The Second Global Patient Safety Challenge:

SAFE SURGERY SAVES LIVES

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BACKGROUND PAPER

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SAFE SURGERY SAVES LIVES

EXECUTIVE SUMMARY:

Safe Surgery Saves Lives is a project established by the World Health Organization and its World Alliance for Patient Safety to improve the safety of surgery across the globe. The Alliance has created a program called the Global Patient Safety Challenge which seeks to galvanize global commitment to specific patient safety issues that present a significant risk to patients in all member states.

The goal of the second Challenge, Safe Surgery Saves Lives, is to improve the safety of surgical care around the world. The strategy is to define a simple set of minimum standards for surgical care that are practical and can be universally applied across countries and settings. A measurement system will be created in parallel to monitor progress and improvement. The task over the next several months will be to carefully identify these standards, evaluate the evidence for their inclusion, estimate the impact they might have, and develop measurement tools to assess their effects on performance and safety.

These potential interventions can be categorized into four basic themes: **Clean Surgery** (through antisepsis and control of contamination at all levels of patient care), **Safe Anesthesia** (through patient monitoring as a means to identify potentially lethal anesthetic problems before they cause irreversible harm), **Safe Operators** (by ensuring a technically competent operation through minimum training and credentialing standards and an emphasis on teamwork), and **Quality Assurance** (using mechanisms for assessment, monitoring, and feedback). Most interventions fall into one of these four Surgical Safety Themes. This provides a convenient and logical approach for framing the issues of standards creation and implementation. In addition, the principles of **simplicity, wide applicability, and measurability** will instruct the decisions made during the challenge. The final set of core standards must meet these principles or the Challenge risks being unachievable.

The aspirations created by a "challenge" should lead to improvements in safety and quality in all environments, from the richest to the poorest. The Second Global Patient Safety Challenge is based on the recognition that every country can improve the safety of surgical care. Through the creation of a culture of safety, the World Alliance for Patient Safety and WHO can promote practice standards that reduce injuries and saves lives.

1. INTRODUCTION

Safe Surgery Saves Lives is a project established by the World Health Organization to improve the safety of surgery across the globe. In light of the mounting attention focused on medical errors, the WHO, through its World Alliance for Patient Safety, established a program for action that focuses on a number of patient safety concerns. The Global Patient Safety Challenge seeks to galvanize global commitment to specific patient safety issues that present a significant risk to patients across the member states. The first Challenge, called Clean Care is Safer Care, addressed hand washing as a means to prevent the spread of infection. In this second Challenge, Safe Surgery Saves Lives, the focus will be on improving the safety of surgical care in order to prevent errors, avoid injury, and save lives.

Medical errors are responsible for a large number of preventable injuries and deaths throughout the world. Adverse events have been estimated to range from 4 to 16% of all hospitalized patients.[1,2,3,4] More than half of these occur in surgical care and more than half are preventable. This is despite dramatic improvements in surgical safety, especially in the field of anesthesia. Anesthetic safety and monitoring standards instituted in developed countries have made significant inroads in preventing unnecessary death and disability. Three decades ago, a patient undergoing general anesthesia had an estimated 1 in 5000 chance of death from anesthesia. With the improvement of techniques and knowledge, and the introduction of monitoring and equipment standards, the risks have dropped to 1 in 200,000 in the industrialized world – a 40-fold improvement.[5] Similar claims cannot be made for surgery as a whole, however.

As outlined in the World Alliance for Patient Safety Forward Programme 2006-2007, an estimated sixty-three million people a year require surgical treatment for traumatic injuries, thirty-one million for malignancies, and ten million for obstetric complications.[6] Surgery is among the most complex and expensive service for health systems to deliver. Problems associated with surgical safety are well recognized in many developed countries. There are, however, few internationally agreed standards for the provision of these services. In the developing world, the poor state of infrastructure and equipment, unreliable supply and quality of medications, shortcomings in waste management and infection control, poor performance of personnel due to low motivation or insufficient technical skills, and severe under-financing of essential operating costs of health services make the probability of adverse events even higher.

1.1 Goal of the Challenge

The goal of the Safe Surgery Saves Lives challenge is to improve the safety of surgical care around the world. The strategy is to define a simple set of minimum standards for surgical care that are practical and can be universally applied across countries and settings. A measurement system will be created in parallel to monitor progress and improvement. The task over the next several months will be to carefully identify these standards, evaluate the evidence for their inclusion, estimate the impact they might have, and develop measurement tools to assess their effects on performance and safety. The means of implementation must also be considered. A mechanism must be created to facilitate incorporation of the standards into practice without undue burden on the system and the providers or resistance from implementing clinicians may undermine the effort.

The goal is not to set a low bar that all countries can easily achieve, but rather to provide standards and tools that represent a challenge for member states to improve surgical safety. The

aspirations created by a "challenge" should lead to improvements in quality in all environments, from the richest to the poorest. The Second Global Patient Safety Challenge is based on the recognition that every country can improve the safety of surgical care.

1.2 The Burden of Surgical Disease

The 2002 Global Burden of Disease Report suggests that much of the disability from disease in the world is due to conditions treatable by surgical intervention. A preliminary analysis of the data suggests that 228.2 million of the 1.5 billion Disability-Adjusted Life Years*, or 15% of all DALYs, are due to diseases potentially treated by surgery (Appendix 1).[7] Currently no good data exist to estimate the worldwide availability of surgery. Likewise, no good data exist to measure the quality or safety of surgery. The difficulty of this challenge will be to adequately balance the goals of improved safety with the reality of limitations that already restrict access and availability of surgical care in substantial portions of the world. In healthcare, where resources may be stretched and technical capacity can range from extensive to nonexistent, creating an equilibrium between efforts to improve safety and efforts to improve access is exceedingly difficult. Yet there is no denying that patients will suffer from unsafe surgical care.

A surgical condition has commonly been defined as "any condition that requires suture, incision, excision, manipulation, or other invasive procedure that usually, but not always, requires local, regional, or general anesthesia."[8] The authors proposing this definition defend it based on two observations: surgery does not have to be performed by surgeons, and the concept of surgery should include minor surgical procedures that nurses or general practitioners could perform. While the utility of such a definition is compelling, risk in surgery is closely related to the invasiveness of the procedure as reflected by the need for profound sedation or regional or general anesthesia. Therefore a more restrictive definition is needed here. With respect to the Safe Surgery Saves Lives Challenge, *surgery is any procedure involving the incision, excision, manipulation, or suturing of tissue that usually requires regional or general anesthesia, or profound sedation to control pain.*

1.3 Framing the Issue

During a surgical patient's hospital course, one can trace a routine sequence of events: preoperative evaluation, surgical intervention, and postoperative care. By examining each of these in turn, themes for systematic improvements emerge, each with specific areas amenable to standardization. In the preoperative phase provision of informed consent, availability of trained personnel, appropriate and judicious use of antibiotics, confirmation of the correct operative site and patient prior to incision, and standardized evidence-based antisepsis and cleansing procedures are all amenable to potential interventions. During the operative phase appropriate patient monitoring, competent anesthetic and surgical judgment, efficient teamwork, and meticulous surgical technique are all necessary to ensure good outcomes. Finally, in the postoperative phases, sound techniques of wound care based on evidence, a commitment to quality monitoring, and the submission of surgical complications to peer review may all improve the performance of

* The Disability-Adjusted Live 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. (Sources: 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.)

