



SURGICAL LOAN SETS

THE LEGAL IMPLICATIONS

ANDREA HAYWARD 2019

GOOD MORNING



RESPONSIBILITIES



WHY DO WE LOAN SETS?

- ❖ **Rapid changes in techniques.**
- ❖ **Different surgeons require different sets.**
- ❖ **Assets are a liability**
- ❖ **Costs**

ROLE OF SUPPLIER?

- ❖ Inspect sets before dispatching.
- ❖ Make sure end users understand their responsibilities.
- ❖ Ensure that surgeons have been trained in correct handling and management of sets

- ❖ CSSD staff should be trained. This should be confirmed before CSSD person takes on the responsibility of accepting loan sets.
- ❖ When loan sets are ordered CSSD must be informed which sets have been ordered.
- ❖ A loan set checklist must be initiated.

ROLE OF HOSPITAL

- ❖ Enter details of set in loans control book.
- ❖ Include date and type of set.
- ❖ Name of delivery person.
- ❖ Name of receiving person.
- ❖ Name of Company, date and time of delivery.

- ❖ Pack and label set. Remember to add surgeon's name.
- ❖ A form with date and time of procedure AND surgeon and assistants' names.
- ❖ Training of all staff iro. ordering, checking, reprocessing etc.

Background to the problem

- ❖ The operating room (OR) is known to be the most cost intensive environment of a hospital.
- ❖ For various reasons it is also where adverse events are most likely to occur.

- ❖ Because of the cost factor, the preference of surgeons and individualised needs of patients, the use of loan sets continues to increase .
- ❖ Introducing loan equipment increases the risk of equipment related adverse effects possibly resulting in litigation.

Where are my instruments? Hazards in delivery of surgical instruments

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been reported [6, 11–13]. Equipment-related incidents were observed in 15.9 % of surgical procedures [6]. Around 40 % of these incidents were due to the unavailability of equipment [6, 11], mostly instruments, and each

SURGERY BOOKED:

