

# SAFE SURGERY SAVES LIVES



## **First International Consultation, Global Pulse Oximetry Project**

WHO Headquarters, Geneva

29<sup>th</sup>-30<sup>th</sup> October, 2008

The purpose of this first consultation is to:

- 1 – Establish the importance of pulse oximetry as a vital component of every operation in the context of the Safe Surgery Saves Lives project and the WHO Surgical Safety Checklist
- 2 – Discuss the need for universal pulse oximetry as a standard monitoring tool during surgery and characterize the pulse oximetry gap – why it exists, where it exists and how big it is
- 3 – Establish a set of specifications for a low cost pulse oximeter that could be manufactured and distributed to low resource settings
- 4 – Discuss procurement and distribution options and potential training models for widespread introduction of pulse oximetry
- 6 – Discuss measurement tools on both a local and global level

29 October, 2008

### Welcome Remarks - Pauline Philip

In 2002, the World Alliance for Patient Safety was created by the World Health Organization to increase awareness of the importance of patient safety among our 193 member nations. The Global Patient Safety Challenge was developed from this initiative. The first challenge was Clean Care is Safer Care, which has focused on improving hand hygiene and reducing the number of hospital-acquired infections. From this project, an alcohol based hand gel has been developed and is currently being distributed worldwide. The second challenge, Safe Surgery Saves Lives, which began in 2007, has focused on reducing complications and deaths related to surgery. From these efforts, the WHO Surgical Safety Checklist was created. Over 280 professional organizations have endorsed the Checklist since its launch in June of 2008. Pulse oximetry is a critical

component of the Checklist and making it attainable for every operating room in the world is one of the main reasons we are here today.

### The Global Pulse Oximetry Project: An overview of the meeting's goals – Atul Gawande

The goal of the Safe Surgery Saves Lives program is to reduce deaths and complications from surgery. When we began this project last year, we thought about ways in which previous efforts had addressed global health challenges. We quickly learned that there would be no easy solution. There was no manual to rely on or textbook to reference. We needed to define the scope of the problem to make progress. Estimating the amount of surgery in the world seemed to be a logical starting point. We conducted a comprehensive review of the published literature and obtained data from health ministries and WHO reports. From this work, we estimated that in 2004, there were over 230 million surgical procedures across the world – 1 operation for every 25 people on the planet. This work was published in the Lancet earlier this year. As a frame of reference, this number already exceeds the number of annual childbirths worldwide (approximately 150 million) and is 10-100 times as risky.

This worldwide surgical volume is expected to increase significantly over the next several decades as the average life expectancy increases with improvements in infectious disease therapies and nutrition in low-resource settings. For example, in many parts of India, where much of my family still lives, advancements in irrigation techniques and crop development have resulted in dramatic improvements in farming and subsequently, nutrition. As a result, malnutrition is no longer the major cause of death. Infectious disease is no longer the number one killer either. Rather, it is cardiac disease. Deaths from road traffic accidents and cancer are also among the top 10. This epidemiologic shift is also occurring in China, the Middle East, and Latin America among other areas where life expectancies have risen substantially over the past several decades. As a result, “surgical diseases” such as cancer, traumatic injuries and cardiovascular disease are becoming major health concerns in these regions. Health care systems originally tailored toward infectious disease treatment are being forced to address these new challenges. With this new realization of the massive burden of surgery on health care systems around the world, the provision of safe surgery will be a critical component for public health planning in the future.

To understand how we could reduce the estimated 7 million surgical complications and 1 million deaths annually, we conducted a thorough literature review and identified the major sources of complications and deaths. We identified a number of steps that we felt should be mandatory during the course of any operation. These steps were aimed at reducing the three most common causes of complications and deaths in surgery – infections, bleeding and anaesthesia mishaps. They ranged from proper identification of the patient before incision to timely administration of antibiotics to ensuring that at least two peripheral IVs were present in cases where blood loss was expected to be greater than 500 milliliters. Only one step involved a relatively expensive piece of technology not readily available in every operating room across the world – a pulse oximeter.

To improve the quality of surgical care, we felt that we had to do more than develop guidelines or issue recommendations. We needed to measure the effects of implementing our recommendations. Additionally, many avoidable complications seemed to be related to inadequate communication among team members, including surgeons, anesthesiologists and nurses. To make surgery safer, we needed to improve communication and teamwork, in addition to ensuring that standards of care such as antibiotic administration and airway evaluation were being followed. We decided to accomplish this by borrowing an idea from the airline industry – the use of a checklist.

For many years, the airline industry has used checklists to ensure safety for pilots and passengers. Prior to the initiation of any flight, the pilot must complete a series of checks to ensure that the equipment is functioning and the plane is safe. As a result, checklists have become part of all pilot training programs, and the airline industry is much safer than it was in the past. Within the past several years, our colleagues at Johns Hopkins have proven that the checklist can also be an effective tool for delivering medical care. A simple checklist for central line insertion was developed and tested at Johns Hopkins and subsequently implemented in the state of Michigan. The results were dramatic. Blood stream infections, previously thought to be largely unavoidable after central line placement, decreased significantly. Thousands of lives and millions of dollars have been saved. We thought that a checklist could also be effective in surgery if it were easy to complete, relatively short, and applicable in all settings around the world. We also wanted it to focus on team building.

We decided to take the 19 steps that were previously identified as critical components for any operation and create the WHO Surgical Safety Checklist. To measure the effectiveness of the checklist, we conducted a pilot study in eight centers around the world, representing both large academic centers in the developed world (Canada, New Zealand, the U.K and the U.S) and more resource-limited settings (Tanzania, India, Jordan and the Philippines). Both process and outcome measures were assessed, including anaesthesia crises (reintubation, cardiac arrest, inadequate IV access), complications, and deaths. Nearly 3500 patients were included in the baseline analyses. Anaesthesia crises occurred in 1.2% of patients, while overall complication and death rates were 10.7% and 1.4%, respectively. Only 34.7% of patients received all of the safety measures which we identified as critical parts of any operation (use of a pulse oximeter, time out to confirm patient identity and site, an objective airway evaluation, antibiotic administration, adequate IV access when an estimated blood loss exceeded 500 milliliters). In other words, two out of every three patients did not receive even the most basic safety measures during surgery. This was true in both developed and developing settings. For some reason, knowledge was not being transformed into behavior.

After implementation of the checklist in each of these settings, the results were quite striking. The percentage of patients who received all of the safety measures outlined in the checklist nearly doubled (67.4%) and the death rate dropped by nearly 50%, from 1.3% to 0.7%. Surgical site infections also dropped from 4.3% to 3% and the incidence of “any complication” decreased from 9.6% to 6.5%. The inclusion of a simple checklist

that could be completed anywhere in the world had a dramatic impact on complications and death.

