SAPORG Meeting 28th October 2017 Report

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1.1 Introduction

By Dr Alex Torborg

The second national SAPORG meeting entitled “Closing the Loop” was held at the University of Cape Town Medical School on Saturday the 28th October. Perioperative researchers from around the country attended the meeting. The meeting was live streamed to people in

various locations around South Africa, as well as Prof Rupert Pearse who joined from London.

The first part of the meeting was about the SAPORG research priorities that have been addressed.

Dr Larissa Cronje and Dr Alex Torborg reported back on the South African Surgical Outcomes Study (SAPSOS study). They gave some preliminary results and discussed some of the challenges they faced with this large collaborative study.

Prof Bruce Biccard gave a report back on the ASOS study which was since published.

Following on from the ASOS study, Dr Hyla Kluyts used the data to develop a risk stratification calculator for adult patients coming for surgery in Africa. She discussed how the calculator works.

Part two of the meeting looked at the SAPORG priorities which are being addressed or still need to be addressed.

The national critical care database has taken a long time to develop and should be ready in the near future. Dr Rob Wise discussed how far they have progressed and what some of the issues have been thus far.

Dr Christella Alphonsus presented her PhD study, the BETTER pilot trial which will start recruiting patients soon.

Dr Dorinka Nel proposed her PhD study, a prospective observational study of perioperative outcomes in district hospitals. Everyone offered to support her in this endeavor as it is a massive project.

The ASOS Obstetric substudy results were presented by Dr Dave Bishop.

A proposal for an African Pragmatic Interventional Trial to improve surgical outcomes in adults (based on ASOS) was presented by Prof Bruce Biccard. His plan is to run this study in early 2019.

Dr Salome Maswime presented her proposal for an African (or South African) Pragmatic Interventional Trial to improve surgical outcomes in obstetric patients (based on ASOS Obstetric substudy. She is looking at an intervention to prevent death from postpartum haemorrhage.

This was followed by discussions on the way forward for the following;

1. a stepped-wedge trial of an enhanced recovery after surgery programme for (a) surgery, (b) obstetrics, (c) emergency surgery, and (d) trauma surgery;

2. a stepped-wedge trial of a surgical safety checklist on patient outcomes in SA;
3. Dr Belinda Kusel presented progress realting to short-course interventions to improve anaesthetic skills in rural doctors;
4. studies of the efficacy of simulation training to improve (a) patient outcomes, (b) team dynamics, and (c) leadership; and
5. Dr Alex Torborg presented a short proposal for APSOS: African Paediatric Surgical Outcomes Study.

The third part of the meeting was about 'Closing the loop'. After the national observational studies that have been done, the question was asked regarding how this group would proceed with "Closing the Loop". There was discussion regarding proposals for pragmatic interventional trials to improve perioperative outcomes for South Africa and Africa

Prof Bruce Biccard discussed quality-improvement programmes and whether SAPORG should drive these.

A proposal for an African Pragmatic Interventional Trial to improve surgical outcomes in adults (based on ASOS) was presented by Prof Bruce Biccard. His plan is to run this study in early 2019.

Dr Salome Maswime presented her proposal for an African (or South African) Pragmatic Interventional Trial to improve surgical outcomes in obstetric patients (based on ASOS Obstetric substudy. She is looking at an intervention to prevent death from postpartum haemorrhage.

Dr Larissa Cronje spoke about a South African Pragmatic Interventional Trial to improve surgical outcomes in paediatric patients (based on SAPSOS). This is something that will need to be planned once the final data analysis has been done for SAPSOS.

Some of the issues which were discussed in the last session were:

Getting the Department of Health on board with perioperative research.

Funding – how to get grants and funding for the research priorities.

MRC – getting the MRC on board with perioperative research.

How SAPORG should move forward from now. The possibility of making a board for SAPORG and including a person with business acumen.

How to approach public relations and the promotion of what SAPORG is doing. It was suggested that social media may be useful.

There wasn't enough time to vote for the office bearers. It was suggested that all members get emailed the CVs of the proposed office bearers and voting can take place via email.

This was a great opportunity to see what SAPORG has done over the past three years. Everyone who attended this meeting felt very inspired at the end of the day and very proud of what SAPORG has achieved so far.

