Surgical Research, Surgical Audit and Safe Surgery

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Rahima Dawood Oration, delivered at the 60th ASEA and 10th COSECSA AGM and Conference, Kigali, Rwanda, 2 December 2009

Mr Chairman, Mr President, Ladies and Gentleman,

I want to thank the Royal College of Surgeons for nominating me as Rahima Dawood Travelling Fellow, the COSECSA council for accepting that nomination, the Rahima Dawood Foundation for their support, and every colleague, surgical trainee, hotel porter, taxi driver or anybody else who made this trip possible and an exciting adventure.

One of the centres we visited on this trip was Nakuru. In 2008 the winner of the Satima prize for essay writing, Rose Njeri Ng’ang’a from Egerton University in Nakuru, in her essay titled “Daring to Live Anew” quoted Jesus Urteaga from his book, MAN THE SAINT, with these words “To be daring means to achieve today what tomorrow’s generation would want ...”. According to this definition nobody was more daring than Rahima and Dawood.

By today’s definitions Rahima would be considered illiterate. Dawood was a brilliant mathematician even though he had had very little schooling. One day Dawood met a colonial official who could only speak English, but it was Dawood who was viewed as the one who was “uneducated”. He then decided that never would any of his children have to suffer such humiliation. He sent his daughter to school, which was unheard of in those days for a Muslim family in Pakistan. The eldest three boys,
standing at the back on this photograph, became lawyers; the younger two became doctors. Today one is a chest physician in Karachi and the other, whom some of you might recognise sitting here at his father’s feet [Figure 1], came to Nairobi in 1961 as a surgeon, where he established himself not only as one of the greats of this society, operating on over 1000 patients per year, but also as a prolific writer and a great philanthropist. This oration is in honour of the bravery shown by Rahima and Dawood, and Yusuf Kodwavwalla.

I owe much to this society. In 1985, while working as a young doctor at Nkhoma Hospital, Malawi, I attended an ASEA regional meeting in Blantyre. I remember three things from this meeting. Firstly Imre Loeffler, another great from this society, gave a lecture on first and second class surgeons, as only he could. I remember how he said that a first class surgeon could operate in a hammock slung between two palm trees and have better results than a second class surgeon operating in the most modern theatre. Until today I remember that, as a surgeon, you can choose whether you want to be herbivore or carnivore. The second thing I remember is a talk about a series of patients with strangulated inguinal herniae, presented by a clinical officer from rural Malawi. Interestingly, those patients who had to wait 6-8 hours for their operations had better outcomes than those operated immediately, probably because they had some intravenous fluid while waiting for surgery. To this day I have retained an interest in critical care. I lead on CCrISP for the Edinburgh College and just a few days ago taught basic critical care to emergency surgery health officer MSc students in Hawassa, Ethiopia.

That evening there was an ASEA dinner at the old Ryall’s hotel in Blantyre. I sat next to Ann Bailey, then in Lusaka, and she said to me that if I was interested in surgery, I should go and get the qualification. I therefore owe it to this society that I decided to become a surgeon. I am not sure that my wife will share in that gratitude. And so, as I returned to the region [Figure 3] to deliver lectures on “Surgical Research and Audit” and on “Safe Surgery Saves Lives”, and met trainees of all levels, I thought to share with you some of the things we discussed:

**Surgical Research**

We firstly defined clinical research in surgery, and used the definition from Penson and Wei: “Clinical research intends to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health. It involves interaction with patients, diagnostic clinical data or populations”(1). I think this is a very good definition because it stresses that in clinical research we still work with patients. We must never forget that.
We discussed the inductive method of Isaac Newton and how we should allow the data to speak for itself. We are not physicists or mathematicians who use the deductive method and come up with a theory that stands as long as you cannot prove it wrong. We also reminded ourselves how important it is to follow Louis Pasteur’s IMRD system (Introduction, Methods, Results, Discussion) to provide structure to designing and reporting research. Pasteur, of course, delivered so much to Africa through developing the first rabies vaccine.