We officially launched the Checklist in July 2008. It has subsequently been endorsed by over 280 professional organizations. Five countries have even committed to implementing the Checklist in every operating room in their country (the U.K., Ireland, the Philippines, and Ecuador and Jordan). We hope that by the end of 2009, the Checklist will be in use in at least 2500 hospitals across the world. We are also measuring “Surgical Vital Statistics” including the number of surgeons available in each hospital, the number of operating rooms, number of anaesthetists and the amount of surgery in each hospital. Day of surgery deaths and in-hospital mortality is also being followed. To track these measures we are working closely with WHO and have developed a GIS Surgical Safety Web Map which will represent these figures graphically.

Despite the simplicity of the Checklist, there is one component that is not possible in every operating room in the world – pulse oximetry. The main barriers are the cost and the fact that it requires clinical knowledge for effective use. With the support of the Safe Surgery Saves Lives program and each of you here today, we can make universal pulse oximetry a reality.

The goal of this meeting is to review with anesthesia, procurement and manufacturing experts the size of the pulse oximetry gap, possible designs of an affordable oximeter, approaches to procurement and distribution, training options, and methods for measuring the effect of our intervention. We are hopeful that this will be the beginning of a powerful public health initiative that will significantly reduce complications and deaths from surgery and improve the quality of anesthesia care around the world.

#### Why is universal pulse oximetry our goal? - Alan Merry

Despite the beliefs of most of us here today, there are still some who question the benefit of pulse oximetry. In a Cochrane Review published in 2002, the authors stated that “its use does not appear to influence a person’s cognitive function, length of hospital stay, or incidence of complications after anaesthesia.” I simply do not agree with this conclusion and a closer examination of the available data seems to tell a different story.

Of the six relevant randomized pulse oximetry trials considered in the Cochrane review, only 4 were included in the analysis. The other two either had inadequate data or were not randomized. Of the remaining four, one included 35 postoperative cardiac surgery patients and demonstrated a decrease in the number of clinically unapparent desaturations in the oximeter group (Moller JT, et al., BJA, 1992). A second study, by the same lead author, included 200 surgical patients. Again, there was a decrease in the number of clinically unapparent desaturations (5 vs. 0) in the pulse oximetry group. A third study by Moller which was published in 1993 involved over 700 patients and demonstrated a decrease in cognitive function in the group that did not receive pulse oximetry. There was no difference between the two groups at 6 weeks however.

In 1993, the largest study to date was published by Moller and colleagues. Over 20,000 patients were randomized to either pulse oximetry or no pulse oximetry during surgery. Intraoperative complications and postoperative complications were measured. As the authors state clearly in their manuscript, the study was not powered to detect a mortality effect of pulse oximetry. That study would involve nearly 1 million patients. As expected, there was no reduction in postoperative complications. However, the authors found a nearly 20 fold increase in the detection of hypoxemia in the OR and the PACU ( $P < .001$ ). There was also more frequent detection of endobronchial intubation, hypoventilation, and respiratory events. Myocardial ischemia was also decreased (0.1% vs. 0.2%;  $p = .03$ ) as was cardiac arrest (.04% vs. 0.1%;  $p = .06$ ). If the authors would have added the intraoperative and postoperative cardiac arrests and ischemic events, the decrease in the pulse oximetry group would have been statistically significant (78 events vs. 47 events;  $p = .005$ ). If strokes would have been included, the results would have favored pulse oximetry even more (97 events vs. 60 events;  $p < .0001$ ). Thus, the Cochrane review was heavily skewed toward one large trial which, if analyzed differently, would have showed more than an increase in hypoxia detection. It would have showed that pulse oximetry significantly decreased the frequency of serious adverse events. Thus, we disagree with the conclusion of the Cochrane authors.

What about oximetry compared to capnography? Simply put, oximetry is more robust, cheaper, and better for developing settings. Given the significant training requirements that will be needed for pulse oximetry, we should focus our efforts on oximetry at this point. The literature also supports this notion. In a study published in *Anesthesiology* in 1991 by Dr. Cote, pulse oximetry first detected 41 events while capnography first detected only 5 events in 402 children. Blinding clinicians to the oximeter data caused a tripling of the desaturation rate, but blinding capnography data did not change the frequency of major events.

As one author has put it, “Evidence-based medicine implies tracking down the best external evidence with which to answer our clinical questions.” In addition to these randomized trials, there have also been multiple reviews which strongly support the use of pulse oximetry. Many countries such as the US, the UK, Australia, New Zealand, Uruguay and Nigeria have already mandated pulse oximetry during surgery. We need to make this possible in every operating room in the world.

#### Reactors – Olaitan Soyannwo, Gonzalo Barreiro

In Nigeria, pulse oximetry is frequently not available. Often, one of the first signs that a patient is hypoxic is when the surgeon tells the anesthesia provider that the blood is blue or the patient has a cardiac arrest. In our teaching hospitals in Nigeria, over 90% of patients have pulse oximeters during surgery, and there are many episodes of desaturation that would not be detected without oximetry, especially because our patients have darkly pigmented skin. The percentage of patients who receive oximetry monitoring during surgery in district hospitals is much lower. Not having pulse oximetry available and not knowing the level of oxygen in each patient is very stressful. A stethoscope on the chest

and a finger on the pulse are not enough. With proper training, oximetry improves judgment and allows anesthesia providers with limited training to deal with the stress of surgery. We believe that oximetry is a critical monitoring tool and strongly support this project.

In Uruguay, there were very few oximeters in the early 1990s. Nearly 5 years later, 75% of cases involved pulse oximetry and in 2005, over 95% of operating rooms were equipped with oximeters. Because anesthesia providers had to know how to treat hypoxia if pulse oximetry was going to be effective, the level of anesthesia training and education improved after widespread use of pulse oximetry. This created a scientific approach to anaesthesia in our country. Most anesthetists in Uruguay now believe strongly in other monitoring modalities as well – NIBP, carbon dioxide monitoring, and EKG. The implication is that once you have one monitor and realize its value, it will be widely adopted and other technology will follow if the resources are available.

### Open discussion

The group was asked to consider whether other monitoring modalities such as capnography, EKG monitoring, defibrillators or other diagnostic tests should be pursued rather than universal pulse oximetry. The consensus was that pulse oximetry was the preferred modality for many reasons. In previous studies, anaesthesia providers with capnography data available often ignored it until the pulse oximeter alarmed.

The benefits of defibrillators were discussed but most agreed that oximetry was more likely to save lives in resource-limited settings. Defibrillators could bring patients back, but oximetry could help prevent patients from arresting in the first place. Several participants also agreed that the potential benefit of having pulse oximeters in operating rooms could extend to other areas of the hospital, such as the paediatric wards. This is important to consider, as 2 million children die from respiratory infections each year. Regarding EKG, it is a potentially valuable monitoring tool, but oximetry seems to be the more immediate need in surgery.

### What is the pulse oximetry gap? – Tom Weiser

As previous global health projects have demonstrated, providing an accurate market size calculation is critical for the success of the Global Pulse Oximetry Project. For instance, for the four-drug fixed-dose regimen for TB and autodestruct syringes, market estimations either underestimated or accurately estimated the demand. Both of these projects were successful. On the other hand, the weighing scale project overestimated the market and costs were higher than expected. Eventually, investments in the project were too significant to abandon and large scale production was pursued with limited success. What we learned from these projects is that market estimation and cost projections are critical.

