma, entry into a hollow viscus, devitalized tissues, presence of surgical drains and suture material, dead space • Inappropriate or untimely antimicrobial prophylaxis

Presurgical skin disinfection

The aim of skin disinfection is to remove and rapidly kill skin flora at the site of a planned surgical incision. The antiseptics that are currently available do not eliminate all microorganisms (*146*), and coagulase-negative staphylococci can be isolated even after three applications of agents such as iodine–alcohol to the skin (*147*).

The United States Food and Drug Administration defines a skin disinfectant as a "fast acting, broad-spectrum and persistent antiseptic-containing preparation that significantly reduces the number of microorganisms on intact skin" (*148*). There is no clear-cut level of bacterial skin load that should be removed or killed before surgery, and 80% of bacteria in surgical site infections originate from the skin of the patient (*149*). Therefore, the Food and Drug Administration and authorities in Europe and elsewhere have set standards that a disinfectant for presurgical skin preparation must meet before it can be legally marketed. The Food and Drug Administration requires testing at both 10 minutes and 6 hours: disinfectants should reduce colony-forming units (CFU) by more than 2 $\log_{10}$ at dry sites (e.g. abdominal skin) and by 3 $\log_{10}$ at moist sites (e.g. groin).

Most guidelines recommend a scrub-paint technique for applying a disinfectant. One study indicated, however, that spraying might be sufficient (*150*). The number of bacteria expected at a surgical site ultimately determines the number of disinfectant applications. As a general rule, three applications are sufficient; however, in areas with high densities of bacteria, this might not be sufficient to kill all vegetative bacteria (*151*).

Before a patient's skin is prepared for a surgical procedure, it should be cleansed of gross contamination (e.g. dirt, soil or any other debris) (*38*). Although preoperative showering has not been shown to reduce the incidence of surgical site infection, it might decrease bacterial counts and ensure that the skin is clean (*152*). The antiseptics used to prepare the skin should be applied with sterile supplies and gloves or by a no-touch technique, moving from the incision area to the periphery (*38*). The person preparing the skin should use pressure, because friction increases the antibacterial effect of an antiseptic. For example, alcohol applied without friction reduces bacterial counts by 1.0–1.2 $\log_{10}$ CFU compared with 1.9–3.0 $\log_{10}$ CFU when friction is used. Alcoholic sprays have little antimicrobial effect and produce potentially explosive vapours (*153*).

Alcoholic compounds: For centuries, alcohols have been used for their antimicrobial properties. Ethanol and isopropanol act within seconds, are minimally toxic to the skin, do not stain and are not allergenic. They evaporate readily, which is advantageous for most disinfection and antisepsis procedures. The uptake of alcohol by intact skin and the lungs after topical application is negligible. Alcohols have better wetting properties than water due to their lower surface tensions, which, with their cleansing and degreasing actions, make them effective skin antiseptics. Alcoholic formulations used to prepare the skin before invasive procedures should be filtered to ensure that they are free of spores; otherwise, 0.5% hydrogen peroxide should be added (*153*).

Alcohols have some disadvantages. If alcoholic antiseptics are used repeatedly, they may dry and irritate the skin. In addition, they are flammable (the flash-point should be considered) and cannot penetrate protein-rich materials. The exact mechanism by which alcohols destroy microorganisms is not fully understood. The most plausible explanation for their antimicrobial action is that they coagulate (denature) proteins, such as enzymatic proteins, thus impairing specific cellular functions (*154*). Ethanol and isopropanol at appropriate concentrations have broad spectra of antimicrobial activity that include vegetative bacteria, fungi and viruses. Their antimicrobial efficacies are enhanced in the presence of water, with optimal alcohol concentrations being 60–90% by volume.

Alcohols such as 70–80% ethanol kill vegetative bacteria such as *S. aureus*, *Streptococcus pyrogenes*, *Enterobacteriaceae* and *Ps. aeruginosa* within 10–90 seconds in suspension tests (*155*). Isopropanol is slightly more bactericidal than ethanol (*154*) and is highly effective against vancomycin-resistant enterococci (*156*). It also has excellent activity against fungi such as *Candida* spp., *Cryptococcus neoformans*, *Blastomyces dermatitidis*, *Coccidioides immitis*, *Histoplasma capsulatum*, *Aspergillus niger* and dermatophytes and mycobacteria, including *Mycobacterium tuberculosis.* Alcohols generally do not, however, destroy bacterial spores, and fatal infections due to *Clostridium* species have occurred when alcohol was used to sterilize surgical instruments.

Both ethanol and isopropanol inactivate most viruses with a lipid envelope (e.g. influenza virus, herpes simplex virus and adenovirus). Several investigators found that isopropanol had less virucidal activity against naked, nonenveloped viruses (*157*). In experiments by Klein and DeForest (*158*), 2-propanol, even at 95%, did not inactivate nonenveloped poliovirus type 1 or coxsackievirus type B within 10 min, whereas 70% ethanol inactivated these enteroviruses. Neither 70% ethanol nor 45% 2-propanol killed hepatitis A virus when their activities were assessed on stainless-steel discs contaminated with faecally suspended virus. Of the 20 disinfectants tested, only three reduced the titre of hepatitis A virus by more than 99.9% in 1 min (2% glutaraldehyde, sodium hypochlorite with > 5000 ppm free chlorine, and a quaternary ammonium formulation containing 23% HCl) (*159*). Bond et al. (*160*) and Kobayashi et al. (*161*) showed that 2-propanol (70% for 10 minutes) or ethanol (80% for 2 minutes) rendered human plasma contaminated with hepatitis B virus at high titre non-infectious for susceptible chimpanzees. Both 15% ethanol and 35% isopropanol readily inactivated human immunodeficiency virus (HIV), and 70% ethanol rapidly inactivated high titres of HIV in suspension, independent of the protein load (*162*). The rate of inactivation decreased when the virus was dried onto a glass surface and high levels of protein were present (*163*). In a suspension test, 40% propanol reduced the rotavirus titre by at least 4 $\log_{10}$ in 1 min, and

both 70% propanol and 70% ethanol reduced the release of rotavirus from contaminated fingertips by 2.7 $\log_{10}$ units (*164*), whereas the mean reductions obtained with liquid soap and an aqueous solution of chlorhexidine gluconate were 0.9 and 0.7 $\log_{10}$ units, respectively (*165*). Alcohol is thus the most widely used skin disinfectant. Alcohols used for skin disinfection before invasive procedures should be free of spores; although the risk of infection is minimal, the low additional cost for a spore-free product is justified. One study indicated that isopropanol in a commercial hand rub could be absorbed dermally, transgressing the religious beliefs of some health-care workers (*166*), although the results have been put into question by a recent trial (*167*). WHO resolved the issue in their most recent guidelines on hand hygiene by carefully analysing the available information and concluding that use of alcoholic compounds for patient care does not transgress religious beliefs (*168*). Alcoholic compounds are not suitable for use during surgery at or in close proximity to mucous membranes or the eyes.

Chlorhexidine: Chlorhexidine gluconate, a cationic bisbiguanide, has been widely recognized as an effective, safe antiseptic for nearly 40 years (*169*,*170*). Chlorhexidine formulations are used extensively for surgical and hygienic hand dis-infection; other applications include preoperative showers (for whole-body disinfection), antisepsis in obstetrics and gynaecology, management of burns, wound antisepsis and prevention and treatment of oral disease (plaque control, pre- and postoperative mouthwash, oral hygiene). When chlorhexidine is used orally, its bitter taste must be masked; it can also stain the teeth. Intravenous catheters coated with chlorhexidine and silver sulfadiazine are used to prevent catheter-associated bloodstream infections (*171*).

Chlorhexidine is most commonly formulated as a 4% aqueous solution in a detergent base; however, alcoholic preparations have been shown in numerous studies to have better antimicrobial activity than detergent-based formulations (*172*). Bactericidal concentrations destroy the bacterial cell membrane, causing cellular constituents to leak out of the cell and the cell contents to coagulate (*169*). The bactericidal activity of chlorhexidine gluconate against vegetative Gram-positive and Gram-negative bacteria is rapid. In addition, it has a persistent antimicrobial action that prevents regrowth of microorganisms for up to 6 hours. This effect is desirable when a sustained reduction in microbial flora reduces the risk for infection, such as during surgical procedures. Chlorhexidine has little activity against bacterial and fungal spores except at high temperatures. Mycobacteria are inhibited but are not killed by aqueous solutions. Yeasts and dermatophytes are usually susceptible, although the fungicidal action varies with the species (*173*). Chlorhexidine is effective against lipophilic viruses, such as HIV, influenza virus and herpes simplex virus types 1 and 2, but viruses like poliovirus, coxsackievirus and rotavirus are not inactivated (*169*). Blood and other organic material do not affect the antimicrobial activity of chlorhexidine significantly, in contrast to their effects on povidone–iodine (*153*). Organic and inorganic anions such as soaps are, however, incompatible with chlorhexidine, and its activity is reduced at extremely acidic or alkaline pH and in the presence of anionic- and nonionic-based moisturizers and detergents.

Microorganisms can contaminate chlorhexidine solutions, and resistant isolates have been identified (*174*). For example, Stickler and Thomas found chlorhexidineresistant *Proteus mirabilis* after extensive use of chlorhexidine over a long period to prepare patients for bladder catheterization (*175*). Resistance of vegetative bacteria to chlorhexidine was thought to be limited to certain Gram-negative bacilli such as *P. aeruginosa, Burkholderia* (*Pseudomonas*) *cepacia*, *P. mirabilis* and *S. marcescens*, but genes conferring resistance to various organic cations, including chlorhexidine, have been identified in *S. aureus* clinical isolates (*176*,*177*).

There are several other limitations to the use of chlorhexidine. When it is absorbed onto cotton and other fabrics, it usually resists removal by washing (*169*). Long-term experience with use of chlorhexidine has shown that the incidence of hypersensitivity and skin irritation is low, but severe allergic reactions including anaphylaxis have been reported (*178*,*179*). Although cytotoxicity has been observed in exposed fibroblasts, no deleterious effects on wound healing have been found in vivo. While there is no evidence that chlorhexidine gluconate is toxic if it is absorbed through the skin, ototoxicity is a concern when chlorhexidine is instilled into the middle ear during operations. High concentrations of chlorhexidine and preparations containing other compounds, such as alcohols and surfactants, may also damage the eyes, and its use on such tissues is not recommended (*180*).

Iodophors: Iodophors have essentially replaced aqueous iodine and tincture as antiseptics. These are chemical complexes of iodine bound to a carrier such as polyvinylpyrrolidone (povidone) or ethoxylated nonionic detergents (poloxamers), which gradually release small amounts of free microbicidal iodine. The most commonly used iodophor is povidone–iodine. Preparations generally contain 1–10% povidone–iodine, equivalent to 0.1–1.0% available iodine. The active component appears to be free molecular iodine (*181*). A paradoxical effect of dilution on the activity of povidone–iodine has been observed: as the dilution increases, bactericidal activity increases to a maximum and then falls (*182*). Commercial povidone–iodine solutions at dilutions of 1:2 to 1:100 kill *S. aureus* and *Mycobacterium chelonae* more rapidly than do stock solutions (*183*). *S. aureus* can survive a 2-minute exposure to full-strength povidone–iodine solution but cannot survive a 15-second exposure to a 1:100 dilution of the iodophor. Thus, iodophors must be used at the dilution stated by the manufacturer.

The exact mechanism by which iodine destroys microorganisms is not known. It may react with the microorganisms' amino acids and fatty acids, destroying cell structures and enzymes (*182*). Depending on the concentration of free iodine and other factors, iodophors exhibit a broad range of microbiocidal activity. Commercial preparations are bactericidal, mycobactericidal, fungicidal and virucidal but not sporicidal at the dilutions recommended for use. Prolonged contact is required to inactivate certain fungi and bacterial spores (*157*). Despite their bactericidal activity, povidone–iodine and poloxamer–iodine solutions can become contaminated with *B. (P.) cepacia* or *P. aeruginosa,* and contaminated solutions have caused outbreaks of pseudobacteraemia and peritonitis (*184*,*185*). *B. cepacia* was found to survive for up to 68 weeks in a povidone–iodine antiseptic

solution (*186*). The most likely explanation for the survival of these microorganisms in iodophor solutions is that organic or inorganic material and biofilm provide mechanical protection.

Iodophors are widely used for antisepsis of skin, mucous membranes and wounds. A 2.5% ophthalmic solution of povidone–iodine is more effective and less toxic than silver nitrate or erythromycin ointment when used as prophylaxis against neonatal conjunctivitis (ophthalmia neonatorum) (*187*). In some countries, povidone–iodine alcoholic solutions are used extensively for skin antisepsis before invasive procedures (*188*). Iodophors containing higher concentrations of free iodine can be used to disinfect medical equipment. However, iodophor solutions designed for use on the skin should not be used to disinfect hard surfaces because the concentrations of antiseptic solutions are usually too low for this purpose (*157*).

The risk of side-effects, such as staining, tissue irritation and resorption, is lower with use of iodophors than with aqueous iodine. Iodophores do not corrode metal surfaces (*182*); a body surface treated with iodine or iodophor solutions may absorb free iodine, however. Consequently, increased serum iodine (and iodide) levels have been found in patients, especially when large areas were treated for a long period. For this reason, other disinfectants should be considered for patients with hyperthyroidism and other disorders of thyroid function *(181)*. Because severe local and systemic allergic reactions have been observed, iodophors and iodine should not be used in patients with allergies to these preparations (*189*). Iodophores have little if any residual effect; however, they may have residual bactericidal activity on the skin surface for a limited time, because free iodine diffuses into deep regions and also back to the skin surface (*182*). The antimicrobial efficacy of iodophors is reduced in the presence of organic material such as blood.

Triclosan and chloroxylenol (para-chlorometaxylenol): Triclosan (Irgasan DP-300, Irgacare MP) has been used for more than 30 years in a wide array of skin-care products, including handwashes, surgical scrubs and consumer products. A review of its effectiveness and safety in health-care settings has been published (*190*). A concentration of 1% has good activity against Gram-positive bacteria, including antibiotic-resistant strains, but is less active against Gram-negative organisms, mycobacteria and fungi. Limited data suggest that triclosan has a relatively broad antiviral spectrum, with high-level activity against enveloped viruses such as HIV-1, influenza A virus and herpes simplex virus type 1. The nonenveloped viruses proved more difficult to inactivate.

Clinical strains of bacteria resistant to triclosan have been identified, but the clinical significance remains unknown (*191*). Triclosan is added to many soaps, lotions, deodorants, toothpastes, mouth rinses, commonly used household fabrics, plastics and medical devices. The mechanisms of triclosan resistance may be similar to those involved in antimicrobial resistance (*192*), and some of these mechanisms may account for the observed cross-resistance of laboratory isolates to antimicrobial agents (*193*). Consequently, concern has been raised that widespread use of triclosan formulations in non-health-care settings and products might select for biocide resistance and even cross-resistance to antibiotics. Environmental surveys have not, however, demonstrated an association between triclosan use and antibiotic resistance (*194*).

Triclosan solutions have a sustained residual effect against resident and transient microbial flora, which is minimally affected by organic matter. No toxic, allergenic, mutagenic or carcinogenic potential has been identified in any study. Triclosan formulations can help control outbreaks of methicillin-resistant *S. aureus* when used for hand hygiene and as a bathing cleanser for patients, although some methicillin-resistant *S. aureus* isolates have reduced triclosan susceptibility (*190*). Triclosan formulations are less effective than 2–4% chlorhexidine gluconate when used as surgical scrub solutions, but properly formulated triclosan solutions can be used for hygienic hand washing. *para*-Chlorometaxylenol (chloroxylenol, PCMX) is an antimicrobial agent used in hand-washing products, with properties similar to those of triclosan. It is available at concentrations of 0.5–3.75%. Nonionic surfactants can neutralize this compound.

Octenidine: Octenidine dihydrochloride is a novel bispyridine compound and an effective, safe antiseptic agent. The 0.1% commercial formulation compared favourably with other antiseptics with respect to antimicrobial activity and toxicological properties. It rapidly killed both Gram-positive and Gram-negative bacteria as well as fungi in vitro and in vivo (*195*,*196*). Octenidine is virucidal against HIV, hepatitis B virus and herpes simplex virus. Like chlorhexidine, it has a marked residual effect. No toxicological problems were found when the 0.1% formulation was applied according to the manufacturer's recommendations. The colourless solution is a useful antiseptic for mucous membranes of the female and male genital tracts and the oral cavity, but its unpleasant taste limits its use orally (*197*). In a recent observational study, the 0.1% formulation was highly effective and well tolerated in the care of central venous catheter insertion sites (*198*), and the results of this study are supported by those of a randomized controlled clinical trial (*199*). Octenidine is not registered for use in the United States.

Table II.6.6 lists antimicrobial agents that are recommended for surgical skin preparation.

Table II.6.6 – Antimicrobial agents recommended for surgical skin preparation

Solution	Comment
60–90% isopropanol	Not for use on mucous membranes
7.5–10% povidine–iodine	Can be used on mucous membranes
2–4% chlorhexidine	Not for use on eyes, ears, mucous membranes
Iodine, 3% preparation	Not for use on mucous membranes; can cause skin irritation if left for a long time
para-Chlorometaxylenol (PCMX)	Not for use on newborn babies; penetrates skin

Adapted from reference (206)

Special cases for decontamination

Vaginal and uterine surgery: Endometritis and wound infection are common significant postoperative complications of vaginal surgery, with reported infection rates varying between 5% and > 50%. The best-recognized risk factors for post-caesarean endometritis involve the introduction of large quantities of bacteria from the vagina and cervix into the uterine cavity. Therefore, reducing bacterial contamination of the vagina and cervix by vaginal swabbing with povidone–iodine solution before caesarean section is a reasonable approach. In one study, this led to a significant decline in the rate of postoperative endometritis (*200*); however, a randomized controlled trial failed to demonstrate an effect (*201*). Vaginal decontamination may be particularly useful in indigent patients or in settings where the bioburden of the vagina might be high.

Digestive-tract surgery: Selective decontamination of the digestive tract has been recommended for decades to decrease the rates of postoperative pneumonia and, to a lesser extent, surgical site infections (*202*). These effects should, however, be balanced against the cost, workload and risk for the emergence of multiresistant pathogens. Several recent trials indicates that a mouth rinse with chlorhexidine had a similar effect to selective decontamination of the digestive tract in patients undergoing cardiac surgery (*203–205*).

Antibiotic prophylaxis

Before the late 1960s, most 'prophylactic' antibiotics were administered after the end of a surgical procedure and were therefore found to be ineffective. Patients who received antibiotics had a higher rate of infection than patients who did not, probably because they were administered ineffectively and given only when the surgeon recognized an increased risk (*207*). Classic experiments in animals by John Burke demonstrated the sequence of events that occur in a surgical incision before infection and the importance of administering the antibiotic before wound contamination occurs (*208*,*209*). Subsequent placebo-controlled trials in humans showed a significant reduction in surgical site infections when antibiotics were used preoperatively. One prospective trial indicated that starting antibiotics before the immediate preoperative period was not beneficial (*210*), and a large retrospective examination of the time of antibiotic administration showed an increase in surgical site infection rates when antibiotics were given more than 2 hours before incision or after the incision (*211*). Initially, prophylactic antibiotics were given when the patients were called to the operating room, but subsequent studies showed that intravenous administration immediately before (average, 20 minutes) anaesthesia induction achieved better serum and tissue levels both at the beginning and at the end of the operation (*212* and J. DiPiro, personal communication). DiPiro found that cefazolin given on average 17 minutes (range 7–29 minutes) before incision achieved an average tissue level of 76 mg/l, while cefoxitin given 22 minutes (range 13–45 minutes) before incision achieved an average tissue level of 24 mg/l. The interval between being called to the operating room and the start of most operations is highly variable, and this unpredictable interval leads to an extended delay between delivery of antibiotics and skin incision. Consequently, the tissue levels of antibiotic are often less than ideal at the start of the operation. A recent review of total joint arthroplasty operations in the Netherlands confirmed the importance of preoperative administration of prophylactic antibiotics and showed that the lowest infection rate was associated with administration within 30 minutes of incision (*213*,*214*). Vancomycin is one of the few antibiotics that require adjustments in timing; commencement of infusion should be timed such that completion is achieved within an hour of incision (*215*,*216*).

