IMPROVING OUTCOME THROUGH SAFETY AND KNOWLEDGE

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Outcome after Anaesthesia has been defined as the occurrence of an unanticipated complication or death during or following anaesthesia that may be attributable to an anaesthetic(-Lee: Lum 1996) The spectrum of outcomes may range from minor events such as headache, nausea, to major complications such as myocardial infarctions, strokes and deaths.

It is important to realise that Anaesthesia has no curative or therapeutic value, and therefore to suffer a complication due to that is not acceptable, whatever the circumstances. However complications do occur. The death of Michael Jackson due to the inappropriate use of an anaesthetic drug is such an occurrence. Both globally and locally there are frequent media reports of serious complications including deaths after anaesthesia.

The College of Anaesthesiologists of Sri Lanka started collecting data on critical events which occur in our theatres. Although there has been severe under reporting the analysis of the first 100 reports showed that critical incidents do occur in our theatres too. This analysis showed that most of the problems were due to management of the airway followed by other situations such as pharmacological errors and equipment failure. These events lead to adverse outcomes in nearly 45% of these patients.(Jayasooriya J, Fernando C, Fernando M)
Anaesthetic and surgical outcomes globally show a fairly high incidence of adverse effects. In the USA adverse effects which were 3.3% in 2000 (Institute of Medicine Report) had increased to 19% in 2015. (Claessen 2015). About 400000 preventable death occur in a year, and 37% of surgical patients have complications. In Europe 52% unplanned admissions to the ICUs occur after surgery. In Liberia 140 deaths per 100000 surgeries. In Norway 18.3% adverse effects, Australia 13.2% Switzerland 17%. Globally 3.3% cardiac arrests and 0.9% neurological damage occurs while under anaesthesia. (Fasting 2003, Heller 2007 Beyer 2009) In the UK 5.4 deaths per million General Anaesthetics have been recorded (NAP4 2011) and it has been found that 40% of Anaesthesia related deaths are due to airway problems. (Schiff JH, Welker A Fohr B 2014) However in Sri Lanka, there is a complete paucity of data. In France in 1999 there were 5.4 deaths per 100000 anaesthetics, Netherlands 13.7 in 1995, Australia 1.9 in 2005. Most importantly more than 75% of these deaths were found to be preventable.(Clergue F, Heller G, Scemama J 2011: Staender SP. Mahajan RP 2011)
Causes of anaesthetic morbidity and mortality

- Airway management
- Haemorrhage management
- Central line placement
- Inadequate patient evaluation (38-42% of deaths)
- Incorrect preoperative management
- Human errors (51-77% of deaths)

(Haller, Laroche, Clergue 2011)

As can be seen from the above hazards from anaesthesia can occur due to a variety of reasons and all of them can occur during the practice of a routine anaesthetic.

To improve outcome, outcome needs to be measured and monitored. As said before there is a complete paucity of data on outcome after anaesthesia in Sri Lanka. This lack of knowledge may cause practitioners and authorities to be complacent, with ever increasing danger to patients.

Measurement of outcome

To improve outcome, it needs to be measured first. Outcome can be measured with subjective methods such as patient perception and patient satisfaction and objective methods such as post operative morbidity studies, mortality surveys and audits. Objective methods may be better.

Plan to improve outcome

To improve outcome with an existing system, the system has got to be changed. The faults in the system needs to be identified and a new plan designed and acted upon and tested with if necessary new additions being incorporated. In a medical system, this may mean identifying areas where diagnosis was deficient and could be bettered with the addition of new information. The incorporation of checklists particularly into hospitals where consultant anaesthetists are not available, would improve assessment and delivery of care in an uniform manner.

Pre operative assessment plays a crucial role in preventing peri operative mismanagement and complications. A check list may become useful in this situation too, as it would ensure that all areas are covered in each and every patient and also very importantly make sure that the information is passed over at hand over and change of shift.
This is a sample check list, and after being trialed for over a year has been found to be extremely useful.