In our background document, we estimated that 90,000 to 150,000 pulse oximeters would be needed to populate every operating room in the world that does not currently have one. How did we calculate this projection? We used 2 different methods. The first relied on an extrapolation of the number of hospital beds in each country. Based on limited survey data, we estimated that there were on average 2 operating rooms per 100 hospital beds. Using World Bank data and survey data, we split countries into 1 of 3 groups – low income countries with a 95% pulse oximetry gap, lower-middle income countries with an 80% gap, and upper-middle income countries with a 50% gap. Admittedly, this was a rough calculation and we welcome any additional insight or data you could provide. With these projections, nearly 150,000 oximeters would be needed.

Our second calculation involved projections based on surgical volume. Again, though this method certainly has its weaknesses and needs refinement, it is based on the principle that a certain number of operating rooms are needed to provide a certain volume of surgery. Once the number of operating rooms can be predicted, the number of necessary oximeters can be estimated based on OR penetrance. This number was roughly 90,000.

Unfortunately, the relationship between the pulse oximetry gap and per capita health expenditures is probably not a linear one as we have assumed. Rather, it is likely a curve with one or two inflection points. The lower inflection point reflects the number at which virtually no oximeters will be purchased if the income is below that point. Countries and providers are more likely investing in more basic needs such as infrastructure, clean water and electricity. The upper inflection point reflects the point at which penetrance is likely 100% and additional expenditures on health would not increase the usage of pulse oximetry. With data from additional countries, we hope to refine our projection over the next several months. Of note, three countries - India, Russia and China – comprise nearly 75% of the worldwide gap.

There is also a third projection model that should be considered. If one considers what the rate of pulse oximetry use should be for a given population, thereby ignoring the current limitations on a nation's capacity to provide health care, potentially 1 million oximeters would be needed.

#### Reactors – Jin Liu, Jane Kabutu

In China there are several different types of hospitals, 95% of which are funded by the government. There are government hospitals, province hospitals, city hospitals, county hospitals, and township health centers. The first three levels, representing nearly 5,000 hospitals, likely have 100% penetrance. Of the 15,000 county hospitals, the penetrance is 80%. Thus, the gap is 3,000 for those ORs. A recent survey of 15 township centers revealed that 14 oximeters were present in 29 ORs. If these numbers were extrapolated across the country to each of the nearly 40,000 township health centers, the gap would be roughly 40,000. Thus, a rough estimation of the Chinese pulse oximeter gap is 43,000. How do the township hospitals get pulse oximeters? A request is made to hospital director. Since many of these hospitals are in resource-limited settings, the hospital

budgets tend to be limited as well. Currently, pulse oximetry is difficult to purchase for every operating room.

In Kenya, there are government, private and faith-based hospitals. The gap in government and private hospitals is probably less than estimations suggested by Dr. Weiser although I do not have an exact number. It is probably accurate in faith-based hospitals where pulse oximetry is not a priority. Overall, the gap is probably 60-70%. Anaesthesia providers with limited training often view oximetry as tedious and intimidating, particularly when patients become hypoxic and surgical team is looking to the anesthesia provider to intervene. Many find it easier to simply not use oximetry. Also, the “availability” gap and “utility” gap are probably different. Just because an oximeter is present in the operating room does not mean that it will be used by the provider. Probe replacement and a consistent electrical supply are also major problems. Overall, in Kenya the norm is to perform surgery without oximetry. The main limitations are funding, education and infrastructure.

#### The WFSAs Global Oximetry Project – Iain Wilson

The Global Oximetry (GO) project is a collaboration between the WFSA, the Association of Anaesthetists of Great Britain and Ireland and GE Healthcare. The main objectives are to define the barriers to global oximetry in 4 settings - the Philippines, Vietnam, India and Uganda. Optimal design features of a low cost oximeter, preferred training methods, maintenance and resupply were also studied. The gaps in Uganda, Vietnam, and India ranged from 60% - 75%. In the Philippines, there were oximeters available for most operations but there was a large gap in the PACU. In some places, anesthesiologists had purchased their own oximeters. However, in emergency areas, ICUs, and the wards, the gap was often 100%. TuffSat oximeters were used in the Philippines and TruSat oximeters were used in the other sites. The best design features included a robust design (drop test), easy operation and maintenance, long battery lives (not AA; rechargeable), a pulse signal, and alarms. The probe was a critical component of the design as well.

Each anesthesia provider in Uganda and Vietnam received equipment training and underwent a basic course covering the principles of pulse oximetry. The educational course involved theory, TruSat operation, response to hypoxemia, clinical scenarios, and testing of each participant. Two half days were required for this training. This proved to be most challenging in Vietnam, where providers did not speak English.

In Vietnam, India and the Philippines, the oximeters were donated to the hospitals, whereas in Uganda, the oximeter became the personal property of the clinical officer who was charged with care of the equipment. Clinical officers looked after the machines very well and there were no instances of loss or equipment damage with this management setup. As expected by the GO project leaders in all sites, the probe seemed to be more vulnerable than the oximeter itself. All oximeters were accounted for at the end of the study and only 4 probes were damaged over 1 year.

Logbooks were kept by the anesthesia providers who recorded hypoxic events, responses to hypoxia, provision of preoxygenation and postoperative oxygenation, condition of the oximeters and ownership. For successful implementation of global oximetry, each setting needs to be analyzed independently as different settings involve different challenges.

### Reactors – Florian Nuevo, Tapani Niklander

In the Philippines, despite the reported gap of 0 in our test site (because anaesthesia providers are required to own their oximeters and frequently have inexpensive finger probes), there is a substantial gap across the country. One important observation was that the use of pulse oximetry decreased the costs related to oxygen utilization. We estimated that 5% of the oxygen provision cost was saved. Throughout the GO project, teamwork improved as did the educational level of the anesthesia providers. We are now beginning to include pulse oximetry as part of the medical school curriculum.

One issue raised by several participants was the large number of providers that will be needed to implement training worldwide, especially if pediatric and neonatal populations are included. A “train the trainer” type of model might be effective for pulse oximetry. A substantially lower number of providers could be trained as oximetry instructors, and they would have the skills and knowledge to train the rest of the provider population.

### Open discussion

A major benefit of universal oximetry is that it will raise the anesthesia skill sets of thousands of providers. As previous WHO efforts have demonstrated, the initial model will likely be adapted to meet each setting’s needs depending on the level of expertise in a particular setting. Solar power options were also discussed. There was both optimism and concern about solar options, given the problems with power when sunlight is not available.

Sustainability of the equipment will also be a major issue. According to one participant, 70-80% of equipment in the developing world is non-functional. In Namibia, there is 1 biomedical engineer for the entire country. A potential partner in this project would be equipment groups such as the clinical engineering division of the International Federation of Biomedical Engineering, which is focused on educating equipment repair personnel in the developing world. One example is a group from Luxemburg which is participating in an equipment repair pilot project in several settings in the developing world.

