



Meeting Summary

First Consultation *Safe Surgery Saves Lives*

WHO Headquarters, Geneva,
11th-12th January, 2007

The purpose of this first consultation was fourfold:

- 1 - To present and discuss the current evidence of a set of proposed interventions to improve the safety of surgery worldwide;
- 2 – To deepen understanding of the nature and profile of surgical services across a range of countries and health systems;
- 3 – To determine how specific interventions might be implemented and standardized based on their current implementation worldwide, and the barriers and opportunities to improve safety; and
- 4 – To discuss priorities for determining which standards will be used based on their potential impact, their feasibility, and their acceptability.

11 January, 2007

Welcome Remarks – Pauline Philip

The World Alliance for Patient Safety was created after the 2002 World Health Assembly passed a resolution urging member states to pay the closest possible attention to the problem of patient safety, and to establish and strengthen science-based systems necessary for improving patient safety and the quality of healthcare. It was a broad resolution to address patient safety in a variety of care settings. The World Alliance for Patient Safety has partnered with several organizations and leading experts since its inauguration in 2004. As part of this initiative, the Global Patient Safety Challenge was created. The first challenge was Clean Care is Safer Care which focused on hand hygiene to prevent hospital-acquired infections. Lessons learned from the first challenge can be applied to this second challenge, Safe Surgery Saves Lives.

The Second Challenge – Atul Gawande

The goal of the second challenge is to improve the safety of surgery around the world. It is the first marriage of surgery and public health in such a wide and encompassing setting. It will bring together the diverse range of expertise in economics, measurement, surgery, and public health. Circumcision is an example of the way in which surgery and public health can intersect. With the recent studies demonstrating the protective benefits of circumcision with respect to HIV acquisition and transmission,

science has shown that if we want to save lives, we must think about surgical care in a public health context.

The purposes of this meeting are to ascertain baseline data with respect to surgery worldwide and determine what the goals are, what approaches are appropriate, and if the goals we have identified are the right ones. We hope to see what areas are possible to create standards in.

Infections have been the major cause of death in the past. But with the changes in health, sanitation, and antibiotics this has diminished as a proportion of the burden of disease. Surgical issues now are a major source of disease burden. Complications from surgery are a common issue and represent a gap between what we aim to do and what we actually do.

How often do things go wrong? In our Utah/Colorado study, we found a 3% complication rate for all hospital admissions, half of which were preventable. Two thirds of all major injuries were a result of surgical intervention or treatment. This creates a substantial disease burden through our actions in surgery. In evaluating risk factors for injury, the most common problem identified was lack of competence on the part of the surgical provider, followed by communications failures.

Another factor we will have to consider is provider volume and density. In many areas, surgical providers are faced with a huge patient need and demand. How do surgeons survive in areas with low physician density? They do this through a combination of triage and the weighing of risks and benefits of treatment for each patient. I will give an example from India, where I recently spent some time working. The surgeons at the hospital I visited saw some 200 patients a day. Once, a woman arrived with an advanced cancer of her breast eroding through the skin. I would have thought that they would not have the resources to treat her and would have dismissed her as a hopeless case. Instead she was admitted and chemotherapy was begun the very same day. They treated her to the best of their ability, but there were some things they did not do – they did not administer her medications through a central line but through a peripheral IV, and they did not confirm the diagnosis with a biopsy. They weighed the risks and benefits, as well as the cost and resources, and provided care knowing that there were some elements of care that were less than ideal, but that they could still provide reasonable care without them. Resources, rational organization, and guidance will be essential to consider as we evaluate the changing demographics and longevity of the world population.

I envision four goals of this challenge:

- 1 – To raise awareness and the priority of safety in surgery among professionals;**
- 2 – To articulate specific minimum standards for safe surgical practice, and achieve them;**
- 3 – To develop consensus WHO guidelines for safe surgery and disseminate best practices;**
- 4 – To define and implement ways to measure the safety of surgical practice.**

In order to accomplish this, several principles must be considered: simplicity, wide applicability, a raising of quality (i.e. a genuine prospect of saving lives), and measurability.

We have defined three thematic areas for work: clean surgery, safe anesthesia, and safe surgeons. These we will address as we move through the next two days. Finally, we must keep the perspective of both patients and clinicians – for patients, what should perspective patients be able to expect; for clinicians, what safety measure should be on their minds as they care for people?

Our challenge will be to ensure that whatever we do will have an impact.

Lessons from the First Challenge – Didier Pittet

There are an estimated 1.4 million hospital acquired infections (HAI) per day. This represents a huge patient safety gap, and while some institutions have the resources to control risk, the gaps in safety are important to recognize. They exist within countries and between countries. The First Global Patient Safety Challenge (GPSC) is currently underway, and offers countries the opportunity to commit to improve patient safety through the prevention of HAI.

The objectives of the first challenge were threefold: Global awareness raising, country pledges, and technical work. For global awareness raising, we hoped to advance the initial commitment to establish a biennial Challenge (a core element of the Alliance), raise the priority of HAI as a patient safety issue at the global level, and catalyze all stakeholders to commit to make Clean Care is Safer Care an essential component of their programs to tackle HAI. For country commitments we hoped to catalyze country level dedication by making the Clean Care is Safer Care program essential to the reduction of HAI. And for technical work we hoped to do several things: develop Consensus Guidelines on Hand Hygiene in Health Care; develop an appropriate and adaptable framework to facilitate implementation of hand hygiene guidelines; identify, develop, test and evaluate tools and resources to aid implementation; test and evaluate the Guideline recommendations (in terms of feasibility, validity) in pilot sites worldwide; and issue a final revised, updated Guideline.

We are now in the process of evaluating whether we have met these objectives and what have we learned from this first challenge.

1 – Awareness raising: Infection control is now highly regarded. The power of WHO is in its ability to raise and change commitment. It has made infection prevention essential to reduction of HAI and has moved infection control to the political agenda. We have accomplished this in part by spreading the word in peer reviewed literature. We determined early on that we had to move into the academic world and influence academicians through publications in respected journals. Now we must follow up on country commitment by monitoring and reporting on performance and improvement.