Surgical Resources and Environment		
Running water, Consistent light source, Consistent suction, Supplemental oxygen, Minimum equipment and instrument requirements		
Clean Surgery	**Safe Anesthesia**	**Safe Operators**
Handwashing Appropriate and judicious use of antibiotics Skin preparation Wound care Instrument decontamination	Presence of trained anesthetist Pulse oximetry Heart rate monitoring Blood pressure monitoring Temperature monitoring	Presence of trained operator Correct patient/correct site Provision of pain control Daily evaluation of patients Informed consent Availability
Quality Assurance and Monitoring Peer review Ongoing review of complications		

Table 1: The Nature of the Challenge – The processes of Clean Surgery, Safe Anesthesia, and Safe Operators are fundamental to improving the safety of surgery and saving lives. Overlying much of the discussion are basic but important infrastructure issues, and underlying all of it is the ability to monitor and evaluate any changes instituted as a result of this project.

the surgical system, thereby promoting patient safety and improving outcomes. The infrastructure and available physical resources are also important.[9]

Potential interventions can be categorized into four basic themes: **Clean Surgery** (through antisepsis and control of contamination), **Safe Anesthesia** (through patient monitoring), **Safe Operators** (by ensuring a technically competent operation), and **Quality Assurance** (using mechanisms for assessment, monitoring, and feedback), each placed within the contextual structure of the health system, or surgical environment. All of the above-mentioned components of safety fall into one of these four Surgical Safety Themes, providing a convenient and logical approach for framing the creation and implementation of standards for safe surgery (Table 1).

1.4 Guiding Principles

Three guiding principles are important in the development of the Safe Surgery Saves Lives Challenge. The first is simplicity. A host of standards and guidelines might create a package that would improve patient safety, but such comprehensiveness would be complicated to implement and difficult to market. 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 attention on a specific resource milieu might change the types of issues considered for discussion (e.g. addressing minimum equipment standards for resource poor settings). However the goal of the challenge is to target all environments and settings, from the resource rich to the resource poor. Every setting and provider environment can improve, from the poorest to the richest. Therefore, the standards must be widely applicable so all member states can rise to the Challenge.

The third is measurability. The ability to measure impact is a key component of the Challenge. Meaningful metrics must be identified, even if they only evaluate surrogate processes, and be reasonable and quantifiable by all practitioners in all contexts. If these three principles are

followed – **simplicity, wide applicability, and measurability** – then the goal of successful implementation can be both effective and feasible.

Box 1: How a Patient Sees It, How a Surgeon Sees It:

When evaluating standards for the improvement of safety in surgical care, two perspectives might be considered: the patient's and the surgeon's.

Patients expect high quality with respect to the care they receive. One purpose of the Challenge is to define what patients can reasonably anticipate from their surgical care. The Surgical Safety Themes of Clean Surgery, Safe Anesthesia, Safe Operators, and Quality Assurance might guide these expectations. Patients certainly ought to expect that the surgical provider caring for them is well trained and competent to perform the proposed operation, that they be treated with dignity, and that care will be provided without bias related to ethnicity, religion, gender, or age. They should expect to have their treatment explained to them and the risks and benefits discussed with them, be able to refuse treatment if they so desire, and have surgical pain adequately controlled. They should also expect providers to adhere to certain minimum standards of safe practice. The first three of these expectations address qualitative attributes that are highly subjective and exceedingly difficult to measure. The rest are quantifiable as process measures. Specifically, the issues of minimum standards of safe practice are what the Challenge might be able to provide.

An ideal result of the Challenge from a clinician's perspective would be to define what safety measures surgical teams should think about and concentrate on during every operation. In other words, what are simple but important issues that all surgical providers ought to think about as they prepare to care for their patients? These must be straightforward and appropriate, and most importantly they must save lives. Such standards could include ensuring: 1) that the surgery is clean and contamination is controlled through the appropriate use of antibiotics and skin cleansing techniques, 2) that the patient is appropriately monitored throughout the procedure and during postoperative recovery, 3) that the clinician is adequately prepared to perform the operation by reason of training and experience, 4) that all essential equipment is on hand and working appropriately, and 5) that there exists a commitment to professional improvement through continuing education and the processes of peer review and quality assurance.

The purpose of this background paper is to set the stage for exploring possible standards that will improve the safety of surgery. In the following sections each Surgical Safety Theme will be described in greater detail, the component parts of each will be delineated, the current evidence for each component will be briefly reviewed, and a series of questions and issues will be raised that should provide a basis for discussion at the first consultation meeting in January.

2. CLEAN SURGERY – Antisepsis and Control of Contamination

Although the worldwide incidence and cost of surgical site infections are unknown, surgical infections are likely to be a major cause of morbidity and mortality. Infection complicates approximately 2% of clean surgery and 10% of contaminated operations.[10] Recent studies in the international literature and comprehensive review articles suggest that the rate of clean case surgeries complicated by wound infections may even be as high as 10-15%, with significantly higher rates occurring in contaminated cases.[11,12,13] Despite the magnitude of surgical site infection, no clear consensus exists to define it. In fact, the Center for Disease Control and Prevention (CDC) definition, which is in wide use in the United States and the United Kingdom, has never been validated.[14] Even assuming an infection rate of 5% for all major surgical cases (a probable underestimate), significant improvements in patient outcome could be made by even minor interventions that address this problem.

