



Comparative Study of Pre-Cleaning Methodologies on the Cleaning Efficacy of Challenging Instruments

Stephen Murphy (AE(D))

Introduction – Who am I?

Varied background with apprenticeship with Ferranti Plc/ GEC Marconi to become qualified Electronics engineer (Instrumentation calibration, radar systems Hawk/Harrier aircraft, PADS - position and azimuth detection systems Chieftain tanks)



Introduction – Who am I?

Apollo computers/HP (third party repair of monitors, disk drives, motherboards, printers, etc)

- Omron systems – EPOS (Electronic point of sale systems for major stores)
 - Contour systems – SUN Microsystem third party repair from Technical engineer to Technical / Quality Manager developing quality management system
 - At this point I entered the world of NHS and decontamination



Introduction – Who am I?

2002 – Health Facilities Scotland, Validation Engineer (now known as Competent Person (Decontamination)).

- Initially testing Local decontamination equipment (LDU), (Dental & podiatry sterilisers / washer disinfectors)
 - Central decontamination equipment (CDU) & Laboratory equipment
 - Endoscope washer disinfectors (set up service & only HFS engineer to test over whole of Scotland for a few years)
 - Developed in-house quality procedures for HFS Validation team and completed inhouse validation engineer audits & involved with UKAS external audits
 - Completed Master degree in Medical Device Decontamination via Highlands and Islands remote learning
 - Given opportunity for 2-year secondment to train as an Authorising Engineer (Decontamination)



Introduction – Who am I?

2018 – Authorising Engineer (Decontamination)

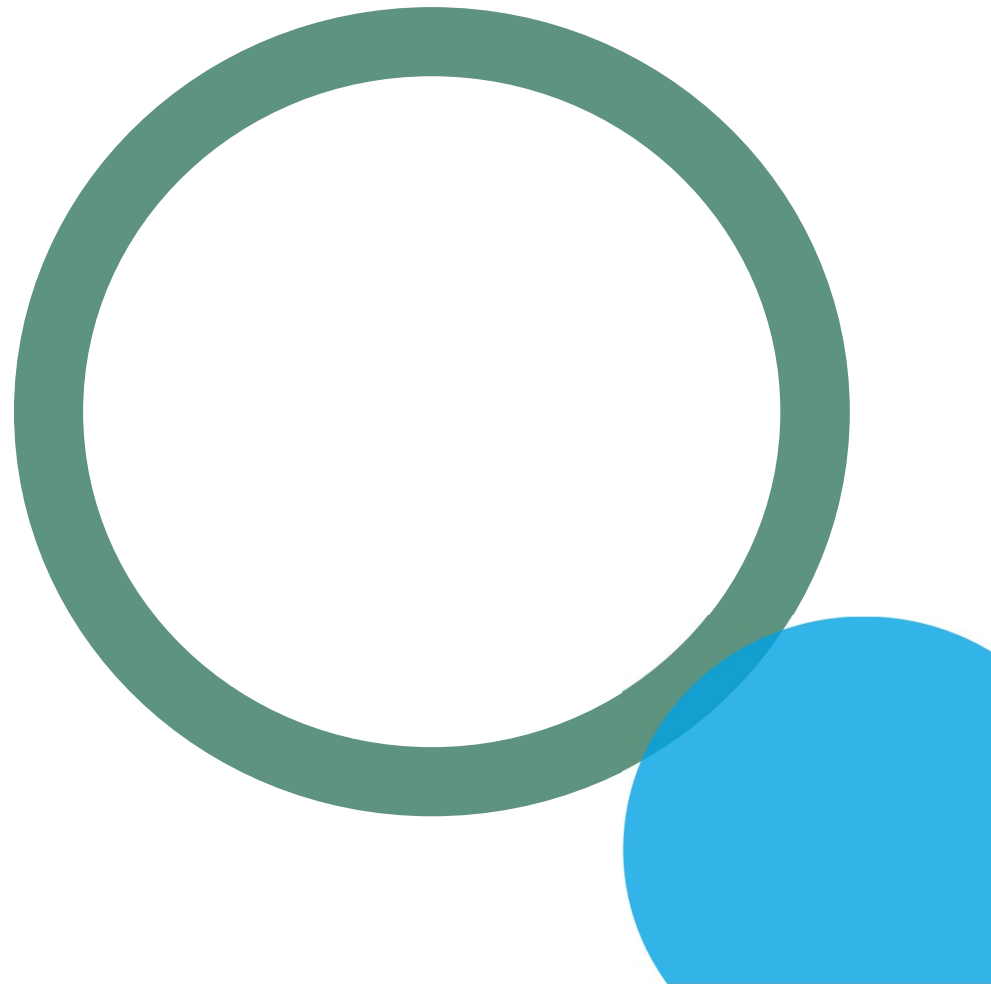
- Completed first revised IHEEM AE(D) competency framework over a period of two years (previously three-week intensive course)
 - Currently now three qualified AE(D)s to cover Scotland with another fourth validation engineer just qualified as another AE(D)
 - Boards are currently shared between us with my Boards currently being Lothian, Lanarkshire, Forth Valley, Western Isles and share GG&C
 - Assessed every three years for CPD via IHEEM and other AE(D) colleagues



Background – CJD/vCJD

First case of Bovine spongiform encephalopathy (BSE) known as mad cow disease first detected in Britain in 1985.