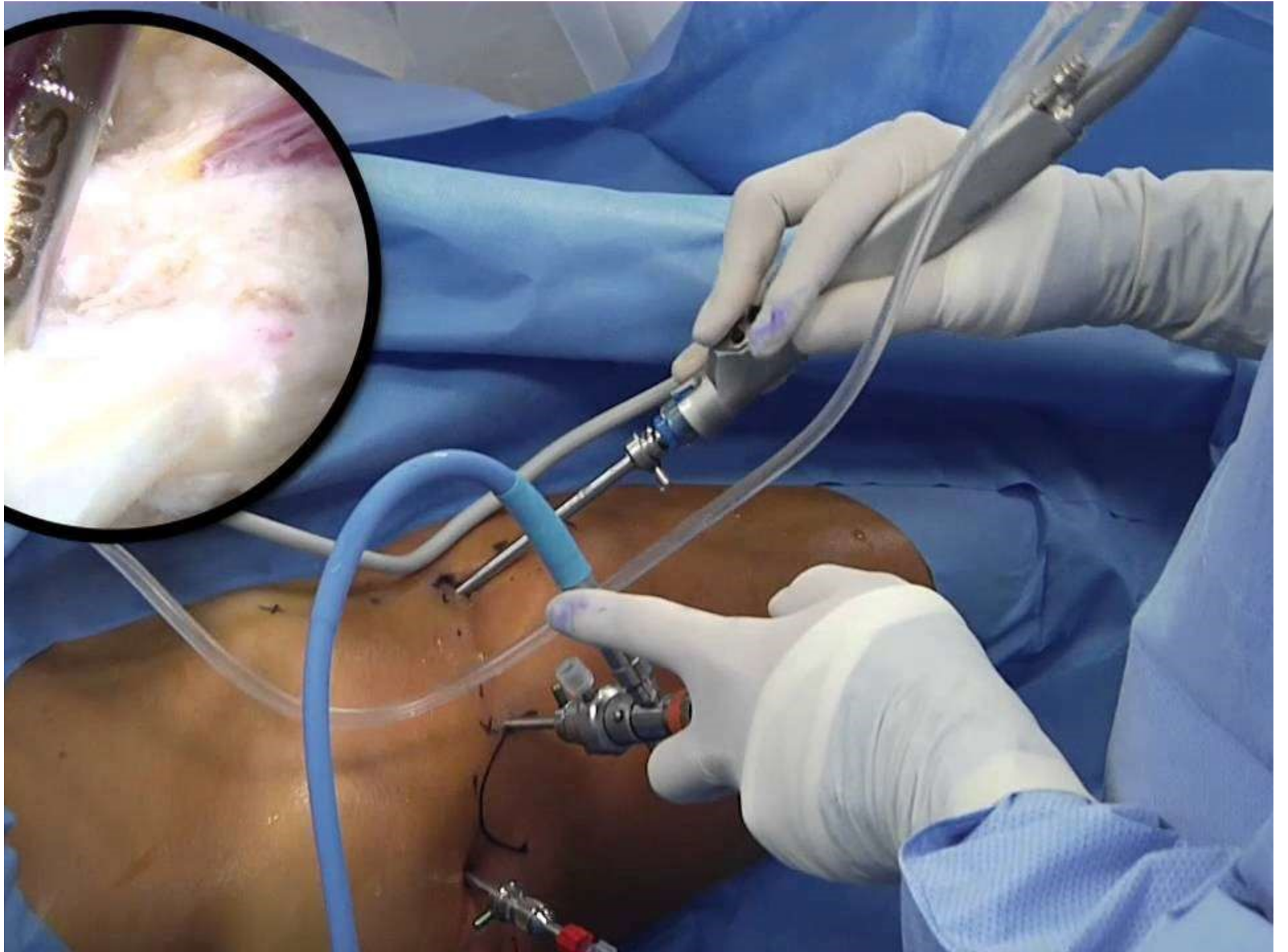
HIP ARTHROSCOPY

Before Use : CSSD Responsibilities

- ❖ **Loan Sets need to comply with a checklist ensuring the contents are correct.**
- ❖ **All documentation is present**
- ❖ **Deliver to the Operating Rooms with the tray list and sterilization records.**
- ❖ **A loan set should pass through a validated decontamination process prior to use .**

