Principles of Tracking/Traceability

Its our last line of Defence!

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Disclaimer

This presentation is my personal interpretation for education purposes only and not related to my employment.

This presentation is to promote continual improvement and expresses the need for concise guidance to all stakeholders within the Decontamination industry.

What's your interpretation?

Why should we put tracking and traceability systems in place when we decontaminate medical devices?

Reasons for Decontamination:

- To protect the patient from disease/death
- To protect staff from disease
- To protect staff from litigation/dismissal
- To protect the organisations reputation/ prevent financial liquidation

Decontamination
The Challenge?

- Decontamination is a combination of processes, including cleaning and disinfection and/or sterilization, used to render a re-usable item safe for further use.

- Effective decontamination requires the attainment of acceptable standards at all stages of the life-cycle.

- Do we record all stages within the life-cycle?
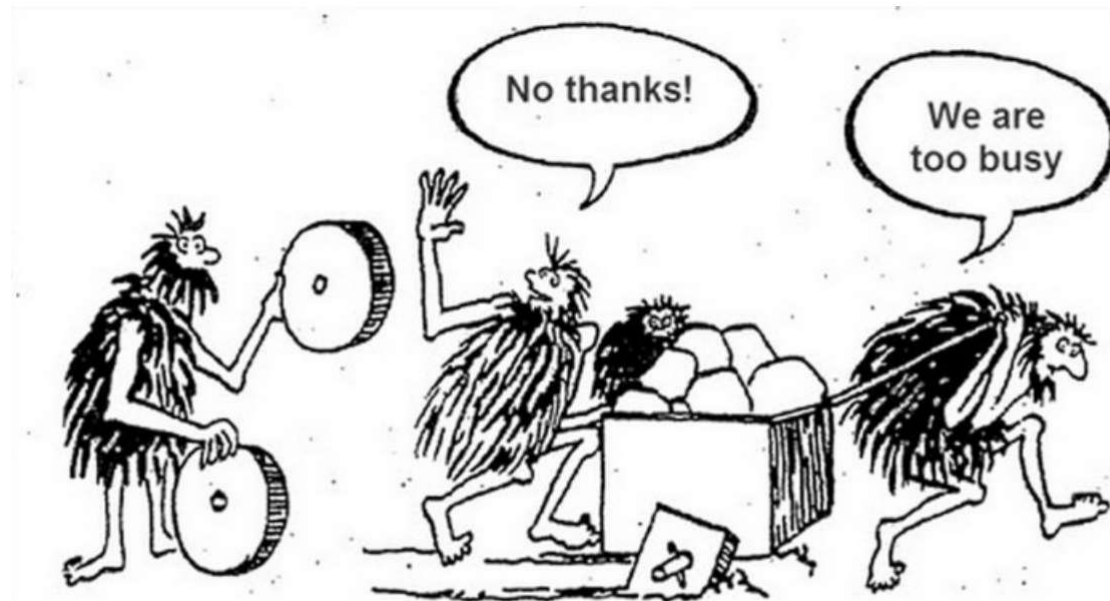
Decontamination Life Cycle
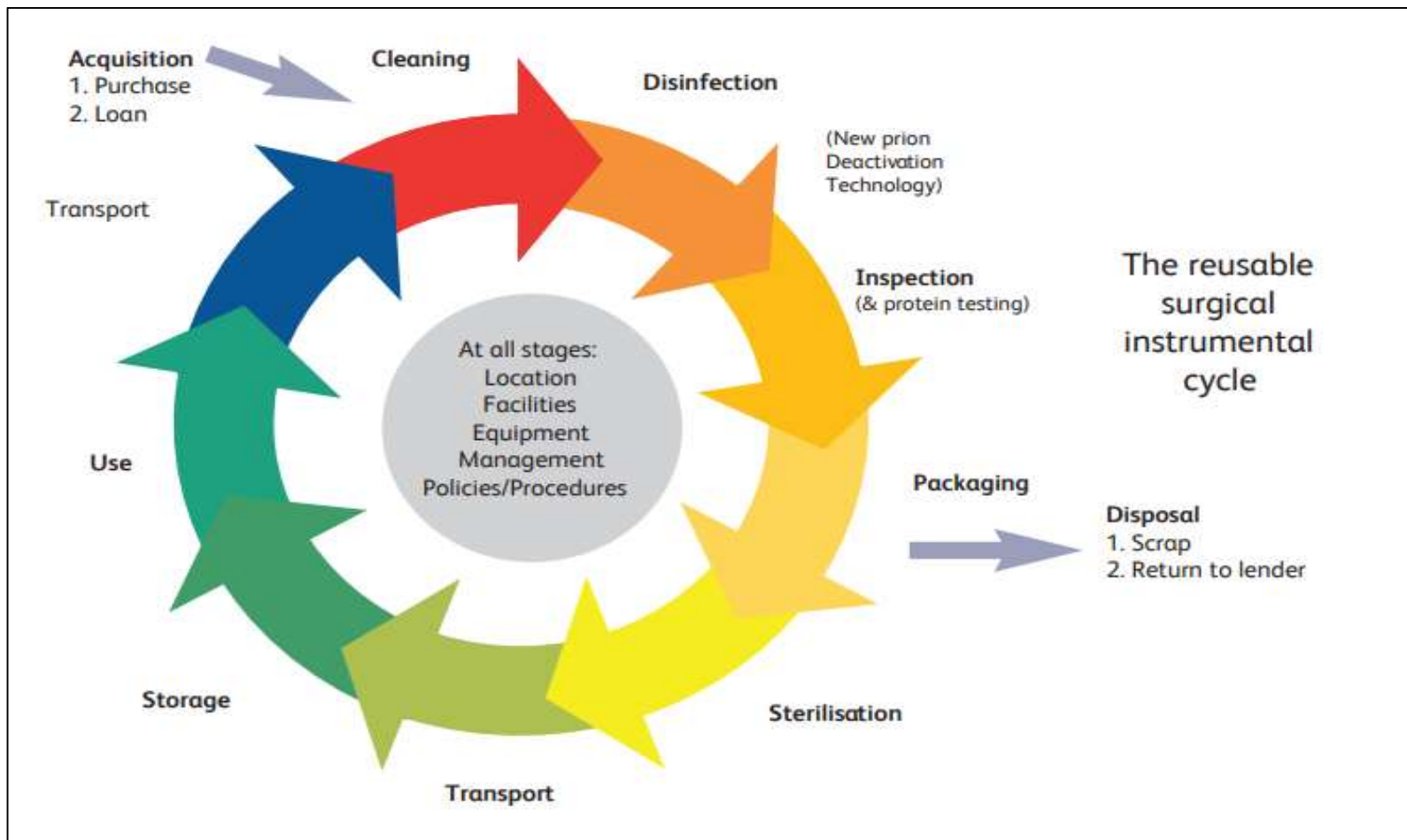
Can we guarantee decontamination systems?