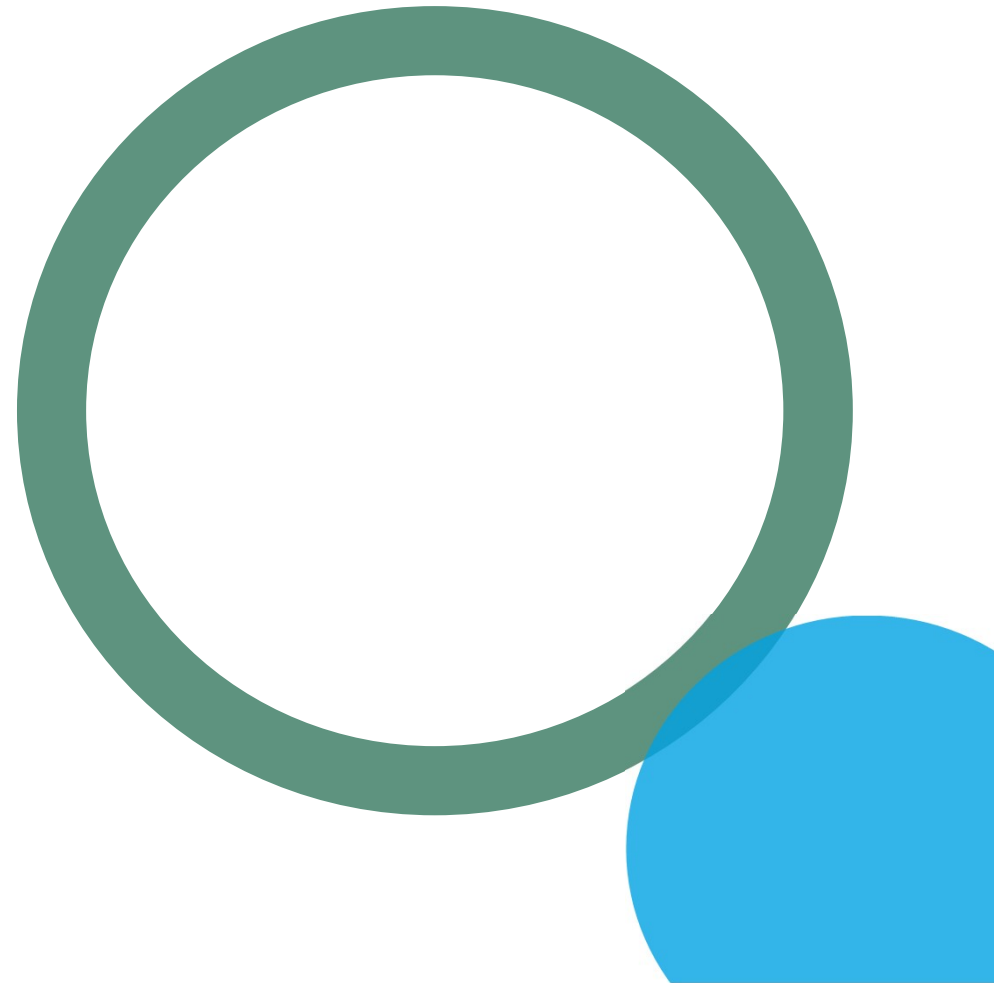
- In the period of 1990-2024, a total of 3,302 people died in the UK of probable and definite Creutzfeldt-Jakob disease (CJD) with 178 deaths from variant CJD (vCJD) (National CJD research & surveillance unit)
 - More recently BBC news reported in May 2024 first case of BSE since 2021 found in Ayrshire



Background

**House of Commons: After the storm?
UK blood safety and risk of variant
Creutzfeldt-Jakob Disease report July
2014**

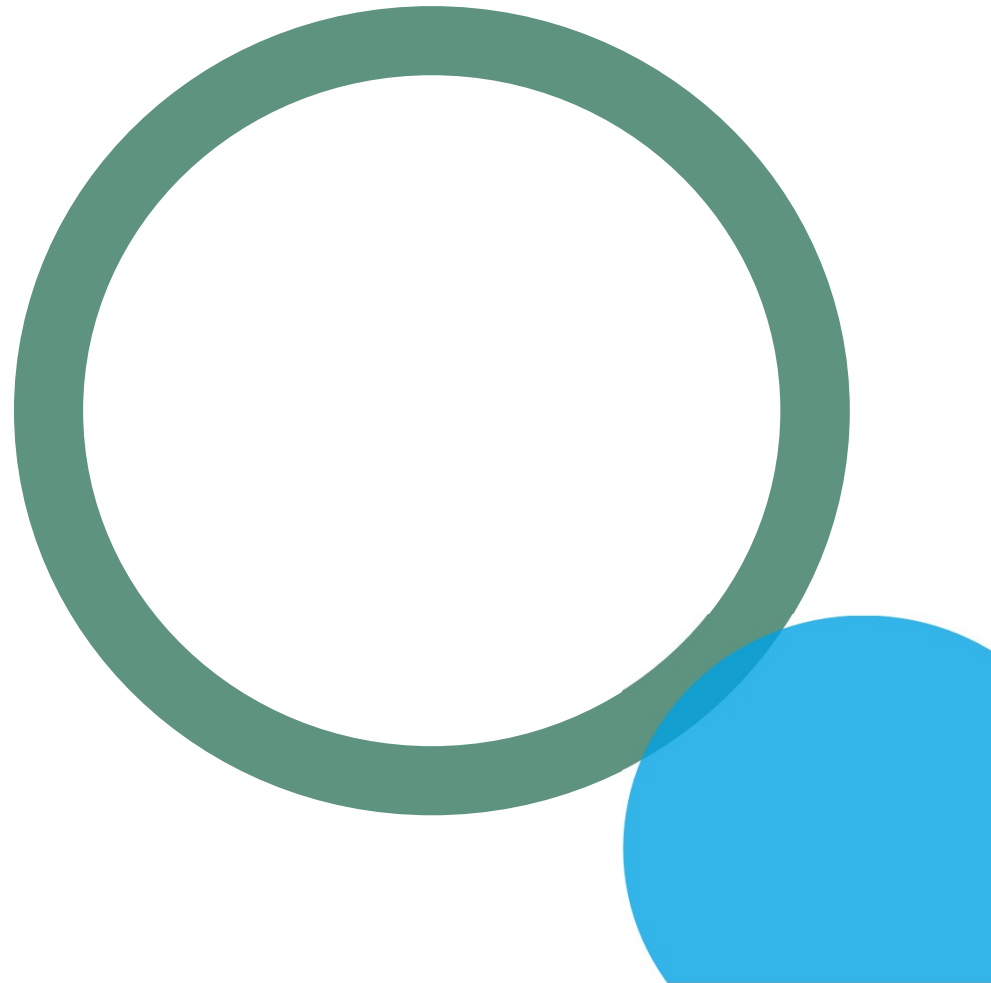
<https://publications.parliament.uk/pa/cm/201415/cmselect/cmsctech/327/327.pdf>