2 – Country commitment: Multiple countries have pledged their support, and are continuing to do so. By the end of 2006 over half the world's population will be covered by countries pledging to support the challenge.

3 – Technical work: Stakeholder intelligence and communication has been facilitated through establishing a database of 1,500 individuals to which a NewsAlert is disseminated monthly. We have also created an advanced draft guidelines document and have published multiple articles in the peer-reviewed literature.

In summary, we have had a number of successes. Thirty eight countries have committed to tackle HAI by pledging to the Challenge, and another twelve countries are planning or running nationwide hand hygiene promotion campaigns. We have developed a consensus, peer-reviewed guideline of 204 pages developed by over one hundred renowned international experts with an accompanying suite of practical tools for implementation. We have given about fifty keynote and plenary lectures at major conferences worldwide, and have fourteen peer-reviewed publications in major and subspecialty journals.

There are a number of major lessons from this challenge. Leverage was attained from a well-planned strategy and the engagement of worldwide experts. Our recommendations were evidence-based but adapted and translated to make them applicable. We created effective internal partnership within WHO. Our strategy included the creation of supportive toolkits to guide implementation. We established effective relationships with regional patient safety focal points. Critical to our success were a clear cut mission statement, a clear vision of the current challenge and its future, and adequate financial and human resources. In addition, strong project leadership with an expansive vision that including international connections, a credible leader, time commitment from the leader and the team, robust institutional support, and an excellent backup team were important for success.

How could we do it better? We should have had better data on the burden of disease, a better appreciation of the vision and scope, and a clearer understanding of our objective, resource requirements, project structure, and data output. In addition, there are clear risks to success. The project must be adaptable, have clear reporting and communication structures, deadline requirements, translation services, and be sustainable after the challenge ends. Finally, all assumptions, both internal and external – but especially internal – must be challenged.

How Do We Improve Safety? – Peter Pronovost

Surgery has been divorced from public health, and safety has been divorced from science. The need to improve safety is too great and resources are too few, so we must get it right the first time. The biggest barrier will be behavioral and cultural - we have the technical capacity but need to adapt and evolve it to local capacity and resources. Our group at Johns Hopkins has created a model structure to address this: Engage, Educate, Execute, Evaluate. Any project has several attributes to consider: the project goals must drive measurement; a data collection and management plan must be designed; we can give up on quantity but not quality; it must strive for scientifically sound, feasible, and useable data; and it must create a learning community. For example, in this challenge, we might ask, “Is pulse ox present? Is it used and to what extent? What is the rate of adverse events with and without pulse ox?” From this we can draft patient level measures, gain consensus, develop and pilot a test study, and develop a measurement tool kit. The right questions are essential.

Open Discussion

During this general discussion we review the articulated goals of raising awareness, creating minimum standards and disseminating them, developing consensus for WHO guidelines, and implementing measurement for the project. We still need to

define our knowledge base and pull together the components for what is involved in safe surgery. We asked of the participants: Are these the right goals, and what are your thoughts about this? What are we missing from the discussion, and who (what groups of people) are we missing?

The following points are a distillation and summary of the discussion:

- There is a concern for our ability to set standards for the surgical operator. This is vitally important for safety from a technical standpoint, but difficult to achieve.
- Worldwide promotion will be an issue, particularly in the marriage of the multiple disciplines involved in the various components of safety. With respect to cleanliness, ID specialists and nurses must be involved. Likewise anesthesiologists and nurses must be involved for anesthesia, and surgical providers for technical issues. Additionally, we might consider joining together some of the initiatives already existing around the world.
- We also have the option of creating a stepwise approach rather than a single standard working towards conformity. The project could then give direction and guidance that might better reflect the disparities in surgical care and resources.
- There do not appear to be any efforts to address the multidisciplinary aspects of care through team training in either the agenda or the background paper. This must be addressed as well. Team dynamics are essential to safe surgical care. The technical capacity and knowledge often exists in surgical settings, but the support system is lacking. Patients may be under the auspices of the surgeon, even when the anesthesiologist or nurse is the one providing care, and these dynamics must also be considered and addressed. In this regard, inclusiveness will be essential. We should consider the use of the word “practitioner” in place of doctor, surgeon, or anesthesiologist, as much of these services may be provided by non-MDs.
- We must address some of the fundamental issues of brain drain and lack of human resources as well as the problems of infrastructure that are so lacking in much of the world.
- We might create a medical curriculum to impart a sense of safety and the essentials of safe practice. This might be included into prior WHO work such as Surgical Care at the District Hospital. It could also be included in training regiments of surgical providers.
- Given the disparate resources and settings where surgery occurs, a checklist might be useful to promote safe practices, teamwork, and act as a reminder of the elements essential for the operation to be performed safely.

Clean Surgery

Antibiotic Use During Surgery – Iskender Sayek

There exist lots of standards and guidelines, but adherence is limited. Surgical Site Infections (SSI) are the second most common type of nosocomial infection; 2-5% of clean extra-abdominal cases and up to 20% of intra-abdominal cases are complicated by SSI. Good surgical technique, proper asepsis and antisepsis, modification of risk factors,

and antimicrobial prophylaxis all play a role in preventing SSIs. Antibiotic misuse includes incorrect timing, duration, choice, indication, defective clinical trials and results in increased cost, decreased cost effectiveness, development of microbial resistance, and a false sense of confidence for the surgeon.

In summary, prophylaxis is not an alternative to other methods of prevention, and all must be considered in parallel. Routine use should be selective, given at an appropriate time including intraoperative redosing where appropriate, a single dose is adequate for most cases, and selection should be based on clinical trials.