There is widespread agreement and good evidence to support the use of prophylactic antibiotics before all gastrointestinal (including appendicitis), oropharyngeal, vascular (including abdominal and leg), open-heart and obstetric and gynaecological procedures, orthopaedic prosthesis placement, spinal operations, craniotomy and even some 'clean' procedures (*217*,*218*). The typical reductions in infection rates seen in early placebo-controlled trials of prophylaxis are shown in Table II.6.7. While there is some controversy about the use of prophylactic antibiotics for designated 'clean' operations, it is well accepted for open-heart operations, joint replacement, vascular prostheses and craniotomy in which the absolute number of infections is low but the consequence of any infection is severe (Table II.6.8). The reduction in infection rate is similar for other 'clean' procedures (*219–222*), but the absolute number of infections prevented is lower when the underlying infection rate is lower (*220*,*223*). If the number of administrations of routine prophylaxis needed to prevent one infection is high, the morbidity of the infection should be high, or the cost, both financial and medical, of the prophylaxis should be low.

Table II.6.7 – Typical rates of infection and reduction with prophylaxis in placebo-controlled trials

Operation (reference)	Prophylaxis (%)	Placebo (%)	Number needed to treat to avoid one surgical-site infection
Colon (*224–227*)	4–12	24–48	3–5
Other (mixed) gastointestinal tract (*228-231*)	4–6	15–29	4–9
Vascular (*232*,*233*)	1–4	7–17	10–17
Cardiac (*234*,*235*)	3–9	44–49	2–3
Hysterectomy (*236*)	1–16	18–38	3–6
Craniotomy (*237–239*)	0.5–3	4–12	9–29
Spinal (*240*)	2.2	5.9	27
Total joint replacement (*241*,*242*)	0.5–1	2–9	12–100
Breast and hernia (*221*)	3.5	5.2	58

Table II.6.8 – Preoperative Wound Classification of the Centers for Disease Control and Prevention (United States)

Clean Wounds: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.
Clean-Contaminated Wounds: Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category provided no evidence of infection or major break in technique is encountered.
Contaminated Wounds: Includes open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered are included in this category.
Dirty or Infected Wounds: Includes old traumatic wounds with retained or devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

Few studies have examined the ideal dose of prophylactic antibiotics. A study of morbidly obese patients showed a two-thirds reduction in surgical site infection rates when the dose of cefazolin was increased from 1 g to 2 g (*243*). Early trials involving patients undergoing cardiac surgery demonstrated a correlation between risk for infection and absence of antibiotic in the serum at the end of the operation and low levels of antibiotics at the time of cannulation (*244, 245*). In a study of prophylaxis in patients undergoing colectomy, the strongest association with avoidance of surgical site infection was the level of drug in the serum at the end of the operation (*246*). Repeated administration of the drug at one to two half-lives or use of a drug with a long half-life during lengthy operations also reduced infection rates (*247*,*248*). Thus, the most important aspect in the timing and dosing of prophylactic antibiotics is achieving effective levels throughout the time that the incision is open.

Early trials of antibiotic prophylaxis usually involved a three-dose regimen, with the first and last dose separated by 12 hours. Within a short time, many placebo-controlled trials demonstrated the efficacy of a single preoperative dose of prophylactic antibiotic. Nevertheless, the practice of continuing prophylactic antibiotics postoperatively, often for days, is widespread. For example, there is no evidence to support the common practice of using prophylactic antibiotics until all central lines and drains have been removed. Many trials in which shorter duration of prophylaxis was compared with longer failed to show any benefit of longer duration (*249–251*). Other studies show that more resistant bacteria are recovered from patients who receive prophylaxis for a long time (*252*). An expert panel assembled by the United States Center for Medicare and Medicaid Services recommended that prophylactic antibiotics be initiated during the 60 minutes before incision and stopped within 24 hours of the end of the operation (*14*).

Many different antibiotics have been shown to reduce the incidence of surgical-site infections. The primary consideration is that the antibiotic used is active against the spectrum of bacteria commonly encountered during the procedure and recovered from surgical site infections. There is general agreement that the antibiotic agents used for prophylaxis should be different from those usually chosen for first-line treatment of established infections, although this supposition has never been studied systematically. A number of societies and organizations, including the Surgical Infection Society (*218*), the Infectious Diseases Society of America (*217*), the American Society of Hospital Pharmacists (*253*), Johns Hopkins University (*254*), the *Medical Letter* (*255*) and the Scottish Intercollegiate Guidelines Network (*256*), have published well-researched guidelines and recommendations for surgical antibiotic prophylaxis.

Table II.6.9 gives recommendations published by various professional societies and organizations. Usually, a single first-generation cephalosporin for operations not expected to encounter anaerobes or a single second-generation cephalosporin with anaerobic activity for anaerobic operations based on local susceptibility patterns is sufficient. For clean operations on the skin and subcutaneous tissues that do not involve any portion of the gastrointestinal tract, a semi-synthetic penicillin resistant to penicillinases, such as oxacillin or cloxacillin, is probably effective, although there are limited published data to support this recommendation. Administration of antibiotics that are active against enteric anaerobes for procedures involving the lower gastrointestinal tract should be considered routine. Procedures on the upper gastrointestinal tract should involve use of antibiotics with activity against Gram-positive cocci and common Gram-negative organisms but which are not active against anaerobes. Procedures that do not enter any portion of the intestinal or genitourinary tract are sufficiently covered with antibiotics that are primarily active against Gram-positive cocci.

Table II.6.9 – Current recommendations of agents for surgical prophylaxis

Procedure	Agents
Colectomy	Cefotetan, cefoxitin, cefazolin plus metronidazole, ampicillin/sulbactam or ertapenem; metronidazole combined with an aminoglycoside, a quinolone or trimethroprim/sulfamethoxazole, or clindamycin combined with an aminoglycoside, a quinolone, aztreonam or trimethroprim/sulfamethoxazole[a]
Other gastrointestinal surgery	Cefotetan, cefoxitin, cefazolin or cefuroxime[b]
Hysterectomy	Cefotetan, cefoxitin, cefazolin or cefuroxime, cefazolin plus metronidazole[c]
Vascular and cardiac surgery	Cefazolin or cefuroxime, penicillinase-resistant penicillins such as oxacillin and cloxacillin, or vancomycin or clindamycin
Total joint replacement	Cefazolin or cefuroxime or a penicillinase-resistant penicillin

Not all agents listed have been tested in prospective placebo-controlled trials, but most are widely used and fulfill the criterion of being active against the usual pathogens encountered in these settings.

[a] *The recommendations for metronidazole and clindamycin combined with various Gram-negative agents as listed above have had limited or no testing but represent logical choices on the basis of antibiotic susceptibility patterns and known colonic flora. In addition, they have all been used successfully in the treatment of infections originating in the colon.*

[b] *Procedures of the stomach and pancreatic and biliary systems are managed with any of these agents. Distal ileal and appendix operations are more appropriately managed with the agents listed for colectomy.*

[c] *Early studies showed no difference between agents with (cefotetan, cefoxitin) and without (cefazolin, cefuroxime) anaerobic activity. More recent trials demonstrate better results with agents active against anaerobes.*

ß-Lactam allergies are often cited as a contraindication for antibiotic prophylaxis. Many patients who are reported to be allergic on their medical record do not, however, have a true antibiotic allergy but have experienced nonsevere adverse reactions, such as *Candida* overgrowth or gastrointestinal upset. Before choosing an alternative prophylactic agent for a patient with a history of 'allergy', the nature of the previous reaction should be confirmed. Patients who have had immediate, anaphylactic type reactions should not receive an antibiotic to which they are allergic. For operations in which the risk is primarily from skin organisms, vancomycin or teicoplanin is a common choice for patients allergic to ß-lactam. If local susceptibility patterns are favourable, clindamycin can be used. Some experts recommend that in hospitals with a high rate of methicillinresistant *S. aureus*, a glycopeptide should be used prospectively for procedures involving a risk for infection with skin organisms. There is, however, no agreement about the level of methicillin-resistant *S. aureus* that would justify this approach. The only prospective trial performed to address this question showed no reduction in surgical site infections with the prophylactic vancomycin and an excess number of infections due to methicillinsensitive *S. aureus* (*257*). There have been no controlled trials of antibiotic prophylaxis for colon operations with agents appropriate for patients allergic to ß-lactam. Logic suggests that a combination of clindamycin or metronidazole with either an aminoglycoside or a fluoroquinolone, or even trimethoprim and sulfamethoxazole or a combination of clindamycin with aztreonam, should be effective.

Prophylaxis for caesarean section: Caesarean section, one of the most commonly performed operations, carries a significant risk for postoperative infection. Infectious complications have been estimated to occur in 7–20% of such patients (*258*). Griffiths et al. reported an overall surgical site infection incidence of 9.9% in a case–control study (*259*). A Cochrane review concluded that the two-third reduction in wound infections and the three-fourths reduction in endometritis justify recommendation of prophylactic antibiotics in both elective and non-elective caesarean section (*260*). First-generation cephalosporins are the most commonly used agents. Debate about the optimal timing of administration of prophylactic antibiotics continues. Concern about neonatal exposure to antibiotics and the effect on neonatal sepsis have led to delays in administering antibiotics until after the umbilical cord has been clamped — the WHO *guidelines Managing complications in pregnancy and childbirth* recommend a single dose of prophylactic antibiotics after the cord is clamped and cut (*261*). Thigpen et al. found in a recent randomized clinical trial that there was no difference in maternal infectious complications, including neonatal sepsis and admissions to an intensive care unit, whether antibiotics were given before skin incision or at cord clamping (*262*). Sullivan et al. reported that administration of antibiotics before skin incision resulted in a decrease in infectious complications when compared with administration at the time of cord clamping (*258*). Finally, changes in policy leading to administration of prophylactic antibiotics before skin incision led to a significant decline in post-cesarean infections (*263*). Prophylaxis is most effective when given before incision for every other operation studied, and a recent meta-analysis did not show clear evidence of harm to the child from this brief exposure to antibiotic at the time of birth (*264*). Prophylactic antibiotic administration during the hour before incision is likely more effective than waiting until the umbilical cord is clamped. The Royal College of Obstetricians and Gynaecologists recommend offering antibiotics prophylactically while the American College of Obstetricians and Gynecologists recommend antibiotic administration for prophylaxis, but neither makes conclusive recommendations regarding timing (*269*). Clearly, there is controversy on this question, and either practice is acceptable and more effective for preventing post-caesarean infection than placebo (*267*).

Prophylaxis in children: Very few trials of surgical antibiotic prophylaxis have been done in paediatric populations, but the issue has been reviewed by the American Academy of Pediatrics, which concluded that the basic biological principles of prophylaxis are unlikely to be different in paediatric patients and adults (*268*). They recommend that the same basic principles be followed but that the doses be adjusted according to standard dosing principles for paediatric patients.

Subacute bacterial endocarditis prophylaxis in patients undergoing surgical procedures: Guidelines for subacute bacterial endocarditis prophylaxis are available for patients who are at risk for endocarditis and undergoing an operation. The American Heart Association recently released a new guideline, which has been endorsed by the Infectious Diseases Society of America and the Pediatric Infectious Diseases Society (269). Endocarditis prophylaxis is not recommended for patients undergoing surgical procedures, including endoscopy, except for those with prosthetic valves or previous infectious endocarditis, cardiac transplant recipients who have cardiac valvulopathy, or the following examples of congenital heart disease: unrepaired cyanotic congenital heart disease (including patients with palliative shunts and conduits), congenital heart defects completely repaired with prosthetic materials only during the first 6 months after the procedure, and repaired congenital heart disease with residual defects at or adjacent to the site of a prosthetic patch or prosthesis. The guidelines state that "no published data demonstrate a conclusive link between procedures of the gastrointestinal or genitourinary tract and the development of infectious endocarditis. Moreover, no studies exist to demonstrate that the administration of antimicrobial prophylaxis prevents infectious endocarditis in association with procedures performed on the gastrointestinal or genitourinary tract…. For patients with the conditions listed above who have an established gastrointestinal or genitourinary tract infection, or for those who receive antibiotic therapy to prevent wound infection or sepsis associated with a gastrointestinal or genitourinary tract procedure, it may be reasonable that the antibiotic regimen include an agent active against enterococci, such as penicillin, ampicillin, piperacillin, or vancomycin; however, no published studies demonstrate that such therapy would prevent enterococcal infectious endocarditis. Amoxicillin or ampicillin is the preferred agent for enterococcal prophylaxis for these patients. Vancomycin may be administered to patients who do not tolerate ampicillin. If infection is caused by a known or suspected strain of resistant Enterococcus, consultation with an infectious diseases expert is recommended." For patients with the conditions listed above "who undergo a surgical procedure that involves infected skin, skin structure, or musculoskeletal tissue, it is

reasonable that the therapeutic regimen administered for treatment of the infection contain an agent active against staphylococci and ß-hemolytic streptococci, such as an antistaphylococcal penicillin or a cephalosporin. Vancomycin or clindamycin may be administered to patients unable to tolerate a ß-lactam or who are known or suspected to have an infection caused by a methicillin-resistant strain of staphylococcus…. Prophylaxis at the time of cardiac surgery should be directed primarily against staphylococci and should be of short duration. The choice of an antibiotic should be influenced by the antibiotic susceptibility patterns at each hospital."

Minimizing contamination in the operating room

In addition to the risks that the patient, the operation and the team bring to the procedure, the environment of the operating room can also pose a risk to patients. Effective, appropriate planning and forethought in the construction of an operating room minimize such risks. Regular maintenance and cleaning of surgical suites are essential.

Disinfection of surfaces: The surfaces in operating rooms should be kept clean by the use of water, detergent and wiping. As surfaces are considered 'noncritical' according to Spaulding's classification system, keeping them clean should be enough for safety (*270*). Use of disinfectants, either in a cleaning solution or vaporized into the air, has not proven to make a difference in the rates of surgical site infections and can pose risks to health-care workers (*271*).

Surgical attire: The use of masks that cover the mouth and nose, hair-coverings such as caps, sterile surgical robes and impermeable sterile gloves is standard for surgical teams. Some correspond to basic principles of aseptic technique and their use is based on laboratory or microbiological studies or rationale, but scientific evidence of their impact in preventing surgical site infections is not available or has been disputed.

The use of masks to cover the mouth and nose is standard practice. The purpose is to prevent contamination of the patient's tissues with microorganisms from the upper respiratory tract of the surgical team and also to prevent exposure of the mouth and nose of operating room staff from splashes of blood or other fluids from patients during a procedure. Use of masks significantly reduces contamination of the surgical site, but the association between mask use and surgical infections is less clear (*272*,*273*). Tunevall randomly assigned 115 weeks of wearing masks or no mask during 3967 surgical operations in the period 1984–1985 and reported 184 surgical site infections (4.6%) (*274*). When the randomization of weeks was assessed, no differences between groups were observed in terms of age, type of surgery, elective or not elective or clean or not clean, and no difference in rates was documented whether masks were used or not. Few studies have investigated whether the type of mask affects the rate of infections, and no clear conclusions can be drawn because of low power due to the small numbers of persons studied (*275*). There is evidence that the use of masks protects from splashes of blood or other fluids from patients during surgery, but its role in preventing the transmission of microorganisms is not clear (*276–278*).

Sterile robes are used to prevent bacteria on the skin of surgeons from coming into contact with the patient's tissues and also to prevent blood and fluids from patients from coming into contact with the skin of the surgical team. Some fabrics are less permeable than others to fluids, moisture or bacteria. The use of different fabrics did not make a difference in contamination in experimental studies that did not involve actual surgery (*279*). No difference in the rates of surgical site infections by *S. epidermidis*, *S. aureus* or other agents was observed in randomized controlled trials of patients undergoing cardiac surgery by surgeons wearing surgical attire made of disposable materials or reusable cotton fabric (*280–282*).

The use of sterile gloves for surgery is standard practice; however, 8–15% of surgical gloves are torn or punctured during procedures (*283–285*). No difference in surgical site infections rates was observed when gloves were damaged or not during surgery, and the use of two pairs of gloves (double gloving) did not decrease the rates (*286*,*287*). When double gloving was used, the outer glove had more perforations than the inner glove, and the hands of the surgical team were less contaminated with blood or other body fluids. In a study of cerebrospinal fluid shunt surgery, the use of double gloves was associated with a 50% reduction in infections of the shunt as compared with use of single gloves (*288*).

The use of shoe covers for transit in the operating room or during surgery is a frequent practice, although the relation between contamination of the floor of the operating room and the rate of surgical site infections has not been established. In a systematic review of studies published between 1950 and 2003, it was found that the dispersion of microorganisms from the floor to the air was low and that there was no association between the dispersion and contamination of the surgical wound or the rate of surgical site infections (*289*).

Guaranteeing the sterility of surgical instruments: sterility indicators

Sterilization is the process by which an item is purged of all microorganisms and spores. The use of sterile materials for surgery is considered standard practice internationally. Microorganisms have different degrees of resistance to sterilization methods depending on their type, capacity to form spores, sensitivity to heat, chemicals and disinfectants, and the composition and thickness of the bacterial cell wall or viral envelope. Microbial agents can be organized by their resistance to sterilization procedures: medium-sized viruses tend to be the least resistant to destruction, while bacterial spores tend to be the most resistant. Any process that kills bacterial spores is considered to be able to eliminate all other infectious agents, and elimination of bacterial spores is a satisfactory indicator that sterilization has been achieved. Processes that kill *M. tuberculosis* but neither bacterial spores nor prions are considered to achieve 'high-level disinfection'. (The destruction of prions requires special procedures and is not described in this document.)

In the classification system of Spaulding et al., devices that enter normally sterile tissue, body cavities or the vascular system should be sterile (*270*). Articles that come into contact with intact mucous membranes and that do not ordinarily penetrate sterile tissue are classified as 'semicritical' and should receive at least high-level disinfection. Although the categories of disinfection may be oversimplified in this system, it is currently the most useful means of categorizing instrument decontamination.

Achieving sterility, particularly for reusable surgical instruments, requires a sequence of cleaning and mechanical removal of gross contamination, inspection and assembly, packaging, sterilization, storage, transport and delivery to the operating room, and certification of the sterilization process. Cleaning is the mechanical or chemical removal of any residual matter, organic or inorganic, from an item with water, detergents and mechanical means. Cleaning decreases the microbial load but does not destroy microorganisms. It can be achieved manually or with automatic equipment. Residual organic matter interferes with the efficacy of sterilization and disinfection by preventing contact of the microbicidal agent with the surface of the instrument or prolonging the time of exposure required to achieve destruction of microorganisms (*290–292*). Because of the significant reduction in microbial load due to cleaning, it has also been called 'decontamination', especially when chemical agents are used. Inspection consists of direct visualization of cleaned instruments, usually through a magnifying glass, to detect residual matter (including oils or lubricants) that can interfere with sterilization. Packaging of instruments and tray assembly must allow the sterilizing agent to reach every item and effectively kill all microorganisms. For successful tray packaging, the tray must not be overloaded. The packaging should also allow handling of the tray after sterilization without contaminating the items on it. Each sterilizing agent and method has its own requirements for tray packaging to ensure successful sterilization (*293*). The packaging system should be permeable to the sterilizing agent but resistant to traction and manipulation.

Sterilization is the exposure of instruments, devices and other materials to a sterilizing agent. All remaining microorganisms and spores should be eliminated by use of this agent. A wide variety of methods is available for sterilization, and Table II.6.10 lists the advantages and limitations of those most frequently used. The choice of method should be based on the characteristics of the instruments and devices, the need for proper cleaning and packaging, the time required for exposure and sterilization, the temperature and pressure achieved, the humidity and its potential to damage devices or items, the existence of a vacuum and circulation of the agent within the sterilization chamber (*293*). These relations are shown for the most frequent methods of sterilization in Table II.6.11.