### Initial draft specifications for a low cost pulse oximeter – David Whitaker

The following specifications are either required or highly desired for a low cost pulse oximeter for the developing world:

- Required
  - Robust design and durable (“dropability”)

- Accurate oxygen saturation measurement (+/- 2%)
- Audible and visual alarms
  - Fixed 90% oxygen saturation alarm
  - Heart rate alarm (? high 120 / low 60)
  - High and low alarm priorities
  - Low battery alarm
- Pulse waveform display (although this is subject to debate; see below)
- Variable pulse tone (lower saturation, deeper tone)
- Numeric displays for oxygen saturation and pulse rate
- An ergonomic display
- Mains electrical supply with a rechargeable battery
- Highly desired
  - High performance in low perfusion states and during periods of patient movement
  - Alarms potentially for both high and low oxygen saturations. High alarms would be desired for neonates due to the risk of retinal ischemia and blindness that accompanies large amounts of supplemental oxygen administration.
  - Ensuring that the oximeter could be attached to another object, such as an IV pole or OR table

#### Open discussion

- Power supply
  - At least six hours of battery power is a reasonable expectation. The battery should fully recharge within 10 hours.
  - A dual power source should be strongly considered – mains supplied with a battery backup.
  - The power supply in some settings is not regulated and interruptions in power supplies should be considered in those settings. An independent DC power supply is an option, although there would be safety concerns if this method were selected (flammable anesthesia and fires); theft prevention would need to be considered.

- Windup capabilities could be considered as primary or alternative power sources. In current models, 1 minute of winding can provide at least 10 minutes of power. Foot pedals are another option for manual powering.
- A solar powered unit would most likely require 1 hour of sunlight for 1 hour of function. One must be very careful when relying on solar because if the power runs out and it is dark or cloudy, there are no other options unless an electrical backup exists.
- Surge protection should be considered.
- There are multiple options for a battery type although a lithium ion battery will likely be the smallest and most dense source of energy.
- Probes/sensors/cables
  - Much of the cost of pulse oximetry is related to probe and cable design. A robust cord design (flexibility and durability) is critical.
  - Cables and sensors are the weak point of an oximeter because they are the human interface of the machine and are subjective to repetitive strain types of damage.
  - For probe design, the goal is to minimize pressures points on the skin but maximize contact with the skin. One current design is a glove which fits over the hand and fingers.
  - One option to consider is the separate development of the probe, sensor and cord so that each component could be individually replaced if it fails.
  - Sensors degrade over time and become less accurate (they can overestimate or underestimate oxygenation) particularly at lower oxygen saturation levels.
  - 6-12 months is a minimal expectation for the duration of a probe. A number of sensors are already guaranteed to function longer than 1 year.
  - Disposable probes exist but are usually a more costly long term solution. Adhesive probes may be difficult to use on pediatric patients.
  - Wrapping the cord around the oximeter can lead to cord damage (3 meters is the most common cord length). Having a way to secure the cord without requiring cord wrapping would be helpful (“clipability”). A maximally robust cord may be stiffer and thus too rigid to sit on the finger properly.
  - A carrying case for the oximeter would increase durability.
  - A brightly colored cord and probe could prevent inadvertent damage by providers.

- A mechanism for locking the oximeter to objects such as the OR table may be desirable
- Safety measures can be built into the cable to reduce danger from “dirty electricity.
- A proprietary connection between the oximeter and the probe is a controversial area. On one hand, manufacturers cannot guarantee reliability or accuracy when probes and oximeters from different manufacturers are combined. Mismatches in sensors, software, and voltage are potential sources for inaccuracies. On the other hand, a universal connection between the machine and the probe would increase flexibility for providers.
- Some industry research shows that end users (providers) prefer interchangeable probes for oximeter devices, but the problems listed above will apply.
- Without a spectrophotometer, it is difficult to reliably calibrate sensor accuracy once the products are purchased. The instrument portion (hardware) can be tested more easily.
- Non-invasive hemoglobin measurement is currently available but involves much more sophisticated technology (many more LEDs per probe) and is more expensive.
- Adult probes can be used for pediatric and even neonatal patients although manufacturers cannot guarantee accuracy in these settings.
- A bacteriostatic probe is another option to consider
- Display
  - Bar graph displays are less expensive than waveform displays. The optimal choice for a low cost pulse oximeter is debatable because many practitioners would prefer the more expensive option – the waveform display. LEDs can show bar graphs but they cannot show a waveform display. LCDs can show both.
  - LCD monitors are more expensive than LED monitors, but LCDs use less power. LEDs are considered to be more durable and easier to replace than LCDs.
  - An OLED is another option to consider. An OLED may be easier to use because of the increased display quality and easier navigation through the menus. This can minimize dependence on language but is typically more costly.

- One option for display is to use different colors for different saturation ranges (e.g. blue indicates normal oxygenation and red indicates hypoxemia). Both bicolor LEDs and LCDs could accomplish this.
- A smaller screen could potentially mitigate the inferior durability of LCDs as compared to LEDs.
- Alarms
  - Variable tone alarm is critical. Low tones should reflect worsening hypoxemia.
  - Digital displays of the heart rate and oxygen saturation are required.
  - Given the risk of blindness in neonates who receive supplemental oxygen, a high oxygen saturation alarm would be important if the oximeter will be used for neonates.
- Additional features
  - Participants largely agreed that additional features such as non-invasive blood pressure, EKG, and capnography should not be included. Pulse oximetry alone is the preferred option at this point. It should be thought of as not only a critical monitoring tool, but a way to improve the overall quality of anesthesia care. The training and knowledge required to use a pulse oximeter effectively will hopefully change the culture of anesthesia care in the developing world.
  - Building a modular style oximeter allowing the future addition of other monitoring tools is possible but probably not desirable for this project.
- Cost/Procurement
  - The cost of the oximeter over its lifetime should be carefully considered, not just the initial cost. If you can increase the durability of the machine and the probes, it might be worth a higher initial cost. This is referred to as “high value per dollar.”
  - One option is to establish pricing with the health ministry. Subdistributors would be forced to maintain prices at that level, rather than increase them. One example of this model is in Egypt where the Health Ministry purchased pulse oximeters for ambulances. This has been an effective way to maintain stable pricing for that market.
- Distribution/Maintenance
  - In Sub-Saharan Africa, there are few direct industry representatives present. Sales are often conducted by distributors who may have subdistributors. These subdistributors could have even more

subdistributors. As a result, price markups can occur along the chain and are difficult for the manufacturer to control.

- Distributors may be able to create “swap pools” which could allow quicker turnaround of sensors, probes and cables (possibly within 1-2 days).
  - Regional supply centers could be created to supply probes in a more cost effective manner. Perhaps pricing could be guaranteed at these regional supply centers and markups by subdistributors could be limited.
  - If manufacturing occurs in places like the US and is exported to resource-limited settings, the end price could double or triple due to distribution costs.
  - Contact information for manufacturing and repair representatives should be included on the monitor (names and numbers of individuals to contact)
  - In-country repair options for cables, probes and sensors are desired.
  - Perhaps a kit which includes training and extra parts (spare probes, extra batteries) would be ideal.
- Miscellaneous
    - Weight specifications will be important (e.g. <2 kg for transport).
    - Adherence to international quality standards such as ISO 485 will be required.
    - It is our goal to have oximeters present in at least 50% of developing world operating rooms within 3 years.