Infections can occur from contamination during the procedure or during the wound healing process. The source of contamination can be the patient, any of the operating room personnel, or polluted surgical equipment and devices. Interventions that address both patient and provider as sources of contamination should improve care and prevent infection. Ensuring proper sterilization of reusable equipment is also important in preventing inadvertent contamination. HIV transmission has been well studied in injection safety, for example, but only limited work has been done on the risks of HIV infection from contaminated surgical equipment. Most of the reports are anecdotal, yet evidence points to a large potential transmission effect due to interactions with the health system.[15,16]

The first Global Patient Safety Challenge addressed the issue of hand washing as a means of transmitting infections to patients in the hospital setting.[17] The work from this challenge resulted in guidelines aimed at improving practices of hospital staff responsible for patient care. Their studies revealed the importance of improving practice in this arena.[18] Likewise, a number of well-performed studies have evaluated mechanisms to reduce the incidence of surgical site infections and control nosocomial infections. The CDC has published an extensive guideline for surgical practice. In it they reviewed numerous studies revolving around the issues of surgical infections.[19] They include issues of patient characteristics, preoperative issues, intraoperative issues, postoperative issues, and surveillance. This framework is a convenient means of compartmentalizing the systems of infection control. Antisepsis and contamination control must be instituted at all levels of patient care, and identifying specific areas for systematic change makes the problem manageable.

2.1 Use of Antibiotics Before, During, and After Surgery

Antibiotic prophylaxis has clearly been proven to prevent surgical site infections. The timing of antibiotic administration prior to skin incision has also been well-established by controlled clinical trials.[20] The results are unambiguous: prophylactic antibiotics should be given within two hours of skin incision to reduce the risk of wound infection. CDC guidelines recommend intravenous antibiotics be given "such that a bactericidal concentration of the drug is established in serum and tissues when the incision is made."[21] The National Surgical Infection Prevention Project has also issued recommendations for the United States that have been endorsed by several national surgical societies including the American College of Surgeons.[22] Despite clear evidence that the timing of prophylactic antibiotics is important, the strategy is unevenly applied in even the best of circumstances.[23] It is of clear utility in all types of surgery, including caesarean sections, one of the most common operations in the world.[24]

Given the range of organisms that could potentially contaminate the surgical field, a review of the types of antibiotics and their specific uses and timing is beyond the scope of this report. However, simple standards to inform decisions on antibiotic use for surgical infection prophylaxis are very important and may be worth undertaking. Antibiotics are frequently misused or used inappropriately. In resource poor settings, poor selection based on antimicrobial activity and frequent substitution of antibiotics during a single therapeutic course is a major problem. In developed areas, the selection, duration, and timing of dosages can be problematic. Stressing to surgical providers the importance of proper antibiotic selection and timing could have profound effects on the use and misuse of such therapies. Standards might help to direct resources in appropriate and cost-effective ways, prevent antimicrobial resistance, avoid infectious complications, and improve the overall safety of surgery using readily available resources in a targeted and efficient manner.

2.2 Hand Washing and the Surgical Scrub

Surgical hand cleansing techniques have been analyzed in a number of studies and are reviewed in the CDC guidelines paper.[25,26,27,28,29] Specific agents are the subject of a number of these reviews. WHO has conducted an extensive review of the evidence during its first Global Patient Safety Challenge and has issued recommendations for surgical hand washing based on the available data and the expertise of its working group members.[30] These guidelines recommend frequent hand washing, particularly the washing of hands by providers before and after any contact with patients. Their work incorporated recommendations for surgical hand preparation that including timing and technique, and advocated the use of an alcohol-based solution if water quality cannot be assured.

2.3 Skin Preparation

A variety of skin preparation solutions are available for use in the operating room. These include cleansing scrubs based predominantly on iodine, alcohol, chlorhexidine, or a combination of these decontaminants. All have been well studied. However, no one particular method of skin antisepsis has gained predominant use. Alcohol works by denaturing proteins, has an excellent activity profile on a host of different organisms, and is rapid in its effect. It is volatile, however, and has no residual effects once evaporated. Iodine kills organisms through oxidation/substitution reactions within the cell. It too has an excellent activity against a range of different organisms such as gram positive and gram negative bacteria, mycobacterium, fungi, and viruses. Its effect is not as rapid as alcohol, and it has minimal residual activity. Contact with blood probably renders it ineffective, meaning that once incision occurs, its activity as an antimicrobial decreases. Allergic reaction, absorption with possible toxicity, and skin irritation are potential issues when using this method of antisepsis. Chlorhexidine disrupts cell membranes and has a fairly good antimicrobial profile against most skin flora. It is only weakly effectual against mycobacterium, is intermediate in its speed of activity, but is one of the only widely used skin antimicrobials to have an excellent residual activity profile. This residual activity explains why it has been advocated for use in the process of central line placement based on research showing a significant decrease in central catheter infections using chlorhexidine as the skin preparation solution.[31,32] While no one solution is perfect, work by WHO suggests that an alcohol based surgical scrub may be best suited for adaptation into guidelines or standards due to its ease of use, availability, cost, and mechanism of action. Further discussions should revolve around whether this is an adequate standard or whether other solutions ought to be contemplated. Availability and cost will be important considerations when evaluating this issue.

2.4 Wound Care

The CDC has proposed guidelines for postoperative wound care based on evidence gathered in clinical trials.[33] Clean wounds that have been closed in the operating room should be protected with a sterile dressing placed in the operating room for 24-48 hours. Hands should be washed before and after any dressing changes or contact with the surgical site. Sterile technique should be used if the dressing needs to be changed prior to 24-48 hours due to drainage or the need to examine the wound. No specific recommendations have been made for treatment of wounds that are left open other than to adhere to sterile technique for the first 24-48 hours and use sterile bandages and dressings during this time period. Such guidelines may serve as a basis for potential standards for wound care in this Challenge.

2.5 Instrument Decontamination

Instrument decontamination is an important component of clean surgery. A number of technologies exist to address decontamination and sterilization of instruments. Heat has been the preferred method for sterilization, and steam sterilization is the most effective and inexpensive means of using heat.[34] Dry heat is also useful in sterilization procedures. Alternative techniques for sterilizing instruments and devices have been introduced in part to address the issue of heat-sensitive materials. Ethylene oxide gas sterilization is a more expensive and complex process and avoids damage to materials from excessive heat. Liquid chemical sterilization can also be used when steam, dry heat, or gas sterilization processed cannot be undertaken, but the indications for its use are much more variable. In practice, this usually entails soaking instruments in bleach or other disinfectants. Quality control mechanisms to ensure appropriate sterility and microbial testing are difficult when using this process. In addition, chemical disinfectants are often unstable and may break down, rendering them ineffective.

Currently, no standards or guidelines for decontamination exist in the international setting. Many requirements formulated by government agencies and hospitals address not only the process of sterilization but also the outcome. Careful quality control is essential. Meticulous attention to ensuring the sterility of instruments undergoing disinfection through frequent microbiologic testing is usually mandated in industrialized countries. Indicator mechanisms such as tapes that change color with heating or chemical sterilization processes are also important and can alert operating room staff of problems with the decontamination procedure. Since so many different methods exist to process equipment for their sterile use in surgery, outcome measures such as frequent confirmation of adequate disinfection may be the most useful direction for standards in this area.