Reaction – Aberra Gobezie and Gia Tomadze

The technical aspects and tissue handling are of utmost importance. Patient characteristics, availability of medications, and environmental and resource issues are all problems with respect to universal applicability. Guidelines will, however, be very helpful for surgeons, and should take into account the type and site of surgery. Overuse of antibiotics is also a problem. Where surveillance exists, changing from passive to active surveillance may make a substantial difference in infection rates and administration of antibiotics. Recommendations might be passed through ministries of health, particularly when making specific recommendations for specific choices of antibiotics and timing of administration in clean and clean contaminated cases.

Open Discussion

Measurement will be an issue and process indicators might be best for this part of the challenge. We may use surveillance of antibiotic use, the type, amount, and which surgeons order what as measurement indicators. Institutional measures already in place are useful and should be utilized. Recent developments would suggest that a 30 minute to 1 hour time frame prior to incision is the best window for antibiotic delivery.

Hand Hygiene – Andreas Widmer

Wound infections are a major issue in surgery. Antisepsis made a drastic change in mortality at its introduction, and with the introduction of aseptic techniques, antimicrobial prophylaxis, and laparoscopic surgery, improvements continue.

Infection is not necessarily associated with bacterial load. Preoperative showers lower bacterial load, but are not related to incidence of SSI and data do not support this activity. There is no proven efficacy for any specific type of solution, although iodine appears to have best profile. Regarding scrubbing versus spraying, studies indicate that painting only is equivalent to scrub and paint in abdominal surgery (unless gross contamination is noted). As a standard, iodine seems to be the best candidate for wide promotion to be used as a skin preparation solution.

Reactors – Sergelen Orgoi, Kate Woodhead, Didier Pittet

WHO guidelines for skin preparation and hand washing exist and have been useful for implementation in the past, particularly in remote or resource poor areas. There are no data to really evaluate whether they are being used and are accessible. Iodine and/or chlorhexidine appear to be the most widely used around the world. With alcohol, there is a concern of OR fires. In industrialized countries, training and education

are essential, but in developing countries, reducing bacterial load may be more important. Any recommendations must be widely distributed and promoted.

Open Discussion

Protocols are available and work, but they are not always followed – and not just because they are not known. We have both the technical and scientific information. Our job now is to ensure it reaches practitioners and that they follow such standards. Adherence is a primary issue, and education needs to be tailored to all providers, especially those most involved in the practice of skin antisepsis, particularly within the team framework. All team members must be engaged. We can turn existing knowledge into more effective reality, partly through simplifying and consolidating existing guidelines. Tools for implementation are essential, so we must facilitate these tools to allow implementation. The educational system might also be addressed, as trainees will also disseminate information and can act as agents for change, but these types of efforts must be maintained.

Decontamination of Equipment – Bjorn Fahlgren

Delivering clean and sterile devices is an issue of management more than science. From a risk management perspective, there are key technical elements – the transmission of pathogen, the residual elements from disinfection (including the chemicals themselves), the criticality of the devices, and the invasiveness of the device. Technically, instruments must undergo the removal of material, cleaning, disinfection, sterilization, and the maintenance of sterility. The technical details are well known, but the component elements of what needs to be sterilized, and how quality is assured, are an organizational issue that impacts the safety of the instruments. Safety comes from appropriate organization. The capacity to create or adopt standards may be influenced by the level of activity and the quantity of surgical devices to be processed. A final influencing factor on the safety of devices is the architectural structure and organizational means of the facility providing surgical services. All these elements must be considered when addressing decontamination.

Reactor – Yow Ng

The equipment necessary is not too expensive, but there is a problem of assurance of sterility. There is also the issue of cost-effectiveness of single use versus reusable items which will complicate considerations. Ultimately, quality assurance is the most important issue.

Open Discussion

Is this a priority? What is the evidence that this is a problem in causing surgical infections? Is this more of an institutional issue? The data are lacking. Most of the studies are done in the west. Can we generalize the outcome of these studies to rural areas with low infrastructure? There are cultural issues as well, and we risk a colonial approach to creating standards. If the system does not work, the standard will not work. We must work to the system.

If we are to suggest a single standard, the proposal to adopt steam-heat sterilization was advanced due to its large margin of safety. As a measurement

technique, we might focus on a single device, like swabs or linen or sponges, as a marker to focus efforts on reusable versus sterile devices.

Countries look to WHO for guidance on the issue of reusable versus single use devices. Can we engage manufacturers in developing devices for reesterilization? Can we make a statement on reusable devices? Reuse of non-reusable equipment is not very efficaciously addressed in a guideline, since most practitioners do not want to reuse materials when it is contraindicated. These topics should not be excluded from consideration. It would be worthwhile discussing with the medical technology industry possible solutions to these problems, such as making the reuse of disposable devices impossible and/or producing easy-to-resterilize devices instead of single use devices and/or reducing the cost of disposable devices by improved engineering and manufacturing technologies. Much can be done in the interest of safer surgery by improving the medical devices being used. The International Federation for Medical and Biological Engineering (IFMBE) Technology Assessment and Clinical Engineering Divisions could be helpful in exploring these issues. Biomedical engineering research into medical devices and surgical (simulation) procedures could also contribute to improving patient safety

The problem of quality assurance exists because many hospitals do not have their own bacteriological labs, so they cannot examine or control their own QA. Boiling sterilization is frequent, indicator tapes are not a priority, and equipment is not upgraded or maintained. In addition, discharge from a hospital poses risks to surrounding community. This is not just from disposable devices but from bed sheets, laundry, etc.

Hospitals run out of material, but surgery cannot be postponed. Guidelines will not solve the problem. Resterilization rates are high because of the resource issues, even of single use equipment. Practitioners make economic decisions and weigh the risks of not reusing the device versus the risk of reusing it, creating a cost-effectiveness issue.

Much of the resource issues are reflective of hospital function, and equipment shortages are a marker of hospital problems. The problems seem to build the poorer the setting is. A separate aim to develop an effective strategy and tools for implementation – this challenge is not just about guidelines but **about** safety. We must understand that we are taking western studies and applying them to extremes of conditions. We will need conviction in our program, yet we do not want to set accreditation standards as this is not the role of the project or WHO.