Background

House of Commons: After the storm? UK blood safety and risk of variant Creutzfeldt-Jakob Disease report July 2014

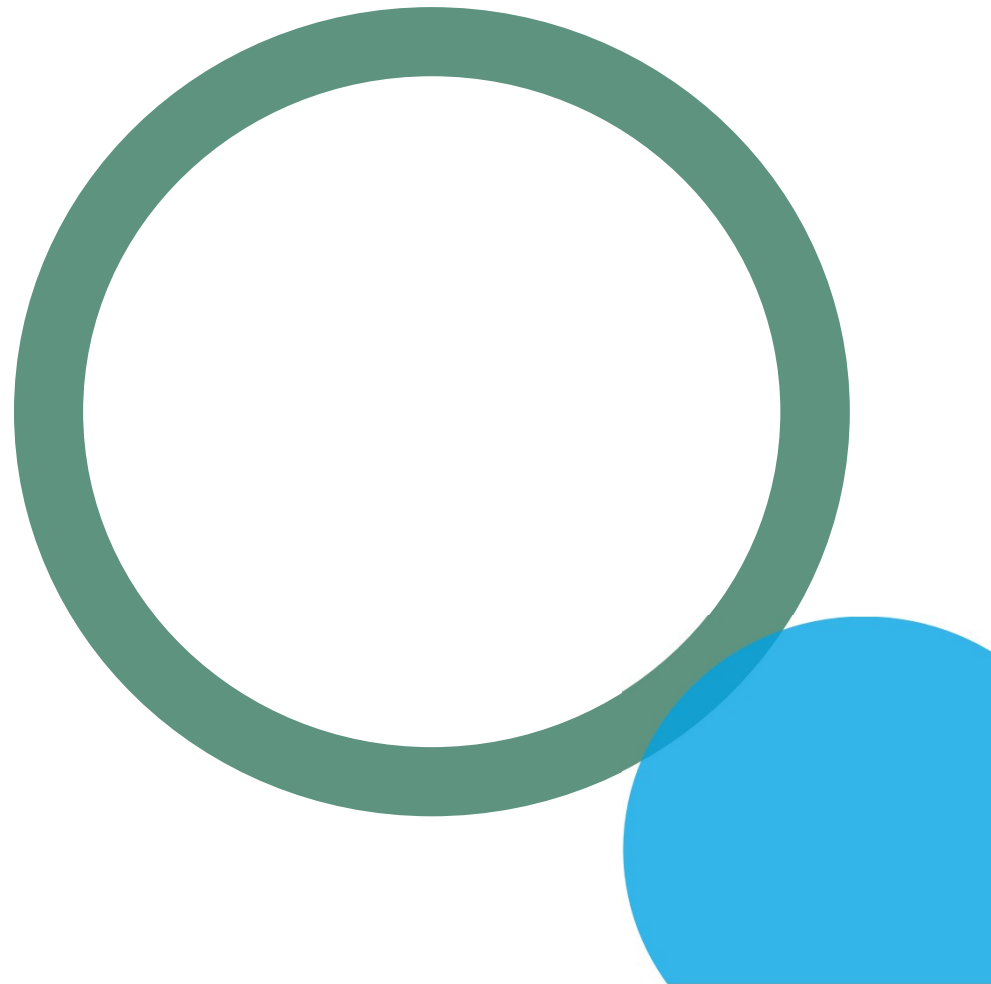
- Recognised pathogens are constantly emerging and evolving



Background

House of Commons: After the storm? UK blood safety and risk of variant Creutzfeldt-Jakob Disease report July 2014

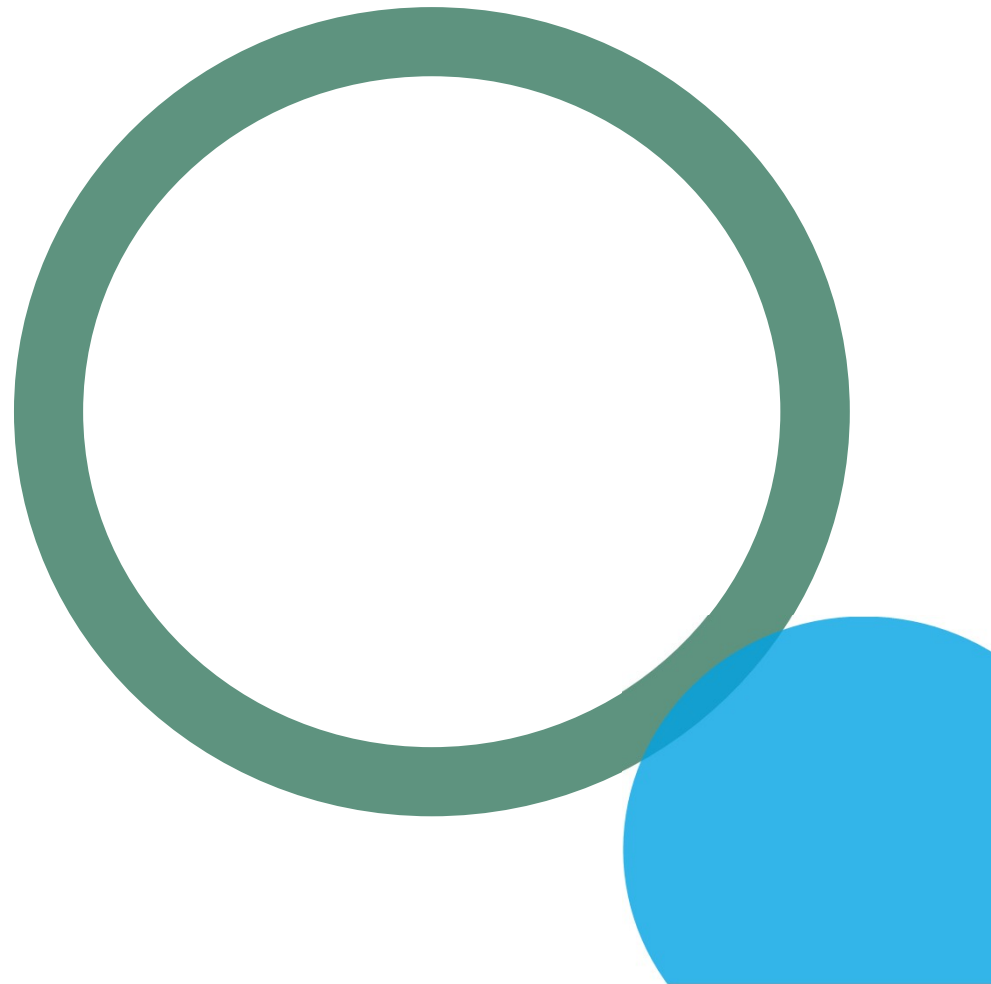
- Recognised pathogens are constantly emerging and evolving
 - Pose a risk to patients via contaminated surgical instruments as a potential source of prion transmission