3. SAFE ANESTHESIA – Patient Monitoring

No single improvement in the care of surgical patients has had as profound an impact as the advancement of safe practices in anesthesia. In practice anesthesia is dangerous to patients in a number of ways. Respiratory suppression from anesthetic medication leads to hypoxia, while maneuvers to control the airway can lead to injury. Aspiration is a significant risk in all patients undergoing sedation. Inadequate resuscitation, hypo- and hypertension, cardiac depression and elevation, and medication reactions and interactions are all potential life-threatening problems. In fact, anesthesia used to be quoted as more dangerous than surgery itself. Yet anesthesiology as a medical specialty has been held up as a model for the manner in which a system can be improved to take advantage of technology, skill, and redundancy for the benefit of patients. Much of the improvements in the delivery of anesthetic care came from examination of what are known as High Reliability Organizations (HROs). HROs such as the airline industry and nuclear power plants 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.[35] The field of anesthesia acknowledged human error as inevitable. By focusing efforts on standardizing instrumentation and building systems to alert operators in advance of impending problems, anesthesiologists have reduced the mortality rate due to anesthetic complications from one in five thousand patients to one in two hundred thousand patients.

In the United States, the American Society of Anesthesiologists (ASA) adopted standards for equipment arrays that included built-in safety and lockout devices to prevent accidental harm to patients. These simple interventions protected patients from a substantial portion of injury due to human error. In addition, the ASA codified a set of behavioral safety standards in 1986. The work supporting the creation and adaptation of standards was pioneered by the Department of Anesthesia at Harvard Medical School.[36] The investigators of this study published a set of standards that had to meet criteria including "…availability; cost; simplicity of use; intraoperative distracting influence; the relative sensitivity, specificity, and predictability (freedom from breakdown or aberrant output) of each monitoring modality; and … whether the standards represented 'reasonable care'…."[37] In addition, "the standards had to be realistic, technically achievable, and affordable in terms of both personnel and equipment utilization."[38] The standards can be summarized as follows:

- The presence of an anesthesiologist or nurse anesthetist in the operating room at all times;
- Measurement of blood pressure and heart rate at least every 5 minutes;
- Continuous display of patients' electrocardiogram;
- Continuous monitoring of ventilation and circulation by palpation, auscultation, and/or observation;
- Breathing system monitoring with audible alerting mechanism for disconnection;
- Continuous analysis of oxygenation in the breathing system;
- Ability to measure temperature.

The implementation of these standards was undertaken after an extensive review by a risk management committee organized by the Harvard hospitals' insurance carrier. The main goal was to identify practices that would reduce morbidity and death through the review of malpractice claims. In doing so, the committee set the standards for anesthesia safety that are in practice in the United States and throughout much of the developed world.

3.1 Presence of a Trained Anesthesiologist or Anesthetist

The first standard put forth by the Harvard group addressed a simple but fundamental behavioral issue of practice. Underlying the standard is an understanding that intermittent observation alone is insufficient to provide safe care to surgical patients. It recognizes that reaction to observations and monitoring feedback is essential for the safe delivery of anesthetics. Obviously the training that providers receive is important to the process. The separate issue of training the anesthetist is beyond the scope of this paper, but the importance that an experienced anesthetic provider contributes to the overall safety of an operation must be recognized.

3.2 Continuous Use of Monitoring Equipment

Additional standards address the issue of vital signs monitoring and the safe delivery of mechanical ventilatory support. The main components of vital sign monitoring are the measurements of heart rate, blood pressure, respiration/oxygenation, and temperature. Many of the measurement systems outlined in the standards appear redundant on first inspection, and in fact they may be. But due to their importance and ease of acquisition this redundancy is essential for safety and ensures accurate information from monitoring devices is transmitted to the provider.

There is no argument that ignorance of a patient's heart rate, blood pressure, or oxygenation can lead to disastrous consequences. Which of these, then, is most important? In creating worldwide standards to improve the safety of surgery, should one or two be measured as a minimum, or should all be measured together? There are no clear data that would suggest an answer. Since these standards were adopted as a bundle, the individual contributions of each are difficult to assess. Some work has been done to address the impact on care of one of the more recent monitoring devices: pulse oximetry. In a study of over 20,000 randomized patients, the use of pulse oximetry was found to improve the ability of the anesthesia provider to detect hypoxemia and decrease myocardial ischemic events, but was not associated with concurrent reduction of postoperative complications.[39,40] Yet the WHO, in their publication Surgical Care at the District Hospital, has advocated its wide use: "The pulse oxymeter should be the minimum standard of monitoring in every operating room where regular major surgery is carried out."[41] No one appears ready to argue on behalf of removing pulse oximetry as a standard monitoring tool either in the operating room or during recovery. As one of the authors of the above-mentioned study phrased it, "The question is not whether or not we can prove the benefits of monitoring, but how do we prove the benefits of monitoring."[42] Monitoring oxygen saturation makes sense intuitively, creates redundancies that ensure accurate interpretation of data, and fulfills some of the criteria for High Reliability Organizations - preoccupation with failure, sensitivity to operational issues, and commitment to resilience. Yet proving its value in a quantitative way has been frustratingly elusive. Complications from anesthesia have declined, so whatever improvements are being made seem to be having a beneficial effect on patient care.

Anesthesia monitoring has the added advantage in that it may also be useful as measurement tools for outcomes research. Work by surgeons at the Harvard School of Public Health has identified three intraoperative parameters that appear predictive of thirty day morbidity and mortality: mean arterial blood pressure, heart rate, and estimated blood loss.[43] The results are then converted into a ten point score that is predictive of thirty day mortality. These intraoperative parameters take advantage of physiologic variables of the patient as well as the complexity of the operation and extent of tissue trauma vis-à-vis estimated blood loss. Recording these parameters and validating such a score as a means of estimating likelihood of complications

in an international setting will go a long way towards improving our ability to evaluate the safety of surgical care. It is simple, easily obtainable, and inexpensive.

3.3 Pain Control

Surgery depends on reliable and safe pain control. Surgical pain is a cause of great anxiety among patients and a threat to safety and wellbeing. There is no agreed upon standard for controlling pain, and clinicians attempt to address it as effectively as possible without adversely affecting the patient through over-sedation. An appropriately anesthetized patient is essential in producing a safe environment for surgical intervention. It produces a state of relaxation, limits the physiologic response of the patient to the tissue trauma inflicted on the body by surgical intervention, and allows manipulation of tissues under controlled circumstances. It also permits patients to ambulate postoperatively and provides pain relief for patients to tolerate deep respirations, activities associated with prevention of the postoperative complications of deep venous thrombosis for the former and pneumonia for the latter. With the introduction of anesthetics, control of pain was substantially improved, and advances in surgical technique and therapy were made possible with the introduction of medications that rendered patients anesthetized. Specific criteria for controlling pain will be difficult to determine, but pain control is certainly a qualitative measure of the effectiveness of the surgical provider in relieving suffering and successfully managing a surgical patient.