We then walked through the different steps of developing a study proposal:

1. Title: We said that you must continuously ask yourself “What am I working on?”, and stay focused.
2. Contributors: Who will be part of this study and will everybody make an active contribution?
3. Research Question: This is the most important part of the research plan. You must ask “What do I want to find out?”, or “What is the significance of my study?” I stressed that it was important that clinical research must have clinical relevance, i.e. it must make patient care better. It is possible to produce results that are statistically significant but of no clinical relevance. It is my opinion that research that only helps you to get an MMed or, for that matter, a professorship but does not help patients, is self-serving and useless.
4. Background knowledge: We talked about how important it is to study both successful and unsuccessful research in your field of interest, read relevant textbooks and journal papers, discuss ideas with colleagues and then compile 5-10 key references. That way you will be an expert on your topic even before you start your research.
5. Define a Study Group: It is important to consider future patient characteristics when designing your study; i.e. ask again “Will my research add value for future patients?”
6. End Points: You must ask yourself “What outcome(s) do I want to measure?” As surgeons we think of mortality and morbidity, which can be immediate (e.g. post-operative complications), medium term (e.g. cancer recurrence) or late (e.g. disability). There are other important outcomes that are important to patients, however. In colorectal surgery one of our major complications is an anastomotic leak. As a colorectal surgeon I can have excellent leak rates if I do no anastomoses after anterior resection but give all patients colostomies, but my patients will suffer significant disability, poor quality of life, low patient satisfaction and poor quality of care. Another aspect of quality of care is patient safety. It is important that each end point must contribute to answering the research question. Therefore the study design must ensure the end points can be measured and the research question answered.
7. Variables: We discussed different factors that could influence results and how to classify these medically, e.g. sex, age, co-morbidity, surgical detail.
8. Data analysis: Who will analyse your data and by what method? We must remind ourselves that there are many people who work in universities that know much more about statistics than surgeons, and we should ask their help. They will often show us that our data is actually simple to analyse, even though we were flummoxed by it.
9. Feasibility: If we plan for potential obstacles these are less likely to halt the progress of our study. Cost is always a problem, but one can do good clinical audit that improves practice without big expenditure. The one obstacle we always have to face is ethical approval but a simple test is: are you happy to enter either arm of your study?
10. Review the proposal: Lastly we discussed how important it is to get the opinions of your departmental head, educational supervisor, ethics committee and other review bodies; working through their opinions will only improve your proposal.

Trainees often asked me “How will my research be of value?” or “How will I get wider recognition for my work?” Of course all of us want to leave something worthwhile behind. My answer usually is one of the following:

1. If you do research that improve patients’ lives in your own community your research will be of tremendous value, more than you ever can measure.
2. You can do qualitative research.
3. Establish a system of sustainable clinical audit processes in your hospital.

We have referred to the first point, so let us next discuss the other three:

**Qualitative Research**

Qualitative research consists of methods to understand human experience of illness, health and treatments. It explores how patients or health care workers find meaning in illness and health, and how it affects their work, lives, relationships etc. It uses interviews, questionnaires and case studies to explore people's personal experiences. I will discuss one example: for my own educational research I have looked at what characteristics of surgical professionalism are valued most by different groups, namely surgeons, trainees, nurses and patients. Patients view professionalism very differently from us. As surgeons we often think of professionalism in abstracts such as respect, honesty, excellence. Patients think in terms of specifics, e.g. “look me in the eye when you talk to me”, “be prepared to go the extra mile”, “have enough time for me” and “be truthful when you talk to me”. In fact, the only abstract characteristic rated in the top five by any patient group was “approachability”. Qualitative research is very foreign to surgeons as we see ourselves as scientists but it allows us to understand how our patients experience our interventions. We must never forget that surgery is a form of assault and patients find that traumatic.

**Surgical Audit**

It helps to remind ourselves that in Audit we ask “What happens?” and in Research we ask “How” or “Why does it happen?” There are many definitions of clinical audit. The British audit support group defines clinical audit as “a process that improves the quality of patient care through systematic review of care against explicit criteria and supports changes in practice to meet those criteria”\(^2\). As a research tool audit means that you are “assessing individual practices honestly enough to notice differences in outcome and report such data.” It implies that we will be honest when we look at our practice data and recognise what can be improved, that we will be big enough to admit deficiencies and make the necessary improvements, and then audit our patients’ outcomes again. It does not mean that audit has to be threatening. In Quality Improvement Scotland (QIS) we look at multiple datasets in the surgical profiles of all the Scottish Health Boards and as long as a unit’s data distribution lies within the 95\(^{\text{th}}\) percentile, or two standard deviations off the mean, it will be acceptable; this provides wide enough scope for individual variation in practice.