Table II.6.10 – Advantages and limitations of methods for sterilizing articles in health-care settings

Method	Advantages	Limitations
Heat (steam sterilization)	• Short exposure • Effective for prions • Not toxic for humans or the environment • Easy certification • Low cost • Widely available • Easy to operate	• Not compatible with thermolabile items • Does not eliminate pyrogens • Cannot be used for oils or powders
Heat (dry air)	• Not corrosive • Deep penetration • Not toxic for humans or the environment • Easy to operate • Widely available	• Long exposure • Not compatible with thermolabile items • Hard to certify • High cost • Efficacy against prions not known
Ethylene oxide	• Compatible with thermolabile items • Penetrates certain plastics • Easy to operate	• Long exposure • Not effective for prions • Toxic for humans and • the environment
Hydrogen peroxide plasma	• Compatible with thermolabile items • Short exposure • Not toxic for humans or the environment • Easy to operate	• Not all materials are compatible • Not effective for prions • Does not reach the centre of long lumens effectively
Liquid peracetic acid in automatic equipment	• Short exposure • Easy to operate • Not toxic for the environment	• Useful only for materials that can be immersed • In existing equipment, few containers can be processed • Not effective for prions • Processed items must be used immediately
Formaldehyde	• Compatible with thermolabile items • Short exposure • Easy certification	• Not all materials are compatible • Not effective for prions

Table II.6.11 – Standardized conditions for sterilization with saturated steam, dry heat and ethylene oxide

Time after temperature and pressure are reached	Temperature (°C)	Pressure (atm)
Saturated steam		
15 min	121	1.5
10 min	126	2.0
3 min	134	2.9
Dry heat		
60 min	170	
120 min	160	
150 min	150	
180 min	140	
Overnight	121	
Ethylene oxide		
5 h	35	
2.5 h	55	

Storage, transport and delivery are the processes by which the instruments and devices are maintained until their use in the operating room. Means of preserving the integrity and impermeability of the packaging by keeping the sterilized materials in appropriate storage (ideally in closed, dust-free shelves and in a dry environment) must be available.

Certification is the method by which sterilization is ascertained and confirmed. It requires a number of procedures to verify that the process has been successful. The physical parameters of sterilization, such as temperature, pressure and length of exposure to the sterilizing agent, must be measured for every sterilization cycle and load. For automatic equipment, this is frequently measured and documented by the equipment itself. Manual equipment should be operated by trained personnel, and calibrated thermometers, barometers, clocks and load sensors should be used. Biological indicators contain a known load of the most resistant microorganism killed by the sterilizing method. Spores of *Geobacillus stearothermophilus* for saturated hot steam, hydrogen peroxide plasma and formaldehyde and *Bacillus subtilis* var *niger* for dry heat and ethylene oxide are usually used. After the process has finished, the viability of the microorganisms is assessed. If there is no microbial activity, the process is considered successful. The frequency of use of biological indicators has not been standardized; however, it should be used on every load of implantable materials, at least once a week for other materials, and always after sterilizing equipment has been repaired. The results of these biological indicators may be available within hours or days, depending on the type of indicator, but rarely immediately or by visual inspection by the operating team at the time of surgery. Chemical indicators must be used routinely to monitor the performance of the equipment and sterilization. Existing chemical indicators are made of thermochromic ink which changes colour when exposed to the sterilizing agent. Most sterilization indicators turn from beige to black once sterilization is finished. Different types of indicators react to different processes and serve different purposes:

- Processing indicators, such as indicator tape, are placed outside each package to show whether the materials within were processed. Used chemical indicators should be discarded before packaging, and a new indicator should be used for each package.
- Parametric indicators are used inside each package to demonstrate that sterilization was effective.
- A special use of chemical indicators is the Bowie-Dick test for prevacuum sterilizing methods (such as some steam autoclaves), which allows confirmation of the effectiveness of the vacuum pump in the sterilization chamber (293). The Bowie-Dick test should be performed daily when autoclaves of this type are used.

Maintaining records of sterilization also appears to be useful, by allowing tracking of machinery and maintenance, verification of the sterility of surgical equipment and quality control.

There are numerous methods for controlling contamination and reducing infectious complications of surgical care. A system as complex as surgery requires the coordination of many individuals to ensure that appropriate procedures and processes are in place to guarantee the cleanliness of the operating room and the sterility of the instruments and equipment used during surgery. Measures known to reduce infection must also be implemented in a timely fashion. Policies for systematically minimizing the risks for infection can make a tremendous difference in the outcome of surgical care, save numerous lives and prevent much morbidity.

Recommendations

Highly recommended:

- Prophylactic antibiotics should be used routinely in all clean–contaminated surgical cases and considered for use in any clean surgical case. When antibiotics are given prophylactically to prevent infection, they should be administered within 1 hour of incision at a dose and with an antimicrobial spectrum that is effective against the pathogens likely to contaminate the procedure. Before skin incision, the team should confirm that prophylactic antibiotics were given within the past 60 minutes. (When vancomycin is used, infusion should be completed within 1 hour of skin incision.)
- Every facility should have a routine sterilization process that includes means for verifying the sterility of all surgical instruments, devices and materials. Indicators should be used to determine sterility and checked before equipment is introduced onto the sterile field. Before induction of anaesthesia, the nurse or other person responsible for preparing the surgical trays should confirm the sterility of the instruments by evaluating the sterility indicators and should communicate any problems to the surgeon and anaesthetist.
- Redosing with prophylactic antibiotics should be considered if the surgical procedure lasts more than 4 hours or if there is evidence of excessive intraoperative bleeding. (When vancomycin is used as the prophylactic agent, there is no need for redosing in operations lasting less than 10 hours.)
- Antibiotics used for prophylaxis should be discontinued within 24 hours of the procedure.
- Hair should not be removed unless it will interfere with the operation. If hair is removed, it should be clipped less than 2 hours before the operation. Shaving is not recommended as it increases the risk for surgical site infection.
- Surgical patients should receive oxygen throughout the perioperative period according to individual requirements.
- Measures to maintain core normothermia should be taken throughout the perioperative period.
- The skin of all surgical patients should be prepared with an appropriate antiseptic agent before surgery. The antimicrobial agent should be selected on the basis of its ability to decrease the microbial count of the skin rapidly and its persistent efficacy throughout the operation.

- Surgical hand antisepsis should be assured with an antimicrobial soap. The hands and forearms should be scrubbed for 2–5 minutes. If the hands are physically clean, an alcohol-based hand antiseptic agent can be used for antisepsis.
- The operating team should cover their hair and wear sterile gowns and sterile gloves during the operation.

Recommended:

- 'On call' orders for administration of antibiotic prophylaxis should be discouraged.
- If hair is to be removed, the use of depilatories is discouraged.
- Tobacco use should be stopped at least 30 days before elective surgery if possible.
- Surgical patients should take a preoperative shower with antiseptic soap.
- Prior infections should be eliminated before a scheduled operation.
- The operating team should wear masks during the operation.
- Surgical drapes that are effective when wet should be used as part of the sterile barrier.
- Sterile dressing should be maintained over the surgical wound for 24–48 hours.
- Active surveillance for surgical site infections should be conducted prospectively by trained infection control practitioners.
- Information on the surgical site infection rate should be provided to surgeons and appropriate administrators.

Suggested:

- A high fraction of inspired oxygen (80%) should be administered throughout the operation, and supplemental oxygen should be administered for at least two hours postoperatively.
- Positive pressure air flow should be maintained in the operating room.
- The operating room should be cleaned thoroughly after 'dirty' or 'infected' cases and at the end of each operating day.
- Standardized infection control policies should be implemented.
- Surgical teams should be educated about infection prevention and control at least annually.

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Objective 7

The team will prevent inadvertent retention of instruments and sponges in surgical wounds

Inadvertently leaving a sponge, needle or instrument in a patient at the end of an operation is a rare but persistent, serious surgical error. Because of its rarity, it is difficult to estimate the frequency with which it occurs; the best estimates range from 1 in 5000 to 1 in 19,000 inpatient operations, but the likelihood has been estimated to be as high as 1 in 1000 (*1–4*). Retained sponges and instruments tend to result in serious sequelae, including infection, re-operation for removal, bowel perforation, fistula or obstruction and even death. A number of factors contribute to this error, but the evidence points to three clear risk factors: emergency surgery, high body mass index and an unplanned change in the operation (*3*). Other risk factors that may contribute are high-volume blood loss and the involvement of multiple surgical teams, although these factors did not reach statistical significance in the study. Sponges and instruments can be retained during any surgical procedure on any body cavity, regardless of the magnitude or complexity.

A team process for manually counting all instruments and sponges at the start and conclusion of a surgical operation is standard practice for numerous nursing organizations. The Association for Perioperative Practice (formerly the National Association of Theatre Nurses, United Kingdom), the Association of peri-Operative Registered Nurses (United States), the Australian College of Operating Room Nurses, Operating Room Nurses Association of Canada and the South African Theatre Nurse have all established recommendations and standards for sponge and instrument counts to reduce the incidence of retained sponges and instruments during surgery (*5–9*). Measures such as incorporating radio-opaque material in sponges make it possible to find those that have been retained using intraoperative radiographs if there is a miscount. The standards have several common elements, including standardization of the counting procedure and systematic tracking and accounting of items on the sterile field and in the wound.

Manual counting methods are not fool-proof, as they are subject to human error. Newer techniques, which include automated counting and tracking of sponges, appear to increase the accuracy of counting and the detection of inadvertently retained sponges. New methods include use of bar-coded sponges and sponges with radiofrequency identification tags. A randomized trial of a bar-coded sponge system showed a threefold increase in detection of miscounted or misplaced sponges (*10*). The cost of such systems, however, can range from US$13 per case for bar-coded sponges to US$75 per case for radiofrequency-tagged sponges.

General criteria for counting

As part of the overall tracking of items in the operating room, each facility should have a policy for surgical counts that specifies when they should be performed and by whom, what items should be counted and how counts (including incorrect counts) should be documented. A specific procedure for counting should be established to ensure that the protocols are standardized and familiar to operating room personnel. Specific low-risk procedures (e.g. cystoscopy, cataract surgery) can be exempted from the counting protocols, but they should be exceptions rather than a general rule. Most established protocols include all or nearly all the recommendations listed below.

A full count of sponges, sharps, miscellaneous items (especially small items such as tapes, clips and drill bits) and instruments should be performed when the peritoneal, retroperitoneal, pelvic and thoracic cavities are entered. Counts should also be done for any procedure in which these items could be retained in the patient, and must be conducted at least at the beginning and end of every eligible case. A tally of all counted items should be maintained throughout the operation. Any items designated as part of the counting protocol that are added during the procedure should be counted and recorded upon entry onto the sterile field. Ideally, preprinted count sheets for sponges, sharps and instruments should be used and included in the patient's record whenever possible. Other recording strategies, such as using whiteboards to track counts, are also acceptable, in accordance with hospital protocol.

Counting should be performed by two persons, such as the scrub and circulating nurses, or with an automated device, when available. When there is no second nurse or surgical technician, the count should be done by the surgeon and the circulating nurse. If a count is interrupted, it should be started again from the beginning. Ideally, the same two persons should perform all counts. When there is a change in personnel, a protocol for transfer of information and responsibility should be clearly delineated in hospital policy.

Items should be viewed and audibly counted concurrently. All items should be separated completely during a count. Counts should be performed in a consistent sequence, for example, sponges, sharps,

miscellaneous items and instruments at the surgical site and immediate area, then the instrument stand, the back table and discarded items.

The team member responsible for the count should be aware of the location of all counted items throughout the operation. Items included in the count should not be removed from the operating room until the final count is completed and the counts are reconciled. The results of counts should be announced audibly to the surgeon, who should give verbal acknowledgement. In the event that an incision is re-opened after the final count, the closure count should be repeated. When a count cannot be performed, an X-ray should be taken before the patient leaves the operating room, if the patient's status permits, or as soon as possible thereafter.

Sponge count (e.g. gauze, laparotomy sponges, cotton swabs, dissectors): An initial sponge count should be done for all non-exempt procedures. At a minimum, sponges should be counted before the start of the procedure, before closure of a cavity within a cavity, before wound closure (at first layer of closure) and at skin closure.

When available, only X-ray-detectable sponges should be placed in body cavities. Sponges should be packaged in standardized multiples (such as 5 or 10) and counted in those multiples. Sponges should be completely separated (one by one) during counting. Packages containing incorrect numbers of sponges should be repackaged, marked, removed from the sterile field and isolated from the other sponges. Attached tapes should not be cut. Non-X-ray-detectable gauze used for dressing should be added to the surgical field only at skin closure.

When sponges are discarded from the sterile field, they should be handled with protective equipment (gloves, forceps). After they have been counted, they should be organized so as to be readily visible (such as in plastic bags or the equivalent) in established multiples. Soiled dissecting sponges (e.g. peanuts) should be kept in their original container or a small basin until counted.

Sharps count (e.g. suture and hypodermic needles, blades, safety pins): Sharps should be counted before the start of the procedure, before closure of a cavity within a cavity, before wound closure (at first layer of closure) and at skin closure. Suture needles should be counted according to the marked number on the package. The number of suture needles in a package should be verified by the counters when the package is opened. Needles should be contained in a needle counter or container, loaded onto a needle driver or sealed with their package. Needles should not be left free on a table.

Instrument count: Instruments should be counted before the start of the procedure and before wound closure (at first layer of closure). Instrument sets should be standardized (i.e. same type and same number of instruments in each set) and a tray list used for each count. Instruments with component parts should be counted singly (not as a whole unit), with all component parts listed (e.g. one retractor scaffold, three retractor blades, three screws). Instruments should be inspected for completeness. All parts of a broken or disassembled instrument should be accounted for. If an instrument falls to the floor or is passed off the sterile field, it should be kept within the operating room until the final count is completed. No instrument should be removed from the operating room until the end of the procedure.

Documentation of counts

Counts should be recorded on a count sheet or nursing record. The names and positions of the personnel performing the counts should be recorded on the count sheet and in the patient's record. The results of surgical counts should be recorded as correct or incorrect. Instruments and sponges intentionally left with the patient should be documented on the count sheet and in the patient's record. Any action taken in the event of a count discrepancy or incorrect count should be documented in the patient's record. Reasons for not conducting a count in cases that normally demand a count should be documented in the patient's record.

Count discrepancies

Every health-care facility should have a policy for the procedure to follow in case of a count discrepancy. When counts are discrepant, the operating-room personnel must perform a recount, and, if they are unable to reconcile the counts, they should immediately notify the surgeon and the operating room supervisor and conduct a search for the missing item, including the patient, floor, garbage and linen. If the counts remain unreconciled, the team should ask for a radiograph to be taken—when available—and document the results on the count sheet and in the patient's record. When a count ought to be performed but is not, the surgeon and operating room supervisor should be notified, a radiograph taken at the completion of the procedure and an accurate record of why the count was not undertaken and the results of the radiographs noted.

Methodical wound exploration before closure

Alternative methods for tracking and accounting for surgical sponges, instruments, sharps and other items should be considered as they become available and validated. Manual counts nevertheless remain the most readily available means of preventing retained sponges and instruments. Counting clearly prevents retained items from being left in a patient's body cavity but is fraught with error. In a study of retained surgical instruments, Gawande et al. noted that in 88% of cases of retained sponges and instruments in which counts were performed, the final count was erroneously believed to be correct (*3*). This implies a dual error: leaving an item in the patient, and a counterbalancing miscount that results in a false 'correct' count.

Preventing the unintentional retention of surgical objects in a surgical wound requires clear communication among the team members. All operating-room personnel have a role to play in avoiding this error. While the task of keeping track of sponges and instruments placed within a surgical wound is commonly delegated to the nursing or scrub staff, the surgeon can decrease the likelihood of leaving a sponge or instrument behind by carefully and methodically examining the wound before closure in every case. This practice has been advocated by the American College of Surgeons as an essential component of preventing retained sponges and instruments (*11*). This type of evaluation addresses counterbalancing errors in counting that might lead to a false 'correct' count. It is cost-free and provides an added safety check to minimize the risk of leaving a sponge or instrument behind.

Recommendations

Highly recommended:

- A full count of sponges, needles, sharps, instruments and miscellaneous items (any other item used during the procedure that is at risk of being left within a body cavity) should be performed when the peritoneal, retroperitoneal, pelvic or thoracic cavity is entered.
- The surgeon should perform a methodical wound exploration before closure of any anatomical cavity or the surgical site.
- Counts should be done for any procedure in which sponges, sharps, miscellaneous items or instruments could be retained in the patient. These counts must be performed at least at the beginning and end of every eligible case.
- Counts should be recorded, with the names and positions of the personnel performing the counts and a clear statement of whether the final tally was correct. The results of this tally should be clearly communicated to the surgeon.

Suggested:

- Validated, automatic sponge counting systems, such as bar-coded or radio-labelled sponges, should be considered for use when available.

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Objective 8

The team will secure and accurately identify all surgical specimens

While there are considerable data on processing and diagnostic errors associated with surgical specimens, there is scant evidence about the incidence and nature of errors due to inadequate or wrong labelling, missing or inadequate information and 'lost' specimens, all of which can potentially hinder patient care and safety (*1*,*2*). An analysis of medico-legal claims for errors in surgical pathology revealed that 8% were due to 'operational' errors (*2*). Such incidents are accompanied by delays in treatment, repeated procedures and surgery on the wrong body part. Such incidents occur in all specialties and all types of tissue (*3*).

In a study of identification errors in laboratory specimens from 417 United States institutions, nearly 50% were due to labelling errors (*4*). Transfusion medicine has led the way in highlighting the importance of specimen labelling, but errors in laboratory tests can also result in patient harm. One in 18 labelling errors results in an adverse event, and, in the United States, it has been estimated that close to 160,000 adverse events occur annually because of mislabelling. Errors in labelling laboratory specimens occur because of mismatches between the specimen and the requisition and unlabelled or mislabelled specimens (*5*). Patient identification on specimens and requisition forms are critical in any attempt to prevent laboratory errors. The Joint Commission made 'accurate patient identification' one of their laboratory patient safety goals (*6*). Improved identification is crucial to preventing errors in laboratory specimen labelling. Rechecking wrist identification bands can decrease specimen labelling error rates and blood grouping errors (*7*–*9*).

Mislabelling of surgical pathology specimens can have more severe consequences than other laboratory errors that occur before specimen analysis (*7*, 10). A recent study by Makary et al. showed that errors occur in 3.7 per 1000 specimens from operating rooms and involve the absence of accurate labelling, omission of details regarding tissue site and the absence of patient name (3). Several simple steps can be taken to minimize the risk of mislabelling. First, the patient from whom each surgical specimen is taken should be identified with at least two identifiers (e.g. name, date of birth, hospital number, address). Second, the nurse should review the specimen details with the surgeon by reading aloud the name of the patient listed and the name of the specimen, including the site of origin and any orienting markings. When required by a facility, the surgeon should complete a requisition form labelled with the same identifiers as the specimen container. This requisition form should be cross-checked against the specimen by the nurse and surgeon together before it is sent to the pathology department and should include the suspected clinical diagnosis and the site (and side or level when applicable) from which the sample was taken.

Recommendations

Highly recommended:

- The team should confirm that all surgical specimens are correctly labelled with the identity of the patient, the specimen name and location (site and side) from which the specimen was obtained, by having one team member read the specimen label aloud and another verbally confirming agreement.

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Objective 9

The team will effectively communicate and exchange critical information for the safe conduct of the operation

"The pursuit of safety … is about making the system as robust as practicable in the face of human and operational hazards" wrote James Reason, one of the pioneers of human error evaluation (*1*). Failures within a system, particularly catastrophic ones, rarely happen as a result of a single unsafe act. Rather, they are the culmination of multiple errors involving the task, team, situation and organization. The factors responsible for these errors may be broadly categorized in the following seven ways: high workload; inadequate knowledge, ability or experience; poor human factor interface design; inadequate supervision or instruction; stressful environment; mental fatigue or boredom; and rapid change.

The greatest threats to complex systems are the result of human rather than technical failures. And while human fallibility can be moderated, it cannot be eliminated. Thus complex systems such as aviation and the nuclear industry have come to accept the inevitability of human error and built mechanisms to reduce and manage it (*2*). These mechanisms include technological innovations such as simulations, team training initiatives and simple reminders such as checklists. Team communication is a central component of managing and averting errors.