During a period of one year with the changing of existing systems, usage of check lists, it was possible to improve outcomes at the centre where we trialed outcome studies.

**PATIENT SAFETY**

Can be defined as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare” (Vincent C 2011)

Patient safety issues can arise from medical errors (Mannut 2002) or medical injuries (Layde 2002)

The patient safety movement of the USA, has made its goal – Zero preventable deaths by 2020. President Bill Clinton addressing the summit in 2015 stated “I believe that the goal of the patient safety movement can be accomplished, and because it can, it has to be done”

Components of patient safety includes,

Product Safety- Which encompasses drugs, devices, equipment, calibration and maintenance.

Services- Anaesthetic Services

Environment- Safe

( WHO regional Strategy)

Safety issues which can arise during an anaesthetic are

1. Identity of patient
2. Site and type of surgical procedure
3. Drugs- Errors, 0.1% -(Haller G 2011)
4. Equipment, safety issues, explosions, malfunction 0.23% (Haller G 2011)
5. Lack of equipment particularly for airway management and monitoring

Therefore to improve outcome and safety several aspects need to be considered

To improve outcome and safety

- Knowledge and skills
- Pre operative assessment and planning
- Outcome data
- Change system
- Availability of required equipment
- Proper functioning of equipment
- Proper intra operative management, under varying patient and surgical circumstances

To improve patient safety the above issues need to be addressed.

Knowledge and skills need to be continuously updated and developed. Regular seminars, workshops, as well as regular clinical practice is essential for this purpose. The College has a major responsibility is addressing this issue.

Inadequate pre operative assessment continues to be an important contributory factor to morbidity and mortality following anaesthesia. Development of a comprehensive check list for this purpose may be a method to improve the efficiency and results of the pre operative assessment. Pre operative anaesthetic clinics may be another method.

Outcome data should be collected, and there should be a willingness and ability to act on those data.

Availability of required equipment, and their maintenance to ensure proper functioning is another important area.

The “Helsinki declaration on patient safety in Anaesthesiology” was a milestone in identifying the importance of safety in anaesthesia. Sri Lanka is not a signatory to this but to the very similar Bengaluru declaration.

The WHO developed the Surgical safety check list to improve safety. This has been adopted by the Ministry of Health in Sri Lanka
In addition the WHO “safe surgery saves lives” campaign aims to
1. Standardise clinical practice
2. Build team work
3. Improve communication
   (Mahajan 2011)

However, although the Ministry of Health in Sri Lanka has adopted the WHO surgical safety checklist, compliance remains poor. It also remains a fact that, although worldwide, the surgical safety check list has had an impact on outcome after surgery, errors due to carelessness, indifference cannot be avoided by check lists.

The World federation of societies of anaesthesiologists has also initiated several steps to improve safety.

Safety and Quality

Aim: To promote global standards in anaesthesiology

Objective 1: To promote and maintain the International Standards for the Safe Practice of Anaesthesia around the globe

Objective 2: To provide guidance concerning the professional wellbeing of anaesthesiologists
However, although the WFSA attempts to maintain global standards, poor quality drugs and consumables continues to plague the anaesthetic and medical practice in Sri Lanka.

### Quality issues with drugs!
**Quality and safety cannot be compromised!**

**Product Recalls**

1. During the year 2011, the market authorization of following products of pharmaceuticals and medical devices were cancelled for a period of one year from the respective dates of cancellation due to continuous quality failures.

2. Sodium Valproate Errectic Coated Tablets 300mg manufactured by Anmolal Sasanka Enterprises Ltd, India (with effect from 04.01.2011)

3. Flumazenil Capsule 0.5mg manufactured by RPG Life Sciences Ltd, India (with effect from 01.02.2011)

4. Promethazine Oral Solution 5mg In 5ml manufactured by B10cal Laboratories Pvt Ltd, India (with effect from 19.05.2011)

5. Disposable Syringe with Needle, 10ml manufactured by Astral Tinkang Medical Products Co. Ltd, China (with effect from 09.07.2011)

After a period of one year, new applications shall be submitted in order to reconsider market authorization for above recalled products.
Equipment issues are another problem in Sri Lanka. Non availability of equipment and malfunctioning of equipment are common issues in Sri Lanka. The relative lack of technical expertise causes major problems during malfunctioning of equipment, causing serious threats to patient safety.