### The procurement process – Peter Evans

Global purchasing is not like shopping. There are forces which control the market which are well understood. Porter’s 5 Forces are relevant for this discussion. The programme choices we make will become part of these forces and will change purchasing realities. They include the power of the seller, new entrants, the power of the buyer (one central point would be ideal), and substitutes. We want to increase the power of the buyer, but how do we get there? What must the buyer do to increase its impact on the market?

Two concepts are critical to understand as we make specification and purchasing decisions - standardization and centralization. Standardization has many advantages to the implementation of a project. It makes training easier, allows lessons learned from one country to be applied to another, and allows standard monitoring and reporting of results. Standardization also affects the way procurement will be conducted. It allows new competitors to more easily enter the market, enables the buyer to switch producers

without needing to retrain medical staff, and increases the volume of the purchase products. If we standardize on the right product, introduction will be much easier.

Centralization of purchasing gives the buyer a strong voice in negotiations and motivates industry to work with the customer because there is nowhere else to sell. It gives control of the product distribution and timing to the purchaser, which can be important when production capacity is limited. It also influences the prices that will be paid.

There are many other things to consider but these two are the most important – standardize and centralize. If these can be accomplished, we will have great control and great reward in the future. Interestingly, these same five forces will apply to the project as it moves from being a buyer of pulse oximetry to a seller of ideas and pulse oximeters.

When this occurs, the project will want to be the monopolistic seller dealing with multiple, weaker buyers with better prices than anyone else. In this setting, there is little competition to sell a product for which a huge demand has been created. Fortunately, we can become both a monopolistic buyer and seller. This will give us tremendous influence over the market.

#### The Clinton Foundation HIV/AIDS Initiative (CHAI) approach to procurement – Maurine Murtagh

The mission of CHAI is to support the rapid expansion of access to high quality HIV/AIDS and malaria care for those who need it by improving the organization of the drug and diagnostics markets and enabling the effective and efficient management of health systems. We pursue our mission through three strategies – access programs, country operations, and special programs. Access programs use business principles to lower cost of and increase access to essential drugs and diagnostics. Our country operations involve partnering with national Ministries of Health to help them achieve their targets for HIV and malaria treatment and to build sustainable public health systems. The third area, special programs, involves several initiatives. The aim of all of them is to develop models that target “hard to reach populations.” This would include rural populations and children, two groups that have difficulty accessing care.

As a former President’s organization, we always work with governments and always at their invitation. Almost everything we do is related to helping them expand access to HIV and malaria treatment and helping them build sustainable systems.

There are many unique challenges in the supply chain for our programs. These are challenges that the Global Pulse Oximetry Project will also face. Referral, regional and district hospitals tend to be located in major cities and towns but once you get below that level, things change. Clinics and posts can be located in very remote areas with poor roads which may even be impassable during certain seasons. Infrastructure also varies significantly. Urban hospitals may have sophisticated labs and instruments while rural

centers often lack electricity, water, or a means for communication. Personal cellular phones are often used as the primary way to communicate.

Data are gathered mostly at the site level. Records are paper-based. The site may report up to a regional center (via paper or phone) and those tallies are aggregated and sent up to a central level. This takes a relatively long time and often prevents these countries from moving from a push system to a pull system for supplies. Human resource capacity is also inadequate.

The typical public health supply chain system in a developing country usually involves the following. Central medical stores (CMS) are the normal place for storing and distributing medical supplies and are often a public entity. Product flows into these sites from a manufacturer and is distributed from these sites to hospitals or clinics using ground vehicles. Data reports generally flow back from the hospital to the Ministry of Health, which will set guidelines, quantify demand, and determine distribution. This is where many challenges lie because while many countries desire a pull system, the lack of data from the site level for inventory and order requirements results in push systems (supplies are sent to areas that may not need them).

For supplier engagement, there are several main concepts to consider. First, potential partners are identified. These include manufacturers who are interested in collaboration, adhere to WHO/FDA quality benchmarks and are capable of manufacturing enough product. Due diligence should be paid to each potential partner. Site visits should be conducted and an understanding of the company's place in the market should be developed. To minimize product cost, the major cost drivers should be identified and unbundled if possible. Areas for process improvements at each level of the value chain should be identified. The impact of increased volume on cost (pricing agreements should generally be volume-based) should also be analyzed. Finally, with price negotiation, make sure a transparent pricing formula is created. Establish a scale curve for future costs and price reductions. Continue to monitor cost as the project progresses.

Regarding pulse oximetry, it may be helpful to consider bundling the price of pulse oximetry with service and maintenance (including replacement probes) because ministries may not have the money to sustain purchasing. If price bundling is not possible, consider negotiating separate service/maintenance agreements beyond the standard warranty period at the time countries procure the pulse oximeters. If possible, negotiate for initial training from the manufacturer, preferably on site. It is also important to make the case with the supplier that there is a strong demand for the instrument in question. Providing a demand forecast for the product over a 2-3 year period is the most helpful information you can give to suppliers. The goal is to demonstrate to the supplier that it should provide the instrument at lower pricing than in the developed world because high volume will be achieved. CHAI utilizes pooled procurement involving regular and aggregate orders. The security of payment from countries comes from secure instruments backing the payments.

### The UNICEF approach to procurement – Ludo Scheerlinck

UNICEF is involved in pulse oximetry procurement because of the importance of pulse oximetry in newborn care and obstetric care. For our program, pulse oximeter specifications were developed in-house and were based on guiding notes and publications from WHO, CDC and MSF among other organizations. Frequent “end-user fit-for-purpose” surveys and market research on potential products and suppliers were also conducted. The chosen specifications were generic and covered technical and functional aspects, spare probes (neonate/infant/adults), a spare battery pack and technical representation in end-user countries. End-user training is also part of the package. Adherence to international quality standards was also verified (supplier: QMS ISO 13485:2003 and product: Safety CE MDD 92/43 or equivalent).

All pulse oximeters and related items are tendered twice per year. Long term agreements with suppliers are established (specific brand or model). The supply solution to end-users depends on funding, direct purchasing from the manufacturer (often at cost in a long term agreement), and specifications. Ninety percent of the procurement is centralized in Copenhagen. Local procurement is much less common. There are few requests for additional probes. The main challenges in this program have been maintenance (this is why the initial supply includes a set of start-up and spare items), tender (different brand selected with every request), and technical assistance.

In 2006, 37 pulse oximeters were procured for \$116,415. In 2007, 59 oximeters were procured for \$167,415. Twenty oximeters were procured in 2008 for \$109,320. During those same years, 365, 1,374, and 334 oxygen concentrators were procured for \$294,500, \$1,014,309, and \$171,675, respectively.

