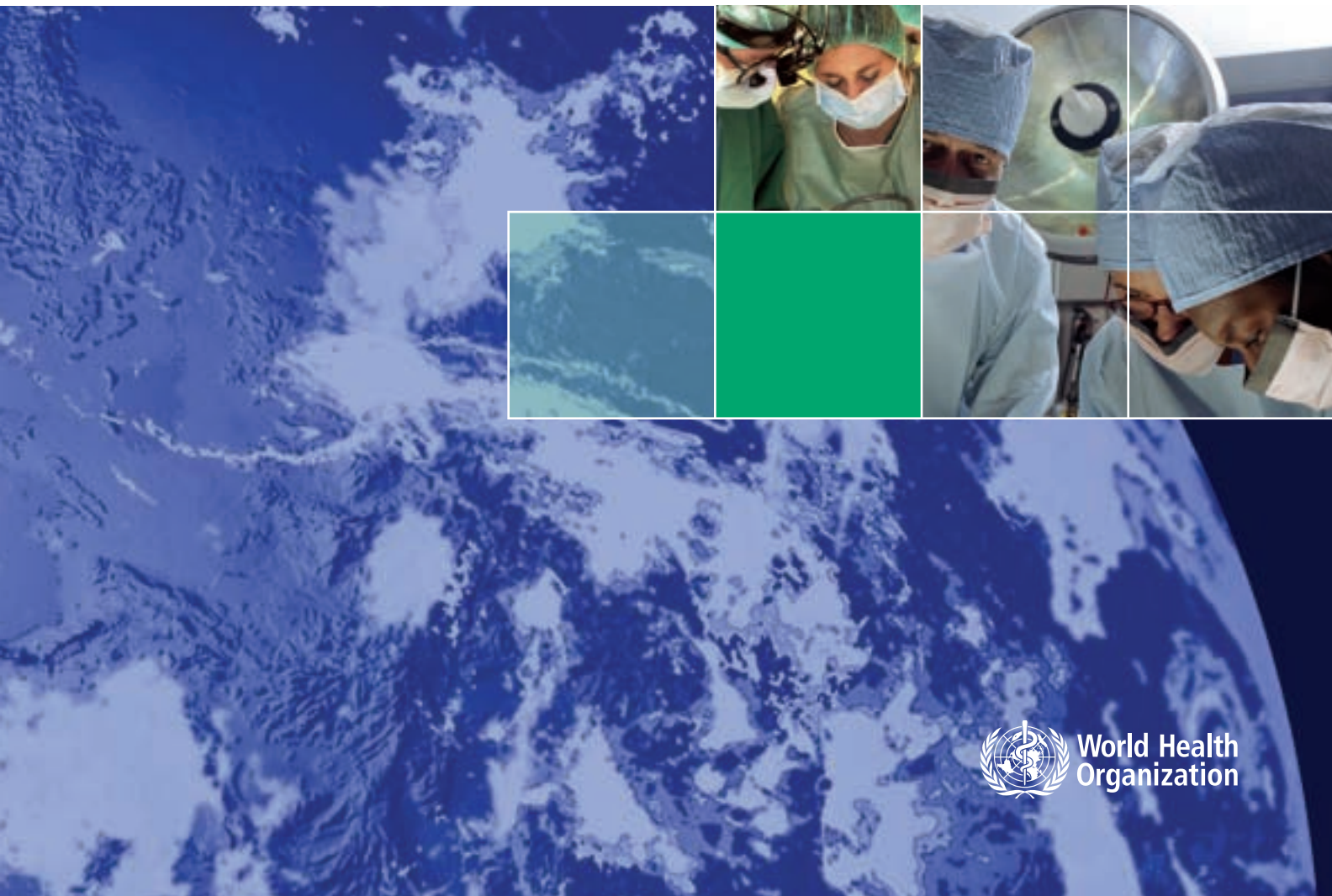




WORLD ALLIANCE FOR PATIENT SAFETY

SAFE SURGERY SAVES LIVES

SECOND GLOBAL PATIENT SAFETY CHALLENGE



WORLD ALLIANCE FOR PATIENT SAFETY

**THE SECOND GLOBAL
PATIENT SAFETY CHALLENGE**

SAFE SURGERY SAVES LIVES



Safe Surgery Save Lives - WHO/IER/PSP/2008.07

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INTRODUCTION

In October 2004 the World Health Organization (WHO) launched the World Alliance for Patient Safety in response to World Health Assembly Resolution 55.18 urging WHO and Member States to pay the closest possible attention to the problem of patient safety. The Alliance raises awareness and political commitment to improve the safety of care and supports Member States to develop patient safety policy and practice. Each year the Alliance organizes programmes covering systemic and technical aspects for improving patient safety around the world.