Methods to combat patient safety in Anaesthesiology

1. Improve anaesthesia safety during pre operative, intra operative and post operative periods
2. Human error is a key factor leading to mortality. Development of guidelines particularly directed at the less experienced may be helpful.
3. Poor team work and communication can lead to 43-65% of sentinel events in the ot. Development of team management in crisis situations and simulation teaching may help.
4. Organizational and management factors have been identified as having contributed to 26% of deaths. These consisted of inadequate resources, inadequate surgical scheduling, production pressure, and inappropriate night-call organisation. Development of safety-management systems would help.

Haller G, Laroche T, Clergue F 2011

As said before knowledge and skills to deal with a huge variety of medical factors, surgical factors, surgical requirements, monitoring requirements are necessary to improve safety of patients during anaesthesia.
The WHO states “... “Even if there are financial constraints, it is the responsibility of hospital management to maintain operating rooms and equipment and to provide an appropriate supply of medications and other consumables.”

The WHO has in fact also made recommendations for the equipment necessary for various categories of hospitals. The recommended list for a teaching hospital theatre in the developing world is as follows.

1. Provision to provide anaesthesia (workstation)
2. Anaesthetic ventilator-electrical powered ***
3. Infusion pumps 2*OT
4. Pressure bags for infusion
5. Electrical/pneumatic suction
6. Oxygen analyser ***
7. Temperature probe and monitor ***
8. Electric warming blanket ***
9. Intubating boogie
10. Anaesthetic gas analyser ***
11. Depth of Anaesthesia monitor ***
12. Flexible intubating bronchoscope ***
13. Cricothyroid cannulae ***
14. Capnograph
15. Pulse oximeter ***
16. Peripheral nerve stimulator
17. Nerve stimulator ***
18. Defibrillator

Those marked with * indicate equipment, which are not routinely available in theatres in Sri Lanka. Goal directed therapy, which has been shown to improve outcomes (Pearse R 2005) is not routinely available in Sri Lanka.

Patient safety in Critical Care

This is another area within the purview of the College of Anaesthesiologists and Intensivists of Sri Lanka. The declaration of Vienna, brought into focus these issues.

“The current pandemic of critical illness will spare few and will be part of the dying process of millions of human beings in the forthcoming decades, with an increasing number of patients requiring intensive care as part of their therapeutic plans or end of life care. Given the narrow therapeutic margins for a significant number of the interventions belonging to our field, it is probable that a significant number of patients will be injured and will suffer from the unattended consequences of medical practice” (Moreno RP, Rhodes A, Donchin Y 2009)
An internal jugular cannula gone in the wrong direction.

A dialysis catheter which caused haemorrhage, airway obstruction and death.

A femoral venous cannulation with catastrophic haemorrhage.

SOLUTIONS TO ENSURE SAFETY IN ICU

- TO SUPPORT CENTRALISATION AND INCREASED VOLUME
  Jones J, Rowna K. 1995

- HIGH ACUITY NURSES-PATIENT RATIO IS COST EFFECTIVE
  Van Veld Ch, Blot Si 2008

- CRUCIAL TO HAVE ADEQUATE STAFFING
  Needleman J, Buerhaus P 2003

- ADEQUATE EQUIPMENT / MONITORING
  Valentin 2011
ICU care has now evolved into complex management with, sophisticated equipment and multidisciplinary care.

The situation in Sri Lanka is as follows.