2.1 SAPORG Priorities Addressed

2.2 South African Surgical Outcomes Study (SAPSOS) – Dr Alexandra Torborg & Dr Larissa Cronje

Dr Cronje and Dr Torborg gave context to the South African Surgical Outcomes Study. They reported that data on paediatric perioperative outcomes in South Africa was lacking and that it was identified as one of the top 10 national perioperative research priorities, making SAPSOS a logical next step.

Dr Torborg reported that recruitment for SAPSOS started on the 22nd of May and that as of October 2017 they had 43 hospitals, 130 investigators, and 1974 patients in the database. Dr Torborg and Dr Cronje highlighted the locations of the hospitals and showed that a large area of South Africa was not represented in the data.

They shared some of the preliminary data:

SAPSOS Preliminary Data

- Days in hospital median=1 day (0-4)
- Mortality 1.2% (0.7 – 1.7%)
- All complications 8.4% (7.2 – 9.7%)
- Rate of admission to ICU 7.5%

In the provisional data, age, HIV, and pulmonary hypertension were not found to be significant predictors of complications. ASA (with increasing severity), indication for surgery - infective, and major surgery were found to be predictors of complications.

Dr Cronje stated that they were working towards the primary publication for SAPSOS, and that they aimed to have a strong and simple message. She said that they had a wealth of data from SAPSOS and that it would be used for various secondary publications as well.

Dr Cronje and Dr Torborg discussed the primary and the secondary objectives, and outcomes measures for SAPSOS.

Dr Torborg and Dr Cronje then turned their attention to the challenges that are faced by collaborative research studies. They found ethical oversight at the different sites to be a positive thing, because it forced investigators to take responsibility and it also strengthened the protocol, as it had to be accepted and go through the various ethics councils. Getting ethics approval at all the various sites were very time consuming and inefficient. They highlighted the discrepancies in how different ethics councils handled ethics applications and said that this slowed down the process significantly. They also found there were different levels of participation and this lead to missing data.

Dr Torborg reported that the majority of managers were favorable about participating in SAPSOS. Hospitals were generally worried about the time clinicians had to sacrifice to participate in the study, and often enquired whether the principal investigators had resources to support them. Dr Cronje stated that auditing should be seen as a day-to-day responsibility by all stakeholders.

Dr Cronje said that it was expensive to undertake a collaborative research study like SAPSOS. They highlighted the costs of ANSA for the website and the REDCap database and support. They had to do site visits to build relationships to ensure participation in some cases. They stated that despite receiving funding from a JPRF grant, and two government departments that they still had a shortfall. Dr Cronje said that they applied to the MRC for a grant which was turned down and that SAPORG will need ways to get funding from the MRC.

Addressing the issue of resources, Dr Cronje said that physical limitations included that some hospitals didn't have internet access and that their data had to be entered offsite. She also addressed the reality that some investigators were forced to use their own time and resources to complete their data.

Dr Torborg said that departmental heads were very helpful and gave their lead investigators time to complete data collection. She also highlighted that the larger hospitals would have been well served by research assistants who could assist with the data collection, and entry of data into the database.

Dr Torborg and Dr Cronje said that as the principal investigators for SAPSOS that they had to mentor and support SAPSOS participants. The participants in SAPSOS ranged from accomplished researchers in academic departments to inexperienced individuals in smaller facilities where there was often a steep learning curve, and a lot individuals grew a lot from this experience.

Dr Cronje and Dr Torborg underlined the requirement for a change in culture and attitude from all stakeholders in the perioperative research process. There is a dedicated group of collaborators who need more support. There were people who didn't want to participate in another outcomes study with problems ranging from it is taking time away from their clinical work, to the issue of remuneration. It is the belief of the Dr Cronje, that outcomes studies are practical to do and can deliver very important data, and that a shift in culture us required towards audit and research. Dr Torborg and Dr Cronje believe that data from these studies can be powerful in effecting policy changes, which would improve outcomes in the country.

2.3 African Surgical Outcomes Study: Obstetric Cohort – Dr David Bishop

Dr Bishop gave context to why the obstetric cohort was added to ASOS. He stated that from the 300 000 women that died annually in childbirth, 99% were in the developing world, and the majority of these cases were from sub-Saharan Africa.

Dr Bishop says that there are noticeable shortcomings when it comes to the reporting of maternal deaths. He highlighted that civil registration and vital statistics (CRVS), other data sources on pregnancy-related mortality, and other data sources on maternal mortality are often criticized for the underreporting of maternal- or pregnancy-related deaths.