During Use : Operating Rooms

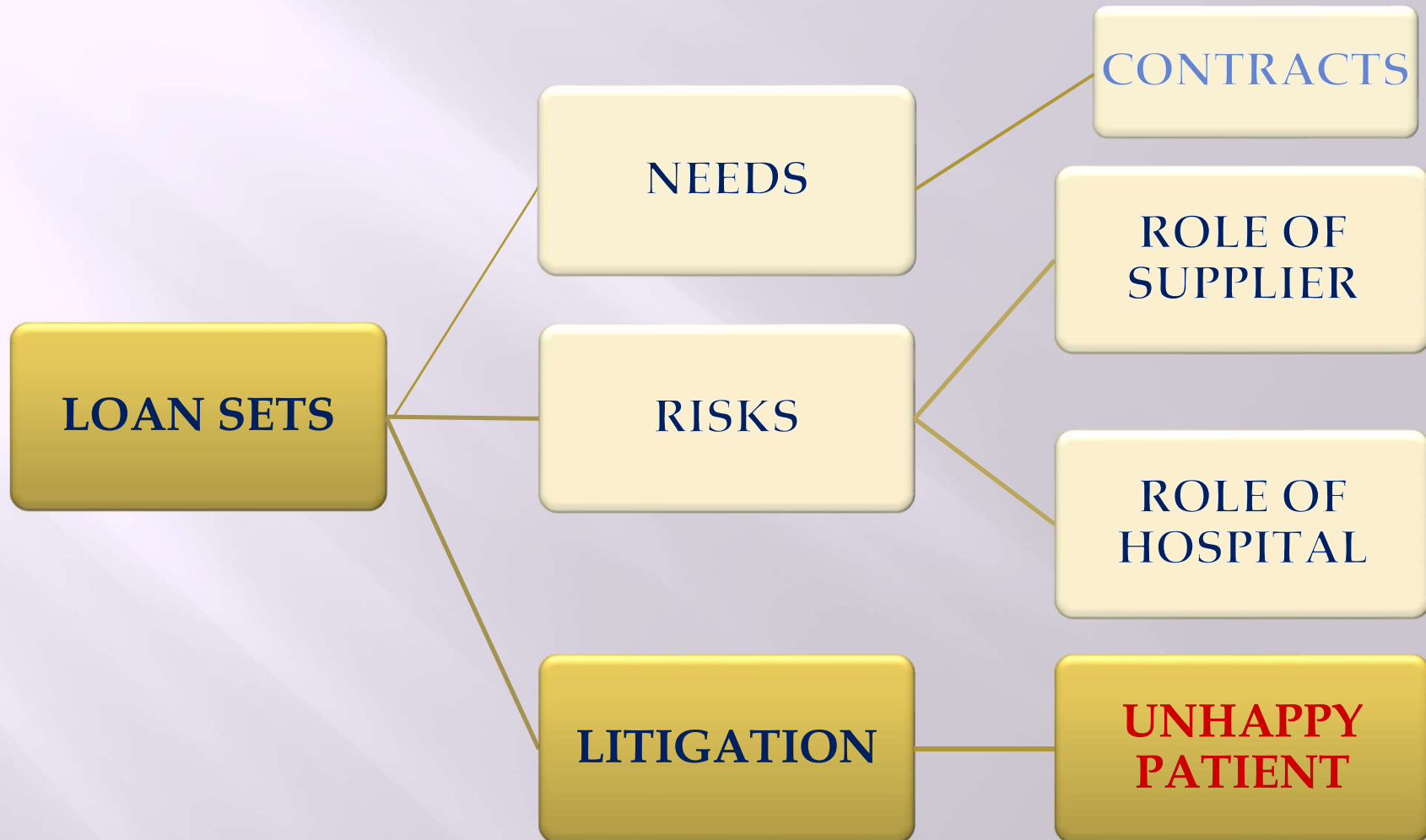
- ❖ All instruments should be checked, counted and documented against hospital list OR count by using the loan set tray list .
- ❖ If not complete notify surgeon.



After use CSSD Responsibilities

- ❖ **Package instruments in original containers for return after cleaning and checking.**
- ❖ **Notify the company when loan sets are ready for collection**
- ❖ **Name of person collecting**
- ❖ **Name of CSSD personnel handing over the loan set.**
- ❖ **Date and time of collection**
- ❖ **Wipe loan set from the board/book.**

RESPONSIBILITIES



ROLE PLAYERS IN MEDICAL LITIGATION

- ❖ **AVOCATE** High Court
- ❖ **ATTORNEYS**
- ❖ **EXPERTS**
 - Surgeons
 - Nurse
 - Commercial Supplier
 - Physiotherapist
 - Occupational therapist
 - Actuaries

ROLE PLAYERS IN MEDICAL LITIGATION

Plaintiff Patient (or family)

Defendant 1 Doctor

Defendant 2 Hospital

LITIGATION

- ❖ Ms Allfal Down works at a supermarket. Whilst stocking the shelves after the shop has closed, she falls and injures her ankle.
- ❖ On the way home she visits the emergency rooms at the local hospital where she is seen by a doctor who straps her foot and sends her home with Panado for pain.
- ❖ The next day, 25/5/16, the pain worsens. She returns to the hospital and is seen by Dr W Dunit, an orthopaedic surgeon.

- ❖ Dr Dunitt will admit Ms Down for an ankle arthroscopy and tells her about the surgical procedure that he will carry out.
- ❖ She arrives at 06:30 on 26/5/2016 as instructed.
- ❖ She went to theatre at about 10:00.
- ❖ When Dr Dunitt does his post surgery rounds he tells Ms Down that the procedure has been successful and he will return later to discharge her.