Safe Anesthesia

Vital Signs Monitoring – Jeffrey Cooper

There already exist standards from Europe published in the European Journal of Anesthesiology in 1993. There were no efforts to implement it and no evidence of its utility, but has strong face validity and anecdotal evidence of its value. Standards were set as a goal, with four priority levels: minimum standards, highly recommended, recommended, and encouraged. Regarding oxymetry, there is no scientific evidence to support its use. Ventilation is probably the most important monitoring element, especially in circumstances of low resources. A good starting point would be to revise and disseminate World Federation of Societies of Anesthesia (WFSA) standards and audit compliance. Additionally, there is a huge opportunity to develop cheap

technologies that are good enough, that is they don't have to be perfect or comprehensive to make a difference.

Reactors – Alan Merry, Meena Cherian

The importance of patient safety has been recognized officially as demonstrated by the elevation of the patient safety committee of WFSA to a standing committee. There are catastrophic consequences of anesthesia, and anesthesia societies and clinicians wish to improve safety. Currently there is an attempt to provide oxymetry for all patients (through partnerships with industry). Although the evidence is in question, randomized controlled trials are not the be-all-and-end-all for evidence, as expert consensus also plays a role. We need to know how to use and respond to pulse oxymetry information, we need to maintain equipment, train providers, engage governments for self-sustaining adaptation, and endorse its importance at a global level. Such a program of implementation needs to go beyond monitoring and focus on personnel in a physician directed fashion. Specialists must be the focus of high standards, and these standards must be continuously revised. To attain this we will need to coordinate and refine existing standards, and then we must disseminate and promote them.

There are other considerations that are not addressed, like medication errors and labeling issues, both of which might be driven by WHO. As for monitoring, we have no agreed definition of anesthesia mortality, so we in anesthesia cannot even support the supposition that mortality is dropping. We will need an internationally agreed definition of what anesthesia mortality is to allow us to measure our success due to changes in the structure and process of anesthetic delivery.

Anesthesia has been forgotten as a specialty with the result that there are now not enough trained personnel. Human resources are a significant issue. Medical students will not choose the field of anesthesia if it is done only by technicians. Vigilance is the most important part of anesthesia with respect to surgery, and we will need to stress the importance of continued training and professional development. A trained provider is an absolute standard.

Finally, can more regional anesthesia be promoted in specific circumstances (i.e. c-section) especially where there is a lack of resources and technology? We must make anesthesia safety a priority of equal importance to surgical safety.

Open Discussion

We do not have any data to support the idea that patients are being harmed in significant numbers by anesthesia. Yet the lack of evidence should not hold us back. A precautionary principle should guide us – one decides in the face of imminent danger that one can do nothing without evidence, or do what appears right until the evidence proves otherwise. There is evidence of no effect and there is no evidence of effect. These levels of evidence take many forms, each with a higher or lower risk of bias, so we must evaluate the risks and benefits. We can recommend standards with much lower levels of risk if there are minimal harmful effects. And all must be weighed against their cost, as any increase in cost will tap financial resources from other projects and programs and can have a potential harmful effect. We do have evidence that teamwork and effective communication is essential. Communication breakdown is a major component of error.

The surgical time out is an activity that involves the entire team, yet we lack the evidence for its efficacy even as we promote its use.

There is no such thing as minor surgery, and we must keep this in mind as we approach this issue of the challenge. Practitioners have all the responsibility but may not have all the medications, equipment, or support. If WHO puts its weight behind these things, policies will change. We can train people and provide safe conditions. If such a program is created by this challenge and is focused, uses the base of knowledge already established, and the strategy well thought out, we might reasonably be able to complete it in 2-3 months.

Much equipment that is purchased is useless. We can arm governments and minister with respect to how resources are used. Middle income countries are a microcosm of the issues we face – cities are high tech while rural areas are very poor. Internationally recognized standards can be used as a lever politically. Economic issues of resource matching must be considered, and may move the project in the direction of a layered approach with different recommendations for rural and urban settings. Finally, medical tourism is having an effect, as is globalization. The private sector is capitalizing on this enterprise.

There is broad variability in quality. We might consider developing a short course for anesthesia to improve safety of care. Professional bodies are protecting their turf, but we might develop protocols that can both address training issues and accommodate professional bodies. Variations in professional development are greater for specialties other than surgeons as there are often no accrediting bodies. Guidelines could include a framework to accredited providers, and those providers would meet a set of minimum standards such as an interdisciplinary Morbidity and Mortality conference or documentation of anesthetic record to allow analysis. We must encourage ongoing improvement through long term commitment.

Access is also an issue. Huge changes in maternal mortality have been demonstrated with improvements in anesthesia. Anesthesia, or lack thereof, is killing people. Yet the motivation for improving things is very different between rich and poor countries. No one defends the rights of patients in the developing world, and there is no consequence for failure in many countries. WHO needs to defend the importance of good anesthesia and good anesthesiologists.

There is also the issue of safety of the practitioner. Where infrastructure issues are poor, practitioners who are able to leave will leave. They see that things can be done differently, so they leave because the system is so dysfunctional.

Pain Control – Olaitan Soyannwo

Pain is an unpleasant, sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. It can be preexisting, caused by surgery, or be combination of the two. Perioperative pain and its control are important to address. Studies from Nigeria indicate that moderate to severe pain is present in 46- 87% of patients before an analgesic dose was due, was present all or most of the time in 33% of patients, and that medications did not arrive immediately 40 – 80% of the time. In resource poor settings drug availability is an issue, as is intermittent dosing. The surgeon is often the sole prescriber of medications, and pain is not monitored. It has numerous adverse effects, such as blood clots and embolism from lack

of ambulation, increased risk of pneumonia, and an increased physiologic stress response. Treatment goals seek to minimize discomfort and physiologic disruption. Involvement of the pharmacist is extremely helpful if one is available. One measure does not fit all patients, and practitioners must be attentive to the individual. We cannot give directives for medications due to resource limitations. Guidelines already exist in many organizations (AHCR, IASP, ASA, JCAHO), and WHO has an analgesic ladder already established based on subjective reporting and rating of pain. Yet there are no universal guidelines for managing pain. Low tech interventions can have a high impact, and pain control may be part of informed consent with respect to implementation.