A core element of the work of the Alliance is the formulation of Global Patient Safety Challenges. Every two years a Challenge is formulated to galvanize global commitment and action on a patient safety issue which addresses a significant area of risk for all WHO Member States.

The first Challenge focused on health care-associated infection, while safe surgery has been chosen as the topic for the second Global Patient Safety Challenge.¹

¹Supporting evidence and citations for the information in this document can be found in: WHO Guidelines for Safe Surgery (First Edition), Geneva, World Health Organization, 2008.

SAFE SURGERY IS A PUBLIC HEALTH PRIORITY

Surgical care has been an essential component of health care worldwide for over a century. As the incidences of traumatic injuries, cancers and cardiovascular disease continue to rise the impact of surgical intervention on public health systems will grow. An estimated 234 million major operations (*see box 1*) are performed around the world each year, corresponding to one operation for every 25 people alive. Yet surgical services are unevenly distributed with 30% of the world's population receiving 75% of major operations. Lack of access to high quality surgical care remains a significant problem in much of the world despite the fact that surgical interventions can be cost effective in terms of lives saved and disability averted. Surgery is often the only therapy that can alleviate disabilities and reduce the risk of death from common conditions. Each year an estimated 63 million people undergo surgical treatment due to traumatic injuries, another 10 million operations are performed for pregnancy-related complications, and 31 million more are undertaken to treat malignancies.

Box 1: Definition used to estimate the volume of major surgery

Major surgery includes any procedure conducted in the operating room involving the incision, excision, manipulation or suturing of tissue which usually requires regional or general anaesthesia or profound sedation to control pain.

While surgical procedures are intended to save lives, unsafe surgical care can cause substantial harm (*see box 2*). Given the ubiquity of surgery this has significant implications for public health. In industrialized countries major complications are reported to occur in 3–16% of inpatient surgical procedures, with permanent disability or death rates of approximately 0.4–0.8%. In developing countries studies suggest a



death rate of 5–10% during major surgery. Mortality from general anaesthesia alone is reported to be as high as one in 150 in parts of sub-Saharan Africa. Infections and other postoperative morbidities are also a serious concern around the world. At a minimum seven million surgical patients are harmed by surgical complications each year including at least one million patients who die during or immediately following a procedure.

Box 2: Five facts about surgical safety

1. Complications after inpatient operations occur in up to 25% of patients.
2. The reported crude mortality rate after major surgery is 0.5–5%.
3. In industrialized countries nearly half of all adverse events in hospitalized patients are related to surgical care.
4. At least half of the cases in which surgery led to harm are considered to be preventable.
5. Known principles of surgical safety are inconsistently applied even in the most sophisticated settings.

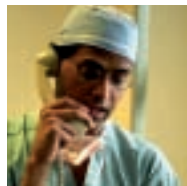
The problem of surgical safety is well recognized throughout the world. In developed countries studies confirm the magnitude and pervasiveness of the problem. In the developing world the poor state of infrastructure and equipment, unreliable supplies and quality of medications, shortcomings in organizational management and infection control, inadequate capacity and training of personnel and severe under-financing all contribute to the difficulties. Therefore a global movement to promote a system-wide approach to safer surgical care could save the lives of millions of people worldwide (see box 3).

Box 3: System-wide approach to improved surgical safety

There is no single remedy that will improve surgical safety. It requires reliable completion of a sequence of necessary steps in care, not just by the surgeon, but by a team of health-care professionals working together within a supportive health system for the benefit of the patient.

Raising the standard to make surgical care safer worldwide

'Surgical care has been an essential component of health systems worldwide for more than a century. Although there have been major improvements over the last few decades, the quality and safety of surgical care has been dismayingly variable in every part of the world. The Safe Surgery Saves Lives initiative aims to change this by raising the standards that patients anywhere can expect.'