Dr Bishop continued to say that available data was of good quality where systems were good, all data were retrospective, and generally centered around mortality. He said that they hypothesized that the incidence of maternal and neonatal complications following caesarean delivery in Africa is substantial and underappreciated.

The ASOS Obstetric substudy ran in conjunction with ASOS. Like ASOS it formed part of, it ran for 7 days, and only recruited patients who were 18 years and older. Dr Bishop reported that they received data from 22 countries and 183 hospitals. Dr Bishop said that the department of anaesthesia & perioperative medicine at the University of Cape Town wrote a statistical analysis plan prior to the data inspection and analysis. They foresaw a sample size of more or less 3000 patients, whilst this would be sufficient to describe the neonatal outcomes in Africa, it wouldn't contain enough data to create a strong logistic regression model. Dr Bishop says that because they expected a maternal mortality rate around 0.5% and neonatal mortality rate along the lines of 1%, they included specific risk factors into a logistic regression model to ensure that they had between 5 and 10 events per variable. The risk factors were based on tenable predictors of maternal and neonatal outcomes.

Preopeartive maternal complications included in the logistic regression model

- Preclampsia / eclampsia
- Major bleeding risk
- Chronic medical conditions
- Preoperative sepsis

Perioperative maternal complications included in the logistic regression model

- Severe infective complications
- Severe cardiac complications
- Severe obstetric haemorrhage
- Anaestetic complications

Neonatal risk factors included in the logistic regression model

- Two AGPAR scores
- Two gestational ages based on the American Academy of Paediatric Task Force on hypoxic, ischemic encephalopathy.

3792 from the 11422 patients included in ASOS were obstetric cases. 1560 (41.1%) of the patients came from South Africa. These 3792 cases contained 34 serious adverse maternal events, and 20 maternal mortalities. Two-thirds of the patients came from middle-income countries.

2.4 African Surgical Outcomes Study (ASOS) – Prof Bruce Biccard

Prof Biccard said that from the 7 billion surgeries performed globally every year, only about 2 billion are deemed as safe. African data are not well represented in either ISOS or

GlobalSurg data. Prof Biccard said that the burden of disease in Africa diverged from that of high-income countries.

The African Surgical Outcomes study was a 7-day, African, multicenter, prospective, observational cohort study of adult patients undergoing surgery. The recruitment week fell in the period from February to May 2016. Patients were followed up until discharge or 30 days in hospital.

A representative sample was taken from every country. This sample had to include at least 10 centres per country, or at least half of the centres if there were less than 10 centres nationally. The centres had to submit the number of eligible patients during the recruitment week and provide at least 90% of this data for eligible patients.

The primary outcome was to see the in-hospital postoperative complications. Secondary outcomes included in-hospital mortality, and mortality following postoperative complications.

Prof Biccard shared the preliminary results which were embargoed, as ASOS was still awaiting to be published by the Lancet. He said that 25 countries, 247 hospitals, and 11422 patients participated in the African Surgical Outcomes Study. See the table below for preliminary results.

Resources (median [IQR])
880 000 [200 000-2mil] population
6 [2-7] operating theatres
3 [0-7] critical care beds
8 [2-17] specialists (anaes, surg, obstets)
0.7 [0.2-1.9] specialists/100,000
Surgical procedures per hospital for the study week was 29 [10-71]
Patient profile
Young (38.5 years (16.1%)),
Female 66.4%
ASA score 1 [IQR 1-2]
Comorbidities exceeding 10%
Hypertension (16.3%)
HIV (11.0%)
Surgical Profile
Surgical checklist (57.1%)
Caesarean deliveries (33.3%)
Urgent or emergent surgery (57%)

Prof Biccard said that the patients generally had a low-risk profile. They were young with an ASA physical status of either 1 or 2. Hypertension and HIV were the only comorbidities beyond 10%, and over half of the surgery was urgent or emergent. A third of surgeries were major surgeries, and the caesarian section the most common procedure. For a little less than half of the surgeries, no surgical checklist was completed.

Primary Outcomes

Complications occurred in 17.4% of patients included in the primary analysis

Secondary Outcomes

- In-hospital mortality occurred in approximately 2.3% of the cases included in the primary analysis
- Severe postoperative complications occurred in 4.8%
    - From the 4.8% of patients with postoperative complications, mortality occurred in 48.5%
- Postoperative complications increased hospital stay to 6 from typical 3 days.

2.5 Development and validation of a risk stratification tool for SA surgery based on the SASOS data; The ASOS Risk Calculator – Prof Hyla Kluyts

Prof Kluyts started off her presentation giving a quick data comparison between the SASOS data and the ASOS data.