**PROBLEMS IN SRI LANKA**

- Majority low volume <6 beds ICU's (70.8% of ICU's)
- Nursing and staffing issues reasonable (11.5% had less than 1:1)
- Multi disciplines may not be available,
  - Cardiology, (40.6%) of ICUs did not have
  - Nephrology (51%),
  - Haematology, (28.1%)
  - Microbiology, (28.1%)
  - Neurology (43.8%)

Source: Survey report on intensive care units of the government hospitals in Sri Lanka 2012

**IN SRI LANKA AVAILABILITY OF EQUIPMENT**

- Electronic CVP 33.3% of ICUs
- Digital Temperature 34.4%
- 12 lead ECG machine 46.0%
- US machine 5.2%
- ECHO machine 0.2%
- Bronchoscope 3.1%
- NO blood gas machine 32.3%
- Ability to measure Lactate 28.1%

(A survey report on intensive care units of the government hospitals in Sri Lanka 2012)

**IN SRI LANKA**

**Equipment per Bed ICU**

- Ventilator 34.4%
- Cardiac Output Monitoring 4.2%
- Invasive Arterial Pressure 16.7%
- CVP Electronic 12.5%
- Monitor 50%
- Suction machines 24%
- Pulse oximetry 55.3%

(An ICU survey 2012)

These are very poor facilities which need to be addressed soon. With these facilities critical care cannot be provided satisfactorily or adequately and patient safety would be at stake.
To improve facilities in Sri Lanka and to provide optimal ICU care, ad hoc opening up of ICUs should be stopped and ICUs should be designed to proper recommended standards. A functional categorization of hospitals and provision of appropriate facilities would be more beneficial to patients and more cost effective to the government. The minimum bed strength of an ICU should be 6 beds, as evidence has proven them to be more effective. Multidisciplinary input should be available for any ICU in the country.

**LONG TERM OUTCOMES AFTER ICU INTERNATIONALLY**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
<td>56%</td>
</tr>
<tr>
<td>Cognitive dysfunction</td>
<td>45-70%</td>
</tr>
<tr>
<td>Depression</td>
<td>16-23%</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>33%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>20-44%</td>
</tr>
<tr>
<td>Muscular Weakness</td>
<td>28%</td>
</tr>
<tr>
<td>Post traumatic Stress Disorder</td>
<td>27%</td>
</tr>
<tr>
<td>Sexual Dysfunction</td>
<td>43%</td>
</tr>
<tr>
<td>Tracheostomy Sequelae</td>
<td>34-50%</td>
</tr>
<tr>
<td>Weight Loss</td>
<td>68%</td>
</tr>
</tbody>
</table>

(Flatten H 2007)

As with Anaesthesia, there is no data available in Sri Lanka on ICU outcomes.

It is mandatory for data on outcomes after Anaesthesia, Surgery, and ICU to be collected, if we are to scientifically and logically improve our services.

Patients have a right to safety and a good outcome following anaesthesia, and the anaesthetists have a right to have access to adequate resources, safe and high quality equipment, drugs and consumables to provide safe anaesthesia and critical care. It is the duty of the College of Anaesthesiologists and Intensivists of Sri Lanka to facilitate both the above requirements.

This can be done by

1. Collecting data on outcome
2. Taking measures to improve safety and quality
3. Having regular training programmes for advancement of knowledge and development of skills at all grades
4. Regularise the setting up and designing of ICUs and providing the required resources

In doing so, the following have to be done,
1. Attitudes of all stakeholders including patients have to be changed.
2. Awareness among the public about safety during Anaesthesia and Critical care
3. The involvement of all anaesthetists and intensivists
4. The College of Anaesthesiologists and Intensivists to work in collaboration with the Ministry of Health

The current situation in Sri Lanka can be expressed as “Patient safety is not a high priority in Sri Lanka. The sad truth is that in our country when it comes to patient safety, anything goes” Prof. Carlo Fonseka, Sunday Island 29th November 2015

The College of Anaesthesiologists and Intensivists of Sri Lanka in collaboration with the Ministry of Health should develop a “National Strategy for Improving Outcome and Safety following Anaesthesia and Critical Care”.