Background

House of Commons: After the storm? UK blood safety and risk of variant Creutzfeldt-Jakob Disease report July 2014

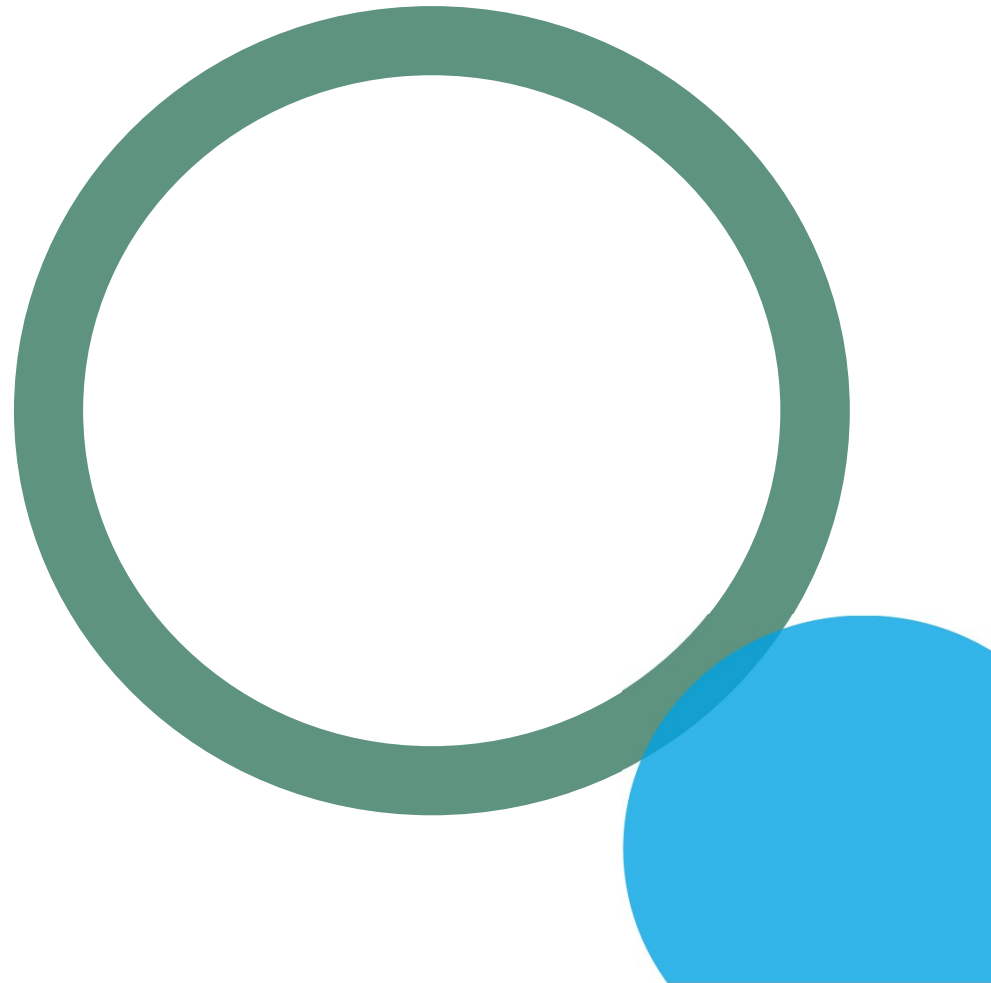
- Recognised pathogens are constantly emerging and evolving, e.g. vCJD, Covid
 - Pose a risk to patients via contaminated surgical instruments as a potential source of prion transmission
 - Failure to mitigate these risks may lead to increased exposure and spread