SASOS	ASOS
≥ 16 years	≥ 18 years
n = 3927	n = 5522 / 9024 (in per protocol analysis)
Obstetrics excluded	Obstetrics included
Outcomes available for risk calculation:	Outcomes available for risk calculation:
➢ Mortality	➢ Postoperative complications
➢ LOS	➢ Mortality
➢ ICU admission	➢ (ICU admission)
	➢ (LOS)

Prof Kluyts said that the results from the SASOS study agreed with the ASOS Risk Calculator variables. She said that the ASOS Risk Calculator could be applied to the SASOS data and accurately predict the surgical outcomes.

ASOS Risk Calculator Variables

- Age
- ASA PS category
- Surgery severity
- Surgery timing
- Surgery type

- Primary indication for surgery
- Comorbid disease

Prof. Kluyts showed the scoring for the ASOS risk calculator. She said that a single point depicted a standard increase in risk (0.25 increase in risk in the logistic regression coefficient), equivalent to a 30% increase in the risk of the outcomes being present.

Age	
18 – 40	0
41 – 60	+1
>60	+2
ASA	
ASA 1	0
ASA 2	+2
ASA 3	+5
ASA 4 and more	+8
Surgery Timing	
Elective Surgery	0
Urgent Surgery	+5
Emergent Surgery	+8
Surgery Severity	
Minor	0
Intermediate or major	+4
Surgery Type	
Gynaecology and obstetrics	0
Other	+3
Orthopaedic	+3
Ear, nose and throat	+5
Plastics and breast	+5
Urology	+5
Neurosurgery	+6
Gastro-instestinal and hepato-biliary	+6

Prof Kluyts said that people with a score greater than 15 were at risk for severe complications. She said that severe complications were defined as a composite of in-hospital mortality, and all postoperative complications defined as severe in the consensus statement by Jammer et al.

Prof Kluyts concluded with a proposal that the ASOS risk calculator can be used in a pragmatic interventional trail to improve perioperative surgical care in Africa.

Part two of the meeting looked at the SAPORG priorities which are being addressed or still need to be addressed.

2.6 National Critical Care Database – Dr Robert Wise

The national critical care database (from here-on referred to as the Shield database) has taken a long time to develop and should be ready in the near future. Dr Rob Wise discussed how far they have progressed and what some of the issues have been thus far.

Dr Wise shared information about the structure and the design of the Shield database. Hospitals using other databases can export their data into CSV format which would be easily recognizable for the Shield database. The Shield database is designed with a tiered data

input structure. This allows for multiple levels of data to be stored in the database from most basic, to advanced. This also allows the database to be easily expandable.

Dr Wise reported on the challenges that they encountered with the Shield database.

- He reported that the developer (who was doing the development pro bono) withdrew from the project with it at about 80% complete.
- Inter-systems was approached to quote for how much it would cost to complete the development of the Shield database. This turned out to be very expensive, and they don't have funding for the project at the moment.
- Getting agreement on the minimum dataset.
- Difficult to get national buy-in.

Dr Wise said that possible solutions for these problems are:

- That Jembi Health Systems, who works with Safe Surgery SA on the Perioperatice Clinical Registry can possibly be approached to complete the development.
- Dr Wise said that they can approach financial groups to possibly fund the rest of the development. He also highlighted that it is easier to sell a working system. Dr Wise also mentioned a non-profit organization specializing in online fundraising. Givengain pics projects

2.7 The BETTER (BNP Evaluation to Target thERapy Surgery Trail Pilot Study) – Dr Christella Alphonsus

Dr Christella Alphonsus presented her PhD study, the (BNP Evaluation to Target thERapy Surgery Trial) BETTER pilot trial which will start recruiting patients soon. The trial will aim

Dr Alphonsus highlighted that high-risk patients are most often identified by using self-reported exercise capacity, and the RCRI. These identifiers have limited ability in differentiating patients, especially in the RCRI1 or 2 classes. 60% of the adverse event cardiac cases fall within these classes.

Prospective observational work indicated that BNP improves predictions with a greater area under the area receiver-operating characteristic curve. This caused a net reclassification improvement in the intermediate group by 84%, which means 84% of these patients could be reclassified into either a high-risk or low-risk group.

Dr Alphonsus continued to say that observational work showed that increasing levels of BNP lead to an increase in the incidence of major adverse cardiac events. She said that the cutoff for different levels, provided the treatment framework for the BETTER study.