Reactors – Marco Baldan, Teodoro Herbosa

The International Committee of the Red Cross/Red Crescent (ICRC) experience may provide a guide. The acute phase response involves a large team, but they avoid introduction of new drugs and drugs with major side effects. Ketamine is widely used but in patients with addiction diseases this needs to be adjusted. Also, whenever ICRC provides narcotics, they must have an antidote readily available. Ethically it is imperative to provide pain control, but from a more remote view, it may not be a universally applicable issue. Priorities for this challenge may not involve pain control, but WHO can still espouse awareness. Knowledge of pain control issues is a problem, but experience would suggest that once monitoring of pain was undertaken, pain control was improved.

Open discussion

Minimum standards work for regulation but not for improvement. There is a barrier of resource availability, so expectations must be stratified to different levels of achievability. A tiered approach is perhaps the best way forward – everyone reaches for a higher bar and the goal would vary based on resources. Yet the opportunity to make standards does not come around too often. We might be inclusive at the beginning, but can focus more narrowly later on. A simple step might be to endorse pain control as a principle and delegate the details of the next steps to the International Association for the Study of Pain (IASP). Also, patient awareness may improve practice.

12 January 2007

Safe Operations

Introduction – Atul Gawande

The first day was about building on prior knowledge. Today is about the safe operation, and about how we create safe teams.

Credentialing and Training – KM Shyamaprasad

Due to the diversity of training systems, duration, types of rotations, and variety of requirements we will probably not be able to set standards for surgical training, but there are things we can do. There is already a professional consensus of technical skills- gentle handling of tissue, handling dangerous instruments safely, sound knowledge of

anatomy, competency in tying knots, distinguishing normal from abnormal tissues, appropriate incisions, and identifying and exposing tissue planes (as described in “Skills Required for Basic Surgical Trainees” in the British Journal of Surgery, 1999). In addition there are the clinical skills, communication skills, and teamwork abilities that are important for a good clinician. There is also a skills deficit and a huge need for allied health services, since even with volume directed training, migration of health workers causes shortages. We will need to identify what is possible – to set goals and educate patients, policy makers, clinicians, and trainees. This project might focus on introducing the concepts and principles of safety into the curriculum. Technical issues might be addressed in such courses as the Advanced Trauma Life Support course and the basic surgical skills course developed by the Royal College of Surgeons. Continuing medical education can focus on skills development. Simulation technology might also be useful, particularly if low cost models are developed to assess skills in a broad fashion. Finally, creation of a patient safety culture is the most important element. We must determine if this is measurable, and if so whether it can be a criteria for accreditation. We might evaluate subjects in medical, nursing, and allied health education, create protocols and checklists, and establish a morbidity and mortality audit. We must understand, however, that this culture must be viewed as generational change. The WHO, by focusing on patient safety in surgery, can make a difference.

Reactors – Ara Darzi, David Benton, Nana Manu, Edmundo Ferraz, Iskender Sayek, Matthias Richter-Turtur

Our ideal training systems are not so ideal. Our profession has not kept up with the changes in practice, and most of the world has no training standards. So we must develop some minimal standards by concentrating on the curriculum of surgical practitioners. Communication skills are essential, as are technical skills, but we must be able to teach and evaluate them. We need to integrate safety skills in surgery since we seem to lack the basic skills to perform safely. Curricula and trainee evaluations should include knowledge but must also look at technical skills assessment. Sets of generic skills can be introduced in such a curriculum. Knot tying, for example, is a simple skill that can be assessed. Finally, we must consider the issue of access, and must transfer knowledge and skills across a wide range of practitioners. The leadership at the College and professional levels appear to be lacking, but WHO can provide direction. New gaps are being identified with respect to communication and training, and we must address them comprehensively.

The nursing model may be instructive. There is a global shortage of nurses which affects access to services. Some governments respond by shortening training but without any long term training strategy the new trainees subsequently lack the skills to be safe. The International Council of Nurses (ICN) deals with this by establishing required competencies regardless of the length and timing of training. They include functional competencies such as those around infection control, for example. From a theoretical standpoint, core competencies are good, but functionally they do not work well. ICN is also attempting to address regulation, moving from self-regulation to regulation with patients and their safety in mind. Functional competence is the strongest element to ensuring safe practice. ICN is trying to bring order to the fact that nursing is being undertaken by a much wider range. Elements of competence relate one to the other. For

this challenge, we can be clear about particular tasks, or we can focus on the educational competence of the people one might delegate tasks to. This latter is more empowering. There is also a fine balance between enabling people to pursue their aspirations and provide skills for poor countries. By trying to focus on the reasons people wish to migrate and suggesting ways for policy makers to address root causes, we attempt to mitigate the migration issue.

In many resource poor settings, any medical doctor must be able to operate. Yet even highly experienced clinicians are not capable of handling all the problems when they are alone. The manual for Surgical Care at the District Hospital is very useful, but does not address the level at which skills should be acquired. One way to address some of the access issues is to spread out the burden to the sub-district level so practitioners can provide more broad-based care. Training of practitioners must be tailored to the issues being faced by them, and must have a formal structure. Basic surgical skills can be mandated, but young clinicians must have access to senior providers in order to create safety in the system. We might use the nurse anesthetist curriculum as a model – these practitioners function very well and at a very high level. It demonstrates that we can set minimum standards for everyone and that training can be quite sophisticated, but it may be in the form of stratified levels of training and skill.

There is also the issue of surgical indication, as unnecessary surgery is performed all over the world. Audit control helps with evaluation and provides feedback and improvements in performance and knowledge. WHO can provide a link to organizations that will propagate recommendations and standards. This creates incentives for performance improvement through monitoring and assessment. For example, we might publish rates of SSI. To do this we need independent observers and a good surveillance system to catch infections in all patients, especially outpatients. We must consider that this may increase reported infection rates which makes departments and hospitals look bad.