- Do we ever fail?
- Do we have incidents of infection?
- Do we have deaths?
- Do we need to meet the legislative requirements?

Decontamination

We will be fine, it won't happen to me?

Incident Example 1

18th August 2011

Patient killed by contaminated equipment

Group A streptococcus infection

A national review into anaesthetic procedures has been called for after a patient died from contaminated equipment.

Jacqueline Thomason was admitted into the Wigan Infirmary on the 29th March 2010 for routine surgery to remove part of her thyroid gland.

The day following surgery she was discharged as planned, but hours later she returned to hospital with symptoms of the Group A streptococcus infection.

Doctor's were unable to save Mrs Thomason, and she died five days later.

An inquiry into Mrs Thomason's death found that cross contamination had taken place in an anaesthetic room.

Incident Example 2
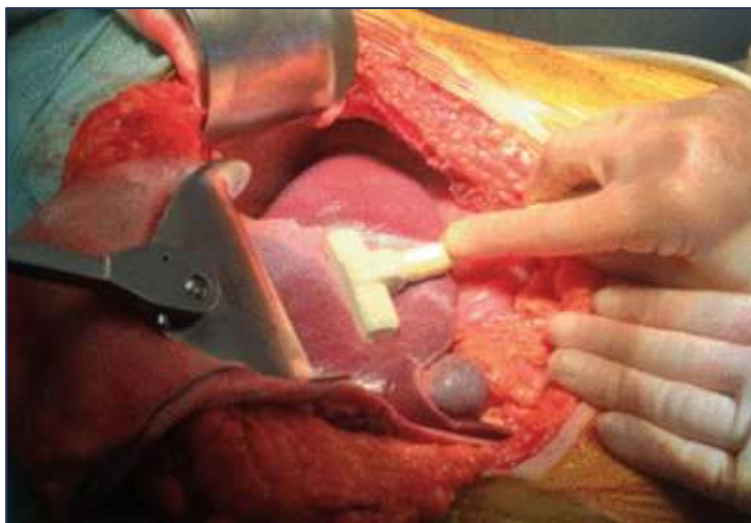
Outbreak of *Serratia marcescens* attributed to ultrasound probe used in digestive surgery ward