Dr Atul Gawande **Associate Professor and surgeon, Harvard School of Public Health and Programme Leader of the Second Global Patient Safety Challenge**



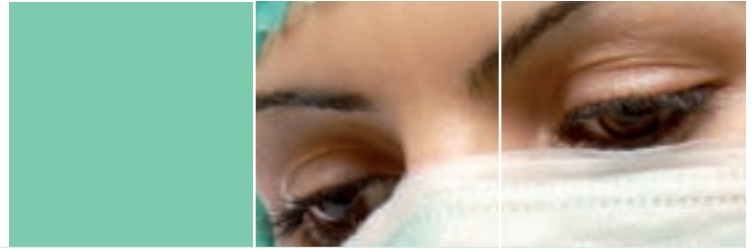
THE SECOND GLOBAL PATIENT SAFETY CHALLENGE: *SAFE SURGERY SAVES LIVES*

WHO has undertaken a number of global and regional initiatives to address surgical safety. The Global Initiative for Emergency and Essential Surgical Care and the Guidelines for Essential Trauma Care focussed on access and quality. The second Global Patient Safety Challenge: *Safe Surgery Saves Lives* addresses the safety of surgical care. The World Alliance for Patient Safety initiated work on this Challenge in January 2007.

The goal of this 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 WHO Member States. To this end, working groups of international experts were convened to review the literature and the experiences of clinicians around the world. They reached consensus on four areas in which dramatic improvements could be made in the safety of surgical care. These are: surgical site infection prevention, safe anaesthesia, safe surgical teams and measurement of surgical services (see box 4).

Box 4: Working groups of the second Global Patient Safety Challenge

- **Surgical site infection prevention:** Surgical site infections remain one of the most common causes of serious surgical complications. Evidence shows that proven measures — such as antibiotic prophylaxis within the hour before incision and effective sterilization of instruments — are inconsistently followed. This is often not because of the cost or lack of resources but because of poor systematization. Antibiotics, for example, are given perioperatively in both developed and developing countries but they are often administered too early, too late or simply erratically, making them ineffective in reducing patient harm.
- **Safe anaesthesia:** Anaesthetic complications remain a substantial cause of surgical death globally, despite safety and monitoring standards which have significantly reduced unnecessary deaths and disability in developed countries. Three decades ago a patient undergoing general anaesthesia had an estimated



one in 5000 chance of death. With improvements in knowledge and basic standards of care the risk has dropped to one in 200 000 in the developed world—a 40-fold improvement. Unfortunately the rate of anaesthesia-associated mortality in developing countries appears to be 100–1000 times higher, indicating a serious, sustained lack of safe anaesthesia for surgery in these settings.

- **Safe surgical teams:** Teamwork is the core of all effectively functioning systems involving multiple people. In the operating room, where tension may be high and lives are at stake, teamwork is an essential component of safe practice. The quality of teamwork depends on the culture of the team and its communication patterns, as well as the clinical skills and situational awareness of the team members. Improving team characteristics should aid communication and reduce patient harm.
- **Measurement of surgical services:** A major problem in surgical safety has been a shortage of basic data. Efforts to reduce maternal and neonatal mortality during childbirth have been critically reliant on routine surveillance of mortality rates and systems of obstetric care to monitor successes and failures. Similar surveillance has generally not been undertaken for surgical care. Data on surgical volume are available for only a minority of countries and are not standardized. Routine surveillance to evaluate and measure surgical services must be established if public health systems are to ensure progress in improving the safety of surgical care.

The second Global Patient Safety Challenge aims to foster improved surgical safety and to reduce deaths and complications during surgery in four ways:

- by providing information on the role and patterns of surgical safety in public health to clinicians, hospital administrators and public health officials;
- by defining a minimum set of uniform measures, or 'surgical vital statistics', for the national and international surveillance of surgical care;
- by identifying a simple set of surgical safety standards that are applicable in all countries and settings and are compiled in a checklist for use in operating rooms;
- by evaluating and disseminating the Checklist and surveillance measures at pilot sites in every WHO region initially, and then to hospitals worldwide.