We have moved from surgical education as an apprenticeship to a structured training program. Now we are making it more global by attempting to provide competency for safer surgery. To do this we must focus not only on surgical training but also on undergraduate training in medical school. We have to move our training from the OR to the bench. While doing this we must also ensure that any standards we create and promote meet the needs of the local society. We must also explore other global standards like those of the World Federation of Medical Education (WFME), as we can promote safety more widely through collaboration and cooperation with this organization. This can also help ensure recommendations for training become a mandatory part of any curriculum rather than voluntary.

The practice of surgery is still a problem, particularly in developing countries. Ultimately, being a good craftsman is most important, which is attained through good theory and good practice. Migration of medical practitioners must be addressed if we are to make a difference in access. The Human Resources for Health division of WHO is missing from this discussion. Training courses might concentrate on two technical skills of high priority in developing countries: standard suturing of gastrointestinal anastomoses and maltreated fractures. Also, surgeons are trained practitioners but not trained teachers, and we ought to think about how we train them to be teachers.

Minimum Equipment – Meena Cherian

Our challenges in this field include the imbalance in human resources between surgery and anaesthesia, the problems of equipment and types of procedures performed, the differences in minimum standards between and within countries, the lack of health personnel in many settings, and the variability in documentation. In creating minimum equipment standards, we must acknowledge that they must: be applicable to meet local situations; simple to implement (preferably through existing country programs); sustainable through buy-in by policy makers, health providers, universities, and professional societies; and measurable through evaluations of compliance and implementation and/or their effects on patients. The task is tremendous, as we cannot ignore issues of infrastructure (such as designated operative and recovery areas, water, and electricity), the functioning of equipment, sterilization, and quality of maintenance and inventory. All this is linked with education and training of the provider. One potential way forward is creating checklists for safety. We might build on available standards from WHO, ICRC, WFSA, and surgical societies. Ultimately any success will depend on integrating existing standards into policy guidelines, making them widely available, and creating political will.

Reactors – Marco Baldan, Andrei Issakov, Neelam Dhingra-Kumar

The issue of equipment has created headaches for relief organizations such as the ICRC. There is no agreement by specialists, so many have tried to come to common agreement on guidelines for appropriate medical technology. There are several components to this. There are the needs assessments, which has been broken down by ICRC to three levels: essential, important, and nice to have. There are maintenance requirements, which also include clear guidelines for training a local force. There is the consideration of the ease of repair, and whether equipment is repairable by non-engineers, whether spare parts are available, and the cost of maintenance and repair. There is the competency required to use equipment. For example, ultrasound may be very useful for one clinician, but others may not use it once he is gone, and it may not be vital for clinical care. We must ask if the technology is already present in the country, if we really want to be the first to introduce it, and if its introduction will create dependency. There are the professional and ethical concerns, particularly regarding donated devices and their servicing. Finally, sustainability is an issue. We do not want to introduce or use equipment that is not sustainable.

WHO initially investigated whether specific equipment standards could be implemented, but the results were not optimistic, as no single standard seemed possible. WHO is now developing a tool to help countries develop their own lists and standards. We can, however, set minimum standards for services and procedures, with associated equipment needed to perform it. Lists can then be changed, merged, and morphed based on skill mix, the medical devices available, and the infrastructure required to maintain them. We might consider the term “critical” rather than “essential”. Items are either critical or non-critical. How we develop these guidelines for infrastructure is still a question.

Open Discussion

Some of the candidate approaches for this campaign includes a checklist for ensuring appropriate antibiotics, anesthesia monitoring, and procedure, a safety curriculum that emphasizes teamwork and preoccupation with safety, and a single safe surgery campaign for something like cesarean section or circumcision. Any campaign must have full WHO support.

Each of these proposed projects work best in its own area: training works in certain areas, checklists in others. Improving professional education can be part of the safety measures. The approach ought to include consideration of economics. Improvements in safety affect costs, and leaders and policy makers must address cost.

A checklist program can have a deeper, more overarching theme. It can be more like a briefing to address team issues, a team training process, and method of addressing team dynamics. Teamwork is fundamental, and a checklist can act as a tool to facilitate this. In anesthesia, safety started with an anesthesia machine checkout which began a cultural shift by getting people to think about safety.

A potential problem with the single surgical campaign approach is that it does not address the systematic issues. This campaign must tackle systematic issues in a systematic way. The financial implications are huge. Health system costs grow in an exponential way. It will cost much less to save lives in the developing world than developed world, and a campaign will make the biggest difference with least money in the poorest areas.

Patient Expectations – Matthias Richter-Turtur

One fundamental question is to what extent a patient has an ability to have expectations. In developed countries, doctors have to provide a good service. In contrast, physicians in poor countries often do not, as they are either the only provider or not subjected to quality assurance mechanisms. Patients expect safe and effective surgery, but the reality is often different. Factors that contribute to this may be patient driven (nature of illness, personal condition, fear and coping strategies, level of education, family situation, religion, and confidence in the doctor) or surgeon driven (knowledge and experience, motivation and empathy, ethics, economic situation, financing, career issues, and the political environment). We ought to create a culture of early communication prior to failure that should include informed consent.

Reactors – Cosmas Kalwambo, Aberra Gobezie

We should all look at ourselves as potential patients. Our standards must reflect upon our own expectations. We should consider that we are setting the standards for the nearest health facility that we might arrive at. The capacity exists, even in the poorest situations, but we need to create the will. We must always remember the patients we are failing and that we ourselves may be patients.

We must fulfill patient expectations. The basic expectations are that adequate investigations and treatment are undertaken, that the care is safe, and that they are not embarrassed. They also want the outcomes they see around them, which may create unrealistic expectations. Some expectations are cultural, and we must plan for this. Doctors must stand for the patients, not only themselves. Finally, we might have to approach the training of other health professionals to allow expectations to be met more broadly.