**Safe Surgery Saves Lives**

Safe Surgery is a specific WHO programme to improve peri-operative patient safety, dependent on using an evidence based safety checklist that is completed for each patient [Figure 4]\(^3\).
About 234 million operations are done globally each year. At mortality and morbidity rates of 0.4-0.8% and 3-16% respectively there at least 1 million deaths and 7 million disabling complications worldwide after surgery each year. This makes surgery and its complications a significant public health concern. More people die each year worldwide from surgical emergencies and complications than from malaria. We know that safety in surgery means much more than a single checklist, but include a wide range of topics such as: Patient selection; Patient pre-assessment; Patient preparation; Surgeon’s preparation; Equipment check and maintenance; Anaesthetic planning; Patient positioning on the table; Safe use of diathermy; Safe sharps management; Awareness of allergies (anaesthetic drugs, antibiotics, plaster); Post-op fluids, drugs, pain relief and on-going patient care.

Publication of the trial of implementation of the WHO safe surgery checklist in the New England Journal of Medicine in January this year, however, has firmly established Safe Surgery as a specific concept associated with the checklist\(^4\). It is my opinion that this is the single publication this year that will have the biggest impact on surgery worldwide. We should therefore look at it in more detail. The checklist was trialled in eight centres worldwide, including at St Francis Hospital in Ifakara, Tanzania.

The checklist is based on the WHO’s 10 objectives for Safe Surgery:
1. The team will operate on the correct patient at the correct site.
2. The team will use methods known to prevent harm from administration of anaesthetics, while protecting the patient from pain.
3. The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
4. The team will recognize and effectively prepare for risk of high blood loss.
5. The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk.
6. The team will consistently use methods known to minimize the risk for surgical site infection.
7. The team will prevent inadvertent retention of instruments or sponges in surgical wounds.
8. The team will secure and accurately identify all surgical specimens.
9. The team will effectively communicate and exchange critical information for the safe conduct of the operation.
10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results.
In my opinion the last two points are especially important as it addresses communication, teamwork and recognition of deficiencies, i.e. it addresses non-technical skills. When we assess the results [Figures 5,6] it is clear that the checklist has contributed significantly to decreased morbidity and mortality in all hospitals. In high income countries the impact on mortality has not been so great, but I suspect that this is because resource rich health care systems have much better diagnostic and intensive care systems available to support patients that do get complications and will therefore prevent such patients from dying, unlike in poorer systems where such supporting systems are not available. This study has been heavily criticised in some circles. Though it was not a randomised controlled trial it still provides level 2 evidence; to have randomised aspects of care such as antibiotics administration for indications of proven benefit in a hospital where it had not been used previously would have been unethical. The results were said to be skewed by the outcomes in three hospitals from poorer systems in Tanzania, India and the Philippines. Again in my opinion, if those are the results of the impact of the checklist on hospitals which the majority of the world population depend on, we should embrace such results and act to make the checklist universal.

There are, however, two more important points to make Safe Surgery work in your hospital:

1. Adapt the checklist for local circumstances and get wide “buy-in”. Short 1-2 week PDSA cycles (Plan, Do, Study, Act) allow rapid progress of this process.
2. Success depends on mature non-technical skills, emotional intelligence and good theatre teamwork.

In Dumfries we have adapted the checklist after wide consultation with all theatre users. We felt it was important that the surgeon was already present at the “Sign In”. We felt it was too late to discuss potential critical events regarding the operation, anaesthesia or equipment only after the patient was anaesthetised, and therefore moved these to the “Sign In”. Some of our surgical colleagues had reservations about discussing airway problems or high blood loss in front of patients and we therefore split the “Sign In” in two, i.e. a section to be checked with the patient and a second section that has to be checked at least within the theatre team. With more openness to patients regarding risks of surgery many find it quite acceptable to discuss these potential critical issues in the presence of patients; it has

<table>
<thead>
<tr>
<th>Results – All Sites</th>
<th>Baseline</th>
<th>Checklist</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases</td>
<td>3733</td>
<td>3955</td>
<td>-</td>
</tr>
<tr>
<td>Death</td>
<td>1.5%</td>
<td>0.8%</td>
<td>0.003</td>
</tr>
<tr>
<td>Any Complication</td>
<td>11.0%</td>
<td>7.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Surgical Site Infection</td>
<td>6.2%</td>
<td>3.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Unplanned Reoperation</td>
<td>2.4%</td>
<td>1.8%</td>
<td>0.047</td>
</tr>
</tbody>
</table>