### The Global Drug Facility (GDF) approach to procurement – John Loeber

The Global Drug Facility was launched in 2001 as an arm of the Stop TB Partnership. Our goal is to ensure access to high quality anti-TB drugs at the lowest possible price for countries in need. We have an innovative approach to furnishing the drugs and supplies needed to fully implement WHO’s Stop TB strategy. GDF has provided anti-TB drugs to 90 countries, including 18 of the 22 countries bearing the highest burden of TB. GDF offers a unique package of services. This includes grant procurement services for free provision of drugs to countries that cannot afford them, direct procurement services (countries with insufficient funds and procurement capacity can have access to the same drugs), and technical assistance for purchasing and distribution (provided for in-country drug management and monitoring). GDF unites these three services under one umbrella.

With the direct procurement service, governments, donors and NGOs can purchase TB drugs and diagnostics. Transitional grants for first line TB drugs can also be provided to countries waiting for disbursement of funds from donor agencies. Procurement services are mandated for second line TB drugs to treat multi-drug resistant TB. Emergency grants of TB drugs are also available to countries facing “stock-outs.” A strategic

revolving fund has been created to provide provisional, reimbursable lines of credit for the purchase of second line drugs.

The GDF approach has many advantages. It provides drugs to countries that lack the resources to purchase them. It competitively and transparently contracts procurement agents, manufacturers and service providers and helps countries access TB drugs quickly. There is a single, simple application procedure which allows this to happen. GDF provides, exclusively, drugs that have been prequalified by either WHO, a stringent national drug regulatory authority, or an independent expert committee commissioned by WHO at GDF's request. With this system, GDF can guarantee the lowest prices and timely procurement. It also offers "one-stop access" for first and second line TB drugs and diagnostics.

There are approximately 20 staff members within GDF and they interact with many strategic partners including business advisory committees, patients, national TB programs, suppliers, freight forwarders, insurance agencies, quality assurance agents (outsourced), NGOs and donors from the World Bank, the Global Fund, UNITAID, the Gates Foundation and CHAI. Operating costs are approximately 5% of our 20 million dollar budget.

The procurement process requires each country to submit a grant application to GDF for drug purchase. Countries prepare these applications on their own unless they ask for help. The Green Light Committee (GLC) then reviews the application. If the application is approved, the grant agreement is finalized and procurement is initiated. The GLC Secretariat notifies the project that the application was approved and sends a letter of agreement for the institution's signature. GDF asks the program to fill out a procurement information sheet with information about the drugs and documents needed for importation. An order is placed with GDZ (Gesellschaft für Technische Zusammenarbeit) which subsequently places orders with suppliers, freight forwarders and quality control agents.

It takes approximately five months from the time an order is placed for the drug to be delivered. A buffer stock should be calculated in each procurement order. Countries are advised to place an order to cover drug needs for one year and request delivery in two or more shipments. Primary suppliers receive 65% of the orders, while secondary suppliers receive 35% of all orders.

#### Reactors – Clive Ondari, Florian Nuevo

It might be beneficial to promote the pulse oximetry market from an access standpoint to attract philanthropic participation. Sustainability and end-user knowledge are critical factors. Ensuring that the oximeter satisfies international quality standards is also important because they may be regulated at a national level. Specifications that focus on the robustness of the product must be emphasized. Generic specifications, such as the ones that UNICEF uses, may be a reasonable place to start.

## Open Discussion

Pooling orders can help rationalize the market and reduce costs. This allows countries with more limited resources to become purchasers. For CHAI, it was important to take some risk away from the manufacturer by providing a market guarantee in case demand was lower than anticipated. This required a careful market assessment, particularly because CHAI's budget was not huge initially. With respect to CHAI's experience in HIV diagnostics, Sub-Saharan Africa was used as a model for forecasting in India and China which tend to have much more regulation and often require in-country processes for approval. This can take up 2 years. Some suppliers were willing to take a lower margin of profit because they saw the humanitarian need and also saw a market for them in the future. In CHAI's experience, countries eventually became responsible for the procurement and distribution. Ministries now approach suppliers and tender at a price guaranteed by CHAI.

With respect to UNICEF, central procurement is used and the process is managed by UNICEF -from procurement down to the end-user. Pulse oximetry specifications are maintained at a basic level. Including spare probes and batteries in the initial package was very important because the device repair process is inefficient in many regions. In-country procurement is the preferred option. GDF is not directly involved with the procurement process. Rather, it subcontracts the procurement process and technical considerations to organizations which specialize in these areas.

When considering which model would work best for the Global Pulse Oximetry Project, we must consider the source of funding. If governments will be the main source, the CHAI model of pooled procurement may work well. If donors are the main source, GDF would be an attractive model. If neither governments nor donors will be the main financial source, a UNICEF model may be ideal. China and India may need to be considered separately given their massive populations and the unique circumstances of each government and health care system. In previous projects, these two countries have developed their own processes for purchasing and distribution.

One potential source of donors is physicians in developed countries who appreciate the importance of pulse oximetry and may be willing to contribute to the purchase of oximeters in developing settings. For instance, a system could be created whereby the purchaser of an oximeter could choose to donate additional funds for the purchase of an oximeter in a developing setting.

In summary, there appears to be value in accurately projecting market sizes and pooling procurement if possible. A modest amount of money can also be used for market guarantees to lower the risk for manufacturers. This was successfully used in the purchasing of pediatric HIV drugs, for example. The next point of leverage may involve individuals, such as physicians and their professional organizations, which may be willing to provide donations. A large donor or group of large donors could also be

pursued. Linking pulse oximetry to maternal and child health organizations could provide an additional source of organizational, technical and financial support.

### Summary of the day – Atul Gawande

The amount of surgery is exploding across the world. The goal of the Safe Surgery Saves Lives program is to ensure that surgical morbidity and mortality are minimized in all settings. Universal pulse oximetry will be an important component of this process, and we have already acknowledged its importance by including pulse oximetry in the WHO Surgical Safety Checklist.

Today, we have discussed a tremendous amount of information. Most importantly, I believe we have established that universal access to a low cost pulse oximeter is possible. We have learned about the size of the pulse oximeter market, the critical specifications for a low cost oximeter and several procurement options which have proven successful in other global health programs. Obtaining financial support will be a challenge that we need to address, but with support from WHO, we have the opportunity to enlist help from both governments and donors. There will undoubtedly be hurdles regarding distribution and training, and we will discuss these challenges tomorrow.

### 30<sup>th</sup>, October 2008

#### What distribution, servicing and other facilities are needed? - Susanne Carai

Pneumonia is one of the leading killers of children less than five years old, accounting for nearly 2 million annual deaths (30% of the total number of deaths). Over 5 million children present to hospitals worldwide each year with hypoxemia. Clinical signs for hypoxemia such as tachypnea, cyanosis, grunting and nasal flaring are often unreliable.