Open Discussion

Patients want the care team to be coordinated and they themselves often want to be a part of that team. They want to be listened to. We should know if the patient has any questions, which can be incorporated into a checklist if this is the direction we are taking. Safety is improved through active involvement of the patient, as advocacy aids.

We are trying to influence a number of people, especially patients and professionals at the point of care. We must also obligate governments to provide some of this influence, so policy makers must be targeted. Our systems are often the source of public health problems, and must be part of the solution.

We need an integrated strategy for safe surgery which could be a multi-pronged approach using teambuilding, skill development, and quality assurance mechanisms in surgical care, documentation, and equipment management. We must define the gaps, particularly with respect to data collection. Countries might even help decide their own programs.

Quality Assurance

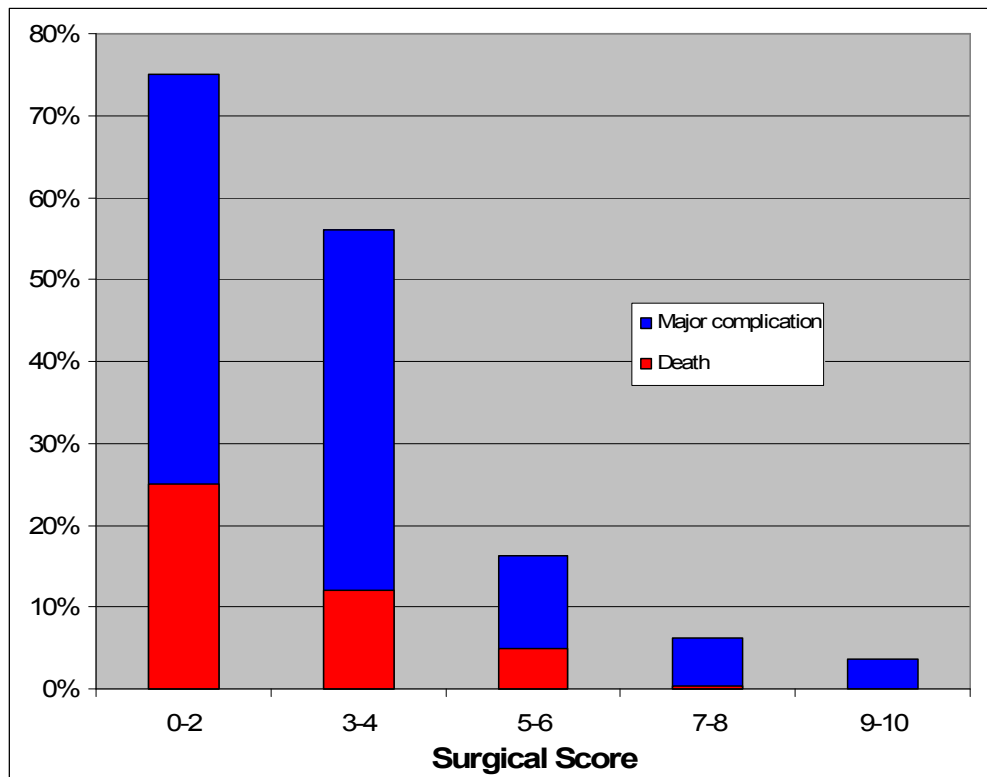
Feedback and Monitoring – Atul Gawande

There currently exists a huge problem regarding the lack of measurement in surgery worldwide. Surgical mortality in the developed world is based on the thirty day mortality rate. This is problematic as it causes trouble in data collection due to its delayed measurement and the huge potential of a loss of follow up. Our research group at Harvard has identified a tool to predict the likelihood of 30-day complications and mortality by using intraoperative estimated blood loss, mean arterial pressure, and heart rate to create a surgical score that predicts this, as demonstrated in Slides 1 and 2 (*see slides below*). We cannot measure thirty-day death rates around the world. We need an immediate measure. There are several candidate approaches to this problem of measurement: we can continue to measure 30 day mortality rates from surgery, with all the associated problems this entails; we could measure in-hospital mortality, which may or may not be reflective of mortality trends and safety; or we could use other immediate measures such as the surgical score we have evaluated or another technique to evaluate surgical performance using outcomes.

Slide 1: 10 Point Surgical Outcome Score

	0 pts	1 pts	2 pts	3 pts	4 pts
EBL (cc)	>1000	601-1000	101-600	≤100	
MAP (low)	<40	40-54	55-70	≥70	
HR (low)	>85	76-85	66-75	56-65	≤55

Slide 2: Thirty-day outcomes for 767 patients undergoing general or vascular surgery, by surgical score.



Reactors – Edmundo Ferraz

There is an importance of documentation to this measurement issue. There is also an importance in the relationships between health personnel. There are qualities that need to be instilled in trainees, and trainees need to be selected in part based on some of these issues. Finally, an accurate surgical audit is important for measurement.

Open Discussion

There must be a connection between measure and the interventions we adapt. Is the surgical score outlined in the presentation reflective of the team, the skills of the providers, as well as the physiology of the patient? Either way, if such a measurement system is to work, teams must believe it is helpful. The concept of scoring patients is well established, but it must be objective and we must have an agreed definition for measurement.

Can we incorporate a single measure into data collection such as is already done by WHO in country profiles for the burden of disease – and equivalent for surgery akin to maternal mortality rates or infant mortality rates? The United States uses SSI rates as a quality measure. Might this be useful?

In Germany, there exists a registry for three sentinel operations: inguinal hernia repair, gall bladder operations, and proximal femur fracture fixation. For each of these, the state measures infection rates, length of immobilization, and length of stay. The

advantage is that not all surgical patients need to be registered – we follow only three disease entities, but can follow a multitude of process and outcome measures. The structure for collecting this data comes from the hospital, and relies on the doctor.

Just by doing surveillance, infections are reduced. This should be part of our concept – that the measurement may be the most important thing we do. The idea of tracer surgeries is interesting as a means of measurement, and particular measures on outcome can come from this. Readmission rate can also be a marker and is an easy surveillance tool.