4. SAFE OPERATORS – Technically Competent Surgical Providers

Ensuring technical competence is fraught with difficulty. There are no scientific studies that describe the best way to train surgical providers, how much training they need, and how to keep them technically proficient. Training programs utilize a Halstead model[†] of gradually increasing responsibility in a regimented training curriculum. Surgical trainees learn from senior members with more practical experience and expertise, and as they rise through the years responsibilities and expectations of accomplished performance rise. Once surgeons complete their training, no single method of ensuring their continued competence has been definitively established to correct errors in technique or management, ensure up-to-date knowledge of the practice, and address issues of continuing medical education. Professional societies recognize the value of retraining and maintaining a current knowledge base. Through meetings and publications they attempt to address deficiencies of their constituents and disseminate advances in diagnosis, treatment, and management of surgical patients.

In considering recommendations for training and credentialing, there is a tension between high standards and broad access. Establishing minimum training and credentialing standards may raise the bar with respect to skill and experience levels, but will undoubtedly inversely affect access by the poorest patients. Worldwide, health workforce and human resource issues are still in the beginning stages of evaluation. The World Health Report 2006 devoted its energy to exploring the relationship between population health and health workforce density.[44] There is little information on the qualification of physician providers. In particular, specialty breakdowns are not described and the extent of the surgical workforce is unknown. An accurate assessment of the amount of surgery that is performed in the world is not available. Can recommendations be made in that absence of such basic information?

4.1 Surgical Training and Continuing Medical Education

Little is known about the relationship of length and type of surgical training to the safety and quality of surgery. The definitive study detailing the amount of training necessary to produce a safe and competent surgeon has never been performed. Relationships between the volume of procedures performed and outcome of those procedures have been investigated in the general, vascular, orthopedic, and urologic surgery literature.[45,46,47,48,49,50] The simplistic answer is that higher volume is associated with improved outcomes. When reviewing the literature, however, there are notable limitations of both the studies and statistical techniques that call into question the validity of purely associating procedure volume with outcome. Provider volume works well in the aggregate, but on an individual level the prediction begins to unravel.[51] The role of provider volume is only one of any number of factors that contribute to outcome. High volume centers also have lower-than average mortality rates, and the system and training characteristics of such centers may in part substitute for individual provider volume.[52] In addition, outcomes are based almost exclusively on mortality, and mortality may not be the gold standard of quality.[53] While the traditional focus of performance improvement has been on individuals, recent work is focusing on the system of health delivery as a means of obtaining improved results.[54,55] No one would deny that experience leads to improved technique and efficiency, but the questions remain: How much experience is enough to attain satisfactory outcomes? What outcome level is satisfactory? And what is the relationship between outcome and quality?

[†] William Stewart Halstead established the surgical training program at the Johns Hopkins University in Baltimore, USA, and was the founder of the American residency training system of progressive responsibility. He based his program on the formal training of surgeons that he observed in Germany in the 1870's.

Recent studies have also focused on assessing surgical ability and technique as a method of measuring proficiency.[56] Technical skill has always been recognized as vital to the result of the procedure, yet only lately have acceptable strategies been developed that quantitatively evaluate technical performance. Incorporating such validated skills-based exams will likely be important in future certification of surgical trainees. To date, such evaluations are still in the investigative phase. The implications are broad, however. In one study, increasing levels of surgical skill predicted an improved ability to recognize errors in surgical technique in standardized simulations.[57] In another, bench-top simulations accurately correlated with seniority and experience amongst cardiothoracic surgical trainees and consultants.[58] What still remains to be determined is the level at which acceptable skills have been attained to allow advancement and clinical practice without oversight. How such work might be reflected in the standards created during the Challenge will be difficult to determine, but given that this is a likely direction for the future of credentialing, such a discussion is warranted.

There are two primary ways to approach the issue of training and competence. The first is to address proficiency and technical mastery at the outset by setting credentialing standards for certifying the competence of trainees prior to granting them permission to practice. The second is to ensure that credentialed providers maintain their skills through continuing medical education and training programs, peer review assessments, and intermittent recertification schemes. Most countries seem to have a process in place to credential and license surgical providers according to some type of consensus set by the government or specialty organizations. Maintaining proficiency is a much more difficult task, particularly in resource limited settings. This is often accomplished through interactions with senior or more experienced colleagues of similar professional background, a task exceedingly difficult to undertake in areas where the health workforce is already of a low density. It often requires travel to professional conferences where such specialists can interact. This may necessitate abandoning the remote regions of a country where surgical support may be lacking. At the poorest levels, even in upper income countries, forsaking ongoing training due to restrictions in timing, finances, and support may be the only option.

Several studies support the concepts of continuing medical education as a useful adjunct in modifying performance. While almost all types of interventions had some impact on provider practice, and the value of any intervention aimed at improving performance appeared to be worthwhile, the type of educational intervention affected the degree of change.[59] Certain interventions, particularly interactive ones that included provider participation, seemed to have the most benefit.[60] Strictly didactic sessions did not appear to quantitatively improve performance or behavior. These findings were supported in several Cochrane Database reviews: interactive workshops were effective in modifying performance to a much greater degree than didactic sessions alone,[61] and educational outreach programs seemed to offer promise of similar behavior modification by practitioners in the primary care/prevention/prescribing arena.[62] Finally, audit and feedback were determined to be effective in improving performance of participating physicians.[63] As feedback is one of the most widely used mechanisms for improving performance, studies that validate it as a strategy make important contributions to legitimating the practice.

4.2 Other Measures of Provider Quality

Appraising quality by evaluating specific process measures as surrogate variables for conscientiousness may be attempted. Conscientiousness is itself a surrogate indicator of quality. Processes such as the availability of a surgical provider for 24-hour patient coverage, adequate pain control for surgical patients, the provision of informed consent, or documentation of daily

evaluations of surgical inpatients are all potential candidates. Other specific outcomes such as morbidity and mortality from surgical procedures might also be measured, but these are notoriously difficult to assess since patient characteristics, poor follow up, and underlying systematic issues concerning the health system complicate any conclusions one might draw. In such a case, the surgical score described in Section 3.2 may be a perfect candidate for evaluation, as it provides immediate information that can predict the likelihood of complications.