Background

**House of Commons: After the storm?
UK blood safety and risk of variant
Creutzfeldt-Jakob Disease report July
2014**

**“...no evidence of harm is not the same
as evidence of no harm”**

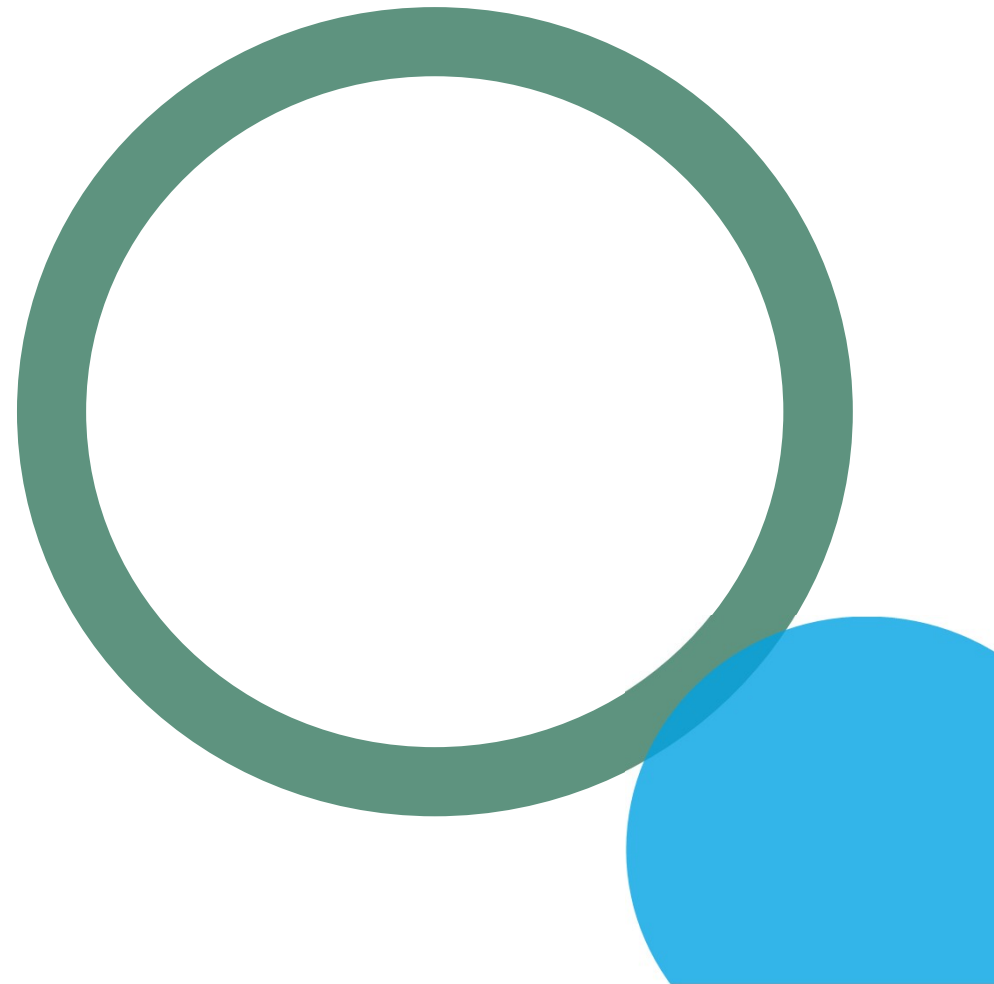


Revised guidance - Minimise transmission risk of CJD and vCJD in healthcare settings

Advisory Committee on Dangerous Pathogens (ACDP) May 2015

<https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group>

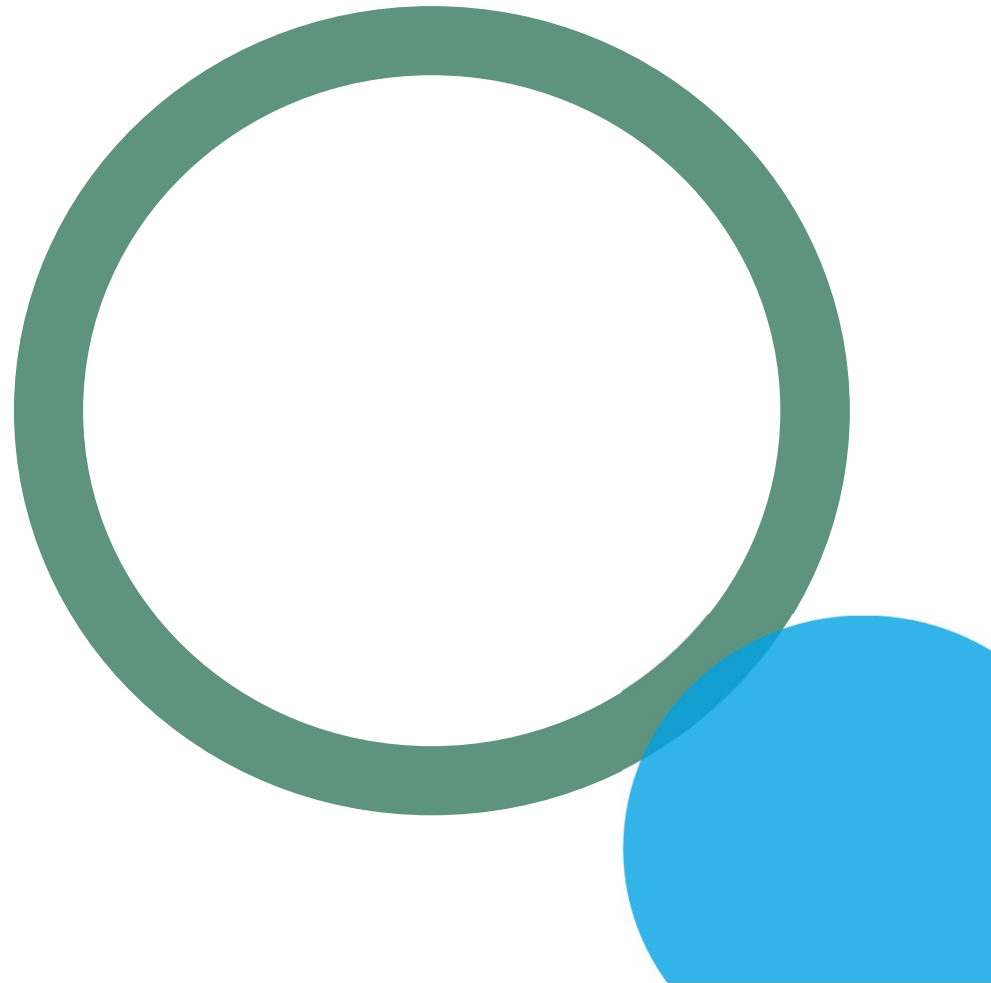
(Updated in Nov 2021, to reflect the latest scientific research)



Revised guidance - Minimise transmission risk of CJD and vCJD in healthcare settings