The four working groups defined ten essential objectives that should be met by every surgical team during surgical care (see box 5). These objectives were summarized in a one-page checklist for use by health-care workers to ensure that the safety standards are met. The Checklist, entitled the WHO Surgical Safety Checklist, is undergoing pilot site evaluation to verify that it is robust, widely applicable and will improve the safety and quality of surgical care in a variety of settings. Lessons learnt from the pilot sites will be applied in the second Global Patient Safety Challenge when it promotes use of the Checklist in operating rooms worldwide.

The second Global Patient Safety Challenge aims to improve surgical outcomes for all patients. This will require strong political commitment and the willingness of professional groups around the world to address the common and potentially deadly problems of unsafe surgical care.

Box 5: Ten essential objectives for safe surgery

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

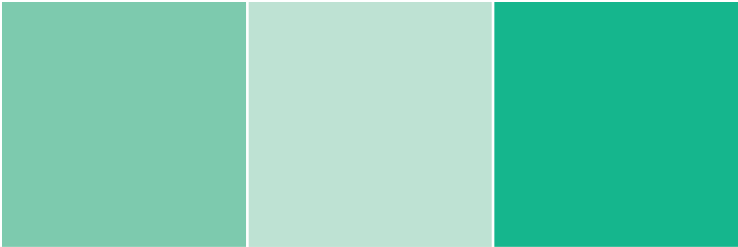


WHO GUIDELINES FOR SAFE SURGERY (FIRST EDITION)

The *WHO Guidelines for Safe Surgery (First Edition)* include a review of the evidence for interventions that can improve surgical safety in a wide range of settings and contexts. The experts, clinicians and patients from around the world participating in the four working groups of the second Global Patient Safety Challenge considered a number of safety standards that could be used to improve surgical patient care. They evaluated the evidence for each before deciding which should be included in the WHO Surgical Safety Checklist. They also estimated the potential effectiveness of each safety practice in reducing patient harm and designed measures to assess the extent to which the interventions, when used as part of the Checklist, could improve patient safety.

The *WHO Guidelines for Safe Surgery (First Edition)* provide evidence for the essential components of safe surgical care, which form the basis of the Checklist. While the *Guidelines* provide the evidence base, the Checklist is a simple, practical tool that any surgical team in the world can use to ensure that the preoperative, intraoperative and postoperative steps that have been shown to benefit patients are undertaken in a timely and efficient way.

The *Guidelines* and the Checklist follow an established framework for safe intraoperative care in hospitals. This involves a routine sequence of events — preoperative patient evaluation, surgical intervention and preparation for appropriate postoperative care — each with specific risks that must be mitigated. In the preoperative phase obtaining informed consent, confirming the patient's identity, the surgical site and the procedure to be undertaken, checking the safety of the anaesthetic machine and medications and adequately preparing for intraoperative events are all amenable to intervention. During the operative phase appropriate and judicious use of antibiotics, the availability of essential imaging, appropriate patient monitoring, efficient teamwork, competent anaesthetic and surgical judgement,

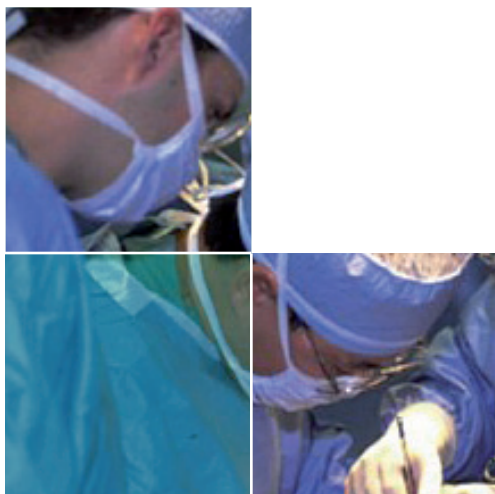


meticulous surgical technique and efficient communication among team members of the various disciplines (surgery, anaesthesia and nursing) are all necessary to ensure good outcomes. In the postoperative phase a clear plan of care, an understanding of intraoperative events and a commitment to quality improvement can all advance surgical care, thereby promoting patient safety and enhancing outcomes.

The aim of the WHO Surgical Safety Checklist is not to prescribe a single approach, but to ensure that key safety elements are incorporated into the operating room routine. This will maximize the likelihood of the best outcome for patients without placing an undue burden on the system and the providers. It is understood that, in nearly all settings, the standards will represent a change in routines; however, the standards were included on the basis of sound evidence or expert consensus that they could produce tangible, life-saving improvements in care in all environments, from the richest to the poorest.