4.3 Wrong Site Surgery and the Surgical Pause

Wrong patient/wrong site errors have received intense attention in the United States and the United Kingdom. In the United States, institutions have adopted a surgical "time out" prior to incision to confirm among all operating room personnel the identity of the patient, site of the surgery, and surgical procedure to be performed. This initiative was inspired in part by the "Sign Your Site" campaign instituted by the American Academy of Orthopedic Surgery (AAOS) during their 1998 Annual Meeting.[64] Wrong site surgery is an infrequent but unacceptable complication. A momentary pause prior to incision is now routine. There is little evidence that this has resulted in any substantial reduction in such complications, as the incidence of such errors is quite small.[65] The pause, however, may be useful in other ways. It can familiarize the personnel with the case, the equipment, and each other. It may be a way to codify into the surgical process a moment of reflection that can be used to anticipate problems before they occur, double check essential equipment, and confirm specific processes such as the administration of antibiotics and the appropriate placement of monitors. It may also improve surgical teamwork.[66]

Teambuilding and teamwork are important components of effective interaction in the operating room. An extended pause has been studied as an adjunct to the "time out" procedure in the United States.[67] This extended pause makes use of a tool called "OR Briefing" that aims to confirm critical information and promote and support open communication during an operation. The concept of teamwork has been studied in other HROs, particularly aviation, and found to be essential to the safety of these environments.[68] The lessons are being applied to surgical teams where effective communication can make a substantial difference in the care a surgical patient receives.[69] Other areas of medicine with high risks and high rates of potential error, such as critically ill patients in the ICU, are being studied concurrently. Effective teamwork and communication has been noted as a critical factor in reducing the likelihood of injury to patients.[70] Methods for improving communication and teamwork are currently under investigation. If such instruments as the "OR Briefing" are found to be useful in improving communication and teamwork, interventions incorporating them into practice might reduce the likelihood of errors in patient care and improve the quality and safety of surgery.

5. QUALITY ASSESSMENT – Mechanisms for Assessment, Monitoring, and Feedback

Assessment and evaluation of surgeons is an integral part in both the training of providers and the maintenance of skills and abilities. The approaches are numerous and include reviews of deaths and complications, data collection and reporting, and legal tactics. The field of Obstetrics was pioneering in its style of evaluation. The Apgar score, for instance, was an essential tool developed for the express purpose of improving clinical outcomes by providing direct feedback to physicians, nurses, and birth attendants, allowing them to measure not only their patients' progress but their own reaction and abilities in dealing with critical situations. In addition, tracking maternal and neonatal mortality rates provided robust data on population health indicators. A system of evaluation and feedback was established, and data gathering mechanisms were incorporated into projects for health improvements and resource targeting. This appears to have been done particularly well in the public health setting. Surgical services can learn much from the instructive lessons of obstetrics.

5.1 Peer Review

In the European Union, Canada, and the United States, all hospitals must perform some type of peer review assessment to fulfill requirements for accreditation. In the United Kingdom, for instance, a postoperative mortality inquiry is initiated after every surgical death.[71,72] In the United States, surgeons participate in a Morbidity and Mortality Conference, its purpose being to identify areas of poor performance, evaluate areas for improvement, share knowledge and experience, and learn from the mistakes of others so they are not repeated by multiple providers. The conference, however, has focused on individual failing and blame.[5] This is in direct opposition to the evidence from HROs that suggest system approaches to problem solving. In the complex world of patient care, where multiple caregivers range from physicians, nurses, and assistants, to educators and family members, it is not always individuals who commit identifiable mistakes leading to injury. Oftentimes systematic problems such as miscommunication lead to errors. If feedback mechanisms only attempt to identify individuals and specific faults, a broad range of structural problems can be missed, leading to repetitive errors in patient care. The commitment to performance review is admirable and justifiable, but such attempts need to recognize the limitations in addressing problems and work towards more inclusive mechanisms to identify system issues. As attempts to identify methods of performance feedback are made, it is important to remember the beneficial qualities of commitment to personal improvement and recognize the weaknesses of any feedback system. Incorporating techniques for evaluating the health delivery system as a whole, moving from individual blame to acknowledgement of the complexities of health delivery and care, will improve the process of error identification and performance improvement.[73]

A literature review on peer assessment found that there is a low degree of physician agreement regarding quality of the peer evaluation process.[74] The author of the review argued for modifying the process in several significant ways: encouraging use of multiple reviewers to evaluate cases, particularly in cases where continued disagreement exists regarding the handling of the case; using more objective assessment procedures; creating higher standards for peer reviewers; eliminating systematic review bias by adjusting for the tendency of reviewers to judge leniently or harshly; using outcome assessments by evaluating how care affected outcome; and using practice standards to direct decisions about the appropriateness of care. This final recommendation is one of the most important. It provides guidance to reviewers as they evaluate the performance of their peers. Standards established during this Challenge can aid in the process

of performance feedback and contribute meaningfully to improved patient outcomes. They can serve as an aid for reviewers as they evaluate the quality of care their patients receive.

6. THE ENVIRONMENT OF SURGERY

Underlying assumptions and concerns regarding resources must also be addressed. Tremendous disparities exist in the resources available for healthcare. The United States leads the list in per capita health expenditure, devoting enormous resources to its healthcare system. In 2003 it spent $5,711 per capita on healthcare. In contrast, 52 countries spent less than $100 per capita on healthcare, and well over half the world's countries spent under $400.[75] Previous WHO work has focused on resources with respect to emergency surgical care. The Global Initiative for Emergency and Essential Surgical Care identified strategies for strengthening training and infrastructure of resource poor countries in the area of emergency services. The Clinical Procedures Unit in the Department of Essential Health Technologies at WHO has compiled lists of essential emergency equipment to be used by hospitals, clinics, and providers as a checklist to guide purchasing and stock requirements.[76] This work was done using a consensus process since quantitative data do not exist to determine minimum resource requirements. Essential emergency equipment and medications are also enumerated in the Surgical Care at the District Hospital manual, where different requirements for different hospital settings are listed.[77] The barriers to implementation, however, remain unchanged. In many settings where resources are lacking, absence of political will, diversion of assets, or lack of human security or political stability limit the ability of the health sector to ensure requisite infrastructure for the delivery of services.

Despite the severe limitations, it is clear that even in resource limited settings, quality surgical care is achievable with appropriate standards, tools, and planning in a manner consistent with best practice evidence. For example, antibiotics are available in most settings where major surgery takes place. Yet the choice of antibiotics and timing of administration are often variable. Well designed studies have clearly shown that administering antibiotics approximately half an hour prior to skin incision has an important effect in preventing surgical site infections.[78] Yet even in the best of circumstances, this is often not done. Significant improvements in care can be accomplished if patients received their antibiotics on time. The effect may be even more pronounced in resource poor settings where diagnostic and therapeutic services are scarce, making such interventions all the more important.