Advisory Committee on Dangerous Pathogens (ACDP) May 2015

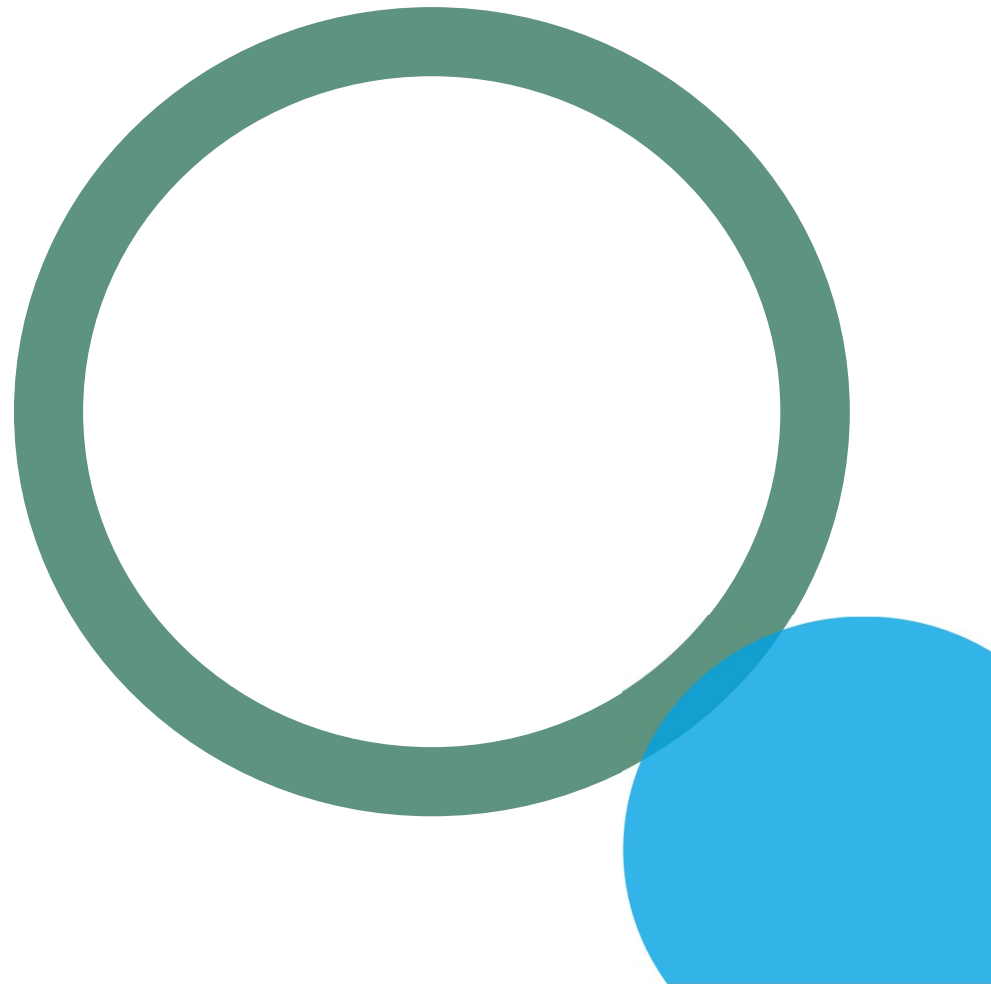
- Transmissible spongiform encephalopathies (TSEs) also known as prion diseases are fatal and degenerative affecting nervous system in humans and other mammals



Revised guidance - Minimise transmission risk of CJD and vCJD in healthcare settings

Advisory Committee on Dangerous Pathogens (ACDP) May 2015

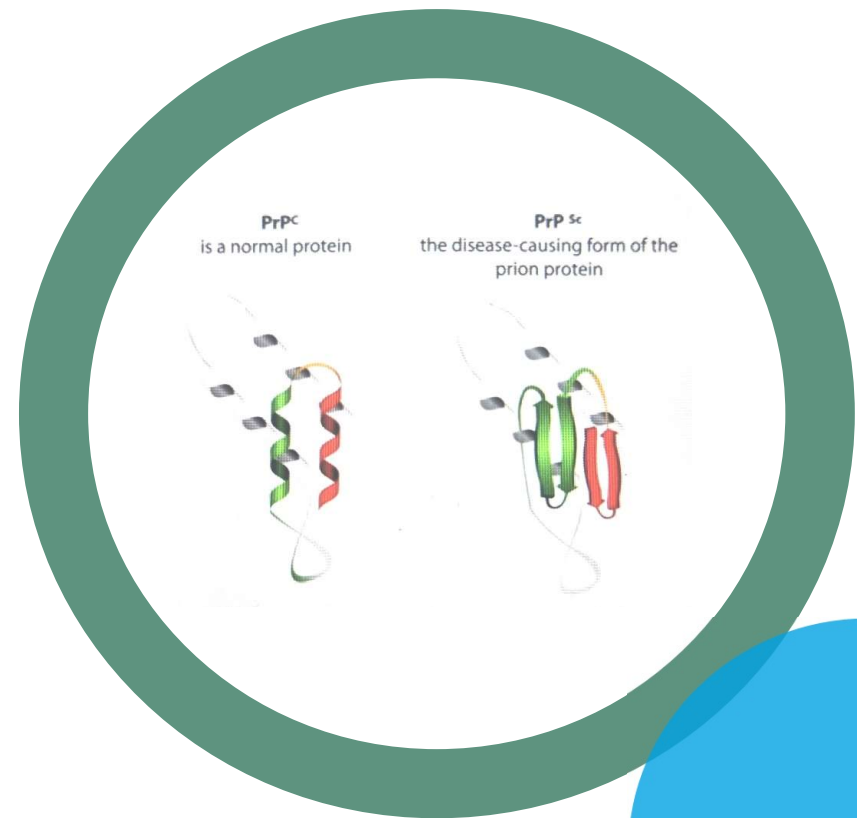
- Transmissible spongiform encephalopathies (TSEs) also known as prion diseases are fatal and degenerative affecting nervous system in humans and other mammals
 - Examples of which are CJD, vCJD in humans, bovine spongiform encephalopathy (BSE) in cattle and scrapie in sheep among others.