- ▣ On discharge he tells the patient that due to the unavailability of the required equipment he was unable to carry out the surgery however he has given her a cortisone injection for the pain and swelling. He explains that she should come back for removal of the stitches in a week

- ❖ When Ms Down returns for suture removal she expresses her unhappiness and wants an explanation for having an anaesthetic but no operation. She also wants to know why she has stitches if there was no operation.

❖ Dr Dunitz explains that the staff did not have the loan set as requested. She should not be concerned. She probably doesn't need the surgery now anyway. He has asked the hospital management to investigate.

- ❖ She explains that this is a COID claim (WCA) and on her discharge form it states that she had an Arthroscopy and that is now incorrect. Where does that leave her?
- ❖ Ms Down is unhappy and seeks legal advice.
- ❖ Dr Dunitt is charged with misconduct.
- ❖ An investigation regarding the loan sets is undertaken.

ABC ATTORNEYS

ATTORNEYS IN MEDICAL LITIGATION

BY HAND

Dr WHO Dunitt

Hospital: Mountain view

Our Ref: WD/MM/sdw/AD67

CHARGE

That you are guilty of unprofessional conduct or conduct

your profession. is unprofessional

patient, Ms All

debridement yo

1.0 Comn

(a)

(b)

2.0 failed or

the guid

1.0 Commenced surgery without adequate preparation in that-

(a) You failed and/or neglected to ensure the availability of equipment required, AND /OR

(b) You failed and/or neglected to ensure functionality of available equipment.

2.0 failed or neglected to comply with the standard of safe care by not adhering to the guidelines laid down by the Surgical Safety Checklist.

ABC ATTORNEYS

ATTORNEYS IN MEDICAL LITIGATION

BY HAND

Dr WHO Dunitt

Hospital: Mountain view

Our Ref: WD/MM/sdw/AD67

CHARGE

That you are guilty of unprofessional conduct or conduct which, when regard is had to your profession, is unprofessional in that on or about 26 May 2016 and in respect of your patient, Ms Allful Down, who had been admitted to undergo an ankle arthroscopy and debridement you:

1.0 Commence

(a) You

requ

(b) You

equip

(a) You failed and/or neglected to ensure the availability of equipment required, AND /OR

(b) You failed and/or neglected to ensure functionality of available equipment.

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COMPANY A DELIVERY NOTE

Number: 60224

Invoice: 1111.6286

Delivery details: Hospital Mountainview Clinic

Procedure date: 26/05/2016

Time: 1030

Surgical sets: Endo - small joint

Joint shaver

Doctor: Dr Who Dunnitt.

Order Information

Date: 24/05/2016

Ordered by: Mr Crow (Clin Tech)

Contact number 27 19 506 6237

Patient : Ms Allfal Down

Checked by : C Reps Print name C Reps Date: 24/5/2016 Time 1730

Received by: Sarah Print name Sarah Date: 24/5/2016 Time 1730

Serial number	Description	Quantity
103327	SMALL JOINT INSTRUMENT SET	1
671824	SMALL JOINT POWER MINI SHAVER	1

Returned	Date: 26/05/2016 (15:00)	Quantity
Serial Number		1

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PERIOPERATIVE FORM

Patient Name: Ms A Down

Operation: Ankle Arthroscopy and debridement.

Date: 26/5/2016

Surgeon: Dr W Dunitt

Anaesthetist: Dr Snooze

Scrub Nurse: A Crow (Clin tech)

Floor Nurse: B Smart E/N

Time in: 1035 **Time out:** 1100

Swab count: Correct

Instrument count: Correct

Loan sets: Checked / Correct

Registered Nurse: _____

Anaesthetic Nurse: _____

RECOVERY ROOM

Patient Name: Ms A Down

Operation: Ankle Arthroscopy and debridement.