As with other complex systems, communication among team members is essential for the safe and effective functioning of a surgical team. But because of the acuity of a patient's condition, the amount of information required and the urgency with which it must be processed, and the technical demands on health-care professionals, surgery often exceeds the complexity of other industries. Other systemic issues including the number of people involved, the heavy workload, stress, fatigue, hierarchical structures and inadequate organization contribute to an error-prone environment (*3,4*). In addition, omissions, misinterpretations and conflict arising from poor communication can result in adverse patient outcomes (*5–7*). Yet, unlike other complex systems, health personnel involved in current surgical practice do not regard human error as inevitable and have attempted only intermittently to build systematic safety features into care.

There is growing evidence that communication failures among team members are a common cause of medical errors and adverse events. The Joint Commission reported that in the United States communication was a root cause of nearly 70% of the thousands of adverse events reported to the organization between 1995 and 2005 (*8*). Furthermore, operating teams seem to recognize that communication breakdowns can be a fundamental barrier to safe, effective care. In one survey, two thirds of nurses and physicians cited better communications in a team as the most important element in improving safety and efficiency in the operating room (*9*).

Team culture and its effects on safety

A central component of team communication is the ability of team members to raise safety concerns. The ability of teams to communicate effectively and avoid unnecessary mishaps requires each member to act on concerns about the safety of the patient or the operation. An essential starting-point for effective team communication is an interdisciplinary discussion to ensure adequate planning and preparation for each surgical case. Constructive team culture creates an environment that permits and fosters such discussions.

Three elements contribute to a team's culture: the structure of the team, the perception of team roles and team members' attitudes to safety issues. The team structure is the team's composition, hierarchy, and the distribution and coordination of work among individuals and professional groups. Operating teams include surgeons, anaesthetists, nurses and other technicians involved in the perioperative care of surgical patients. These disciplines frequently function in what has been termed 'silos' - they ostensibly work together as a team, but the worlds of surgery, nursing and anaesthesia can be very different, and in some environments they barely interact. This professional identification and resulting segregation translate into practice patterns that function independently (and often in parallel) in the same physical space, with some overlapping duties, and that foster distinct expectations and values (*10*). These patterns constrain a team's ability to function effectively, particularly in a complex, unpredictable work environment. Furthermore, operating teams tend to be strongly hierarchical and team members are reluctant to communicate between hierarchical levels (*11*). While simple linear tasks, such as checking equipment, can be performed well in a hierarchical structure, complex tasks such as shared decision-making may be inhibited and require a more collaborative approach to teamwork (*12*).

Team members can make different assumptions about how work is to be distributed and coordinated within the team. For example, surgeons and anaesthesiologists might have conflicting perceptions about who is responsible for ensuring timely administration of antibiotic prophylaxis (*13*). Ambiguity in team structure can be a product of interprofessional disagreements about how tasks should be distributed and valued (*14*). Formalization and standardization are not common in operating room teamwork due to medicine's strongly held value of professional autonomy and its craftsman mindset. These factors promote individualism as opposed to cooperation and can act as barriers to achieving safer health care (*15*).

The attitudes of team members often reflect and reproduce the organizational culture in which they work. Surveys have shown that individuals often have discrepant attitudes about their ability to work as a team and about communication among disciplines. Qualitative evaluations of intensive care unit teams showed that, in contrast to physicians, nurses reported that it was difficult to speak up, disagreements were not appropriately resolved, and more input into decision-making was needed (*11*). In the operating room, the differences in attitudes between surgeons and the other team members can be substantial (*16*). It is important to understand these attitudes. Research in aviation has shown that positive attitudes about teamwork are associated with error-reducing behaviour (*17*). A similar association has been found between attitude shifts and improved patient outcomes in intensive care units (*18*,*19*). Most strikingly, improvements in safety attitudes amongst surgical team members have recently been associated with improvements in outcomes of surgical patients, suggesting that such changes may help explain some of the effect of quality improvement efforts (*20*). Unlike personality, attitudes are amenable to change (*11*).

A culture of teamwork and communication can lead to better patient outcomes. A steep hierarchy exists in most operating rooms that affects the extent to which the teams function effectively (*12*). Professional affiliation, perception of roles, gender differences and seniority can all foster isolation and segregation, limiting interaction and interdisciplinary questioning. Evaluations of other highly reliable organizations such as aviation reveal that strategies such as the use of checklists, standard operating protocols and communication interventions such as team briefings and debriefings aid in task completion and foster a culture of open communication. Such interventions standardize processes and act as reminders, so that team members need not rely solely on memory recall , creating a process known as "error trapping" (*21*). In complex systems in which many people and advanced techniques are involved, appropriate procedures are needed to manage and prevent errors. Without such systems, problems are almost inevitable. Health care comprises an enormous diversity of tasks and goals, whereas aviation, nuclear power generation and railways are relatively homogeneous. Furthermore, the vulnerability of patients increases their liability to serious adverse events by disorganized behaviour patterns.

Patterns of communication breakdown

Observational research in United States academic health centres has revealed patterns of communication breakdown among operating teams. Breakdowns can occur during the preoperative, intraoperative and postoperative phases of surgical care and can result in death, disability or prolonged hospital stay for patients (*22*). A study of communication failures in the operating room found that they occur in approximately 30% of team exchanges (*23*). Fully one third of these breakdowns jeopardize patient safety by increasing cognitive load, interrupting routines and increasing tension. The ability to coordinate activities in the operating room varies widely among hospitals and among disciplines. Both observational data and the experience of operating room personnel indicate a systematic lack of discussion and planning, including the absence of formal error identification mechanisms, before skin incision (*16*, *24*).

While there is some evidence of poor communication patterns in the intraoperative phase, only a few studies have addressed failures in handover of the patient postoperatively (*23, 25 ,26*). Inadequate handover as patients are transferred from one care site to another and during shift changes has been found to be a safety risk (*27, 28*). The absence of structured information flow among team members and ambiguity about responsibilities hinder effective communication throughout the perioperative period (*22*). Failure to communicate intraoperative events can result in inappropriate monitoring of patients postoperatively, absence of enhanced vigilance for specific, predictable postoperative complications, and medication errors such as lapses or delays in administering antibiotics and anticoagulation regimens. The frequency of such omissions remains unknown. In its sentinel event investigations, the Joint Commission has made improving handovers between teams by standardizing the transfer process one of its core goals in patient safety (*29*).

Reducing communication breakdown during surgery

Pre-procedural briefings are critical safety component of other highly complex industries (*30*). Briefings facilitate the transfer of critical information and help create an atmosphere of shared learning and responsibility. The Joint Commission recommends use of a 'time out' or 'surgical pause' to allow the team to confirm the patient, the procedure and the site of operation before the incision (*31*). This is now

a mandatory requirement in all operating rooms in the United States and has laid the foundation for trials of preoperative team briefings, in which additional safety checks are merged into the process. Recent studies suggest that using the time just before skin incision to review the names and roles of all team members, key checks, the operating plan, familiarity with the procedure and issues that might be encountered during the case is of significant value (*32*). In studies in single institutions, use of preoperative operating room briefings was associated with an improved safety culture, a reduction in wrong-site or wrong-procedure surgery, early reporting of equipment issues, reduced operation costs and improvements in the use of prophylactic medication (antibiotics or thromboembolism prophylaxis) in the perioperative period (*33-36*). In fact, if surgical teams providing care exhibit less information-sharing behaviours, the risk of complications and death increases up to fourfold (*37*).

Preoperative checks vary in content according to the centre. They usually include checks to confirm use of infection prophylaxis and the availability of critical equipment and resources. In an observational study of 10 surgical procedures, about 15 resources were added per procedure after the beginning of the operation, indicating that communication problems can have a negative impact on team performance (*26*). Equipment problems are more likely to disrupt workflow, delay case progression and lead to deterioration in the dynamics among team members than compromise patient safety. In a survey of operating room team members, respondents felt that nearly 10% of errors in operating rooms were related to equipment problems (*38*). The American College of Surgeons Closed Claims Study showed that the errors in 5% of claims were equipment-related (*39*). Equipment-related issues not only delay case progression but cause surgeons to adjust their technique and the procedure to work around equipment problems (*26*). Although this phenomenon has not been studied in detail, such adaptation could result in technical errors. The Kaiser-Permanente organization in the United States found that preoperative briefings that included a check on whether the equipment required or expected for the procedure was available resulted in reduced equipment problems and an increase in staff morale (*35*). Training for and implementing the briefing required minimal resources.

Preoperative briefings or checks can also include discussion of modifications to routine operating plans, specific concerns about the patient and the availability of necessary imaging for the operation. The Australian Incident Monitoring Study found that nearly 25% of clinical incidents resulted from poor preoperative information, assessment and preparation (*40*). Imaging can provide independent confirmation of the site for operation, when it is available (*41*). In cases of bilaterality, multiple body parts (e.g. fingers) or multiple levels (e.g. spinal surgery), the American College of Surgeons has proposed that imaging should be prominently displayed in the operating room (*42*). Images can also be important in cases in which intraoperative decisions about the extent of surgical resection are made. Such decisions often depend on a combination of surgical and radiographic evaluation of size and anatomical location of the diseased area (e.g. soft tissue and solid organ tumours).

Preoperative briefing sessions are a means of timely information transfer between team members. Likewise post-procedure debriefings consisting of an exchange of information at the conclusion of an operation gives the team an opportunity to review what was done, share critical events that arose during the case and develop management plans for recovery (*43*). Thus incorporation of safety checks into debriefings can form the basis for a safety intervention. Recent evidence indicates that omission of postoperative debriefings increases the risk of complications (*37*). Most importantly, the combination of team briefings and debriefings significantly improved the perceived collaboration of operating room personnel (32). While some may see the briefings as an interruption, most surgeons, anaesthesiologists, nurses and technicians who have participated in this type of study reported that the benefits outweighed the inconvenience (*36, 43-45*).

Use of checklists to improve safety and communication

Checklists are routinely used in high-reliability organizations such as aviation and the nuclear power industry. In aviation, their use is mandatory for every stage of a flight, and failure to use a checklist is considered a violation of flight protocol and a flight error (*46*). Checklists counteract human failures of omission that are likely to occur with information overload, multiple steps in a process, or departures from routine procedures. Interruptions and distractions are also causal factors in errors of omission (47,48). Checklists have been used successfully in a number of health-care specialties, such as intensive care, anaesthesia and surgery. Their use in health care has met with some scepticism, and resistance to their use stems in part from the perception that they undermine the professional autonomy of clinicians (*46*).

Checklists must be tested in clinical settings to assess their value. They should be simple to accomplish and address the major safety issues that, if omitted, put a patient at risk for harm. They can be poorly designed, however, if they require too many steps to be practicable, cause safety or process problems during execution, or are poorly written. They can also mistakenly seek to enforce behaviours that the practitioners do not agree with or cannot follow, or be designed so rigidly that they cannot adapt to local circumstances and context. ‘Checklist fatigue’ can result from the use of multiple checklists, and use of checklists can actually lead to errors if they are seen as extraneous and unimportant (*46*). If multiple checks are performed by multiple providers, a person may declare that an item has been checked even when it has not, thus perpetuating errors. Exhaustive checklists can slow the process of care and may alienate the users. This may foster negative attitudes and defeat the purpose of a

checklist, which is to create a safety climate. In addition, given the cultural barriers that currently exist and the intensity of work in an operating room, teams may require prompting to use a checklist or briefing, even if it is accepted practice in a facility (*49*).
Two checklists were demonstrated to have significant value for improving patient safety. In an attempt to reduce central venous catheter infections, Pronovost et al. instituted a checklist in over 100 intensive care units in the State of Michigan, United States (*50*). Simple checks ensured that providers washed their hands before the procedure; wore gloves, a gown, a hat and a mask; properly prepared the skin at the insertion site; draped the patient and maintained a sterile field; and evaluated the patient daily to determine whether the catheter was needed. They found a dramatic decrease in the rate of catheter-related infections when teams adhered to these simple measures, providing a model for how a simple checklist can induce clinicians to adhere to known safety measures in their daily practice. In a study of the WHO *Surgical Safety Checklist* developed as a practical tool for implementing these guidelines, complications were reduced by over one third and deaths cut by nearly 50% in eight pilot hospitals representing a variety of economic circumstances and diverse patient populations (51, see Appendix 1).

Record-keeping

Accurate record-keeping is integral to providing high-quality care (*52,53*). Although there is little experimental evidence of its value, broad experience has established its importance for maintaining adequate communications in professional practice (*54,55*). Good record-keeping is regarded as a mark of an organized, safe practitioner. Medical records exist for the benefit of the patient and for reference by future health-care providers. The General Medical Council in the United Kingdom specifies that doctors should "keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients and any drugs or other treatment prescribed." It also states that doctors should "keep colleagues well informed when sharing the care of patients" (*56*). As surgical care is provided by a multidisciplinary team working in a variety of settings and locations, the accuracy and clarity of written records ensures that information that affects care is readily available to all the personnel involved. Patient records allow all team members to reconstruct events and enable them to plan further treatment or interventions based on of full information about clinical history and events. Good record-keeping is an accepted component of surgical care and an important means of promoting high-quality health care.

In order to improve teamwork, all members of an operating team must communicate before, during and after a procedure. Preparation for a complex case should ideally begin before the day of surgery in order to ensure the preparedness of the team for any critical event. Conscientious use of a checklist before induction of anaesthesia, before skin incision and before the patient is removed from the operating room can facilitate communication and focus all team members on the critical steps that will prevent harm and improve safety.

Recommendations

Highly recommended:

- Before skin incision, the surgeon should ensure that team members, in particular nurses, anaesthetists, and surgical assistants are aware of the critical steps of the procedure to be performed, the risk for heavy blood loss, any special equipment needed (such as instruments, implants, intraoperative imaging, frozen section pathology) and any likely deviation from routine practice. The nurse(s) should inform the team members about any critical safety concerns and the lack of availability or preparation of any special equipment. The anaesthetist should inform the team about any critical safety concerns, in particular any difficulty in preparing for resuscitation after heavy blood loss or patient comorbidities that add risk to the anaesthesia.
- In cases of bilaterality, multiple body parts (e.g. fingers or toes) and multiple levels (e.g. spine) or when intraoperative decisions on the extent of surgical resection are to be made in conjunction with radiographic imaging, the team should confirm that the necessary imaging is available and displayed in the operating room.
- Before the patient leaves the room, the surgeon should inform team members of any alterations that were made to the procedure performed, any problems that may occur in the postoperative period and essential postoperative plans (which might include antibiotics, venous thromboembolism prophylaxis, oral intake or drain and wound care). The anaesthetist should summarize the clinical condition of the patient during the operation and any other instructions needed to ensure a safe recovery. The nurse should notify the team of any additional concerns recognized during the operation or for recovery.

- An accurate, complete, signed surgical record should be maintained. All patient records should be:
  - *clear*: the patient clearly identified by his or her name and hospital number on each page, written legibly or typed and each entry signed, dated and timed;
  - *objective*: opinions should be based on recorded facts;
  - *contemporary*: notes should be written as soon as possible after an event;
  - *tamper-proof*: attempts to amend records should be immediately apparent; if computerized systems are used, they should record the date and author of any notes and track any amendments;
  - *original*: records should not be altered or amended once an entry is complete. If a mistake is noticed, amendments or corrections may be added and clearly identified as such. If a change is made to the record, it should be signed and dated, and a note should explain why the change was made.
- Information recorded by the surgeon in the operation note should include, at a minimum, the name of the main procedure performed and any secondary procedures, the names of any assistants, the details of the procedure and the intraoperative blood loss. The information recorded by the anaesthetist should include, at a minimum, intraoperative vital sign parameters recorded at regular intervals, medications and fluids administered intraoperatively and any intraoperative events or periods of patient instability. The information recorded by the nursing team should include, at a minimum, sponge, needle, sharps and instrument counts, the names and positions of the personnel performing the counts, instruments and sponges specifically left inside the patient, any action taken in the event of a count discrepancy, and, if no count was performed, the reasons for not conducting a count. The complete operation record should therefore include the names of all team members involved.

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Objective 10

Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results

Assessment of success, failure and progress in the provision and safety of surgical care relies on information on the status of care. Practitioners, hospitals and public health systems require information on surgical capacity, volume and results, to the extent practicable. Success in other fields of public health, such as the safety of childbirth, reduction of HIV transmission and the eradication of poliomyelitis, has been shown to depend on surveillance (*1–4*). Improvement of surgical safety and access is no different.

The absence of data on surgery in WHO metrics has probably contributed to the failure to recognize the enormous volume of surgery that is performed throughout the world and its contribution to avoidable disability and death (*5*). These guidelines therefore list an essential set of 'vital statistics' for surgical surveillance at a systems level and simple patient-level measures for use by hospitals and practitioners.

The current model for measuring health-care delivery is the Donabedian framework (*6,7*). First introduced in 1966, this framework is based on three levels of measures: those of structure, process and outcome.

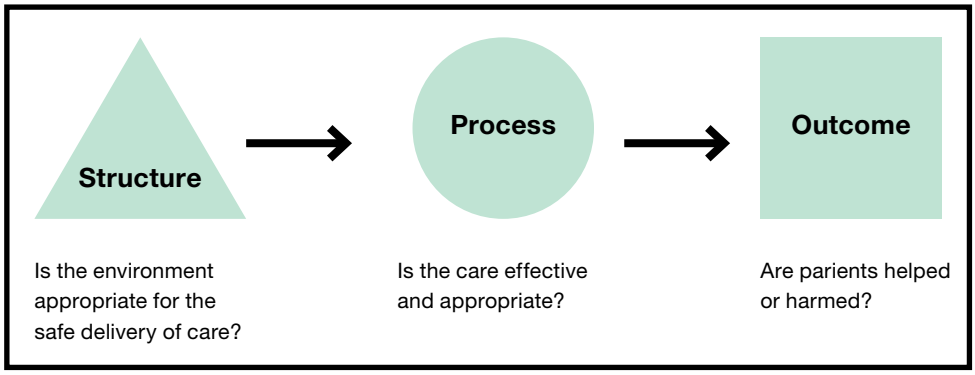
Structure metrics allow assessment of the infrastructure of a health system.

Process metrics allow assessment of how well a health-care protocol is carried out or delivered.

Outcome metrics allow assessment of the results or impact on a population's health.

The strength of the Donabedian framework lies in the relations between these measures. As illustrated in Figure 10.1, structure influences process and process in turn influences outcome (*8*). A comprehensive assessment of health-care delivery requires understanding of all three elements individually and the relations among them.

Figure 10.1 – The interaction of structure, process and outcome on health care



Adapted from (8)

A central objective of the WHO Patient Safety: Safe Surgery Saves Lives programme is to define a set of 'vital statistics' for surgery that incorporates measures of structure and outcome while tracking process efforts such as the use of a safety checklist and implementation of standardized protocols for care. The goal is to assess both access to and quality of care. Because of the significant difficulties associated with almost any form of measurement, the programme sought to maintain simplicity.

There are no simple measures to evaluate surgical care. In public health programmes to reduce maternal and infant mortality, data on structure, process and outcome are used to derive information about the quantity and quality of maternal care. The data include fertility rates, the volume of caesarean sections, the proportion of births assisted by a skilled birth attendant and the number of such attendants in a country, as well as outcome measures such as maternal mortality, infant mortality and Apgar scores. This guideline therefore outlines a similar set of indicators for which standardized data on the volume and safety of surgery can be collected and compared.

Feasibility and implications of measurement

In order to obtain surgical vital statistics, it is essential to have practical indicators and a realistic mechanism for data collection. WHO's Health Metrics Network defines the issues as follows (*9*):

Indicators. A minimum set of indicators and related targets, covering the main domains of health information (determinants, health system inputs and outputs, health service coverage and quality and health status) is the basis for a health information system plan and strategy.

Data sources. There are two main types of data source: those generating populationbased estimates (census, vital statistics and household or population-based surveys and surveillance) and those that depend on health service or administrative records (disease surveillance, health-facility records, administrative records and healthfacility surveys).