Dr Alphonsus said that Preoperative NP has a well-established proof of concept for cardiovascular complications.

She said that the connection between high preoperative NPs and major postoperative cardiovascular complications has been validated in a considerable amount of prospective studies. Adding preoperative NT-proBNP to an established clinical risk index, like the RCRI

provides incremental value, by notably improving the RCRI's prediction of major adverse cardiac events.

Integrating NP into the preoperative risk stratification models resulted in significantly more patients being correctly classified prior to surgery. These findings show clinical utility

Dr Alphonsus said that the review of the state of biomarker research in nonsurgical patients stressed the importance (yet lack) of randomised controlled trials which address the utility of biomarker risk stratification to improve patient outcomes through biomarker directed therapy, management and monitoring.

The BETTER surgery pilot trial will be a randomized control trial. Dr Alphonsus said that they wanted to see if we can develop a pragmatic protocol to test if natriuretic peptide directed medical therapy would improve cardiovascular outcomes compared to standard of care.

Inclusion Criteria

1. Age ≥ 45 years of age.
2. Undergoing intermediate or major non-cardiac surgery and overnight stay in hospital.
3. BNP ≥ 100 or NT-proBNP ≥ 300.
4. At least one of the following 4 criteria:
    - History of ischaemic heart disease
    - History of peripheral vascular disease
    - History of stroke; OR
    - Any 3 of the following 7 criteria:
        1. History of CCF
        2. TIA
        3. Type 1 or 2 DM
        4. HPT
        5. Creatinine > 175µmol/L
        6. Age ≥ 70yrs
        7. History of smoking within 2 years of surgery.

Exclusion Criteria

1. Patient refusal to participate.
2. Surgery cannot be postponed for at least 2 weeks.
3. Percutaneous coronary intervention within the last two weeks.

Dr Alphonsus said that patients will be randomized to standard of care or NP directed medical therapy. In the intervention arm if patients have BNP up to 99 or NT-proBNP up to 300 they can proceed with surgery. These are the threshold values for predicting postoperative mortality and adverse cardiac events. Dr Alphonsus said that if a patient's values are greater than this, then they will have uptitration or additional medical therapy.

Dr Alphonsus said that they would look to get BNP levels, and NT-proBNP levels below the threshold value for those patients who have BNP above 250 or NT-proBNP above 900. She said that if patients cannot wait for the levels to be normal that they would at least like to get the BNP, and NT-proBNP below 250 and 900 respectively.

Dr Alphonsus said that they would use the ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 edition in the management of their medical therapy.

Dr Alphonsus said that because it is a pilot study, that their primary objectives are feasibility, determining resources required and compliance with the protocol. She said that they will also keep track in the intervention arm of the duration of time it takes to achieve change in natriuretic peptide levels, percentage change that is achieved and the percentage of patients who responded successfully to changes in therapy.

In the control group data will be collected on the percentage of patients who were optimally managed according to local best practice guidelines.

In the control group data will be collected on the percentage of patients who were optimally managed according to local best practice guidelines. Dr Alphonsus said that the secondary outcomes they will be looking at are the incidence of 30-day mortality, nonfatal MI, nonfatal cardiac arrest, CCF and MINS.

2.8 The State of Anaesthesia in South Africa – Dr Dorinka Nel

Dr Dorinka Nel proposed her PhD study, a prospective observational study of perioperative outcomes in district hospitals. Dr Nel started off her presentation highlighting that South Africa committed itself to the Lancet Commission of Global Surgery's initiative in 2015. Dr Nel stated that whilst some may argue that the SASOS study found reasonable outcomes in South Africa that we still are very much unaware of what is happening in district hospitals, and that the plight of patients who required surgery and didn't receive it is still unknown to us. Dr Nel stated that whilst most people in South Africa may have access to a hospital, that it didn't necessarily mean that these hospitals could perform Bellwether procedures, and that the healthcare providers in these hospitals are often not adequately trained and equipped. Dr Nel pointed out that it would be a meaningless endeavor to just audit a few hospitals, and that this would need to be a country-wide audit. This would help to identify and quantify the extent of the problem, which would inform the biggest priorities at these hospitals. It is also unknown who is providing anaesthesia in these hospitals. Dr Nel realizes that this is a very ambitious task as there are over 350 hospitals in South Africa. Dr Nel highlighted Everyone offered to support her in this endeavor as it is a massive project.