Figure 5
Change in Death and Complications by Income Classification

<table>
<thead>
<tr>
<th>Income Classification</th>
<th>Change in Complications</th>
<th>Change in Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Income</td>
<td>10.3% -&gt; 7.1%*</td>
<td>0.9% -&gt; 0.6%</td>
</tr>
<tr>
<td>Low and Middle Income</td>
<td>11.7% -&gt; 6.8%*</td>
<td>2.1% -&gt; 1.0%*</td>
</tr>
</tbody>
</table>

* p<0.05


Figure 6

been my personal experience that educated patients would rather want to hear that we are expecting 2-3 units of blood loss, e.g. with a difficult pelvic dissection after radiotherapy, and that we have checked that blood will be available during the operation. We have also added venous thromboprophylaxis to the “Time Out” as this is another patient safety indicator.

Over three months of implementation we have constantly monitored usage on a daily basis, and compliance steadily improved from 50 to 90% over this period. Whenever a specific component of the checklist was skipped or when a colleague had problems with using the checklist these problems were addressed individually. As the checklist became “non-optional” the next step was to incorporate it into our theatre integrated care plan. This concept was based on the principles of the SURPASS system, developed in the Netherlands, which consists of a series of checks along different stages of the patient journey.5

The result is a 12 page theatre document that includes the consent form and space for the surgeon, anaesthetist and recovery room staff to write notes and specific instructions for the ward, but also certain “barriers” that have to be signed off before the patient progresses to the next stage of the theatre journey. In our current system we think this is the safest process we could create for theatre patients. This is most probably too extensive for use in most COSECSA hospitals but I would encourage you to support your surgical trainees in a process to develop a similar system and audit its implementation. You can only make surgery safer in your own institutions.

Non-Technical Skills

The idea of a checklist comes from the aviation industry. As RL Helmreich wrote in Scientific American in 1997: “the airline industry was shocked to realise that well trained and technically proficient crews could crash airworthy craft because of failures of human interaction and communication – areas in which neither training nor formal evaluation was required…”7. As a result the aviation industry developed crew resource management training for all flying crews and was followed by other high risk industries such as air traffic control, the nuclear industry and maritime shipping. It is important to realise that “perhaps the most distinguishing feature of high reliability organisations is their collective preoccupation with the possibility of failure. They expect to make errors and train their workforce to recognise and recover from them”. As surgeons we tend to think that we can control everything and think that, as long as we are well prepared and concentrate hard enough, we will avoid errors. Subconsciously we know that is not the case. When we do make a mistake we tend to say “If you do not get complications it means that you do not operate enough”, or
we try to blame someone or something for such errors. We are usually hardest on ourselves and live with our skeletons in the cupboard.

Recognition and use of non-technical skills is a way to accept that we are fallible, but work in a team that can help us recognise and correct for errors before they become catastrophic. A system for non-technical skills for surgeons, NOTSS, had been developed in Aberdeen by Yule et al. In NOTSS surgeons are assessed in theatre in teamwork, situation awareness, decision making and leadership. Of these I think leadership style is the most important. We have all experienced teaching by humiliation and sometimes we perpetuate this process. Surgery has always depended on a very strict hierarchical structure, and maybe the time has come to challenge that. In theatre surgeons usually see themselves at the top of the pyramid, controlling everything, not unlike a good conductor in a classical music concert, but there is no space for improvisation. In many ways surgery is more like a good piece of jazz or blues music, where somebody will be in charge of the tune and rhythm while one of the other musicians does some improvisation or brings in some variation. Because our patients are all individuals with varying anatomy and pathology we need to be adaptable in theatre. This includes listening to the concerns of others, including the most disempowered members of the theatre team. For this reason the first point on the “Time Out” is “Have we all introduced ourselves by name?” In 2002 in Wales a surgeon accidently removed a patient’s healthy kidney. A medical student noticed that the surgeon was operating on the wrong side and after an initial attempt to tell the surgeon was told that she had it wrong; she did not feel empowered enough to push the point9. We must therefore ask ourselves “Am I such a strong leader that I induce fear with demanding respect, or am I open enough that members of my team will make me aware of my potential errors?” I know what type of surgeons our patients would prefer us to be. Firstly, be safe.

The main learning points from the Safe Surgery process therefore are:

1. The Safe Surgery Checklist (SSC) should not stand alone, but be part of a series of safety checks along the patient journey.
2. The SSC will not work without awareness of non-technical skills and a change in theatre culture, especially in hierarchical structure.
3. Using the SSC strengthens teamwork and actually induces culture change in theatre so that team members become more open with each other.