Revised guidance – Minimise transmission risk of CJD and vCJD in healthcare settings

Advisory Committee on Dangerous Pathogens (ACDP) May 2015

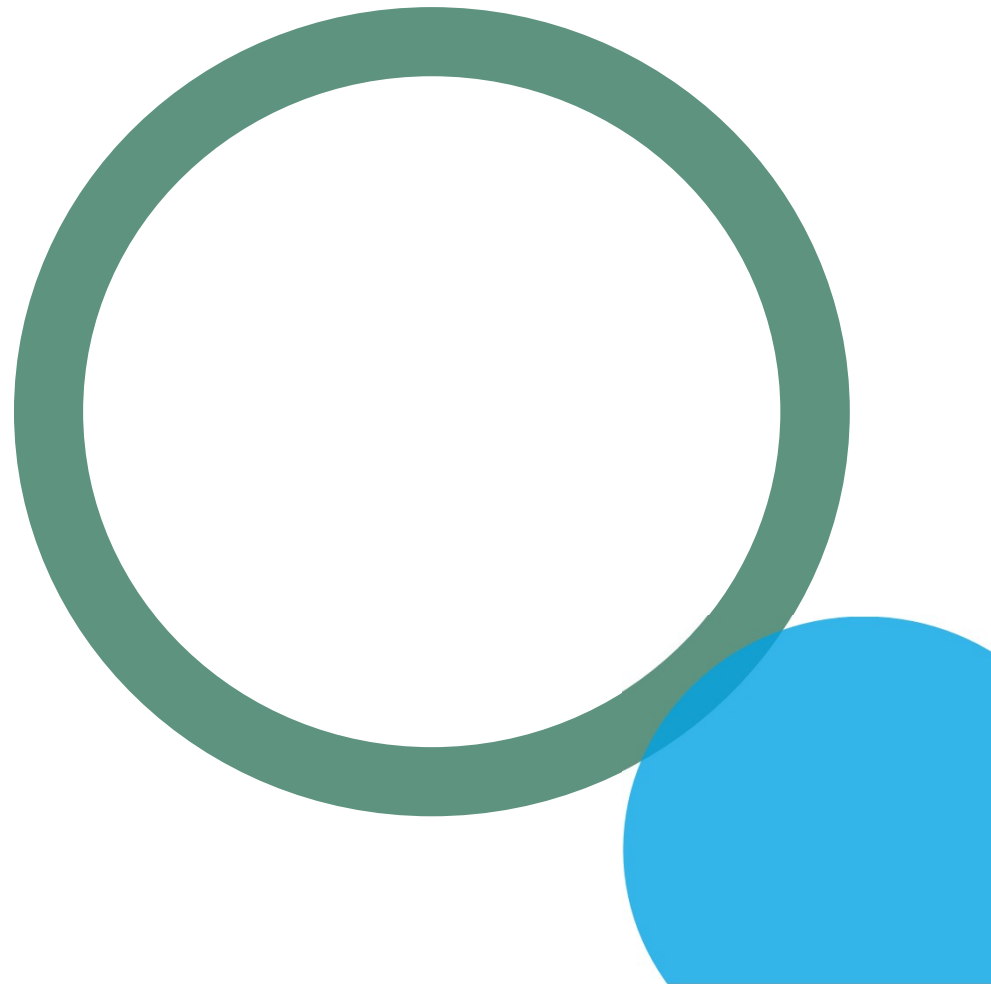
- Transmissible spongiform encephalopathies (TSEs) due to abnormal prion proteins are fatal and degenerative affecting nervous system in humans and other mammals
 - Unique from other microbiological diseases which exhibit different biological properties
 - Prion proteins undergo a structural change rendering the abnormal protein more resistant to degradation