8/9 patients who came into contact with the contaminated probe were infected, most of them were being treated for cancer.

Traceability records as well as medical files and coding data from hospital archives, microbiology laboratory and hospital pharmacy helped identify previously missed cases.

Incident Example 3
Value of traceability

A recurrent outbreak of postoperative infections

Cases were defined as cardiac surgery patients in Ghent University Hospital

Three separate outbreak episodes occurred over the course of 9 months. A total of 8, 4 and 6 patients met the case definition, respectively. All but one patients developed a clinical infection, deaths were reported.

A limitation of this investigation is that we were not able to assign specific TEE probes to cases on a one-by-one basis because of incomplete documentation and under-registration of TEE examinations.

Prompt implementation of a system for full traceability was a major demand of the management board of the hospital when the third outbreak episode occurred.

Legal Requirements

- Under UK Law, it is an offence to cause harm to any person or any persons property.

- Should you be confronted with an accusation, you will need to prove that you took all reasonable steps to manage or reduce the risk.

- As a producer you will be responsible and liable for the performance of the device that you have prepared for use.

Legislation

- Consumer Protection Act 1987:
  - Part 1 implements EU Council Directive 85/374/EEC (product liability) providing compensation to be paid to persons injured by a defective product. There may also be civil liability violations with payment for damages.

- Health and Safety at Work Act 1974
  - Section 3 makes it a criminal offence if a Trust fails to conduct its undertaking in such a way as to ensure that patients are not exposed to health or safety risks. This is a very high standard of care with a reverse burden of proof (i.e. it is for the Trust to prove that it did take all reasonably practicable steps). (Sanction: Unlimited maximum fine).

- Criminal Offence of Manslaughter:
  - If a patient dies as a result of an infection passed on through inadequately decontaminated surgical instruments, then the criminal offences of manslaughter (for individuals) and corporate manslaughter (for Trusts) could also apply.
  - Although a very high hurdle - "defendant's conduct was so bad, in all the circumstances, as to amount to a criminal act or omission"

Health Act

- Health Act (England)

- Code of Practice for health and adult social care on the prevention and control of infections and related guidance
- 'Policed' by the Care Quality Commission
- Purpose of Code to minimise risk of Infections.
- Code not Law but Trusts/Boards etc. must show they comply or better.
- What's the best way to provide evidence of compliance?