2.9 Should SAPORG drive quality-improvement programmes?

Prof Biccard said that opportunities for quality improvement programmes are common. He said that patients often do not receive evidence-based treatments. He said that quality improvement interventions attempt to change clinician behavior. Prof Biccard said that the intervention in quality improvement research is not to discover the ability to produce the intended result in the intervention, but rather determining the effect of the intervention on behavior change.

Prof Biccard said that there were a lot of opportunities for SAPORG to conduct quality improvement programmes. He said that interventions attempt to change clinician behavior to provide evidence-based care, and that the outcomes of the quality improvement programme would be to determine the effect of the intervention on the behavior change.

Prof Biccard said that when high-quality evidence securely established substantial net benefit of existing therapies, measuring the processes of care may be sufficient to establish the benefit of QI interventions. He said that when the benefits of therapies are less securely established, that measurement of improved patient outcomes is necessary to establish the benefit of QI interventions.

Benefit of QI interventions for established therapies

- Designed to enhance the implementation of proven therapies
    - Improve Population Health
- Use data routinely collected tin clinical practice
    - Safe Surgery South Africa (SSSA)
- Often not always considered research, and informed consent is waived by IRBs
    - May be relatively simple projects

Prof Biccard said that studies that had a low risk of bias and high degree of applicability outside the original research setting are needed before QI interventions are widely spread. Prof Biccard said that QI programmes are context specific, and thus the applicability to other sites should be evaluated before it is implemented at a new site. Prof Biccard said that study contexts included the local environment, processes, resources, leadership, culture and traditions. He said that the context of the QI is also important in considering the acceptability and probability of success of the intervention in different settings.

Prof Biccard said that in South Africa the demand is far greater than the supply, that patients are devoid of the necessary care, and that QI programmes affords the opportunity to provide improved evidence-based care to patients. Prof Biccard asked the SAPORG members which QI projects they would consider priority.

2.10 African Surgical OutcomeS-2 Trial (ASOS-2)

Prof Biccard said that the outcomes research should be done in cycles of observational; and pragmatic clinical trials. He said that the pragmatic trial should be based on the hypothesis generated from the observational work.

Prof Biccard said that safe and affordable surgery is a global health priority. He said that ASOS indicated that low-risk patients, with low complication rates, were twice as likely to die after surgery when compared to the global average. The ASOS data produced the most comprehensive data on surgical outcomes for the African continent. Prof Biccard highlighted the fact that 95% of deaths occurred during the postoperative period, indicating that many lives could be saved with better surveillance of the physiological deterioration amongst the patients who developed complications. Prof Biccard believes that the lack of human resources could be a possible cause of the high mortality during the postoperative period.

Prof Biccard said that the low variation in postoperative morbidity and mortality found in African countries means that a continent-wide quality improvement strategy to provide safer post-operative care may be the best initial course of action to decrease surgical mortality in Africa. Prof Biccard says that he believes that a pragmatic quality improvement strategy to identify post-operative patients at risk of death is required.

He said that a simple risk prediction tool like the ASOS Surgical Risk Calculator could help identify at risk patients who requires post-operative surveillance in resource limited areas. Prof Biccard continued to say that simply giving patients access to surgery will result in unnecessary surgical deaths in low risk patients. Prof Biccard said that safe post-operative care needs to be a priority if outcomes in Africa are to improve.

Prof Biccard proposed the African Surgical OutcomeS-2 Trial (ASOS-2), a cluster randomized trial to determine whether increased preoperative surveillance in adult African surgical patients reduces post-operative mortality.

Primary Objective
To determine whether increased postoperative surveillance reduces in-hospital mortality in high-risk adult surgical patients aged 18 years and over in Africa.
Secondary Objective
To determine whether increased postoperative surveillance reduces the incidence of the composite of in-hospital mortality and severe complications in high-risk adult surgical patients aged 18 years and over in Africa

Study Design
ASOS-2 is an international, multicenter, African cluster randomized trial.
Inclusion Criteria
1. Patients: All consecutive adult patients ≥ 18 years undergoing surgery 2. Participating surgical centres: Randomised (stratified by facility level and case load)
Exclusion Criteria
1. Patient refusal 2. Prior participation in ASOS-2

Prof Biccard showed the study flow design. He showed that participating surgical sites would be randomised into either usual post-operative care or into increased post-operative surveillance. He said that they expected consecutive patients aged 18 years and over admitted to participating centres undergoing elective and non-elective surgery to be included in the trial. Prof Biccard said that the hospital would inform the patient that the hospital is participating in the cluster randomized trial, through notices and signage, and that patients are entitled to opt out of the trial.