**Why and how should you be involved?**

By implementing the Safe Surgery checklist and monitoring both the process and its outcomes you can:

1. Save lives and lower the risk of complications.
2. Reduce medical costs related to errors.
3. Become part of a supportive international online network of providers and hospitals using the checklist, and even publish your checklist through the WHO website.
4. Participate in a program that identifies your hospital as a leader in patient safety.

**For surgical trainees who wonder about the potential value of their research I want to say:**

1. I believe that doing small scale clinical audit projects in Safe Surgery have the potential to lead to improved patient outcomes in any hospital where such audits are undertaken.
2. Safe Surgery is a universal concept, i.e. research in Safe Surgery will gain international recognition if well conducted and well presented.

**For surgical trainees the other benefits of doing audit projects in Safe Surgery are:**

1. It is cheap.
2. It does not need ethics approval although you still need to write a proposal.
3. It is based on clinical work.
4. It improves practice and patient care.
5. It makes you used to analysing clinical outcomes and reporting these honestly.
6. It takes you away from a “blame culture” for mistakes and teaches you to analyse the cause of errors.
7. It can improve patient safety.

Trainees might wonder what research or audit can be done in Safe Surgery. In my opinion you can look at one of the following:

(a) Audit the process of using the SSC: e.g. How the SSC is implemented and/or accepted; Practical problems in using different parts of the SSC; Developing a protocol for swab and sharps counts.

(b) The effects of the SSC on changing patient outcomes: e.g. on wound infection or DVT incidence; drug allergic reaction incidence; in speeding up the time it takes to get blood to theatre.

(c) Qualitative research on how the SSC affects practice: e.g. How did introducing the SSC affect theatre teamwork or communication, or: How difficult was it to change theatre practice?

It is my plan to support trainees who want to do projects in Safe Surgery. I had applied to the WHO for a grant to fund up to 20 such audit projects in COSECSA units but unfortunately that application was unsuccessful. I am still available to provide educational support, however, and undertake to donate a small prize for the best paper on Safe Surgery that will be presented by a trainee at the COSECSA conferences in 2010 and 2011. For the purpose of such a presentation “trainee” will include anybody in a training position that relates to theatre, i.e. surgical trainees, interns, medical students, nurses or clinical or health officers. Although I plan to use colleagues both in- and outside COSECSA to provide educational support for projects I will be the sole judge of who gets the research prize.

Ex Africa semper alicui novi [cf. Figure 2]

Eighteen months after I sat next to Ann Bailey at dinner I started as a registrar in general surgery at Tygerberg Hospital and Stellenbosch University. In the first few months, while working in ICU, I was looking after a patient who had developed an ilio-femoral deep vein thrombosis after repair of a femoral aneurysm. I walked some path with this patient. Six years later, as a young consultant, I operated on him again for a rapidly expanding abdominal aorta aneurysm. He almost died from cardiac complications because he was an arteriopath. Today this patient would have had an endovascular stent graft for his aortic aneurysm, now the favoured method of repair for such patients in the West. This is fantastic technology, but did you know that the first prototypes of these intraluminal grafts were developed in Moscow and Buenos Aires respectively.

There is a second reason I mention my patient. He was an Afrikaner farmer who had become an Anglican priest. While talking to him on the Saturday during our initial encounter, in walked the then Archbishop of Cape Town, Desmond Tutu. This was shortly after he was awarded the Nobel peace prize. Meeting him has been one of the defining moments of my life. The other day, while preparing my talk “Nobel prize winning surgeons” for the Surgical Society of Ethiopia conference in Addis Ababa, I thought: in spite of all the wars, all the conflict, all the heartache, Africa has produced more than its fair share of Nobel peace prize winners. I think that it is because Africa has retained a certain humanism that is best exemplified by Albert Schweitzer, who was also awarded the Nobel peace prize for his work in Africa, when he said “I could not but feel with a sympathy full of regret all the pain that I saw around me, not only that of men but of the whole creation...It seemed to me a matter of course that we should all take our share of the burden of pain that lies upon the world”.

And I thought, why only for peace...

Is it not time for our trainees to truly produce something new out of Africa, be daring as Rahima, Dawood and Yusuf were, and produce research and audit that truly make surgery safer for all our patients?

References