How do we compare with other Industries?
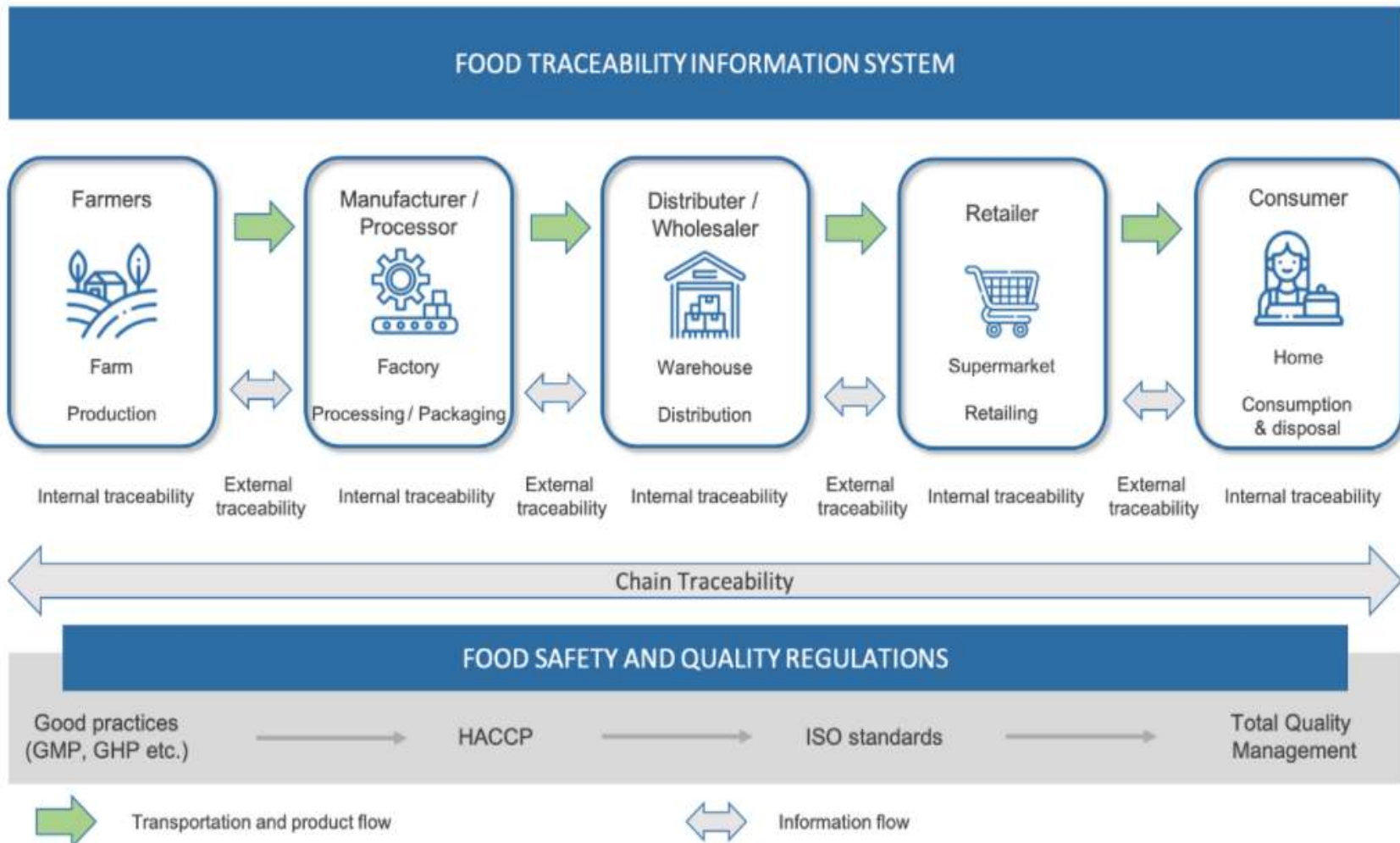
The Food Industry

Food traceability is the ability to follow the movement of a food product and its ingredients through all steps in the supply chain, both backward and forward. ***Traceability involves documenting and linking the production, processing, and distribution chain of food products and ingredients.***

Ref' US Food and Drug Administration

The Food Industry

In the case of a foodborne illness outbreak or contamination event, efficient product tracing helps government agencies and those who produce and sell food to rapidly find the source of the product and where contamination may have occurred. ***This enables faster removal of the affected product from the marketplace, reducing incidences of foodborne illnesses.***

Ref' US Food and Drug Administration

Healthcare Systems

As Healthcare professionals, are we taking traceability as seriously as the food industry?

Tracking/Traceability

- Tracking or traceability refers to the collection of medical device identifiers, reprocessing information and then linking this to the patient record.

- Traceability is essential in an outbreak investigation to determine the extent of patient notifications and device recalls. In a non-outbreak setting, it allows a facility to demonstrate they meet their duty of care to patients and for healthcare accreditation purposes.

- Records should be kept for a period of time specified by the national requirement, or legal considerations. If not specified, record retention should be determined in conjunction with the facility's risk management and infection prevention and control committees.

Tracking/Traceability Options

- Manual and/or Electronic?

- What do you think?

- Are you confident you can defend in the event of a clinical incident?

Manual System

- Log Book to record information
- Often accompanied by manual decontamination process
- Appropriate retention of data?
- Can we read the information (human factors!)?
- Can we find the information in >5 years
- Storage space is critical
- Department refurbishment
- Audit of trace-ability information – challenging?
- Damage in event of flood/fire etc.

Manual System

Hybrid System

- Mix of manual and electronic systems

- Often accompanied by scanning information into notes

- Are systems set up by dedicated officers?