Infrastructure: A country must have an adequate infrastructure for collecting health information, be it based on population surveys or administrative records. Certain minimal structural requirements, such as personnel, training programmes, measurement collection tools and computer or data recording equipment, must be available.
As surgical vital statistics have broad global applicability, the structural limitations of the most resource-constrained countries must be considered. A complex indicator such as the rate of postoperative complications is more difficult to measure than an indicator such as postoperative mortality rate. Common indicators that are clearly defined and require only modest infrastructure are the easiest to measure.

Economic considerations: Closely related to structural feasibility is economic feasibility. In designing a surgical assessment tool, consideration must be given to the direct and indirect financial costs associated with its implementation. In resource-limited settings, certain data collection tools may be impractical for financial reasons. This is particularly true for designs that require computer-based data storage, state-of-the-art medical techniques (such as computed tomography scanners) or other costly equipment. Feasible data collection tools can help a country to manage its information system in order to make surgical care both safe and cost-effective. The cost of efforts to collect data must translate into health savings for the population.

Positive incentives: The existence of a surgical assessment metric will probably improve surgery throughout the world for several reasons. Most importantly, it will provide a global baseline evaluation of the quantity and public health outcomes of the surgical care currently delivered. It will also establish a foundation on which to base evaluations of interventions to improve surgical access and safety. It will help establish health information systems specifically for surgery and surgical diseases that can be further developed and refined over time.

The usefulness of surgical vital statistics may extend beyond these direct consequences. Assessing surgical care on a global basis may improve care simply through the power of measurement and reporting. Better awareness of the accessibility and outcomes of surgical care may cause subtle but tangible improvements in care delivery, thus creating a positive incentive to improve surgical results.

Negative incentives: Data collection can also have a perverse effect on health care, imparting negative incentives for caring for the sickest patients. A country's desire to appear to be performing high-quality surgery at an adequate volume may create an unintended incentive to increase the number of inappropriate elective operations, underreport mortality, discharge sick patients early and fail to operate on critically ill patients. It must be clear that surgical statistics are intended to help a country to improve its health system and the delivery and safety of surgical care, given its available resources. They are not intended or designed for comparing the quality of care in different health systems but represent a benchmark for progress in public health.

Case mix and risk adjustment: Any comparison must account for variations in patient conditions and the complexity of procedures. Methods to evaluate the differences between facilities and practitioners, even within a single institution, must take into account the characteristics of the patients, the case mix, urgency and hospital setting. Such complex data collection is beyond the capacity of most countries at present. Furthermore, the public health goal of this WHO initiative is to reduce complications and deaths from surgery, regardless of whether they are due to patient or institutional factors. Therefore, these guidelines outline the data required to provide basic information on surgical capacity, volume and overall outcomes.

Current measures in surgery

Volume: The global volume of surgery is estimated to be 234 million major operations per year (*5*). This estimate was based on reporting from a minority of countries, as less than 30% of countries have publicly available data on the volume of surgery performed nationally, and the data are infrequently updated. In the absence of standardized reporting, the data are based on various definitions, making analysis difficult. Procedures such as percutaneous interventions, endoscopy, radiographically guided procedures and wound debridements are often excluded, even when performed under anaesthesia. In addition, administrative data systems may not record multiple operations on a single patient; billing data may miss surgical care provided outside the established payment system; facility surveys typically omit certain

types of care facilities (such as private clinics and hospitals); and outpatient surgical procedures are often excluded.

Outcome: Several countries attempt to follow perioperative outcomes. The United Kingdom maintains a system for tracking and reporting perioperative deaths, which has proved feasible to maintain (*10*,*11*). In Canada, Europe and the United States, sophisticated but costly reporting of risk-adjusted complications and mortality has become common in certain specialties, such as cardiac surgery, and in certain health-care sectors, such as the United States Veterans Health System (*12–17*). In Germany, a strategy for tracking specific index or proxy cases has been used in quality assurance programmes. By collecting data from 'tracer' operations—such as inguinal hernia, hip fracture and cholecystectomy—and designing policies on the basis of the findings from these data, the outcome and quality of care have been improved (*18–22*).

Trauma and cancer registries also provide information on the outcomes of clinical care. Frequently, such databases provide metrics that allow facility-level comparisons of treatment modalities and systems of care. Trauma systems have been compared both nationally and internationally (*23–25*), and the information gained from such surveillance has led to recommendations for improvements in infrastructure, planning, training and care (*26–28*). Data from cancer registries such as the United States' National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) database (*29*) has led to confirmation of the positive association between high volume and better outcomes (*30–32*). In addition, data from registries have helped refine the timing and extent of surgical resections for a variety of malignancies and guided systems changes (*33–37*).

Capacity: Current WHO health systems statistics include a range of indicators of health-care capacity. A comprehensive, up-to-date global database on the size of the health-care workforce in countries has been established on the basis of indicators from many sources covering many areas (profession, training level and industry of employment), but the coding does not distinguish specializations *(38)*. The metrics enumerate the ratio of physicians per 1000 population but no sub-strata. Such detailed data do exist in some countries, but the countries most in need of such data are often those in which data gathering systems are weakest. The 2006 World Health Report identified the design of health workforce classification tools that can be effectively integrated into existing reporting instruments as a priority (*39*).

Surgical surveillance: surgical vital statistics for systems-level evaluation

Surveillance of surgical systems must include measures of capacity, volume and outcome to enable public health planning and progress. The data must be easy to collect in countries with limited resources, although countries with more resources may be able to collect more extensive data on surgical care. Interest in expanding data collection is expected to increase once the basic measures of surgery are in place and apparent differences in the outcome of surgical care emerge. Therefore, in addition to defining the basic statistics for all countries, intermediate and advanced surgical vital statistics are described, which, when feasible, could further increase international understanding of the effect of surgical care on public health.

Basic surgical vital statistics: A review of current needs, capabilities and practice was the basis for a set of surgical 'vital statistics'. The goal is that all WHO Member States attempt to collect this information annually and to include it in their annual health reports. It was highly recommended that data from basic surgical surveillance include:

- the number of operating rooms in each country,
- the number of operations performed in operating rooms in each country,
- the numbers of trained surgeons and trained anaesthetists in each country,
- the number of deaths on the day of surgery and
- the number of in-hospital deaths after surgery.

These basic measures are the structural, process and outcome components of surgical delivery systems. The structural metrics indicate the capacity of a country for delivering care. The number of operating rooms and the number of trained surgeons and anaesthetists are measures of the resources available for delivery of surgical care. The number of operations performed in operating rooms is a measure of the services actually delivered within a country. The day of surgery death and overall in-hospital death numbers, when converted into ratios, provide basic indicators of surgical outcomes, much as maternal and neonatal mortality rates do for obstetric outcomes.

The number of operating rooms in each country: Delivery of surgical services is an important component of health systems. Knowing the operating room density will help evaluate the availability, access and distribution of surgical services and coverage. An operating room is defined as an enclosed room specifically dedicated to surgical procedures and equipped to deliver monitored anaesthesia, whether or not it is located in a hospital facility. Potential sources of data for this measure include administrative records based on reported data by inpatient and outpatient facilities and censuses of health facilities with possible adjustment for underreporting (e.g. missing private facilities). Certain procedures, such as incision and drainage of wounds, endoscopy and dilation and curettage, may be performed in procedure rooms that are not suit-able for other types of invasive operations. Minor procedure rooms should not be included unless they meet the definition of an operating room.

The number of surgical procedures performed in operating rooms in each country: The number of surgical procedures performed in an operating room is an indication of access to and use of health care, particularly surgical services. A surgical procedure is defined as the

incision, excision or manipulation of tissue that requires regional or general anaesthesia or profound sedation to control pain. Potential sources of data for this measure include hospital records and routine health service statistics with possible adjustment for underreporting (e.g. surgery in the private sector). If data from only a subset of operating rooms (e.g. excluding private facilities) are reported, the number of operating rooms in the sample should be given.

This indicator does not provide information on the reason for performing a procedure and includes operations that might be performed without a clinical indication, in addition to those that are medically necessary. It is therefore not possible to determine whether a surgical procedure is performed according to clinical need. There is no consensus about the volume of surgery that ought to be performed in a given population, as the surgical rate changes according to the disease burden of the population and as indications for procedures change over time. Baseline rates of surgery can, however, help establish whether a health system is meeting the minimum surgical needs of a population.

Many invasive procedures not typically considered to be 'surgery' might be listed as a surgical procedure, such as endoscopy with or without biopsy and percutaneous vascular interventions. As these procedures may be performed in an operating room or an alternative procedure room, their inclusion may confound the data collection. Invasive procedures that meet the definition but are performed in a procedure room not suitable for larger invasive operations should not be considered in the total number of surgical procedures. If, however, they are performed in an operating room, they should be counted. In addition, the requirement that surgical procedures take place in an operating room does not exclude ambulatory operations, which make up a substantial and growing proportion of surgical care in some countries.

The numbers of trained surgeons and trained anaesthetists in each country: The availability and composition of human resources for health are important indicators of the strength of a health system. Furthermore, as the disease burden shifts from infectious to chronic conditions, welltrained practitioners will be increasingly necessary for providing appropriate care. While there is no consensus about the optimal number of surgeons or anaesthetists for a population, specialist coverage and the quality of the provider are important for safe and appropriate provision of surgical care. In general, a 'surgeon' is a physician who treats disease, injury or deformity by operative or manual methods (*40*). The designation 'trained' refers to those practitioners registered by accepted national standards, each country defining what these standards are. Thus, surgeons are defined as physicians who have achieved certification in one of the surgical specialties as recognized by the accepted standards of the Member State or the national professional organization. Anaesthetists are physicians, nurses and other practitioners who have achieved certification in the provision of anaesthesia as recognized by the accepted standards of the Member State or the national professional organization. Persons who perform surgery or administer anaesthesia but are not appropriately credentialed, including those in training, would not be included in this measure. Data sources for these measurements may include facility surveys, labour force surveys and records from professional and administrative sources.

Number of deaths on the day of surgery: Death on the day of surgery reflects co-morbid conditions and physiological derangements of the patient, the quality and complexity of surgical care, the risks of anaesthesia or some combination of these three. These events are the basis for evaluating the performance of the health system and the state of health of the population. This measure is most useful when converted to day-of-surgery death ratio, defined as the number of deaths on the day of surgery per 100 surgical procedures in a given year or period. Potential sources of data include administrative and hospital records based on health service statistics, with possible adjustment for underreporting (e.g. death on the day of surgery that occurs outside the surveillance system or which is not reported).

Although fairly rare, death on the day of surgery is an important indicator of patient, surgeon, operation and anaesthesia characteristics. There is no consensus about what an acceptable day-of-surgery mortality ratio might be, particularly as it often reflects a combination of factors. This metric will provide valuable insight into the patterns of surgical deaths within a health system, from the burden of disease in a population that prompts them to seek surgical care to the skill, judgement and technical capacity of the surgical and anaesthetic providers. It cannot, however, be used to compare one site, facility or country with another without appropriate, valid, time-consuming risk adjustment.

Number of in-hospital deaths after surgery: Complications and death are not uncommon after surgical procedures. An understanding of this outcome provides insight into the risks associated with surgical intervention. Like the previous measure, this is most useful when converted to a postoperative in-hospital death ratio, defined as the number of deaths in the hospital within 30 days of any surgical procedure per 100 surgical procedures performed in a given year or period. Potential sources of data include administrative and hospital records based on health service statistics, with possible adjustment for underreporting (e.g. in-hospital surgical death that occurs outside the surveillance system or which is not reported).

This measure reflects the number of patients who have undergone a surgical procedure and die in a hospital within 30 days of their operation. Patients who undergo surgery and are discharged but die outside a health facility would not be counted as in-hospital surgical deaths. The number should, however, include patients who undergo a procedure at one facility but are transferred and die in another within 30 days of the operation. The postoperative in-hospital death ratio varies considerably with the type of procedure being performed, the type of health facility, the health of the population and the distribution of the burden of disease. Thus, comparisons of facilities and countries without risk adjustment are discouraged. The measure should instead be used to guide health service workers to improve performance and the outcomes of surgical patients.

The weaknesses of these death ratio measures must be clearly understood. Both are subject to potential misinterpretation because

they do not specify the cause of death. The measures have a potential perverse effect insofar as they may encourage premature discharge of patients to avoid an impending death from occurring in the hospital. These measures are not intended to limit access to care or to subvert the procedure by which patients are evaluated, preoperatively or postoperatively. Moreover these ratios, as noted above, reflect the patient's condition on arrival for surgery, the extent and complexity of the procedure and the quality of care. Patients who die because of lack of timely surgical care are not counted either because of the difficulty of doing so, although such circumstances are also indicative of the quality of care. These are simple metrics that can provide a gauge of the overall outcome of surgical care and a target for progress in public health, but not strict measures of the quality of care.

Collection of the five surgical vital statistics is expected to build a foundation of information about surgical care that will give it the visibility of other important areas of public health. As the strengths and weaknesses of surgical care are ascertained, the information should advance the knowledge of surgical services and provide valuable information for improving safety.

Intermediate-level surgical vital statistics: For countries that can build on the basic statistics, several intermediate-level measures will help further define the capacity, volume and outcome of surgical services. The recommended measures are:

- number of operating rooms by location: hospital or ambulatory, public or private;
- number of trained surgeons by specialty: general surgery, gynaecology and obstetrics, neurosurgery, ophthalmology, otorhinolaryngology, orthopaedics and urology;
- number of other surgical providers: residents, accredited nonsurgeon physicians, medical officers or other skilled providers who are not medical doctors;
- number of trained anaesthetists by level of training: physician anaesthesiologists, nurse anaesthetists, anaesthesia officers;
- number of perioperative nurses;
- number of surgical procedures performed in operating rooms for the 10 most prevalent procedures in the country, urgent or elective;
- proportion of deaths on the day of surgery by procedure for the 10 most prevalent procedures in the country; and
- proportion of in-hospital deaths after surgery by procedure for the 10 most prevalent procedures in the country.

The additional structural variables further describe the facilities and workforce associated with surgery. The number of operating rooms can be disaggregated by their location as hospital-based or ambulatory. The number of surgeons can be disaggregated by surgical specialty to include general surgery, gynaecology and obstetrics, neurosurgery, ophthalmology, otorhinolaryngology, orthopaedics and urology. In addition, other surgical providers who perform surgery, such as surgical residents and non-physician surgical practitioners, can be recorded. A breakdown of the numbers of physician anaesthesiologists, nurse anaesthetists and anaesthesia officers is particularly important for evaluating the strength of the anaesthesia workforce. Disaggregating the number of perioperative nurses involved in surgical care from the total number of nurses in a country adds substantially to knowledge about the health workforce.

In addition to the total number of operations, the numbers of operations by case and acuteness are important details for understanding surgical needs, the burden of disease and the safety and quality of surgery. The types of surgery could include general categories, such as operations on the cardiovascular system, digestive system and nervous system. Data on the ten most frequent operations performed in a country could also be collected. The number of operations should be disaggregated into emergency or elective cases if available and consistently defined.

The intermediate outcome measures are the same death statistics specified as basic statistics, that is, deaths on the day of surgery and in-hospital deaths after surgery. The added value would be to collect these measures for the subgroups discussed above: general categories of surgery, most frequent operations, specific surgical cases and emergency or elective surgery. Mortality per capita and per operation could be calculated for these subgroups, which would help identify specific problem areas.

Advanced-level surgical vital statistics: For countries with advanced capability for data collection, risk-adjusted surgical outcome data may be obtained and could include measures not only of mortality but also of morbidity. Comparisons of surgical statistics among countries are complicated by differences in population characteristics. The age structures of populations vary, as do the level and distribution of wealth and income and the incidence and prevalence of diseases. These and other population characteristics affect the outcome of surgery in a country. To assess the quality of surgical care accurately and not just measure overall outcomes, surgical data must be adjusted to take population differences and case-mix differences into account. Risk adjustment requires detailed information that would be difficult for the most resource-limited countries to collect, but when it is available it can make comparisons of quality measures more meaningful.

Measures of surgical complications also add depth to knowledge of surgical outcomes beyond mortality measures alone. These measures require standard definitions and more extensive data collection. A successful model is the American College of Surgeons' National Surgical Quality Improvement Program, which has drawn up detailed definitions of complications, a statistically sound sampling method and a standard procedure of independent nurse surveillance for follow-up and detection of complications *(41)*.

With these strata, postoperative complications such as wound infection or haemorrhage can be linked to an operation; they can also be defined as any postoperative morbidity, such as cardiac dysrhythmia or pneumonia. Complications can be measured per capita or per surgical procedure. If data are not available on all surgical procedures, it still may be possible to obtain complication rates for a set of index cases (e.g. appendectomy, cholecystectomy) or for a category of operations (e.g. elective cases). Data on complications, like mortality data, should be risk adjusted whenever possible. At a minimum, adjusting or

stratifying the data by age greatly improves comparisons and provides international benchmarks of safety.

Summary of the three-tiered approach to systems level evaluation: This three-tiered approach to measuring the quality of surgical care involves establishing basic surgical vital statistics, which should be feasible for countries around the globe. It also makes use of any additional data available or that can be obtained by countries with moderate resources. Even the basic measures illustrate the impact of surgical care on death, disability and resources, all of which are a vital matter for public health planning now that the global volume of surgical procedures exceeds that of childbirth (*5*).

Surgical surveillance: basic patient measures for hospitals and practitioners

While national data such as vital statistics allow countries to track progress and identify problems from year to year, quality improvement in hospitals requires more regular local feedback for clinicians on outcomes of care (*42*). Thus, these guidelines define a set of basic surgical measures for use by hospitals and practitioners in any setting worldwide.

Day-of-surgery and postoperative in-hospital mortality ratios: Information on the volume of operations, day-of-surgery mortality ratios and postoperative in-hospital mortality ratios will all help institutions to measure the success or failure of care. These data give facilities and practitioners an indication of their surgical activity and of how their patients fare overall, providing a target for improvements in care. These measures are not useful for comparing institutions, as case mixes can differ widely. For example, a hospital that accepts trauma patients or a high volume of urgent cases will have a mortality on the day of surgery profile that is substantially different from a hospital in which primarily elective operations are performed. Measurement of the performance of a single institution over time, however, can allow identification of areas for improvement and tracing of progress as systematic changes are made to care.

Surgical site infections: A substantial proportion of major surgical complications consist of surgical site infections. Infections after surgical interventions have also been identified as a potential indicator of the quality of surgical care (*43–45*). Such infections are monitored in various settings as a means of assessing the consequences of care. While a number of methods are available, the most important principles for effective surveillance are use of standardized, consistent definitions of infection based on objective criteria and the maintenance of accurate data collection following established post-discharge follow-up strategies (*46*). These definitions are described under Objective 6.

Surveillance of surgical site infections is an important component of a hospital's infection control programme and has been used more broadly to improve the rate of infection after a surgical intervention. In the United Kingdom, mandatory surveillance of surgical site infections after orthopaedic surgery was instituted in 2004 with the support of the Surgical Site Infection Surveillance Service (*47*). This programme has led to system-wide evaluations of surgical site infection rates associated with various procedures and subsequent identification of facilities with high and low infection rates (*48*). Surveillance programmes at a number of facilities elsewhere in Europe prompted changes, which led to declining rates of surgical site infection (*49,50*). Studies are now being conducted to evaluate infection rates associated with specific procedures in different countries in order to further reduce infectious complications (*51*). Recent findings suggest that surgical site infection is a strong predictor of other postoperative complications (personal communication from D.A. Campbell, Department of Surgery, University of Michigan, 2008). The frequency of such infections can readily be reduced by improving care (see Objective 6). Institutional surveillance of surgical site infection is essential for improving surgical quality and safety.

The surgical apgar score: a simple outcome score for surgery

Because infection rates and the surgical mortality vital statistics are crude and apply to events that are relatively infrequent, it is difficult for individual practitioners to use them alone to set targets for improvements in outcome. In traditional morbidity and mortality conferences, at which patient complications are discussed among care providers, attempts are made to identify both outcome measures in order to audit surgical performance and results. These conferences, however, focus only on selfreported complications and overlook patterns of harm (*52*).

A simple measure of surgical patient outcome that can give practitioners immediate feedback about the condition of a patient after surgery is the 'Surgical Apgar Score'. This is a 10-point system based on three intraoperation parameters: estimated intraoperative blood loss, the lowest heart rate and the lowest mean arterial pressure (*53*).