Thus every country can improve the safety of surgical care when hospitals:

- use the WHO Surgical Safety Checklist or similar safety checks to ensure that the steps to promote safe surgery are accomplished in a systematic, timely fashion;
- establish routine surveillance of surgical capacity, volume and results.



THE WHO SURGICAL SAFETY CHECKLIST

The WHO Surgical Safety Checklist was developed to help operating teams reduce the occurrence of patient harm. The World Alliance for Patient Safety collaborated with numerous contributors from across all WHO regions with expertise in surgery and its subspecialties, as well as anaesthesia, nursing, infectious diseases, epidemiology, biomedical engineering, health systems, quality improvement and other related fields, and also patients and patient safety groups. Together they identified safety checks that could be performed in any operating room. The result is the Checklist, which aims to reinforce accepted safety practices and foster better communication and teamwork among clinical disciplines (see *figure 1*, and at www.who.int/patientsafety/challenge/safe.surgery). The Checklist is not a regulatory device or a component of official policy; it is intended as a practical, easy-to-use tool for use by clinicians interested in improving the safety of their operations and reducing unnecessary surgical deaths and complications.

The development of the Checklist was guided by three principles. The first was **simplicity**. An exhaustive list of standards and guidelines might create a package that would improve patient safety, but such comprehensiveness would be difficult to use 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 was **wide applicability**. Focusing on a specific resource milieu might change the types of issues considered for discussion (e.g. minimum equipment standards for resource-poor settings). However the goal of the Challenge is to reach all environments and settings, from resource-rich to resource-poor. Furthermore, regular failures occur in every setting and environment and are amenable to common solutions.



The third was **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. They must also 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.

Each safety check is included on the basis of clinical evidence or expert opinion that its inclusion will reduce the likelihood of serious, avoidable surgical harm and that adherence is unlikely to cause injury or unmanageable cost. Many of the steps are already accepted as routine practice in facilities around the world although they are rarely undertaken in their entirety. As a result, surgical departments worldwide are encouraged to use the Checklist and examine how to sensibly integrate these essential safety steps into their normal operative workflow.

The Checklist will help ensure that teams consistently follow critical safety steps and thereby minimize the commonest avoidable risks that endanger the lives and well-being of surgical patients.

World Health
Organization

SURGICAL

Before induction of anaesthesia ►►►►►►►►►►

SIGN IN

☐ **PATIENT HAS CONFIRMED**

- IDENTITY
- SITE
- PROCEDURE
- CONSENT

☐ **SITE MARKED/NOT APPLICABLE**

☐ **ANAESTHESIA SAFETY CHECK COMPLETED**

☐ **PULSE OXIMETER ON PATIENT AND FUNCTIONING**

DOES PATIENT HAVE A:

KNOWN ALLERGY?

☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?

☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

**RISK OF >500ML BLOOD LOSS
(7ML/KG IN CHILDREN)?**

☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS
AND FLUIDS PLANNED

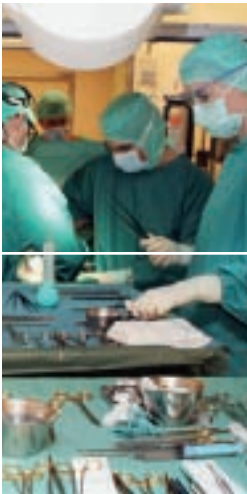
THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND

Box 6. Brief instructions for using the WHO Surgical Safety Checklist

It is essential that a single person leads the Checklist process. This designated Checklist coordinator, who is responsible for checking the boxes on the list, will often be a circulating nurse but 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 prior to induction of anaesthesia (*Sign In*), the period after induction and before surgical incision (*Time Out*), and the period during or immediately after wound closure (*Sign Out*). In each phase the Checklist coordinator must be permitted to confirm that the team has completed its tasks before it proceeds onward.