- Can be confusing, leading to missing information.

- Audit – can be challenging

- Machine information present, but no preclean information?

Electronic System

- Dedicated software used – designed for purpose
- Life cycle traceability can be achieved with hardware
- Configured to sit on a safe server
- Easy to recover information
- Paperless (sustainable)
- Can be integrated with equipment software
- Ease of audit
- Capital investment, quick payback in event of incident

Electronic System
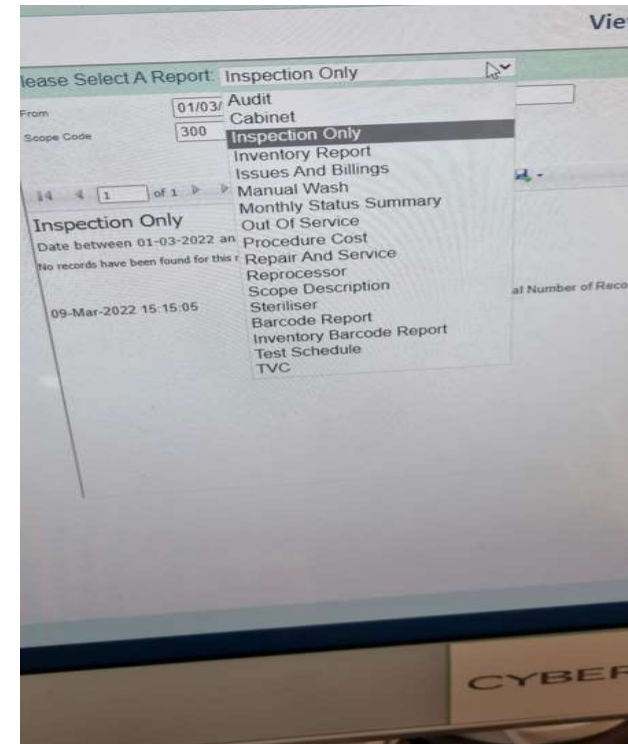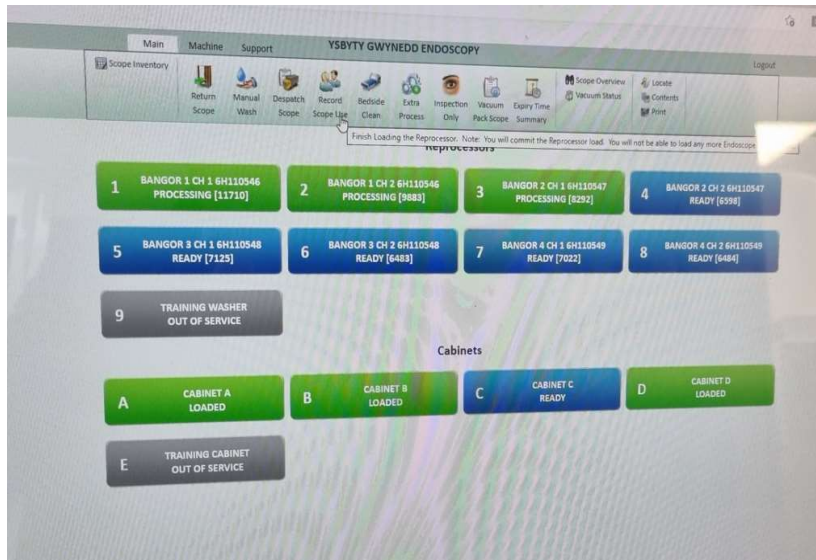
Tracking/Traceability within Ultrasound use.