Date: 26/5/2016

Surgeon: Dr W Dunitt

Anaethetist: Dr Snooze

Signature.....

Signature.....

Recovery room nurse 

Time in: 1105 **Time out:** 1120

Awake and vitals stable. Return to ward.

ABC ATTORNEYS

ATTORNEYS IN MEDICAL LITIGATION

BY HAND

Dr WHO Dunitt

Hospital: Mountain view

Our Ref: WD/MM/sdw/AD67

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SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▶▶▶▶▶▶▶▶▶▶ Before skin incision ▶▶▶▶▶▶▶▶▶▶▶▶▶▶▶▶▶▶▶▶ Before patient leaves operating room

SIGN IN
<input type="checkbox"/> PATIENT HAS CONFIRMED <ul style="list-style-type: none"> • IDENTITY • SITE • PROCEDURE • CONSENT
<input type="checkbox"/> SITE MARKED/NOT APPLICABLE
<input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED
<input type="checkbox"/> PULSE OXIMETER ON PATIENT AND FUNCTIONING
DOES PATIENT HAVE A:
KNOWN ALLERGY?
<input type="checkbox"/> NO <input type="checkbox"/> YES
DIFFICULT AIRWAY/ASPIRATION RISK?
<input type="checkbox"/> NO <input type="checkbox"/> YES, AND EQUIPMENT/ASSISTANCE AVAILABLE
RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
<input type="checkbox"/> NO <input type="checkbox"/> YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT
<input type="checkbox"/> CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE
<input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM <ul style="list-style-type: none"> • PATIENT • SITE • PROCEDURE
ANTICIPATED CRITICAL EVENTS
<input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
<input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
<input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?
HAS AN ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
<input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE
IS ESSENTIAL IMAGING DISPLAYED?
<input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE

SIGN OUT
NURSE VERBALLY CONFIRMS WITH THE TEAM:
<input type="checkbox"/> THE NAME OF THE PROCEDURE RECORDED
<input type="checkbox"/> THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
<input type="checkbox"/> HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
<input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
<input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

SO WHO IS GUILTY?

IS THE DOCTOR GUILTY OF POOR CONDUCT?

DOES ANYONE ELSE SHARE GUILT?

COST OF LITIGATION

■ UPDATED 17 APRIL
2018
Medical malpractice
litigation: Undermining
South Africa's health
system
*South Africans are
becoming increasingly
litigious, with not only the
number of claims rising but
also the size of the claims.*

"explosion" by previous
Health Minister, Dr
Aaron Motsoaledi,

was reported that Gauteng Health
Department alone had paid out at
least R1 billion in lawsuits since
January 2015, while the Eastern Cape
is facing payouts of R14 billion.
The Medical Protection Society SA
(MPS), in 2015 settled a claim of
almost R24 million on behalf of a
member

CLOSING COMMENTS

Procedures & checks in place but not adhered to.
Tracking system is NB.

How many boxes in loan set.

Do scrub staff know how it works?

If we dont adhere what then?

Pt didnt understand op. Would always be a
wound with a stitch

REFERENCES

- ▣ CSSD Forums of South Africa Decontamination and Sterilisation. Standard Operating Procedures 2018.
- ▣ Habraken MM, Van der Schaaf TW, Leistikow IP, Reijnders-Thijssen PM (2009). Prospective risk analysis of health care processes: a systematic evaluation of the use of HFMEA in Dutch health care. *Ergonomics* 52:809–819.
- ▣ Annetje C. P. Gue´don; Linda S. G. L. Wauben; Anne C. van der Eijk; Alex S. N. Vernooij; Frederique C. Meeuwssen; Maarten van der Elst; Vivian Hoeijmans; Jenny Dankelman; John J. van den Dobbelsteen. Where are my instruments? Hazards in delivery of surgical instruments. *Surg Endosc* (2016) 30:2728–2735
- ▣ SAMED Device Code of Ethical Marketing and Business Practice. (2018) 7-15