Like the obstetric Apgar score to rate the condition of a newborn, the Surgical Apgar Score provides a readily available 'snapshot' of how an operation went by rating the condition of a patient after surgery from 0, indicating heavy blood loss, hypotension and an elevated heart rate or asystole, to 10, indicating minimal blood loss, normal blood pressure and a physiologically low-to-normal heart rate. Table II.10.1 demonstrates calculation of the score from information recorded routinely by anaesthetists. A prerequisite for obtaining an accurate score is monitoring and recording of reasonably accurate intraoperative physiological data—a basic accepted standard of anaesthesia care and record-keeping.

The Surgical Apgar Score was derived by analysing the outcomes of patients at a large academic medical centre in the United States who were included in the American College of Surgeons' National Surgical Quality Improvement Program (*53*). The three intraoperative variables used to calculate the Surgical Apgar Score were chosen from an initial pool of more than 60 factors collected from the programme's database, patients' medical charts and intraoperative anaesthetic records, as they were found to be independently predictive of the likelihood of major complications and death within 30 days of surgery. Patients with low scores (< 5) were 16 times more likely to suffer a complication than those with the highest scores (9 or 10). This pattern was validated in a cohort of over 4000 patients in the National Surgical Quality Improvement Program at a different institution (*56*). Table II.10.2 shows the relative risks for complications of surgical patients at a large academic medical centre in the United States, on the basis of their scores. Patients with a score < 5 had a three times greater risk for a postoperative complication, while patients with scores of 9 or 10 had only one third the risk of patients who had a score of 7. Even after careful adjustment for fixed preoperative risk factors due to patients' comorbid conditions and procedure-related complexity, the Surgical Apgar Score conveys additional prognostic information about the likelihood of complications, allowing surgeons to discern objectively whether and by how much their operation increased or decreased a patient's predicted risk for major complications (*57*).

Table II.10.1 – Calculation of the 'Surgical Apgar Score' from intraoperative measurements of estimated blood loss, lowest heart rate, and lowest mean arterial pressure. The score is the sum of the points from each category.

	0 points	1 points	2 points	3 points	4 points
Estimated blood loss (mL)[a]	>1000	601-1000	101-600	≤100	
Lowest mean arterial pressure (mm Hg)[b,c]	<40	40-54	55-69	≥70	
Lowest heart rate (beats per min)[b,d]	>85*	76-85	66-75	56-65	≤55*

*Occurrence of pathologic bradyarrhythmia, including sinus arrest, atrioventricular block or dissociation, junctional or ventricular escape rhythms, and asystole also receive 0 pts for lowest heart rate.

[a] *The estimated blood loss used in the calculation should be the number entered in the official operation record. This is usually computed by the anaesthetist and confirmed by the surgeon. While this method may seem imprecise, estimates of blood loss have been shown to be accurate within orders of magnitude (54,55).*

[b] *The heart rate and blood pressure should be obtained from the anaesthesia record, as values recorded from the time of incision to the time of wound closure.*

[c] *Mean arterial pressure should be used to calculate the blood pressure score. When the systolic and diastolic blood pressures are recorded without mean arterial pressure, the lowest mean arterial pressure must be calculated by selecting the lowest diastolic pressure and using the formula: mean arterial pressure = diastolic pressure + (systolic pressure–diastolic pressure)/3.*

[d] *In cases in which asystole or complete heart block occurs, the score for heart rate should be 0.*

Examples of calculations of a Surgical Apgar Score:

1. A patient has an estimated blood loss of 50 ml, a minimum heart rate of 56 and a lowest mean arterial pressure of 67 mm Hg. He or she would therefore receive 3, 3 and 2 points, respectively, for a score of 8.

2. A patient has an estimated blood loss of 1500 ml (0 points), a minimum heart rate of 75 (2 points) and a lowest mean arterial pressure of 43 mm Hg (1 point) and would thus receive a score of 3.

Table II.10.2 – Relative risks for major complications or death based on the Surgical Apgar Score, with a score of 7 as the reference value (at a United States academic medical center)

Surgical Apgar score	Total no. of patients	No. with complications	Complication rate	Relative risk for complication (95% CI)	p value
0–4	128	72	0.563	3.4 (2.7–4.2)	< 0.0001
5	233	93	0.399	2.4 (1.9–3.0)	< 0.0001
6	487	108	0.222	1.3 (1.1–1.7)	0.017
7	730	122	0.167	Reference	Reference
8	1100	114	0.104	0.6 (0.5–0.8)	< 0.0001
9	1091	55	0.010	0.3 (0.2–0.4)	< 0.0001
10	350	17	0.049	0.3 (0.2–0.5)	< 0.0001
total	**4119**	**581**	**0.141**		

Adapted from reference (*56*)

Findings from international pilot sites: The Surgical Apgar Score was designed for international use as a measure of outcome for surgical patients. It has been validated in published findings for more than 5000 patients undergoing general and vascular surgical procedures at two large academic medical centres in the United States. Preliminary data showed that it also had predictive value in urological and orthopaedic patients in these institutions (*58* and personal communication from T Wuerz, Department of Orthopedic Surgery, Massachusetts General Hospital, Boston, 2008). Its value was further confirmed in eight hospitals in Canada, India, Jordan, New Zealand, the Philippines, the United Kingdom, the United Republic of Tanzania and the United States, participating as international pilot sites in the WHO Safe Surgery Saves Lives programme. These hospitals are a heterogeneous group of institutions, ranging from high- to low-income settings. Data collected throughout the study included the Surgical Apgar Score, inpatient complications and inpatient deaths up to 30 days after surgery in 5909 consecutive adults undergoing non-cardiac surgical procedures under general anaesthesia, including general and trauma surgery, orthopaedic surgery, urological surgery and obstetric and gynaecological surgery. One or more in-hospital complications occurred in 544 patients (9.2%) during postoperative follow-up. Table II.10.3 shows the distribution of these patients by Surgical Apgar Score: patients with a score of 10 had a complication rate of 3.0%, while 32.9% of those with a score less than five had at least one complication.

Table II.10.3 – Relative risks for major complication or death based on the Surgical Apgar Score at eight international pilot sites, with a score of 7 as the reference value (World Health Organization Safe Surgery Saves Lives project data ; p<0.0001 for trend, c-statistic=0.70)

Surgical Apgar score	Total no. of patients	Adjusted complication rate*	Relative risk for complication (95% CI)
0–4	302	32.9 %	3.6 (2.9–4.5)
5	518	20.5 %	2.2 (1.8–2.8)
6	1026	12.2 %	1.3 (1.1–1.7)
7	1365	9.1 %	Reference
8	1445	4.8 %	0.5 (0.3–0.8)
9	1015	4.0 %	0.4 (0.2–0.4)
10	238	3.0 %	0.3 (0.1–1.1)
total	**5909**	**9.2 %**	

** Adjusted to account for clustering at individual sites*

These findings, from diverse institutions around the world, provide confirmation that the Surgical Apgar Score is both feasible to determine and useful as a measure of surgical outcome, regardless of setting or circumstance. While the score is not a substitute for other measures of outcome, it is a meaningful, objective, immediate measure that can give a valid indication of how a patient has fared in surgery.

The score's components capture elements of the patient's overall condition, the extent of the surgical insult and the ability of the team to respond to and control haemodynamic changes during the procedure. Alterations in the heart rate and blood pressure often represent both the physiological status of the patient and the adequacy of anaesthetic management. Blood loss is an indicator of the complexity of an operation and the performance of the surgeon. These components result in a Surgical Apgar Score that gives feedback to clinicians on the relative success of their operation and the relative risks for complications or death.

This measure has several important potential uses. Like the Apgar score in obstetrics, the Surgical Apgar Score can give practitioners a target for care, inciting them to ensure that patients have as high a score as possible. It also identifies groups at high risk for complications, indicating the need for more monitoring, vigilance and readiness to intervene. It can also identify 'near-miss' cases, whether or not complications actually occur. For administrators, it offers a target for quality improvement, either to decrease the proportion of patients with low scores or to increase the proportion with high scores. While the score does not allow comparisons of quality between institutions because of the influence of case-mix and variations in the condition of the patient on presentation, it can be used in any setting, as it is derived from routinely available intraoperative data.

Future directions of surgical surveillance

The surgical statistics proposed here have not been collected in a standardized or systematic fashion. They are the first step towards collecting surgical information in a manner consistent with public health. It is not envisioned that these indicators remain static: they should be used to guide policy and direct the future of surgical data collection. Although these indicators may be limited, the information they provide will add considerable knowledge about the indicators themselves and about the public health benefits of surgery.

Recommendations

Highly recommended:

- For surgical surveillance at the national level, the following data should be collected systematically by WHO Member States:
  - number of operating rooms,
  - number of surgical procedures performed in an operating room,
  - number of trained surgeons and number of trained anaesthetists,
  - day-of-surgery mortality rate and
  - postoperative in-hospital mortality rate.

- For surgical surveillance at hospital and practitioner levels, the following data should be collected systematically by facilities and clinicians:
  - day-of-surgery mortality rate,
  - postoperative in-hospital mortality rate.

Recommended:

- As a more detailed measure of surgical surveillance in WHO Member States with more advanced data capability, the following data should be collected systematically:
  - number of operating rooms by location: hospital or ambulatory, public or private;
  - number of trained surgeons by specialty: general surgery, gynaecology and obstetrics, neurosurgery, ophthalmology, otorhinolaryngology, orthopaedics and urology;
  - number of other surgical providers: residents, unaccredited physicians, medical officers;
  - number of trained anaesthetists by level of training: physician anaesthesiologists, nurse anaesthetists, anaesthesia officers;
  - number of perioperative nurses;
  - number of surgical procedures performed in operating rooms for the 10 most frequent procedures in the country, emergent or elective;
  - proportion of deaths on the day of surgery by procedure for the 10 most frequent procedures in the country; and
  - proportion of in-hospital deaths after surgery by procedure for the 10 most frequent procedures in the country.

- For more detailed surgical surveillance at the hospital and practitioner level, the following data should be collected by facilities and clinicians:
  - surgical site infection rate and
  - surgical Apgar Score.

Suggested:

- In WHO Member States with the resources and capability to conduct risk-adjusted evaluations, countries should adjust outcome data for case mix and extend outcome measures to include morbidity by defining complications and conducting independent clinical surveillance for follow-up and detection of complications.

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Summary of recommendations

Use the WHO Patient Safety surgical safety checklist or similar safety check to ensure that steps to promote safe surgery are accomplished in a systematic and timely fashion.

Public health systems must establish routine surveillance of surgical capacity, volume, and results.

Section III.

The World Health Organization Surgical Safety Checklist

Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?

- ☐ Yes

Is the site marked?

- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?

- ☐ Yes

Is the pulse oximeter on the patient and functioning?

- ☐ Yes

Does the patient have a:

Known allergy?

- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?

- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?

- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:

- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:

- ☐ Are there any patient-specific concerns?

To Nursing Team:

- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?

- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:

- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:

- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

Section IV.

Implementation Manual for WHO Patient Safety Surgical Safety Checklist

Introduction

The *Safe Surgery Saves Lives* programme was established by WHO Patient Safety as part of the World Health Organization's efforts to reduce the number of surgical deaths across the globe. The aim of the programme is to harness political commitment and clinical will to address important safety issues, including inadequate anaesthetic safety practices, avoidable surgical infection and poor communication among team members. These have proved to be common, deadly and preventable problems in all countries and settings.

To assist operating teams in reducing the number of these events, WHO Patient Safety—in consultation with surgeons, anaesthetists, nurses, patient safety experts and patients around the world—has identified ten essential objectives for safe surgery. These were compiled into the WHO Surgical Safety Checklist. The aim of this Checklist (available at www.who.int/safesurgery) is to reinforce accepted safety practices and foster better communication and teamwork between clinical disciplines. The Checklist is intended as a tool for use by clinicians interested in improving the safety of their operations and reducing unnecessary surgical deaths and complications. Its use has been demonstrably associated with significant reductions in complication and death rates in diverse hospitals and settings, and with improvements in compliance to basic standards of care.[1]

How to use this manual

In this manual, the "operating team" is understood to comprise the surgeons, anaesthetists, nurses, technicians and other operating room personnel involved in surgery. Much as an airplane pilot must rely on the ground crew, flight personnel and air traffic controllers for a safe and successful flight, a surgeon is an essential but not solitary member of a team responsible for patient care. All members of the operating team play a role in ensuring the safety and success of an operation.

This manual provides guidance on using the checklist, suggestions for implementation, and recommendations for measuring surgical services and outcomes. Different practice settings should adapt it to their own circumstances. Each safety check has been included based on clinical evidence or expert opinion that its inclusion will reduce the likelihood of serious, avoidable surgical harm and that adherence to it is unlikely to introduce injury or unmanageable cost. The Checklist was also designed for simplicity and brevity. Many of the individual steps are already accepted as routine practice in facilities around the world, though they are rarely followed in their entirety. Each surgical department must practice with the Checklist and examine how to sensibly integrate these essential safety steps into their normal operative workflow.

The ultimate goal of the WHO Surgical Safety Checklist—and of this manual—is to help ensure that teams consistently follow a few critical safety steps and thereby minimize the most common and avoidable risks endangering the lives and wellbeing of surgical patients. The Checklist guides a verbal team-based interaction as a means of confirming that appropriate standards of care are ensured for every patient.

How to run the checklist (in brief)

In order to implement the Checklist during surgery, a single person must be made responsible for performing the safety checks on the list. This designated Checklist coordinator will often be a circulating nurse, but it can be any clinician participating in the operation.

The Checklist divides the operation into three phases, each corresponding to a specific time period in the normal flow of a procedure—the period before induction of anaesthesia, the period after induction and before surgical incision, and the period during or immediately after wound closure but before removing the patient from the operating room. In each phase, the Checklist coordinator must be permitted to confirm that the team has completed its tasks before it proceeds onward. As operating teams become familiar with the steps of the Checklist, they can integrate the checks into their familiar work patterns and verbalize their completion of each step without the explicit intervention of the Checklist coordinator. Each team should seek to incorporate use of the Checklist into its work with maximum efficiency and minimum disruption while aiming to accomplish the steps effectively.

All steps should be checked verbally with the appropriate team member to ensure that the key actions have been performed. Therefore, before induction of anaesthesia, the person coordinating the Checklist will verbally review with the anaesthetist and patient (when possible) that patient identity has been confirmed, that the procedure and site are correct and that consent for surgery has been given. The coordinator will visualize and verbally confirm that the operative site has been marked (if appropriate) and will review with the anaesthetist the patient's risk of blood loss, airway difficulty and allergic reaction and whether an anaesthesia machine and medication safety check has

1 Haynes AB, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *New England Journal of Medicine,* 2009; 360:491-9.

been completed. Ideally the surgeon will be present during this phase as the surgeon may have a clearer idea of anticipated blood loss, allergies, or other complicating patient factors. However, the surgeon's presence is not essential for completing this part of the Checklist.

Before skin incision, each team member will introduce him or herself by name and role. If already partway through the operative day together, the team can simply confirm that everyone in the room is known to each other. The team will confirm out loud that they are performing the correct operation on the correct patient and site and then verbally review with one another, in turn, the critical elements of their plans for the operation, using the Checklist for guidance. They will also confirm that prophylactic antibiotics have been administered within the previous 60 minutes and that essential imaging is displayed, as appropriate.

Before leaving the operating room, the team will review the operation that was performed, completion of sponge and instrument counts and the labelling of any surgical specimens obtained. It will also review any equipment malfunctions or issues that need to be addressed. Finally, the team will discuss key plans and concerns regarding postoperative management and recovery before moving the patient from the operating room.

Having a single person lead the Checklist process is essential for its success. In the complex setting of an operating room, any of the steps may be overlooked during the fast-paced preoperative, intraoperative, or postoperative preparations. Designating a single person to confirm completion of each step of the Checklist can ensure that safety steps are not omitted in the rush to move forward with the next phase of the operation. Until team members are familiar with the steps involved, the Checklist coordinator will likely have to guide the team through this Checklist process.

A possible disadvantage of having a single person lead the Checklist is that an antagonistic relationship might be established with other operating team members. The Checklist coordinator can and should prevent the team from progressing to the next phase of the operation until each step is satisfactorily addressed, but in doing so may alienate or irritate other team members. Therefore, hospitals must carefully consider which staff member is most suitable for this role. As mentioned, for many institutions this will be a circulating nurse, but any clinician can coordinate the Checklist process.

How to run the checklist (in detail)

Before induction of anaesthesia

These safety checks are to be completed before induction of anaesthesia in order to confirm the safety of proceeding. It requires the presence of the anaesthetist and nursing personnel at the very least.

The checklist coordinator may complete this section all at once or sequentially, depending on the flow of preparation for anaesthesia. The details for each of the safety steps are as follows:

Has the patient confirmed his/her identity, site, procedure and consent?

The Checklist coordinator verbally confirms the patient's identity, the type of procedure planned, the site of surgery and that consent for surgery has been given. While it may seem repetitive, this step is essential for ensuring that the team does not operate on the wrong patient or site or perform the wrong procedure. When confirmation by the patient is impossible, such as in the case of children or incapacitated patients, a guardian or family member can assume this role. If a guardian or family member is not available or if this step is skipped, such as in an emergency, the team should understand why and all be in agreement prior to proceeding.

Is the site marked?

The Checklist coordinator should confirm that the surgeon performing the operation has marked the site of surgery (usually with a permanent felt-tip marker) in cases involving laterality (a left or right distinction) or multiple structures or levels (e.g. a particular finger, toe, skin lesion, vertebra). Site-marking for midline structures (e.g. thyroid) or single structures (e.g. spleen) should follow local practice. Consistent site marking in all cases, however, can provide a backup check confirming the correct site and procedure.

Is the anaesthesia machine and medication check complete?

The Checklist coordinator completes this next step by asking the anaesthetist to verify completion of an anaesthesia safety check, understood to be a formal inspection of the anaesthetic equipment, breathing circuit, medications and patient's anaesthetic risk before each case. A helpful mnemonic is that, in addition to confirming that the patient is fit for surgery, the anaesthesia team should complete the ABCDEs – an examination of the Airway equipment, Breathing system (including oxygen and inhalational agents), suCtion, Drugs and Devices and Emergency medications, equipment and assistance to confirm their availability and functioning.

Is the pulse oximeter on the patient and functioning?

The Checklist coordinator confirms that a pulse oximeter has been placed on the patient and is functioning correctly before induction of anaesthesia. Ideally the pulse oximetry reading should be visible to the operating team. An audible system should be used to alert the team to the patient's pulse rate and oxygen saturation. Pulse oximetry has been highly recommended as a necessary component of safe anaesthesia care by WHO. If no functioning pulse oximeter is available, the surgeon and anaesthetist must evaluate the acuity of the patient's condition and consider postponing surgery until appropriate steps are taken to secure one. In urgent circumstances to save life or limb this requirement may be waived, but in such circumstances the team should be in agreement about the necessity to proceed with the operation.

Does the patient have a known allergy?

The Checklist coordinator should direct this and the next two questions to the anaesthetist. First, the coordinator should ask whether the patient has a known allergy and, if so, what it is. If the coordinator knows of an allergy that the anaesthetist is not aware of, this information should be communicated.

Does the patient have a difficult airway/aspiration risk?

The Checklist coordinator should verbally confirm that the anaesthesia team has objectively assessed whether the patient has a difficult airway. There are a number of ways to grade the airway (such as the Mallampati score, thyromental distance, or Bellhouse-Doré score). An objective evaluation of the airway using a valid method is more important than the choice of method itself. Death from airway loss during anaesthesia is still a common disaster globally but is preventable with appropriate planning. If the airway evaluation indicates a high risk for a difficult airway (such as a Mallampati score of 3 or 4), the anaesthesia team must prepare against an airway disaster. This will include, at a minimum, adjusting the approach to anaesthesia (for example, using a regional anaesthetic, if possible) and having emergency equipment accessible. A capable assistant—whether a second anaesthetist, the surgeon, or a nursing team member—should be physically present to help with induction of anaesthesia.