In Georgia, data are received from statistical departments. Each department has a designated person for collecting such data as the number of complications, deaths, and reasons for death. All data are collected centrally. Hospitals and outpatient clinics send their deaths statistics using the same statistical form, which allows outpatient deaths to be catalogued.

In the UK, in-hospital mortality is one of the measurements used. This does not, however, allow for standardization based on disease severity. There is also the Confidential Inquiry into Perioperative Death, which is an expert peer review of all perioperative deaths. It evaluates causation type data to help determine cause of death, but has not helped bring about systematic change in practice.

There is a difference between a monitoring tool for performance and a learning tool that can track improvement. In obstetrics, the Apgar score has never been seen as a black mark, yet perinatal mortality can be used both ways. Perioperative mortality has not been used for performance assessment or improvement. There are other factors that have to be accounted for. For example, if infection is a marker of performance, there will be pressure to make it public for rating both physicians and hospitals. There are mechanisms for anonymous feedback which helps avoid this, but it is difficult. This type of information system can be established and is worth the cost, but the information must be accurate. Trauma registries and cancer registries exist; it can surely be done for surgery in general.

Data is powerful and can be collected in even the worst circumstances. For example, weapons wounded patients showed distinct differences based on location and setting. In the ICRC refugee camps in Kenya, wounded patients had a low (<5%) mortality rate but a high infection rate (>20%). In Mogadishu, patients had a 10% mortality rate but a low infection rate (5%). Time was the triage in Kenya, where delays in referral could be days since the hospital was quite far removed from the fighting. In Somalia the referral was quick but led to higher deaths as the hospital was right in the city where the fighting was. The early intervention in Somalia improved overall infection rates. There was also a notable difference in the types of injuries sustained, and the subsequent treatment and mortality – gunshot wounds need little blood and a short recovery time, whereas mine injuries have long recovery times and require lots of blood. As far as the data collection systems go, ICRC tracked the types of injury or disease, the time between injury and first hospital care, the time to operation, the duration of the operation, and the wound classification. However, the level of reliability is variable, and failure depended on a number of issues including local culture.

As a summary, there appears to be three potential practical ways to measure surgical safety: we can use tracer or index operations and collect comprehensive information; we can monitor in-hospital mortality; or we can use another immediate

measure of surgical performance, such as the surgical outcome score or other indicators. There is no clearly superior technique.

Metrics for Measurement – Martin Makary

How do we know we are safer, and what are the metrics for safety in healthcare? Productivity levels are not measured in healthcare. Structure is measurable, but does not actually capture the process or the outcome. Culture is the element that transcends all levels of care. Our group at Hopkins has created a safety attitudes questionnaire to evaluate the culture of safety among healthcare personnel. We know that there is something about the familiarity of teams that improves care. Our work showed a major disconnect between surgeons and nurses in their perspectives of how well they worked together as a team. Any survey or tool or checklist ought to follow the “Google example”. The Google website is simple, clean, understandable, contains few words, is easy to use, and is accessed by many different types of people with many different skill levels.

If we follow the logic that a checklist might be the ideal tool for this challenge, we can create one with room for additions and tailoring based on specialty and environment. In assessing any intervention, measurements are taken, an intervention occurs, and measurements are taken again. This allows tracking of change. Also, when frontline providers like something, it usually works. If they don't, it usually does not. To determine if a checklist is changing results or improving safety, we can measure the progress of a safety culture through yearly cultural assessments, which our group has undertaken in the past. Results are in the form of an output score from 0-5. Obviously measuring output is ideal, but this is very difficult to do. Measuring the safety culture is a reasonable alternative and can be a surrogate for assessing safety.

Reactors – Didier Pittet, Gerald Dziekan

Data is power, and data feedback will have an impact. In infection control for surgery, for example, just the fact of measurement will make a difference. We must remember that monitoring the structure and process does not necessarily give you the true outcome. However, with a vision for the future - the next five to ten years - these tools can be refined.

Priority setting is going to be a major issue as there will be competing priorities for policy makers, ministers of health, and countries. Ultimately, the most compelling argument to achieve sustainability will need to account for the financing. We must demonstrate the cost-benefit of the intervention. We need to take this into account.

The intervention could be an outcome, as long as it is simple and cheap. Everyone can do something with a tool such as a checklist. The measurement system should be equally simple and relevant.

Summary – William Berry

The agenda was ranked in order of evidence. We can make powerful recommendation based on evidence. For clean surgery, appropriate antibiotic use and skin preparation can have a huge impact. In anesthesia, the ideal scenario is that the anesthetic care is invisible. It goes smoothly, there are no problems or complications, and the patient recovers from the anesthetized state easily and safely. From there we

ventured out of science and the evidence of demonstrable success to the vexing problems of who provides care and how they are trained. This may be more than we can take on. The economic disparities represent the difficulties confronting us. Being able to measure our effect is an important part of our challenge. Ultimately we will need to focus on teamwork. For want of a team there is not much a surgeon can do. Teamwork is perhaps the most important part of safe surgery.

The Way Forward:

Following the First Consultation Meeting for the Second Global Patient Challenge, Safe Surgery Saves Lives, the direction for improving surgical safety has moved towards the creation of a checklist type tool for implementing basic interventions aimed at saving lives. The consultation validated the themes of Clean Surgery and Safe Anesthesia. The issue of Safe Operators was more problematic, but the general discussion of improving teamwork amongst all providers and focusing broadly on the multiple types of providers at the point of care – nurses, anesthetists, surgical operators, and patients and family members themselves – is clearly where this challenge will have its most dramatic impact. A measurement system is indisputably essential, and will likely have the benefit of initiating improvements by the very fact of its implementation.

With this in mind, the goal for this year will be to establish a core guidance group, create four technical working groups based on the themes of clean surgery, safe anesthesia, safe teams, and measurement, and refine a final product for promotion and pilot testing. In addition, a general strategy for promoting this challenge needs to be clearly established. The final result of the challenge should be a set of safety standards aimed at saving lives that are simple to implement, widely applicable, and that are measurable in a systematic and quantifiable way.