Prof Biccard said that he expected the requirement for informed consent to vary according to regulations of the participating nations. He said that the national leaders would have to ensure ethical approval was obtained from their respective countries and centres prior to participation. Prof Biccard said that they would apply for ethics committees to waiver consent, he stated that his reasoning for this was that over 50% of patients in Africa were

urgent or emergent, which may cause a decreased level of consciousness and that this may lead to non-consectutive patient enrolment in ASOS-2 which could cause a biased sample. Prof Biccard said that waiving consent is also common around the world in both interventional and observational research involving time-sensitive procedures. He continued to say that producing biased and poorly generalizable data would not address the research question and would not honour the participation of patients in a resource-limited environment. Prof Biccard said that they believed that the intervention was low-risk and that they would ensure that all patients and their family would be aware that the surgical site was taking part in the surgical trial.

Prof Biccard said that the participating sites will be randomized on the Friday before the first recruitment week. He said that randomization will be stratified according to:

- Level of the surgical facility
- Expected weekly surgical case-load
- Expected mortality of each centre

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2.11 A Pragmatic Intervention Trial The PPH Box Study

Dr Salome Maswime said that intrapartum haemorrhage and postpartum haemorrhage were the leading causes of morbidity and mortality associated with caesarean sections.

She said bleeding before and after caesarean sections is the leading cause of maternal deaths in South Africa. She continued to say that postpartum haemorrage is the leading cause of maternal mortality globally. She said that life-threatening postpartum haemmorhage required immediate attention from a multi-disciplinary team, but that due to resource constraints these roles were often filled by less qualified healthcare workers. Dr Maswime shared research findings that more women died from bleeding after receiving a casearian section, than during the caesarian section. She said that the reason this happened was that the surgical team was better equipped to deal with the bleeding. She highlighted the differences in the following table:

Bleeding during caesarian section	Bleeding after caesarian section
Surrounded by healthcare workers	Alone with timed observations
Multi-disciplinary team	Midwife
Immediate access to fluids	Fluids packed in the ward
Access to essential drugs	Drugs are stored
Surgeon is present	Surgeon has to be called
Only patient	One out of many patients
Emergency blood is available	Blood from the blood bank
Vitals every minute	Vitals checked 30 minutes to 2 hourly
Can immediately do another procedure	Need to wait for theatre availability

Dr Maswime said that in postnatal wards they often become aware of the problem too late. She proposed to do a study where a PPH box will be made available in the post-caesarian section wards. She said that they would compare maternal outcomes with historical

controls. Dr Maswime hypothesised that a box that is easily accessible in the post-caesarean section wards. The box is to be stocked with essential drugs, resuscitation fluids, examination equipment, and a simple decision tree guideline will improve outcomes in women who bleed after a caesarian section.

She said that the idea of the PPH box was to mimic the theatre setting within the ward. She said that it would help with rapid access to essential drugs, resuscitation fluids, a decision tree, suture material, and sterile instruments. She said that the aim of this is to reduce response time, by having all the necessary equipment required to stop haemorrhage in women with massive PPH readily available.

Dr Maswime said that the first phase of the study would be to decide on the design the of PPH box, and content with an expert panel. She said after this there would be a PPH Box which then tests the hypothesis. Dr Maswime outline the next steps in the development of the PPH box study as follows:

Next steps in PPH Box Study

1. Proposals and permissions
2. Funding
3. Expert panel meetings
4. PPH Box Trial

Dr Maswime ended her presentation with the very powerful quote “It is a tragedy when a woman dies because they could not access healthcare services timeously. It is unacceptable for a woman to die because quality healthcare could not be access in a healthcare institution.”

Dr Larissa Cronje spoke about a South African Pragmatic Interventional Trial to improve surgical outcomes in paediatric patients (based on SAPSOS). This is something that will need to be planned once the final data analysis has been done for SAPSOS.

2.12 SAPORG Education

Dr Belinda Küsel said that they had formed a group to share ideas about current medical education and do research on how to improve the training and teaching of perioperative medicine.

Main aims

1. To establish the value and limitations of short course learning
2. To demonstrate an impact of simulation training upon patient outcome

Dr Küsel said that to be able to achieve these goals that they would need to find out what research is already taking place, assess the training needs (especially in district hospitals), and build up the kind of network that can allow multicenter work around all of South Africa.