The risk of aspiration should also be evaluated as part of the airway assessment. If the patient has symptomatic active reflux or a full stomach, the anaesthetist must prepare for the possibility of aspiration. The risk can be reduced by modifying the anaesthesia plan, for example using rapid induction techniques and enlisting the help of an assistant to provide cricoid pressure during induction. For a patient recognized as having a difficult airway or being at risk for aspiration, induction of anaesthesia should begin only when the anaesthetist confirms that he or she has adequate equipment and assistance present at the bedside.

Does the patient have a risk of >500 ml blood loss (7 ml/kg in children)?

In this safety step, the Checklist coordinator asks the anaesthesia team whether the patient risks losing more than half a litre of blood during surgery in order to ensure recognition of and preparation for this critical event. Large volume blood loss is among the most common and important dangers for surgical patients, with risk of hypovolaemic shock escalating when blood loss exceeds 500 ml (7 ml/kg in children). Adequate preparation and resuscitation may mitigate the consequences considerably.

Surgeons may not consistently communicate the risk of blood loss to anaesthesia and nursing staff. Therefore, if the anaesthetist does not know what the risk of major blood loss is for the case, he or she should discuss the risk with the surgeon before the operation begins. If there is a significant risk of a greater than 500 ml blood loss, it is highly recommended that at least two large bore intravenous lines or a central venous catheter be placed prior to skin incision. In addition, the team should confirm the availability of fluids or blood for resuscitation. (Note that the expected blood loss will be reviewed again by the surgeon before skin incision. This will provide a second safety check for the anaesthetist and nursing staff.)

At this point this phase is completed and the team may proceed with anaesthetic induction.

Before skin incision

Before making the first surgical incision, a momentary pause should be taken by the team in order to confirm that several essential safety checks are undertaken. These checks involve all team members.

Confirm all team members have introduced themselves by name and role

Operating team members may change frequently. Effective management of high risk situations requires that all team members understand who each member is and their roles and capabilities. A simple introduction can achieve this. The coordinator should ask each person in the room to introduce him or herself by name and role.

Teams already familiar with each other can confirm that everyone has been introduced, but new members or staff that have rotated into the operating room since the last operation should introduce themselves, including students or other personnel.

Confirm the patient's name, procedure and where the incision will be made

The person coordinating the checklist or another team member will ask everyone in the operating room to stop and verbally confirm the name of the patient, the surgery to be performed, the site of surgery and, where appropriate, the positioning of the patient in order to avoid operating on the wrong patient or the wrong site. For example, the circulating nurse might announce, *"Before we make the skin incision",* and then continue, *"Does everyone agree that this is patient X, undergoing a right inguinal hernia repair?"* The anaesthetist, surgeon and circulating nurse should explicitly and individually confirm agreement. If the patient is not sedated, it is helpful for him or her to confirm the same as well.

Has antibiotic prophylaxis been given in the last 60 minutes?

Despite strong evidence and wide consensus that antibiotic prophylaxis against wound infections is most effective if serum and/or tissue levels of antibiotic are achieved, surgical teams are inconsistent about administering antibiotics within one hour prior to incision. To reduce surgical infection risk, the coordinator will ask out loud whether prophylactic antibiotics were given during the previous 60 minutes. The team member responsible for administering antibiotics – usually the anaesthetist – should provide verbal confirmation. If prophylactic antibiotics have not been administered, they should be administered now, prior to incision. If prophylactic antibiotics have been administered longer than 60 minutes before, the team should consider redosing the patient. If prophylactic antibiotics are not considered appropriate (e.g. cases without a skin incision, contaminated cases in which antibiotics are given for treatment), the "not applicable" box may be checked once the team verbally confirm this.

Anticipated critical events

Effective team communication is a critical component of safe surgery, efficient teamwork and the prevention of major complications. To ensure communication of critical patient issues, the checklist coordinator leads a swift discussion among the surgeon, anaesthesia staff and nursing staff of critical dangers and operative plans. This can be done by simply asking each team member the specified question out loud. The order of discussion does not matter, but each clinical discipline should provide information and communicate concerns. During routine procedures or those with which the entire team is familiar, the surgeon can simply state, *"This is a routine case of X duration"* and then ask the anaesthetist and nurse if they have any special concerns.

To surgeon: what are the critical or non-routine steps? How long will the case take? What is the anticipated blood loss?

A discussion of "critical or non-routine steps" is intended, at a minimum, to inform all team members of any steps that put the patient at risk for rapid blood loss, injury or other major morbidity. This is also a chance to review steps that might require special equipment, implants or preparations.

To anaesthetist: are there any patient-specific concerns?

In patients at risk for major blood loss, haemodynamic instability or other major morbidity due to the procedure, a member of the anaesthesia team should review out loud the specific plans and concerns for resuscitation—in particular, the intention to use blood products and any complicating patient characteristics or co-morbidities (such as cardiac or pulmonary disease, arrhythmias, blood disorders, etc). It is understood that many operations do not entail particularly critical risks or concerns that must be shared with the team. In such cases, the anaesthetist can simply say, *"I have no special concern regarding this case."*

To nursing team: has sterility (including indicator results) been confirmed? Are there equipment issues or any concerns?

The scrub nurse or technologist who sets out the equipment for the case should verbally confirm that sterilization was performed and that, for heat-sterilized instruments, a sterility indicator has verified successful sterilization. Any discrepancy between the expected and the actual sterility indicator results should be reported to all team members and addressed before incision. This is also an opportunity to discuss any problems with equipment and other preparations for surgery or any safety concerns the scrub or circulating nurse may have, particularly ones not addressed by the surgeon and anaesthesia team. If there are no particular concerns, however, the scrub nurse or technologist can simply say, *"Sterility was verified. I have no special concerns."*

Is essential imaging displayed?

Imaging is critical to ensure proper planning and conduct of many operations, including orthopaedic, spinal and thoracic procedures and many tumour resections. Before skin incision, the coordinator should ask the surgeon if imaging is needed for the case. If so, the coordinator should verbally confirm that the essential imaging is in the room and prominently displayed for use during the operation. If imaging is needed but not available, it should be obtained. The surgeon will decide whether to proceed without the imaging if it is necessary but unavailable.

At this point this phase is completed and the team may proceed with the operation.

Before patient leaves operating room

These safety checks should be completed before removing the patient from the operating room. The aim is to facilitate the transfer of important information to the care teams responsible for the patient after surgery. The checks can be initiated by the circulating nurse, surgeon or anaesthetist and should be accomplished before the surgeon has left the room. It can coincide, for example, with wound closure.

Nurse verbally confirms:

The name of the procedure

Since the procedure may have changed or expanded during the course of an operation, the Checklist coordinator should confirm with the surgeon and the team exactly what procedure was done. This can be done as a question, *"What procedure was performed?"* or as a confirmation, *"We performed X procedure, correct?"*

Completion of instrument, sponge and needle counts

Retained instruments, sponges and needles are uncommon but persistent and potentially calamitous errors. The scrub or circulating nurse should therefore verbally confirm the completeness of final sponge and needle counts. In cases with an open cavity, instrument counts should also be confirmed to be complete. If counts are not appropriately reconciled, the team should be alerted so that appropriate steps can be taken (such as examining the drapes, garbage and wound or, if need be, obtaining radiographic images).

Specimen labelling (read specimen labels aloud, including patient name)

Incorrect labelling of pathological specimens is potentially disastrous for a patient and has been shown to be a frequent source of laboratory error. The circulator should confirm the correct labelling of any pathological specimen obtained during the procedure by reading out loud the patient's name, the specimen description and any orienting marks.

Whether there are any equipment problems to be addressed

Equipment problems are universal in operating rooms. Accurately identifying the sources of failure and instruments or equipment that have malfunctioned is important in preventing devices from being recycled back into the room before the problem has been addressed. The coordinator should ensure that equipment problems arising during a case are identified by the team.

Surgeon, anaesthetist and nurse review the key concerns for recovery and management of this patient

The surgeon, anaesthetist and nurse should review the post-operative recovery and management plan, focusing in particular on intraoperative or anaesthetic issues that might affect the patient. Events that present a specific risk to the patient during recovery and that may not be evident to all involved are especially pertinent. The aim of this step is the efficient and appropriate transfer of critical information to the entire team.

With this final step, the WHO Checklist is completed. If desired, the Checklist can be placed in the patient record or retained for quality assurance review.

Additional notes — promoting a safety culture

Modifying the Checklist

The Checklist should be modified to account for differences among facilities with respect to their processes, the culture of their operating rooms and the degree of familiarity each team member has with each other. However, removing safety steps because they cannot be accomplished in the existing environment or circumstances is strongly discouraged. The safety steps should inspire effective change that will bring an operating team to comply with each and every element of the Checklist.

Modification of the Checklist should be undertaken with a critical eye. Surgeons, anaesthetists, and nurses should be involved in the modification process, and the resulting Checklist trialled in simulated and real-life situations in order to ensure its functionality. Additionally, many of the principles used in the development of the Checklist can also be applied to its modification.

Focused The Checklist should strive to be concise, addressing those issues that are most critical and not adequately checked by other safety mechanisms. Five to nine items in each Checklist section are ideal.

Brief The Checklist should take no more than a minute for each section to be completed. While it may be tempting to try to create a more exhaustive Checklist, the needs of fitting the Checklist into the flow of care must be balanced with this impulse.

Actionable Every item on the Checklist must be linked to a specific, unambiguous action. Items without a directly associated action will result in confusion among team members regarding what they are expected to do.

Verbal The function of the Checklist is to promote and guide a verbal interaction among team members. Performing this team Checklist is critical to its success—it will likely be far less effective if used solely as a written instrument.

Collaborative Any effort to modify the Checklist should be in collaboration with representatives from groups who might be involved in using it. Actively seeking input from nurses, anaesthetists, surgeons and others is important not only in helping to make appropriate modifications but also in creating the feeling of "ownership" that is central to adoption and permanent practice change.

Tested Prior to any rollout of a modified Checklist, it should be tested in a limited setting. The real-time feedback of clinicians is essential to successful development of a Checklist and its integration into the processes of care. Testing through a "simulation" as simple as running through the Checklist with team members sitting around a table is important. We also suggest using the Checklist for a single day by a single operating team and collecting feedback. Modify the Checklist or the way that it is incorporated into care accordingly and then try the Checklist again in a single operating room. Continue this process until you are comfortable that the Checklist you have created works in your environment. Then consider a wider implementation program.

Integrated Many institutions already have strategies to insure the reliable performance of many of the processes that are part of the WHO Checklist. Integrating new safety checks into the processes is challenging but possible in nearly all settings. The major additions to existing routines involve the integration of team communication, briefings, and debriefings. These items are of critical importance and should not be removed from the Checklist.

In order to ensure brevity, the WHO Surgical Safety Checklist was not intended to be comprehensive. Teams may consider adding other safety checks for specific procedures, particularly if they are part of a routine process established in the facility. Each phase should be used as an opportunity to verify that critical safety steps are consistently completed. Additional steps might include confirmation of venous thromboembolism prophylaxis by mechanical means (such as sequential compression boots and stockings) and/or medical means (such as heparin or warfarin) when indicated, the availability of essential implants (such as mesh or a prosthetic), other equipment needs or critical preoperative biopsy results, laboratory results or blood type. Each locale is encouraged to reformat, reorder or revise the Checklist to accommodate local practice while ensuring completion of the critical safety steps in an efficient manner. As noted above facilities and individuals are cautioned against making the Checklist unmanageably complex.

Introducing the Checklist into the operating room

It will take practice for teams to learn to use the Checklist effectively. Some individuals will consider it an imposition or even a waste of time. The goal is not rote recitation or to frustrate workflow. The Checklist is intended to give teams a simple, efficient set of priority checks for improving effective teamwork and communication and to encourage active consideration of the safety of patients in every operation performed. Many of the steps on the Checklist are already followed in operating rooms around the world; few, however, follow all of them reliably. The Checklist has two purposes: ensuring consistency in patient safety and introducing (or maintaining) a culture that values achieving it.

Successful implementation requires adapting the Checklist to local routines and expectations. This will not be possible without sincere commitment by hospital leaders. For the Checklist to succeed, the chiefs of surgery, anaesthesia and nursing departments must publicly embrace the belief that safety is a priority and that use of the WHO Surgical Safety Checklist can help make it a reality. To demonstrate this, they should use the Checklist in their own cases and regularly ask others how implementation is proceeding. If there is no demonstrable leadership, instituting a checklist of this sort may breed discontent and antagonism.

Previous quality improvement work has provided a number of models for how to implement such a checklist into the operating room. Experience with the pilot study confirmed the utility of many of these strategies. A number of suggested steps are outlined below for consideration as facilities begin implementation of the WHO Surgical Safety Checklist.

Build a team Commitment by all clinical team members involved in surgical procedures is essential. Start building support by involving clinicians who are likely to be most supportive. Include colleagues from as many clinical disciplines (surgery, anaesthesia, nursing) as possible. Identify a core group of people who are enthusiastic about the Checklist while trying to involve at least one member from each of the clinical disciplines. At this early stage, work with those who are interested rather than trying to convince the most resistant people. Also involve hospital leaders and administrators, if possible. Emphasize the benefits of lower complication rates and the potential for cost savings.

Start small, then expand Start small, testing out the Checklist in one operating room with one team and moving forward after problems have been addressed and when enthusiasm builds. During the original evaluation by WHO, sites that tried to implement the Checklist in multiple operating rooms simultaneously or hospital-wide faced the most resistance and had the most trouble convincing staff to use the Checklist effectively. Once one team is comfortable using the Checklist, spread it to another operating room. Discuss these efforts with different surgical departments and surgeons. Make sure the team members who were originally involved in the process are using the Checklist in their own operating rooms. Customize the Checklist for each setting as necessary, but do not remove safety steps just because they cannot be accomplished. Address resistance as it arises. Clinicians who have used the Checklist and have good experiences with it make great champions for promoting it and defending its use and spread in the hospital.

Track changes and improvements WHO Guidelines for Safe Surgery encourages the monitoring of surgical results and complications. Ideally hospitals and facilities should track process and outcome measures, for example the percent of operations having antibiotics administered at the correct time and the surgical site infection rate.

Evaluating surgical care

Monitoring and evaluation of outcomes is an essential component of surgical care. Many facilities and departments already engage in this process; additional data collection is neither recommended nor encouraged if such a system is already in place and proves useful to the clinicians and staff as a means of improving the quality of care. However, in hospitals where results of surgical care are not routinely tracked and postoperative complications are not recorded, or where surveillance mechanisms have not been sufficient to identify poor practices, WHO highly recommends that a monitoring system be established. In particular, as a means of surgical surveillance at hospital and practitioner levels, death on the day of surgery and postoperative in-hospital deaths should be collected systematically by facilities and clinicians. When combined with operative volume, such information provides departments of surgery with day-of-surgery and postoperative in-hospital mortality rates. Mortality rates can help surgeons identify safety shortfalls and provides guidance to clinicians for improvements in care. In addition, for those facilities with the capacity and ability to do so, surgical site infection rates and the Surgical Apgar Score are also important outcome measures.[2]

In addition to deaths and complications, process measures can also be incorporated into the evaluation system and may help identify safety lapses and areas for improvement. Improved compliance has been associated with better outcomes and may identify weaknesses in the system of care delivery. A few suggestions for measurement, even on an intermittent basis, are the frequencies of compliance with:

- Marking of the operative site by the surgeon
- Performance of an anaesthesia safety check of the machine and medications
- Use of pulse oximetry throughout administration of anaesthesia in all cases
- Objective evaluation of the airway
- Use of sterility indicators to ensure adequacy of sterility practices
- Administration of prophylactic antibiotics within one hour before skin incision
- Verbal confirmation of patient, site and procedure immediately before incision with all team members present
- Preoperative team briefing to discuss clinical concerns, operative plan, and other critical issues
- Post-operative team debriefing to discuss problems during the case and concerns for recovery and management of the patient

Use of the WHO Surgical Safety Checklist has demonstrably improved compliance with basic standards of surgical care in diverse hospitals around the world. While the relationship between adherence to standards and decreases in complication rates is likely multifactorial, improving the safety and reliability of surgical care can save lives and promote confidence in the health system.

2 Gawande AA, et al. An Apgar score for surgery. *Journal of the American College of Surgeons*, 2007; **204**:201-8

Appendix A

Haynes AB, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. New England Journal of Medicine, 2009; 360:491-9

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SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

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ABSTRACT

BACKGROUND

Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. Surgical complications are common and often preventable. We hypothesized that a program to implement a 19-item surgical safety checklist designed to improve team communication and consistency of care would reduce complications and deaths associated with surgery.

METHODS

Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) representing a variety of economic circumstances and diverse populations of patients participated in the World Health Organization's Safe Surgery Saves Lives program. We prospectively collected data on clinical processes and outcomes from 3733 consecutively enrolled patients 16 years of age or older who were undergoing noncardiac surgery. We subsequently collected data on 3955 consecutively enrolled patients after the introduction of the Surgical Safety Checklist. The primary end point was the rate of complications, including death, during hospitalization within the first 30 days after the operation.

RESULTS

The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward ($P=0.003$). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist ($P<0.001$).

CONCLUSIONS

Implementation of the checklist was associated with concomitant reductions in the rates of death and complications among patients at least 16 years of age who were undergoing noncardiac surgery in a diverse group of hospitals.

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Surgical care is an integral part of health care throughout the world, with an estimated 234 million operations performed annually.[1] This yearly volume now exceeds that of childbirth.[2] Surgery is performed in every community: wealthy and poor, rural and urban, and in all regions. The World Bank reported that in 2002, an estimated 164 million disability-adjusted life-years, representing 11% of the entire disease burden, were attributable to surgically treatable conditions.[3] Although surgical care can prevent loss of life or limb, it is also associated with a considerable risk of complications and death. The risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a perioperative rate of death from inpatient surgery of 0.4 to 0.8% and a rate of major complications of 3 to 17%.[4,5] These rates are likely to be much higher in developing countries.[6-9] Thus, surgical care and its attendant complications represent a substantial burden of disease worthy of attention from the public health community worldwide.

Data suggest that at least half of all surgical complications are avoidable.[4,5] Previous efforts to implement practices designed to reduce surgical-site infections or anesthesia-related mishaps have been shown to reduce complications significantly.[10-12] A growing body of evidence also links teamwork in surgery to improved outcomes, with high-functioning teams achieving significantly reduced rates of adverse events.[13,14]

In 2008, the World Health Organization (WHO) published guidelines identifying multiple recommended practices to ensure the safety of surgical patients worldwide.[15] On the basis of

Table 1. Elements of the Surgical Safety Checklist.*

Sign in
Before induction of anesthesia, members of the team (at least the nurse and an anesthesia professional) orally confirm that:
The patient has verified his or her identity, the surgical site and procedure, and consent
The surgical site is marked or site marking is not applicable
The pulse oximeter is on the patient and functioning
All members of the team are aware of whether the patient has a known allergy
The patient's airway and risk of aspiration have been evaluated and appropriate equipment and assistance are available
If there is a risk of blood loss of at least 500 ml (or 7 ml/kg of body weight, in children), appropriate access and fluids are available
Time out
Before skin incision, the entire team (nurses, surgeons, anesthesia professionals, and any others participating in the care of the patient) orally:
Confirms that all team members have been introduced by name and role
Confirms the patient's identity, surgical site, and procedure
Reviews the anticipated critical events
Surgeon reviews critical and unexpected steps, operative duration, and anticipated blood loss
Anesthesia staff review concerns specific to the patient
Nursing staff review confirmation of sterility, equipment availability, and other concerns
Confirms that prophylactic antibiotics have been administered ≤60 min before incision is made or that antibiotics are not indicated
Confirms that all essential imaging results for the correct patient are displayed in the operating room
Sign out
Before the patient leaves the operating room:
Nurse reviews items aloud with the team
Name of the procedure as recorded
That the needle, sponge, and instrument counts are complete (or not applicable)
That the specimen (if any) is correctly labeled, including with the patient's name
Whether there are any issues with equipment to be addressed
The surgeon, nurse, and anesthesia professional review aloud the key concerns for the recovery and care of the patient

* The checklist is based on the first edition of the WHO Guidelines for Safe Surgery.[15] For the complete checklist, see the Supplementary Appendix.

these guidelines, we designed a 19-item checklist intended to be globally applicable and to reduce the rate of major surgical complications (Table 1). (For the formatted checklist, see the Supplementary Appendix, available with the full text of this article at NEJM.org.) We hypothesized that implementation of this checklist and the associated culture changes it signified would reduce the rates of death and major complications after surgery in diverse settings.