A significant issue in establishing minimum equipment and resource standards is the potential for blocking access to care. Does the fact that a hospital or clinic lacks such minimum resources as running water, a consistent light source, suction, or supplemental oxygen necessarily mean it should not provide surgical services? There are no data to determine at what point undertaking an operation is worse than doing nothing at all. For example, under which circumstances is it more harmful to operate on a woman in obstructed labor than to not offer any operation at all? The answer to this question is unknown, and may never be determined.

Given the lack of quantitative data on the subject, there are two choices: an attempt can be made to create a set of minimum equipment standards by consensus agreement, replicating the work of the Clinical Procedures Unit, or it can be concluded that this is an issue in need of further study and move on without fully exploring such minimum requirements. The risks of attempting to create a consensus are twofold. First, addressing such standards focuses on the poorest countries and regions of the world, in contrast to our desire of creating standards that are broadly applicable to all regions and settings. It will also be done with the knowledge that in these settings such standards will be difficult, if not impossible, to attain. Countries and regions that struggle with infrastructure resources such as water, power, and supply delivery issues will be no closer to attaining minimum standards by the very nature of their environment. Second, it may create such a burden on centers unable to guarantee compliance with minimum infrastructure and equipment standards that pressure will be applied to either achieve them or revoke services. Since it is unclear when it is better to provide services – even minimum lifesaving ones – than

providing nothing at all, this difference may ultimately restrict access to care in the very areas where such services may make a dramatic difference. On the other hand, if the issue is not addressed, the interest of poorer countries may be lost and the most vulnerable populations may never be positively affected by minimum safety standards that could improve their surgical care in important ways. The issue will be worth discussing.

7. MEASUREMENT

One of the three guiding principles of the Challenge is measurability. A commitment to evaluate the effects any changes or implementations have on the safety of surgery is a fundamental part of the Challenge. Whatever the final safety standards for surgery look like, they must be measurable. Direct outcomes are difficult to evaluate since they require standardized definitions, long term follow-up, and appraisal of other health system variables and characteristics that complicate the data. For this reason, process measures appear to be likely candidates for assessing performance and monitoring improvement during the Challenge.

Whatever the likely measures might be, pilot testing of both the standards and the tools for implementation and measurement will probably be necessary. The standards, attained through consensus and guided by evidence, must have substantial effects if they are to save lives. Their implementation will take time and devotion, and the mechanisms to facilitate their integration into the surgical care system must be demonstrably effective. In addition, their successful implementation must result in improvements in patient care that are straightforward to evaluate. This will take time and dedication, and necessitate identifying appropriate facilities for test projects. It offers a unique and powerful opportunity to test standards as they are being applied. Proving effectiveness in this way will offer robust evidence that such interventions save lives.

Structure, process, and outcome measures have been well established as a guiding framework for examining medical care since the original publication of this methodology.[9] While the goal of this Challenge is to improve the safety of surgery, direct measurement of surgical outcomes is fraught with difficulty. So many confounding factors contribute to the outcome that a measure of postoperative mortality is too simplistic and ignores the realities of the system. More likely, evaluation of process measures will be the most feasible alternative. Such measures do not directly measure effect. But if standards use data-driven, evidenced-based research to support implementation, the processes should have direct effects on outcome and surgical safety will improve. Much of the final tools for measurement will depend on the types of standards advanced by the Challenge. Strategic thinking in advance will allow these tools to be created in parallel, obviating the need for revision and application of metrics in a retrospective fashion.

8. CONCLUSION

This paper outlines some of the major areas where establishing standards might lead to significant improvements in the safety of surgical care. The four Surgical Safety Themes of Clean Surgery, Safe Anesthesia, Safe Operators, and Quality Assurance provide a framework for evaluating interventions that have the most effect on saving lives. Directions for intervention may become more apparent as understanding of the causes of death and disability in surgical patients is enhanced. Infection after surgery is an enormous problem and might be addressed with conceptually simple interventions such as standard antibiotic protocols. Anesthesia safety has had profound effects in the developed world, and commitments to anesthesia safety may make a valuable impact in terms of lives saved. Assuring the technical competence of surgical providers would be a true victory for this Challenge, but may be so difficult to assess as to become an improbable area for establishing standards. Ensuring evaluation and feedback to all clinicians involved in surgical care would be a profound success as well, and its enduring effect could potentially change the safety of surgery worldwide.

It is impossible to affect all aspects of patient care, but simple interventions are possible. Standards act as a guide for busy practitioners and equip surgical providers with qualitative tools that have far-reaching effects. Each standard that is developed must have a significant impact on safety, must be simple enough to promote in all settings, and must have measurable effects that can be monitored and recorded in a meaningful way. From initial evaluation prior to surgery, to surgical care and postoperative recovery, many things can go wrong for a patient. If a systematic framework for how things ought to go right is established, meaningful improvements can be made to the art and science of surgical care.

APPENDIX I: Disability-Adjusted Life Years due to conditions primarily amenable to surgical treatment

This chart lists the total Global Burden of Disease in Disability-Adjusted Life Years (DALYs). The authors preparing this background paper have estimated DALYs due to surgical conditions by summing all DALYs due to conditions usually requiring surgical treatment (highlighted in green). This is not meant to suggest that surgical therapy would reduce the amount of DALYs to zero. The list is not exhaustive, and many conditions that might require surgical intervention are excluded, including heart disease, birth trauma, and nonspecific categories such as "Other genitourinary system diseases". It may be useful, however, for estimating the amount of surgical services that might be anticipated for the global population.

GBD: Worldwide DALYs by age, sex and cause for the year 2002

Total Population			***6,224,984,806***
Cause			***Total***
All Causes			**1,490,125,643**
Communicable, maternal, perinatal and nutritional conditions			***610,319,230***
A.	**Infectious and parasitic diseases**		**350,332,571**
	1.	**Tuberculosis**	**34,735,908**
	2.	**STDs excluding HIV**	**11,347,067**
		a. Syphilis	4,200,039
		b. Chlamydia	3,571,404
		c. Gonorrhoea	3,365,159
		d. Other STDs	210,465
	3.	**HIV/AIDS**	**84,457,784**
	4.	**Diarrhoeal diseases**	**61,966,183**
	5.	**Childhood-cluster diseases**	**41,479,543**
		a. Pertussis	12,594,810
		b. Poliomyelitis	150,660
		c. Diphtheria	184,710
		d. Measles	21,475,463
		e. Tetanus	7,073,899
	6.	**Meningitis***	**6,191,790**
	7.	**Hepatitis B**	**2,170,326**
		Hepatitis C	**1,003,682**
	8.	**Malaria**	**46,485,868**
	9.	**Tropical-cluster diseases**	**12,245,452**
		a. Trypanosomiasis	1,525,287
		b. Chagas disease	666,764
		c. Schistosomiasis	1,701,795
		d. Leishmaniasis	2,089,888
		e. lymphatic filariasis	5,777,436
		f. Onchocerciasis	484,282
	10.	**Leprosy**	**198,778**
	11.	**Dengue**	**615,529**
	12.	**Japanese encephalitis**	**709,219**
	13.	**Trachoma**	**2,328,780**
	14.	**Intestinal nematode infections**	**2,951,341**
		a. Ascariasis	1,816,942