For '**Sign In**', before induction of anaesthesia, the Checklist coordinator will verbally confirm with the patient (when possible) his or her identity, the surgical site and the procedure, and that consent to operate has been obtained. The coordinator will visually confirm that the operative site has been marked (if appropriate) and will verbally review with the anaesthesia professional the patient's risk of blood loss, airway difficulty and allergies, and also whether a safety check of the anaesthesia machine and medications has been completed. Ideally the surgeon will be present for '*Sign In*', as the surgeon may have a clearer idea of the anticipated blood loss, allergies or other potential complicating factors. However the surgeon's presence is not essential to complete this part of the Checklist.





For **'Time Out'** the team will pause immediately before the skin incision to confirm out aloud that the correct operation on the correct patient and site is being performed; all team members will then verbally review with one another, in turn, the critical elements of their plans for the operation, using the Checklist questions 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.

For **'Sign Out'** the team will review together the operation that was performed, completion of sponge and instrument counts and the labelling of any surgical specimens obtained. They will also review any equipment malfunctions or issues that need to be addressed. Finally the team will review key plans and concerns for postoperative management and recovery before moving the patient from the operating room.

SCALING UP EFFORTS TO REDUCE PATIENT HARM

The WHO Surgical Safety Checklist was evaluated in eight pilot sites to identify potential problems with implementation and acceptance and to confirm that its use can actually improve surgical safety. Evaluation was performed in operating rooms in the six WHO regions (*see figure 2*). The Checklist was launched officially in Washington DC, United States of America, on 25 June 2008 to promote its adoption and use globally.

Successful implementation of the WHO Surgical Safety Checklist — and the potential to improve outcomes for patients around the world — will require adapting the Checklist to local routines and expectations. This will not be possible without commitment of hospital administrators and policy-makers in the highest echelons of professional organizations and ministries of health.

Initiatives to obtain endorsement of the Checklist have already begun. For example, in February 2008, organizations in the United Kingdom of Great Britain and Northern Ireland endorsed the concept at an event hosted by the National Patient Safety Agency in London. The Royal Colleges and national organizations representing anaesthetists, nurses and surgeons publicly endorsed the principles underpinning the *Safe Surgery Saves Lives* initiative.

Nonetheless, for the Checklist to succeed, chiefs of surgery, anaesthesia, and nursing are encouraged to publicly embrace the concept that safety is a priority and that the use of a checklist can make surgical care safer. Unless there is visible, ongoing support from introduction of the Checklist to its integration into routine care, a checklist of this sort may breed discontent and antagonism. It is advised that hospital leadership leads by example, by using the Checklist in their own surgical cases and regularly asking others how implementation is proceeding. This will permit ongoing dialogue to address problems, inefficiencies and scepticism.



Clinical and policy leaders can also highlight the issues of safe surgery and its effect on public health by measuring and assessing the care provided. It is impossible to adequately evaluate surgical care without the means of measuring both the quantity and quality of care, which is an essential component of any successful improvement programme. The *Safe Surgery Saves Lives* initiative has therefore incorporated a simple, viable statistics framework to permit valid comparisons within and across countries at all levels of development. Five surgical 'vital statistics' have been drafted to estimate surgical capacity, volume and results (see box 7). These measures can be used in a wide range of facilities to assess the adequacy and safety of surgical care. They can also help determine the impact of the WHO Surgical Safety Checklist on the services provided.