METHODS

STUDY DESIGN

We conducted a prospective study of preintervention and postintervention periods at the eight hospitals participating as pilot sites in the Safe Surgery Saves Lives program (Table 2). These institutions were selected on the basis of their geographic distribution within WHO regions, with the goal of representing a diverse set of socioeconomic environments in which surgery is performed. Table 3 lists surgical safety policies in place at each institution before the study. We required that a coinvestigator at each site lead the project locally and that the hospital administration support the intervention. A local data collector was chosen at each site and trained by the four primary investigators in the identification and reporting of process measures and complications. This person worked on the study full-time and did not have clinical responsibilities at the study site. Each hospital identified between one and four operating rooms to serve as study rooms. Patients who were 16 years of age or older and were undergoing noncardiac surgery in those rooms were consecutively enrolled in the study. The human subjects committees of the Harvard School of Public Health, the WHO, and each participating hospital approved the study and waived the requirement for written informed consent from patients.

INTERVENTION

The intervention involved a two-step checklist-implementation program. After collecting baseline data, each local investigator was given information about areas of identified deficiencies and was then asked to implement the 19-item WHO safe-surgery checklist (Table 1) to improve practices within the institution. The checklist consists of an oral confirmation by surgical teams of the completion of the basic steps for ensuring safe delivery of anesthesia, prophylaxis against infection, effective teamwork, and other essential practices in surgery. It is used at three critical junctures in care: before anesthesia is administered, immediately before incision, and before the patient is taken out of the operating room. The checklist was translated into local language when appropriate and was adjusted to fit into the flow of care at each institution. The local study team introduced the checklist to operating-room staff, using lectures, written materials, or direct guidance. The primary investigators also participated in the training by distributing a recorded video to the study sites, participating in a teleconference with each local study team, and making a visit to each site. The checklist was introduced to the study rooms over a period of 1 week to 1 month. Data collection resumed during the first week of checklist use.

Table 2. Characteristics of Participating Hospitals.

Site	Location	No. of Beds	No. of Operating Rooms	Type
Prince Hamzah Hospital	Amman, Jordan	500	13	Public, urban
St. Stephen's Hospital	New Delhi, India	733	15	Charity, urban
University of Washington Medical Center	Seattle, Washington	410	24	Public, urban
St. Francis Designated District Hospital	Ifakara, Tanzania	371	3	District, rural
Philippine General Hospital	Manila, Philippines	1800	39	Public, urban
Toronto General Hospital	Toronto, Canada	744	19	Public, urban
St. Mary's Hospital*	London, England	541	16	Public, urban
Auckland City Hospital	Auckland, New Zealand	710	31	Public, urban

* St. Mary's Hospital has since been renamed St. Mary's Hospital–Imperial College National Health Service Trust.

DATA COLLECTION

We obtained data on each operation from standardized data sheets completed by the local data collectors or the clinical teams involved in surgical care. The data collectors received training and supervision from the primary investigators in the identification and classification of complications and process measures. Perioperative data included the demographic characteristics of patients, procedural data, type of anesthetic used, and safety data. Data collectors followed patients prospectively until discharge or for 30 days, whichever came first, for death and complications. Outcomes were identified through chart monitoring and communication with clinical staff. Completed data forms were stripped of direct identifiers of patients and transmitted to the primary investigators. We aimed to collect data on 500 consecutively enrolled patients at each site within a period of less than 3 months for each of the two phases of the study. At the three sites at which this goal could not be achieved, the period of data collection was extended for up to 3 additional months to allow for accrual of a sufficient number of patients. The sample size was calculated to detect a 20% reduction in complications after the checklist was implemented, with a statistical power of 80% and an alpha value of 0.05.

OUTCOMES

The primary end point was the occurrence of any major complication, including death, during the period of postoperative hospitalization, up to 30 days. Complications were defined as they are in the American College of Surgeons' National Surgical Quality Improvement Program[17]: acute renal failure, bleeding requiring the transfusion of 4 or more units of red cells within the first 72 hours after surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma of 24 hours' duration or more, deep-vein thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours or more, pneumonia, pulmonary embolism, stroke, major disruption of wound, infection of surgical site, sepsis, septic shock, the systemic inflammatory response syndrome, unplanned return to the operating room, vascular graft failure, and death. Urinary tract infection was not considered a major complication. A group of physician reviewers determined, by consensus, whether postoperative events reported as "other complications" qualified as major complications, using the Clavien classification for guidance.[18]

We assessed adherence to a subgroup of six safety measures as an indicator of process adherence. The six measures were the objective evaluation and documentation of the status of the patient's airway before administration of the anesthetic; the use of pulse oximetry at the time of initiation of anesthesia; the presence of at least two peripheral intravenous catheters or a central venous catheter before incision in cases involving an estimated blood loss of 500 ml or more; the administration of prophylactic antibiotics within 60 minutes before incision except in the case of preexisting infection, a procedure not involving incision, or a contaminated operative field; oral confirmation, immediately before incision, of the

Table 3. Surgical Safety Policies in Place at Participating Hospitals before the Study.

Site* No.	Routine Intraoperative Monitoring with Pulse Oximetry	Oral Confirmation of Patient's Identity and Surgical Site in Operating Room	Routine Administration of Prophylactic Antibiotics in Operating Room	Standard Plan for Intravenous Access for Cases of High Blood Loss	Formal Team Briefing	
					Preoperative	Postoperative
1	Yes	Yes	Yes	No	No	No
2	Yes	No	Yes	No	No	No
3	Yes	No	Yes	No	No	No
4	Yes	Yes	Yes	No	No	No
5	No	No	No	No	No	No
6	No	No	Yes	No	No	No
7	Yes	No	No	No	No	No
8	Yes	No	No	No	No	No

* Sites 1 through 4 are located in high-income countries; sites 5 through 8 are located in low- or middle-income countries.[16]

identity of the patient, the operative site, and the procedure to be performed; and completion of a sponge count at the end of the procedure, if an incision was made. We recorded whether all six of these safety measures were taken for each patient.

STATISTICAL ANALYSIS

Statistical analyses were performed with the use of the SAS statistical software package, version 9.1 (SAS Institute). To minimize the effect of differences in the numbers of patients at each site, we standardized the rates of various end points to reflect the proportion of patients from each site. These standardized rates were used to compute the frequencies of performance of specified safety measures, major complications, and death at each site before and after implementation of the checklist.[19] We used logistic-regression analysis to calculate two-sided P values for each comparison, with site as a fixed effect. We used generalized-estimating-equation methods to test for any effect of clustering according to site.

We performed additional analyses to test the robustness of our findings, including logistic-regression analyses in which the presence or absence of a data collector in the operating room and the case mix were added as variables. We classified cases as orthopedic, thoracic, nonobstetric abdominopelvic, obstetric, vascular, endoscopic, or other. To determine whether the effect of the checklist at any one site dominated the results, we performed cross-validation by sequentially removing each site from the analysis. Finally, we disaggregated the sites on the basis of whether they were located in high-income or low- or middle-income countries and repeated our analysis of primary end points. All reported P values are two-sided, and no adjustments were made for multiple comparisons.

RESULTS

We enrolled 3733 patients during the baseline period and 3955 patients after implementation of the checklist. Table 4 lists characteristics of the patients and their distribution among the sites; there were no significant differences between the patients in the two phases of the study.

The rate of any complication at all sites dropped from 11.0% at baseline to 7.0% after introduction of the checklist (P<0.001); the total in-hospital rate of death dropped from 1.5% to 0.8% (P=0.003) (Table 5). The overall rates of surgical-site infection and unplanned reoperation also declined significantly (P<0.001 and P=0.047, respectively). Operative data were collected by the local data collector through direct observation for 37.5% of patients and by unobserved clinical teams for the remainder. Neither the presence nor

Table 4. Characteristics of the Patients and Procedures before and after Checklist Implementation, According to Site.*

Site	No. of Patients Enrolled		Age		Female Sex		Urgent Case		Outpatient Procedure		General Anesthetic	
No.	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
			years					*percent*				
1	524	598	51.9±15.3	51.4±14.7	58.2	62.7	7.4	8.0	31.7	31.8	95.0	95.2
2	357	351	53.5±18.4	54.0±18.3	54.1	56.7	18.8	14.5	23.5	20.5	92.7	93.5
3	497	486	51.9±21.5	53.0±20.3	44.3	49.8	17.9	22.4	6.4	9.3	91.2	94.0
4	520	545	57.0±14.9	56.1±15.0	48.1	49.6	6.9	1.8	14.4	11.0	96.9	97.8
5	370	330	34.3±15.0	31.5±14.2	78.3	78.4	46.1	65.4	0.0	0.0	17.0	10.0
6	496	476	44.6±15.9	46.0±15.5	45.0	46.6	28.4	22.5	1.4	1.1	61.7	59.9
7	525	585	37.4±14.0	39.6±14.9	69.1	68.6	45.7	41.0	0.0	0.0	49.1	55.9
8	444	584	41.9±15.8	39.7±16.2	57.0	52.7	13.5	21.9	0.9	0.2	97.5	94.7
Total	3733	3955	46.8±18.1	46.7±17.9	56.2	57.6	22.3	23.3	9.9	9.4	77.0	77.3
P value			0.63		0.21		0.26		0.40		0.68	

* Plus–minus values are means ±SD. Urgent cases were those in which surgery within 24 hours was deemed necessary by the clinical team. Outpatient procedures were those for which discharge from the hospital occurred on the same day as the operation. P values are shown for the comparison of the total value after checklist implementation with the total value before implementation.

Table 5. Outcomes before and after Checklist Implementation, According to Site.*

Site	No. of Patients Enrolled		Surgical-Site Infection		Unplanned Return to the Operating Room		Pneumonia		Death		Any Complication	
No.	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
							percent					
1	524	598	**4.0**	**2.0**	**4.6**	**1.8**	0.8	1.2	**1.0**	**0.0**	**11.6**	**7.0**
2	357	351	2.0	1.7	0.6	1.1	3.6	3.7	1.1	0.3	7.8	6.3
3	497	486	5.8	4.3	4.6	2.7	1.6	1.7	0.8	1.4	13.5	9.7
4	520	545	3.1	2.6	2.5	2.2	0.6	0.9	1.0	0.6	7.5	5.5
5	370	330	**20.5**	**3.6**	1.4	1.8	0.3	0.0	**1.4**	**0.0**	**21.4**	**5.5**
6	496	476	4.0	4.0	3.0	3.2	2.0	1.9	3.6	1.7	10.1	9.7
7	525	585	**9.5**	**5.8**	**1.3**	**0.2**	1.0	1.7	2.1	1.7	**12.4**	**8.0**
8	444	584	4.1	2.4	0.5	1.2	0.0	0.0	1.4	0.3	6.1	3.6
Total	3733	3955	**6.2**	**3.4**	**2.4**	**1.8**	1.1	1.3	**1.5**	**0.8**	**11.0**	**7.0**
P value			<0.001		0.047		0.46		0.003		<0.001	

* The most common complications occurring during the first 30 days of hospitalization after the operation are listed. Bold type indicates values that were significantly different (at P<0.05) before and after checklist implementation, on the basis of P values calculated by means of the chi-square test or Fisher's exact test. P values are shown for the comparison of the total value after checklist implementation as compared with the total value before implementation.

absence of a direct observer nor changes in case mix affected the significance of the changes in the rate of complications (P<0.001 for both alternative models) or the rate of death (P=0.003 with the presence or absence of direct observation included and P=0.002 with case-mix variables included). Rates of complication fell from 10.3% before the introduction of the checklist to 7.1% after its introduction among high-income sites (P<0.001) and from 11.7% to 6.8% among lower-income sites (P<0.001). The rate of death was reduced from 0.9% before checklist introduction to 0.6% afterward at high-income sites (P=0.18) and from 2.1% to 1.0% at lower-income sites (P=0.006), although only the latter difference was significant. In the cross-validation analysis, the effect of the checklist intervention on the rate of death or complications remained significant after the removal of any site from the model (P<0.05). We also found no change in the significance of the effect on the basis of clustering (P=0.003 for the rate of death and P=0.001 for the rate of complications).

Table 6 shows the changes in six measured processes at each site after introduction of the checklist. During the baseline period, all six measured safety indicators were performed for 34.2% of the patients, with an increase to 56.7% of patients after implementation of the checklist (P<0.001). At each site, implementation of the checklist also required routine performance of team introductions, briefings, and debriefings, but adherence rates could not be measured.

DISCUSSION

Introduction of the WHO Surgical Safety Checklist into operating rooms in eight diverse hospitals was associated with marked improvements in surgical outcomes. Postoperative complication rates fell by 36% on average, and death rates fell by a similar amount. All sites had a reduction in the rate of major postoperative complications, with a significant reduction at three sites, one in a high-income location and two in lower-income locations. The reduction in complications was maintained when the analysis was adjusted for case-mix variables. In addition, although the effect of the intervention was stronger at some sites than at others, no single site was responsible for the overall effect, nor was the effect confined to high-income or low-income sites exclusively. The reduction in the rates of death and complications suggests that the checklist program can improve the safety of surgical patients in diverse clinical and economic environments.

Whereas the evidence of improvement in surgical outcomes is substantial and robust, the ex-

act mechanism of improvement is less clear and most likely multifactorial. Use of the checklist involved both changes in systems and changes in the behavior of individual surgical teams. To implement the checklist, all sites had to introduce a formal pause in care during surgery for preoperative team introductions and briefings and postoperative debriefings, team practices that have previously been shown to be associated with improved safety processes and attitudes[14,20,21] and with a rate of complications and death reduced by as much as 80%.[13] The philosophy of ensuring the correct identity of the patient and site through preoperative site marking, oral confirmation in the operating room, and other measures proved to be new to most of the study hospitals.

In addition, institution of the checklist required changes in systems at three institutions, in order to change the location of administration of antibiotics. Checklist implementation encouraged the administration of antibiotics in the operating room rather than in the preoperative wards, where delays are frequent. The checklist provided additional oral confirmation of appropriate antibiotic use, increasing the adherence rate from 56 to 83%; this intervention alone has been shown to reduce the rate of surgical-site infection by 33 to 88%.[22-28] Other potentially lifesaving measures were also more likely to be instituted, including an objective airway evaluation and use of pulse oximetry, though the change in these measures was less dramatic.[15] Although the omission of individual steps was still frequent, overall adherence to the subgroup of six safety indicators increased by two thirds. The sum of these individual systemic and behavioral changes could account for the improvements observed.

Another mechanism, however, could be the Hawthorne effect, an improvement in performance due to subjects' knowledge of being observed.[29] The contribution of the Hawthorne effect is difficult to disentangle in this study. The checklist is orally performed by peers and is intentionally designed to create a collective awareness among surgical teams about whether safety processes are being completed. However, our analysis does show that the presence of study personnel in the operating room was not responsible for the change in the rate of complications.

This study has several limitations. The design, involving a comparison of preintervention data

Table 6. Selected Process Measures before and after Checklist Implementation, According to Site.*

Site	No. of Patients Enrolled		Objective Airway Evaluation Performed (N=7688)		Pulse Oximeter Used (N=7688)		Two Peripheral or One Central IV Catheter Present at Incision When EBL ≥500 ml (N=953)		Prophylactic Antibiotics Given Appropriately (N=6802)		Oral Confirmation of Patient's Identity and Operative Site (N=7688)		Sponge Count Completed (N=7572)		All Six Safety Indicators Performed (N=7688)	
No.	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
									percent							
1	524	598	97.0	98.5	100.0	100.0	95.7	83.6	98.1	96.9	100.0	100.0	98.9	100.0	94.1	94.2
2	357	351	72.0	75.8	97.5	98.6	78.8	61.3	56.9	76.9	9.5	97.2	100.0	100.0	3.6	55.3
3	497	486	74.7	66.3	98.6	100.0	83.8	82.5	83.8	87.7	47.1	90.1	97.8	96.8	30.8	51.0
4	520	545	94.6	95.8	100.0	100.0	66.7	48.6	80.0	81.8	98.9	97.6	97.3	99.1	67.1	63.7
5	370	330	6.2	0.0	68.9	91.2	7.6	2.7	29.8	96.2	0.0	86.1	0.0	92.4	0.0	0.0
6	496	476	46.2	56.3	76.4	83.0	49.2	57.9	25.4	50.6	21.8	64.9	99.4	99.4	1.4	18.1
7	525	585	97.5	99.7	99.4	100.0	32.0	100.0	42.5	91.7	98.9	100.0	100.0	100.0	46.7	92.1
8	444	584	0.5	94.0	99.3	99.5	68.8	57.1	18.2	77.6	16.4	98.8	61.3	70.0	0.0	51.7
Total	3733	3955	64.0	77.2	93.6	96.8	58.1	63.2	56.1	82.6	54.4	92.3	84.6	94.6	34.2	56.7
P value			<0.001		<0.001		0.32		<0.001		<0.001		<0.001		<0.001	

* Prophylactic antibiotics were considered to be indicated for all cases in which an incision was made through an uncontaminated field and appropriately administered when given within 60 minutes before an incision was made. Sponge counts were considered to be indicated in all cases in which an incision was made. P values are shown for the comparison of the total values before and after checklist implementation, calculated by means of the chi-square test. EBL denotes estimated blood loss, and IV intravenous.

with postintervention data and the consecutive recruitment of the two groups of patients from the same operating rooms at the same hospitals, was chosen because it was not possible to randomly assign the use of the checklist to specific operating rooms without significant cross-contamination. One danger of this design is confounding by secular trends. We therefore confined the duration of the study to less than 1 year, since a change in outcomes of the observed magnitude is unlikely to occur in such a short period as a result of secular trends alone. In addition, an evaluation of the American College of Surgeons' National Surgical Quality Improvement Program cohort in the United States during 2007 did not reveal a substantial change in the rate of death and complications (Ashley S. personal communication, http://acsnsqip.org). We also found no change in our study groups with regard to the rates of urgent cases, outpatient surgery, or use of general anesthetic, and we found that changes in the case mix had no effect on the significance of the outcomes. Other temporal effects, such as seasonal variation and the timing of surgical training periods, were mitigated, since the study sites are geographically mixed and have different cycles of surgical training. Therefore, it is unlikely that a temporal trend was responsible for the difference we observed between the two groups in this study.

Another limitation of the study is that data collection was restricted to inpatient complications. The effect of the intervention on outpatient complications is not known. This limitation is particularly relevant to patients undergoing outpatient procedures, for whom the collection of outcome data ceased on their discharge from the hospital on the day of the procedure, resulting in an underestimation of the rates of complications. In addition, data collectors were trained in the identification of complications and collection of complications data at the beginning of the study. There may have been a learning curve in the process of collecting the data. However, if this were the case, it is likely that increasing numbers of complications would be identified as the study progressed, which would bias the results in the direction of an underestimation of the effect.

One additional concern is how feasible the checklist intervention might be for other hospitals. Implementation proved neither costly nor lengthy. All sites were able to introduce the checklist over a period of 1 week to 1 month. Only two of the safety measures in the checklist entail the commitment of significant resources: use of pulse oximetry and use of prophylactic antibiotics. Both were available at all the sites, including the low-income sites, before the intervention, although their use was inconsistent.

Surgical complications are a considerable cause of death and disability around the world.[3] They are devastating to patients, costly to health care systems, and often preventable, though their prevention typically requires a change in systems and individual behavior. In this study, a checklist-based program was associated with a significant decline in the rate of complications and death from surgery in a diverse group of institutions around the world. Applied on a global basis, this checklist program has the potential to prevent large numbers of deaths and disabling complications, although further study is needed to determine the precise mechanism and durability of the effect in specific settings.

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APPENDIX

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Appendix B

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All members of the working groups, as listed in the annex, completed a declaration of conflict of interest and no conflicts were reported.

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