		b. Trichuriasis	1,006,248
		c. Hookworm disease	58,617
		Other intestinal infections	69,534
		Other infectious diseases	41,445,320
B.	**Respiratory infections**		**94,603,349**
	1.	Lower respiratory infections	91,373,521
	2.	Upper respiratory infections	1,795,292
	3.	Otitis media	1,434,536
C.	**Maternal conditions**		**33,631,593**
	1.	Maternal haemorrhage	4,437,585
	2.	Maternal sepsis	6,903,085
	3.	Hypertensive disorders*	2,162,701
	4.	Obstructed labour	3,048,291
	5.	Abortion	4,652,171
		Other maternal conditions	12,427,759
D.	**Perinatal conditions***		**97,335,086**
	1.	Low birth weight	46,334,234
	2.	Birth asphyxia and birth trauma	34,445,758
		Other perinatal conditions	16,555,094
E.	**Nutritional deficiencies**		**34,416,632**
	1.	Protein-energy malnutrition	16,910,328
	2.	Iodine deficiency	3,519,322
	3.	Vitamin A deficiency	792,562
	4.	Iron-deficiency anaemia	12,224,287
		Other nutritional disorders	970,133
Noncommunicable diseases			***697,815,295***
A.	**Malignant neoplasms**		**75,544,632**
	1.	Mouth and oropharynx cancers	3,565,506
	2.	Oesophagus cancer	4,249,995
	3.	Stomach cancer	8,094,635
	4.	Colon and rectum cancers	5,818,467
	5.	Liver cancer	7,135,241
	6.	Pancreas cancer	1,975,135
	7.	Trachea, bronchus, lung cancers	11,228,273
	8.	Melanoma and other skin cancers	690,529
	9.	Breast cancer	6,171,432
	10.	Cervix uteri cancer	3,286,608
	11.	Corpus uteri cancer	1,121,237
	12.	Ovary cancer	1,646,575
	13.	Prostate cancer	1,628,948
	14.	Bladder cancer	1,477,888
	15.	Lymphomas, multiple myeloma	4,307,519
	16.	Leukaemia	4,685,999
		Other malignant neoplasms	8,460,646
B.	**Other neoplasms**		**1,749,031**
C.	**Diabetes mellitus**		**16,194,381**
D.	**Endocrine disorders**		**7,961,019**
E.	**Neuropsychiatric conditions**		**193,278,495**
	1.	Unipolar depressive disorders	67,294,858
	2.	Bipolar disorder	13,952,006

	3.	Schizophrenia	16,149,010
	4.	Epilepsy	7,327,500
	5.	Alcohol use disorders	20,330,909
	6.	Alzheimer and other dementias*	10,396,902
	7.	Parkinson disease	1,570,259
	8.	Multiple sclerosis	1,476,740
	9.	Drug use disorders	7,387,679
	10.	Post-traumatic stress disorder	3,335,194
	11.	Obsessive-compulsive disorder	4,923,365
	12.	Panic disorder	6,757,894
	13.	Insomnia (primary)	3,476,500
	14.	Migraine	7,666,232
	15.	Mental retardation, lead-caused	9,956,313
		Other neuropsychiatric disorders	11,277,133
F.	**Sense organ diseases**		**69,380,870**
	1.	Glaucoma	3,866,098
	2.	Cataracts	25,250,631
	3.	Vision disorders, age-related	14,191,209
	4.	Hearing loss, adult onset	26,033,550
		Other sense organ disorders	39,381
G.	**Cardiovascular diseases**		**148,190,083**
	1.	Rheumatic heart disease	5,862,208
	2.	Hypertensive heart disease	7,646,994
	3.	Ischaemic heart disease	58,644,936
	4.	Cerebrovascular disease	49,200,096
	5.	Inflammatory heart diseases	5,854,370
		Other cardiovascular diseases	20,981,480
H.	**Respiratory diseases**		**55,153,199**
	1.	Chronic obstructive pulmonary disease	27,756,187
	2.	Asthma	15,334,025
		Other respiratory diseases	12,062,987
I.	**Digestive diseases**		**46,475,768**
	1.	Peptic ulcer disease	4,630,282
	2.	Cirrhosis of the liver	13,977,190
	3.	Appendicitis	394,825
		Other digestive diseases	27,473,471
J.	**Genitourinary diseases**		**15,217,418**
	1.	Nephritis and nephrosis	8,393,626
	2.	Benign prostatic hypertrophy	2,466,301
		Other genitourinary system diseases	4,357,490
K.	**Skin diseases**		**3,748,381**
L.	**Musculoskeletal diseases**		**30,169,104**
	1.	Rheumatoid arthritis	4,866,446
	2.	Osteoarthritis	14,861,311
	3.	Gout	3,293,423
	4.	Low back pain*	2,320,149
		Other musculoskeletal disorders	4,827,774
M.	**Congenital anomalies**		**27,381,058**
	1.	Abdominal wall defect	124,357
	2.	Anencephaly	598,592

	3.	Anorectal atresia	28,878
	4.	Cleft lip	138,751
	5.	Cleft palate	154,173
	6.	Oesophageal atresia	36,833
	7.	Renal agenesis	71,171
	8.	Down syndrome	4,102,094
	9.	Congenital heart anomalies	15,321,964
	10.	Spina bifida	1,695,847
		Other Congenital anomalies	5,108,398
N.	**Oral conditions**		**7,371,856**
	1.	Dental caries	4,769,367
	2.	Periodontal disease	302,093
	3.	Edentulism	2,185,312
		Other oral diseases	115,084
Injuries			**181,991,119**
A.	**Unintentional injuries**		**133,111,628**
	1.	Road traffic accidents	38,675,847
	2.	Poisonings	7,401,134
	3.	Falls	16,200,516
	4.	Fires	11,470,813
	5.	Drownings	10,840,263
	6.	Other unintentional injuries	48,523,056
B.	**Intentional injuries**		**48,879,491**
	1.	Self-inflicted injuries	20,766,781
	2.	Violence	21,429,346
	3.	War	6,328,217
		Other intentional injuries	355,146

Total DALYs due to surgical conditions	**228,246,296**
% of total DALYs due to surgical conditions	**15.32%**

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