Pulse oximetry offers a more accurate alternative for identifying hypoxemia and determining the duration for which supplemental oxygen is required. Thus, oximetry is a very valuable tool, particularly in the developing world where oxygen supplies or concentrators may be limited. A recent study published in the Lancet suggested that pulse oximetry along with oxygen not only saves oxygen and money, but also has a mortality benefit. We now recommend that all children with suspected pneumonia should be screened for hypoxemia on admission and should be monitored at least every 3 hours with pulse oximetry if they are receiving supplemental oxygen. The duration of oxygen therapy should be guided by pulse oximetry.

We have measured the availability of pulse oximetry in three countries – Malawi, Mongolia and Papua New Guinea. In Malawi, 4 hospitals out of 15 had pulse oximetry available on the pediatric wards. Several oximeters were non-functional due to broken sensors. Spare sensors were not available. Twelve hospitals were studied in Mongolia. 33% had oximeters on the pediatric wards, but they were often locked away for

safekeeping. In New Guinea, pulse oximetry was available in all 5 district hospitals due to a program ensuring oximetry availability.

There were multiple barriers to widespread use on the pediatric floors. In some settings, pulse oximeters simply were not present. If they were, the batteries were depleted or the oximeters were kept in locked storage areas. In others, they were present but not used because the equipment was broken and there was no maintenance system in place. In several hospitals, oximetry was not part of the admission evaluation for pediatric patients with pneumonia. Inadequately trained staff was another challenge.

For a hypoxemic child to be successfully treated, several steps must be taken. Hypoxia must be assessed on presentation. Oxygen must be available and accessible. Oxygen delivery equipment must be available and knowledgeable staff must be able to correctly administer oxygen. These steps have proven difficult to achieve. In New Guinea, one study revealed that 22% of seriously ill children with respiratory disease did not receive oxygen on admission because it could not be accessed. In South Africa, another study showed that 39% of rural health clinics had no oxygen.

For effective and sustainable oxygen delivery systems, the pulse oximeter design should be based on acceptable specifications. The method of oxygen delivery – concentrators or cylinders - should be considered. Delivery via nasal prongs needs to be possible. Training of physicians, nurses, and engineers should be included when the devices are delivered. Local suppliers should also provide servicing, maintenance and spare parts. There should be a clear mechanism for ordering these parts. The budget should include spare parts, cost of servicing, and training.

From our experience, pulse oximeters usually have a lifetime of at least five years. Sensors often have a shorter lifespan and because of this, initial delivery should include spare sensors. Oximeters should work on mains power with a rechargeable internal battery with an operating time of at least 8 hours. A basic model should at least display oxygenation and pulse. Models with fewer features (no alarms, no plethysmographs) are currently on the market and are available at relatively low prices (US \$100-300).

To meet the need for improved oxygen delivery systems, the Child and Adolescent Health program and the Essential Health Technology program at WHO have developed a manual – “The Clinical Use of Oxygen” - to share the lessons learned in several countries. Key topics addressed in the manual include the importance of hypoxemia in patient care, issues in the availability and use of oxygen in district hospitals, sources of oxygen, methods for oxygen delivery and the organization of oxygen delivery on the wards.

#### Reactors – Alan Merry, Mobido Dicko

There are several recurring themes mentioned in this presentation. Training, spare parts, and device repair will be critical issues to consider. The oximeter should be designed as a simple machine, although tonal alarms and at least a bar graph display are preferable for

the OR. Perhaps we could collaborate with Child and Maternal Health to help make oximetry available for pediatric patients on the wards.

In previous programs involving vaccines and equipment delivery in the developing world, training and equipment maintenance have proven to be important. For vaccination, in-service training is provided yearly. The first training program is 2 weeks and then for 3-5 days annually. If the program does not return annually, it is difficult to know if the provider is using the equipment properly. Outside maintenance providers are typically more effective than in-house maintenance due to the presence of a contract with outside maintenance groups.

### Open discussion

Since manufacturers have had difficulty obtaining access to the pulse oximetry market in many of the settings we will need to penetrate, we should not rely solely on industry for assistance with maintenance and service. In-country representation by a manufacturer is nearly impossible to achieve given the lack of manpower. One potential solution is the establishment of service centers in each region. The end user should and does (by law) have access to the manufacturer if there are problems with equipment functionality, but it is not feasible for manufacturing representatives to be present in each hospital.

Distributors and subdistributors are present in most countries and may be able to assist with maintenance and repairs. In many settings, they may not be the best option for providing education or training. Working with local biomedical experts may also be helpful. Several manufacturers mentioned that they would be willing to be involved in service and training programs. Delivery of educational modules via the web, CD ROM or flash drives should also be considered. A repair toolkit could be included in the oximetry packaging.

With respect to infants, there is a tremendous need for oximetry. Uncontrolled 100% oxygen is expensive and can be dangerous for infants. A high alarm should be considered (e.g. >92%) to reduce both the risk of blindness and the cost. Several manufacturers indicated that their models could be used for neonates and adults. The sensors are the components that need to be different, although “multisite” sensors do exist and can be applied on either neonates or adults. Sensitivity, however, may not be guaranteed.

Perhaps preset default settings for adults, pediatric patients and neonates could be included. It would be ideal if the user could change settings with the flip of a switch. Including checklists in the oximeter packaging would also be possible according to the manufacturers, especially if it is supported by WHO documentation. The WHO Surgical Safety Checklist and perhaps an OR “hypoxia checklist” or “childhood pneumonia checklist” could be included as well.

What is a potential training model for wide introduction of a low cost pulse oximeter? – Angela Enright

We hope to achieve several goals with the introduction of pulse oximetry. We want to teach the relevant physiologic principles and demonstrate appropriate responses to hypoxemia. We want to provide knowledge regarding the pulse oximetry device and how to care for and maintain the machine. To achieve these goals, we need to focus on physician training programs (practitioners, supervisors, teachers, and leaders), schools for non-physician providers and WFSA training programs as a source of instructors (e.g. train the fellows to teach). There are 20-30 WFSA fellows who are trained annually in 11 centers throughout the world.

We must develop a model that eventually places responsibility into the hands of the local practitioners. One potential training model would be similar to the Primary Trauma Care model where workshops are implemented to “train the trainer.” Once new instructors are adequately trained, they can return to their home institutions and run courses in those areas. Local champions must also be sought out regardless of which type of training program we choose. These programs will need frequent follow up and logistic support to maintain training at a high level.

There are several training modalities at our disposal. Interactive clinical scenarios including role play and simulation are quite effective as many providers are experiential learners. Video and simple print material in native languages could also be effective, although printed materials may be difficult to use given language barriers. Electronic media such as CDs, DVDs, and web-based educational tools are other possibilities that will likely be utilized. Posting hypoxia algorithms in operating rooms is another possibility. Laminated cards with simple use instructions could be included with each oximeter as well. Contact information for local experts who could provide assistance with oximeter care would also be beneficial.