Ultrasound probes are used throughout many hospital departments. During use ultrasound probes can contact a range of patient tissues, including sterile tissue, the bloodstream, mucous membranes, non-intact and intact skin.
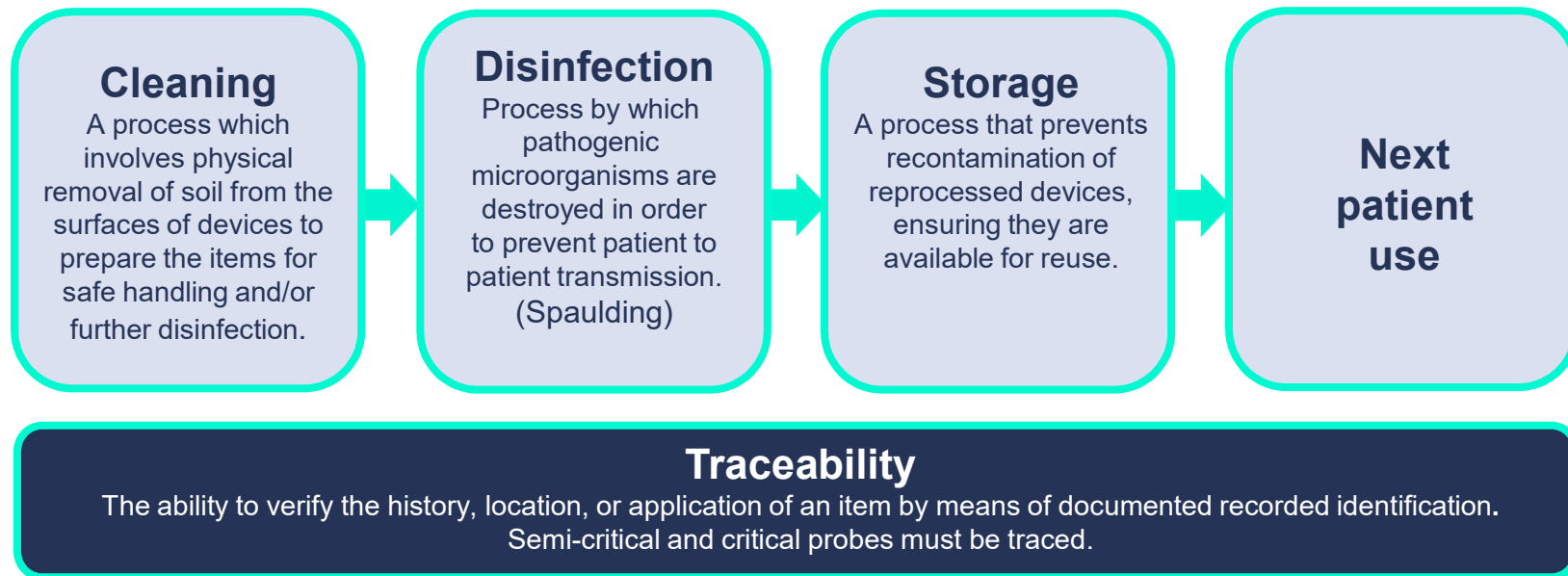
Appropriate probe reprocessing according to the intended use of the device is essential to help protect the next patient from infection risk.

Are the risks any less than any other medical devices?

Stages of ultrasound probe reprocessing

Each step is important to help keep patients safe

Cleaning
A process which involves physical removal of soil from the surfaces of devices to prepare the items for safe handling and/or further disinfection.

Disinfection
Process by which pathogenic microorganisms are destroyed in order to prevent patient to patient transmission. (Spaulding)

Storage
A process that prevents recontamination of reprocessed devices, ensuring they are available for reuse.

Next patient use

Traceability
The ability to verify the history, location, or application of an item by means of documented recorded identification. Semi-critical and critical probes must be traced.

Traceability methods – managing complexity

Data to collect

- ✓ Record of pre-cleaning systems
- ✓ Batch code of pre cleaning solutions
- ✓ Person undertaking tasks
- ✓ date and time of HLD
- ✓ results of minimum effective concentration testing
- ✓ temperature
- ✓ exposure time
- ✓ activation date (if relevant)
- ✓ reuse-life date (if relevant)
- ✓ shelf-life date
- ✓ person performing HLD
- ✓ unique probe identification
- ✓ lot number
- ✓ HLD status
- ✓ cycle number
- ✓ cycle pass status
- ✓ date/time
- ✓ Record patient ID (coded) in logbook *or*
- ✓ Record logbook entry number on patient notes
- ✓ Physician/sonographer performing procedure

Methods

Manual
- all parameters hand written in logbook

Semi-digitised
- printed labels
- logbook

Fully-digitised
- RFID scanning
- electronic linkage to patient identifier

Time to record & search for information

Conclusion

We need to review systems within our organisation.

Work towards electronic traceability systems across all providers within our organisation (including Ultrasound).

Undertake regular audits of our traceability systems.

We can always improve!

Many Thanks

Questions?

Do we need to think about defence??