Dr Küsel highlighted the following obstacles the SAPORG education group encountered:

- The interests and ideas of the stakeholders are very broad

- The Education group does consider simulation as a tool, but the outcomes that they would measure with simulation was the cause of many headaches.
- Where they would get funding, as equipement is very expensive and not freely available.
- It would also take time out of clinical work for them to run courses.

Dr Küsel shared the following structured portfolio of learning:

Structured portfolio of learning

1) Undergraduate Skills
    a) Medical School Anaesthetic Programs
2) Internship Training
3) Basic Skills
    a. MEPA
    b. ESMOE
    c. ACLS/ATLS/PALS
    d. Short Course
4) Focussed Skills
    a. SAFE Paed
5) Specialist Qualifications
    a. FCA(SA)
6) Subspecialist Training
    a. Cert Crit Care
    b. Cert Paeds Anaes
    c. Cert Cardiac Anaes

Dr Küsel said that it was crucial for that the undergraduate platform in anaesthesia to be strengthened. She said that diverging anaesthesia curricula existed across South African medical schools. She said that they needed to standardize undergraduate training, whilst also keeping in mind what undergraduate training is required to ensure that a student would become a successful post-graduate student.

Dr Küsel reported on an intern training study done at Pietermaritzburg where previous interns reported an excessive focus on theoretical training. The interns wanted to get more hands-on practical experience and be more autonomous. She said that a possible study could be done on the development of a national intern curriculum. She said that they believed a structured uniform training curriculum was necessary.

Dr Küsel highlighted the importance of the training of CSOs, MOs and rural doctors. She said that this also creates the opportunity for possible research studies:

Possible studies

- Short course intervention: training for doctors that give anaesthesia after internship
- Simulation training around difficult or failed laryngoscopy/intubation, with a standardized simulation scenario for standard and difficult intubations
- MEPA

Dr Küsel said that it is important to find out what research is already being done and build up a network around that. She said that it was important that training around the country was assessed and that they started doing multicenter research in South Africa.

She said that going forward that they will separate the education into 2 groups, simulation, and short course development. She said that they will try to identify people in both levels. Dr Küsel said that they will need to assess the training needs in South Africa.

2.13 An African National, Multi-Centre Fourteen Day Evaluation of Patient Care and Clinical Outcomes for Paediatric Patients Undergoing Surgery – Dr Alex Torborg

Dr Torborg started by asking the question whether the African Paediatric Surgical Outcomes Study is necessary. She said that they thought it was important. She said that they were concerned that others were doing individual interventions, and that PaedSurg, WHO, and Safe Surgery weren't planning any interventions and that all stakeholders should be approached to build strong partnerships with them. She said that they could possibly build on the foundations and relationships built in ASOS to get APSOS of the ground.

Dr Torborg said that they had concerns with regards to running a study like APSOS, and that they would need finances. She said that they the Medical Council for Research couldn't continue turning their back on perioperative researchers. She shared estimates of what it would cost to run a study like the APSOS study. She said that they would consider employing temporary research assistants.

Finances		
SSSA (ANSA) Website, communication, design data collection tool, etc.		R120 000
Site visits		R160 000
Statistics		R20 000
Research Assistants	R10 000 per month 2 x 6	R120 000
Total		**R420 000**

Dr Torborg said that they would get buy-in from facilities and investigators by having a very basic one page. She also said that they would help large centres with research assistants.

Dr Torborg shared their timelines for the APSOS study:

Timelines

- Protocol write up and submission 0 – 1 month
- Ethics and site approvals 1 – 6 months
- Start of data collection 18 months (May/June 2019)
- Completion of data collection 18 – 36 months
- Data analysis abd write up 36 – 37 months

Dr Torborg concluded that APSOS would deliver powerful data, hasn't been done before and that ASOS had laid the foundations and that APSOS would be the logical next step.

How SAPORG should move forward from now. The possibility of making a board for SAPORG and including a person with business acumen.

How to approach public relations and the promotion of what SAPORG is doing. It was suggested that social media may be useful.

There wasn't enough time to vote for the office bearers. It was suggested that all members get emailed the CVs of the proposed office bearers and voting can take place via email.

This was a great opportunity to see what SAPORG has done over the past three years. Everyone who attended this meeting felt very inspired at the end of the day and very proud of what SAPORG has achieved so far.