Given the scale of this training program, we will need help. National and regional anesthesia societies should be used as resources. The WFSA has a strong interest in global oximetry and, with its 122 member states, would be an excellent group to partner with. The Foundation for European Education in Anaesthesiology also runs courses in basic anesthesia training. Other international groups such as Operation Smile and Interplast may be interested in collaboration as well. The key concept to remember is that pulse oximetry is a tool that is only as good as the end-user. Proper training is essential to make it effective.

Reactors – Jane Kabutu, Mohammad A.R. Al Dabbas

We must keep several groups of providers in mind when considering training – physicians and non-physicians, providers who have completed training and those who are currently training. Providers who are finished with training (particularly the non-physician providers) may be satisfied with maintaining the status quo and may require

extra effort to reinforce the importance of oximetry. Providers who are currently training may be more likely to view pulse oximetry as a vital part of their armamentarium because they have not experienced anesthesia without pulse oximetry. Collaboration with health ministries and other professional organizations will be a critical part of this process.

Data from six hospitals in Jordan was discussed. Overall, there does not appear to be a significant pulse oximeter gap in the operating room. Each hospital had an adequate number of pulse oximeters to supply every operating room with at least one device. If post anesthesia recovery rooms are included, only 2 out of the 6 hospitals had an adequate number of pulse oximeters. Prince Hamza Hospital was a notable exception. Ninety four oximeters were available for 10 ORs, 9 recovery rooms and 375 hospital beds.

Of note, all anesthetics in Jordan are administered by physician anesthetists. In rural areas, some anesthetics are administered by non-boarded physicians. Anaesthesia technicians who have completed two years of anaesthesia training are allowed to monitor patients during surgery, but cannot administer anaesthesia. Knowledge of pulse oximetry is considered essential, but formal training is a challenge.

### Open discussion

The option to include laminated cards within the oximetry package is an attractive one. Information such as routine oximeter operation or even a hypoxia checklist could be included. It will be important to present this information in a simple, straightforward manner. Allowing local modifications would encourage local providers to take ownership of the information.

The user interface should be a primary consideration when designing the oximeter. Users need to understand how to change the settings and troubleshoot the device. For instance, several Global Oximetry investigators observed instances where an oximeter battery was presumed dead because the device did not immediately recharge once it was plugged into mains. In reality, the device just needed adequate time to recharge and was perfectly functional. However, these devices were not used until the Global Oximetry team was able to educate the providers.

The educational needs will vary significantly in different areas of the world. Our training program should be able to account for these differences by allowing different levels of detail depending on the audience. We will also need to consider “booster teaching sessions” because the ability to sustain a change in practice after one training session may be limited. Manufacturers can ensure that the end-user is educated on the specifics of the device, but the clinical education will be guided almost entirely by the clinicians.

How will we know our intervention is a success? - John Eichhorn

In order to design a pilot study for pulse oximetry, a series of questions must be considered. We need to know what our outcome is. Would closing the oximetry gap alone be considered a success? Most anesthesiologists in this room would probably say “no.” Is hypoxia an appropriate outcome to measure or do we need to measure critical incidents, complications or death? Can process be a surrogate for outcome? In other words, can we assume that if hypoxia decreases, patients will have better outcomes? How would we collect this data? Individual logbooks have been used in previous studies, such as the Global Oximetry study and the WHO Surgical Safety Checklist pilot study.

Would we also collect surgical vital statistics, which include day of surgery and in-hospital mortality rates? This technique has worked well for the Surgical Safety Checklist which was designed as a pre/post intervention study. Will it be possible to differentiate the Checklist effect from the pulse oximeter effect? Would this even be important? Does the research design need to be a pre/post intervention study, or for instance, could we randomize patients to different training programs? Questionnaires, interviews and focus groups with practitioners could help answer questions which are not easily measured in a trial, such as impressions and attitudes toward pulse oximetry. Ultimately, we need to decide whether we want to measure process, outcome or both.

### Open discussion

One potential design model could include 6 to 12 pilot sites where pulse oximetry is made universally available and training is implemented. Instead of relying on logbooks to store information on hypoxia, we could rely on the oximeter to continuously record oxygen saturation data for each patient. This data could eventually be uploaded onto a computer and transferred to the research team. Surgical vital statistics could also be followed. If one could show that the amount of hypoxia decreased over time, one could make the argument that anesthesia care improved and patient outcomes improved.

Is hypoxia a good enough outcome or do we need to show a mortality benefit? Most anesthesiologists agreed that it would be ideal to show an improvement in the anesthesia crisis, complication, or death rate rather than just a reduction in hypoxia. They also acknowledged the enormity of that task which would require many patients and a careful research design. Regardless of which outcome is chosen, we will need to think about how hypoxemia is measured. If oximeters are used to collect and store hypoxia data, we will need to work closely with both industry and providers to ensure a reliable, accurate system for recording the data. The potential for problems with artifact exists but could probably be addressed by industry.

### Meeting summary and closing thoughts - Atul Gawande

We have discussed a lot of material over the past two days. We started by defining the need and value of pulse oximetry. There is clear recognition that pulse oximetry saves lives. It is a safe and essential device for monitoring during surgery. The volume of

surgery provided worldwide is exploding. We may also see an explosion in surgical deaths if we do not continue to improve the safety of surgery worldwide. The WHO Surgical Safety Checklist is a good start, and pulse oximetry is an important part of that Checklist.

The specifications for a low cost pulse oximeter were discussed. We now have a better understanding of what is required for a low cost oximeter to be user-friendly and effective. A starter unit needs to be simple to use and easy to troubleshoot. It should be seen as a culture change device. As patients in the operating room benefit over time, pulse oximetry use will likely spread to other areas of the hospital, such as emergency rooms and post anaesthesia recovery areas.

For procurement, we learned about the models used by CHAI, UNICEF and GDF. Each of these procurement methods has advantages and disadvantages. We will consider each of them carefully as this project progresses. Pooling resources seems to be an effective way of increasing purchasing power but may not be possible in all settings.

Teams not only need to have pulse oximeters available in their operating rooms, but they need to understand what it measures and what to do when a patient becomes hypoxic. Training will be a challenge, but it can be implemented effectively. It will involve teaching at both the national level and the local level. If it can be coupled with a simple hypoxia checklist which includes three or four steps, our ability to change knowledge into behavior may be substantially improved.

Maintenance is also a major part of this program. Providers must know who to contact when their machines fail, the battery dies, or the probe breaks. Ideally, in-country support will be available and will minimize the amount of time that providers must wait for their equipment to be repaired.

To measure the effect of our intervention, we would like to demonstrate that oximetry improves the quality of anaesthesia provision and benefits patients. With implementation of the WHO Surgical Safety Checklist, we are already following day of surgery mortality and in-hospital mortality as part of our surgical vital statistics collection. With the addition of hypoxemia data, we could measure the effects of pulse oximetry and training. A pilot study will be designed over the next several months.

In closing, we would like to thank each of you for attending this meeting. As anesthesia providers, procurement experts, and manufacturers, you have all provided us with critical information. Your assistance will continue to be needed as this project progresses. We are hopeful that your excitement and leadership will help make universal pulse oximetry a reality over the next few years. Thank you.