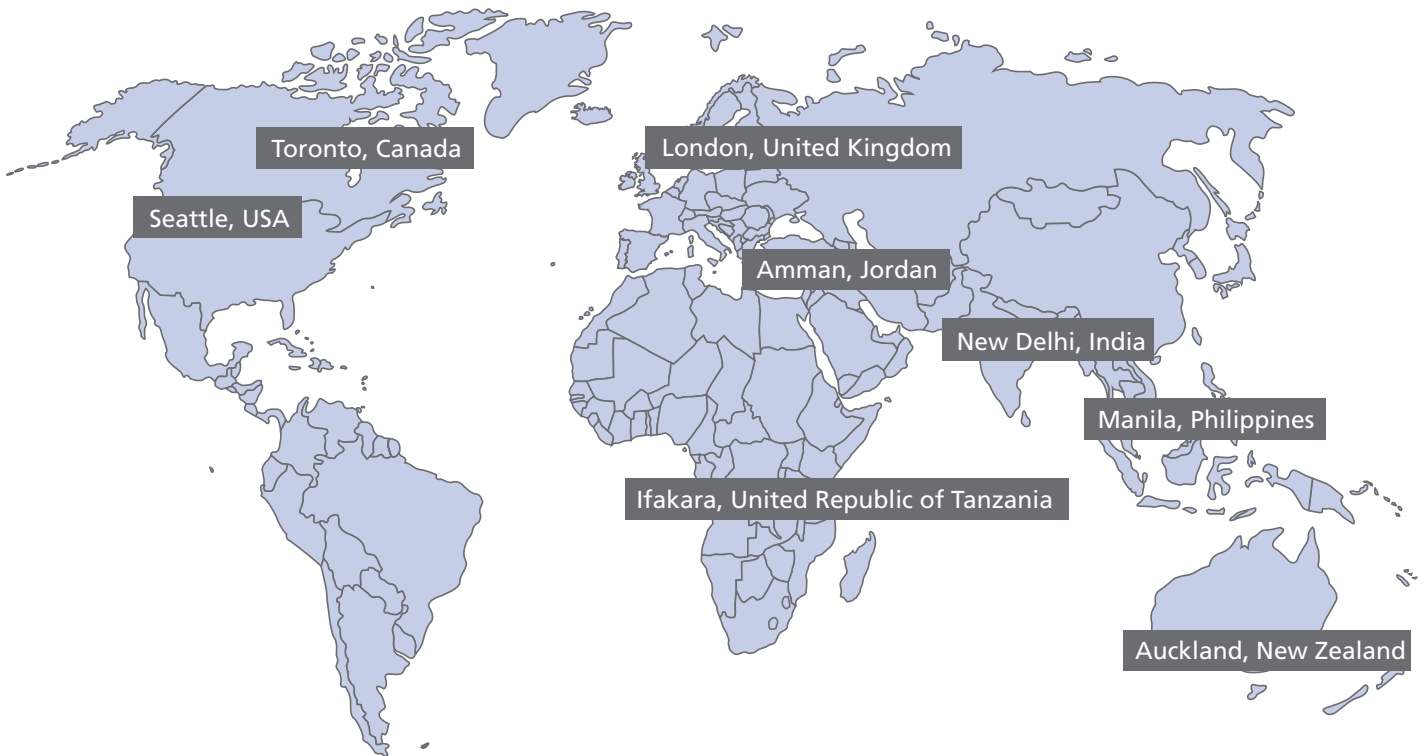
In addition to developing, promoting and disseminating the Checklist, the second Global Patient Safety Challenge will include a number of new projects. One will be to develop and promote low-cost pulse oximetry solutions in operating rooms worldwide. It also hopes to encourage use of performance assessment and quality improvement tools, such as a proposed Surgical Apgar Score, an easily computed outcome predictor based on intraoperative blood loss, heart rate and blood pressure.

Safe Surgery Saves Lives is a multifaceted, participatory initiative to reduce patient harm through safer surgical care. All Member States, every hospital or clinic in the world and each surgical team are invited to take up this challenge which includes:

- 10 essential objectives for safe surgery,
- 5 surgical 'vital statistics' to measure progress, and
- 1 Surgical Safety Checklist for each surgical procedure.

It is essential that safe practices be integrated into surgical care. Systems must support the goal of improving care in every resource setting.

Figure 2. Sites for testing the Surgical Safety Checklist





Box 7: Surgical vital statistics

To ensure basic surgical surveillance, WHO Member States should collect the following information:

- the number of operating rooms in each country;
- the number of operations performed in operating rooms in each country;
- the number of trained surgeons and the number of trained anaesthesia professionals in each country;
- the number of deaths on the day of surgery; and
- the number of in-hospital deaths following surgery.

These last two items will permit calculation of the mortality rates associated with surgical procedures:

$$\text{Day of surgery mortality rate} = \frac{\text{deaths on the day of surgery}}{\text{total surgical cases}}$$

$$\text{Post surgical in-hospital mortality rate} = \frac{\text{inpatient deaths following surgery}}{\text{total surgical cases}}$$

Further resources

For further information on the second Global Patient Safety Challenge, to download the WHO Surgical Safety Checklist and related materials or to participate in testing the feasibility of using the Checklist, please visit:

<http://www.who.int/patientsafety/challenge/safe.surgery/>.



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