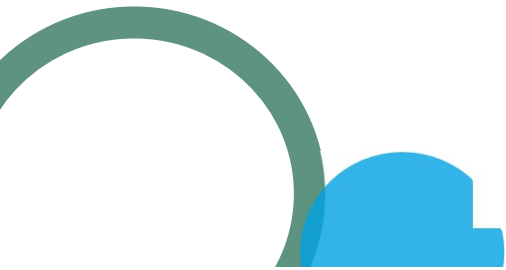
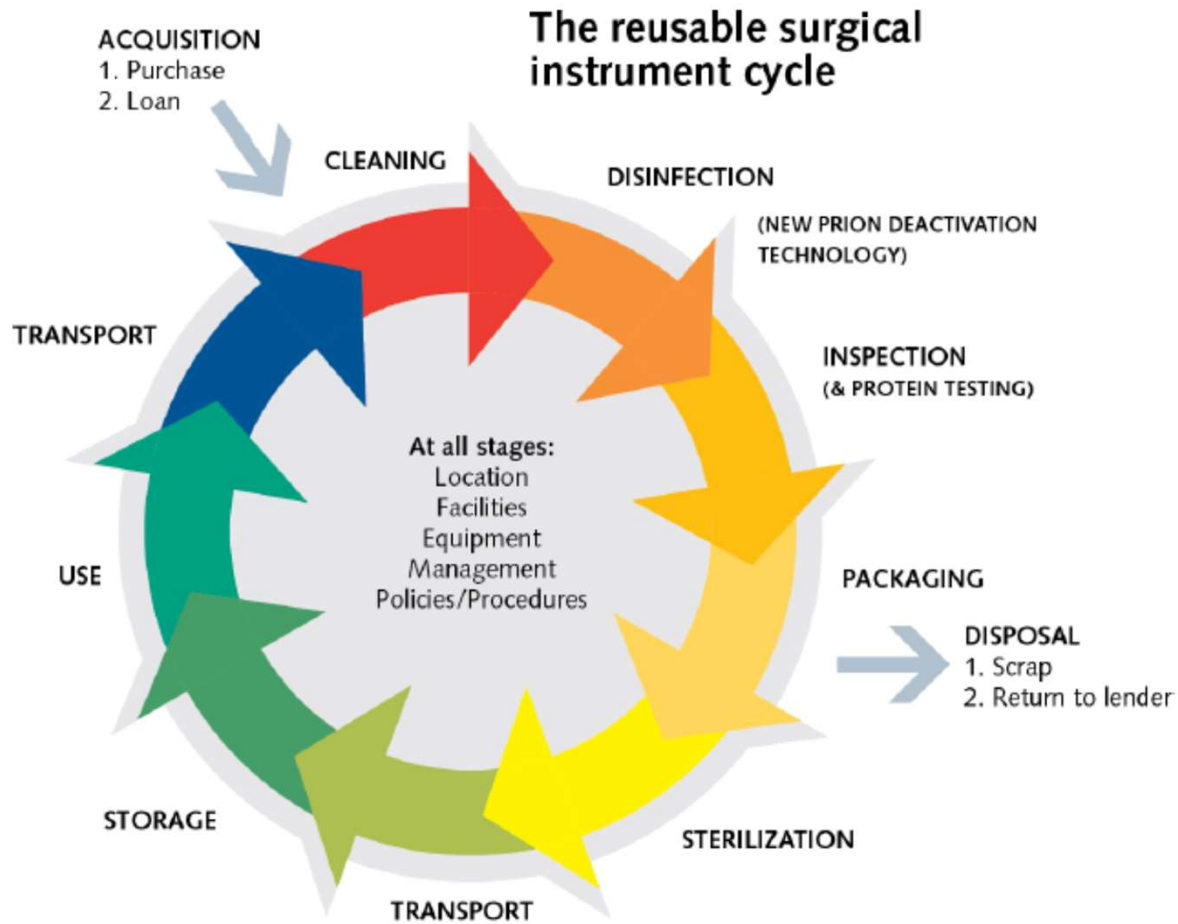
Revised guidance – Minimise transmission risk of CJD and vCJD in healthcare settings

Alzheimers Association

- CJD / vCJD has been linked to dementia with CJD causing a type of dementia that gets worse unusually fast
- Acquired CJD results from exposure to an external source of abnormal proteins with the two most common sources being meat or medical procedures involving instruments used in neurosurgery, growth hormone or certain transplanted human tissues
- Source – Alzheimers association website <https://www.alz.org/alzheimers-dementia/what-is-dementia/types-of-dementia/creutzfeldt-jakob-disease>



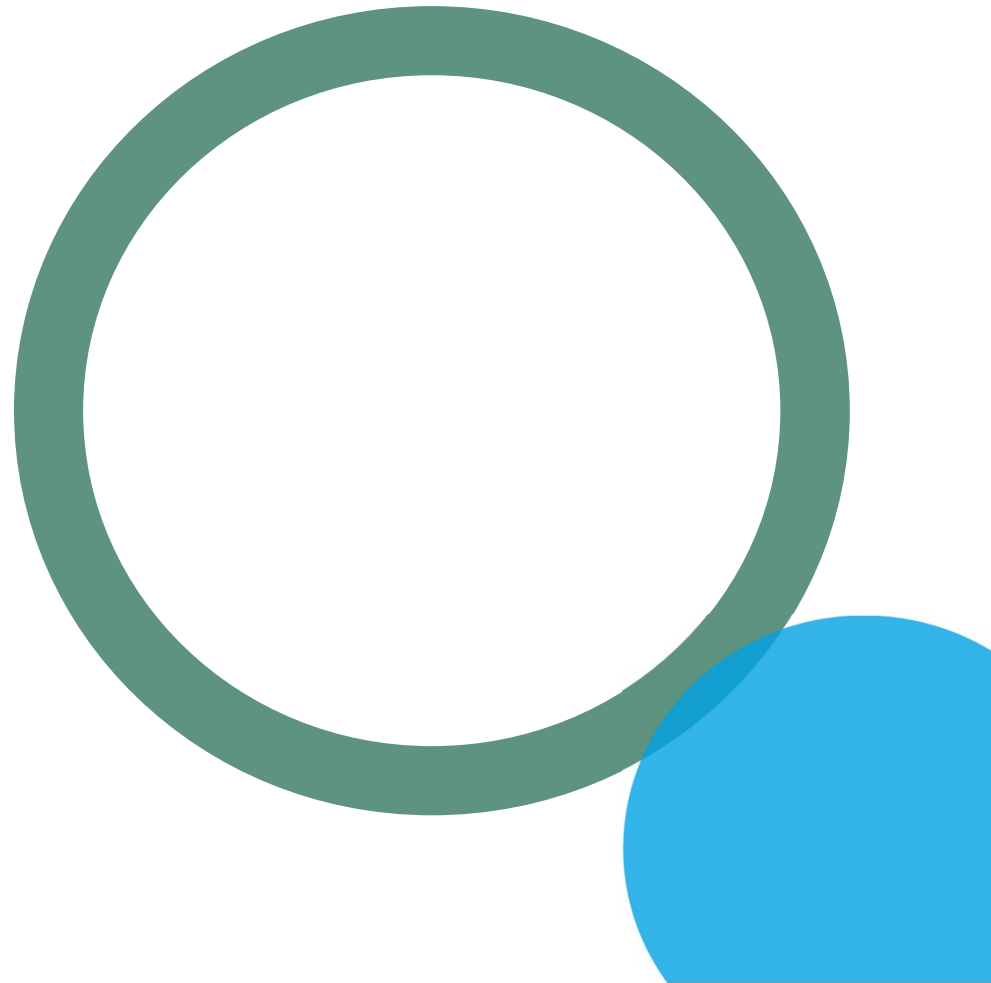
Decontamination Cycle for reusable medical equipment



Revised guidance - Minimise transmission risk of CJD and vCJD in healthcare settings

Advisory Committee on Dangerous Pathogens (ACDP) May 2015

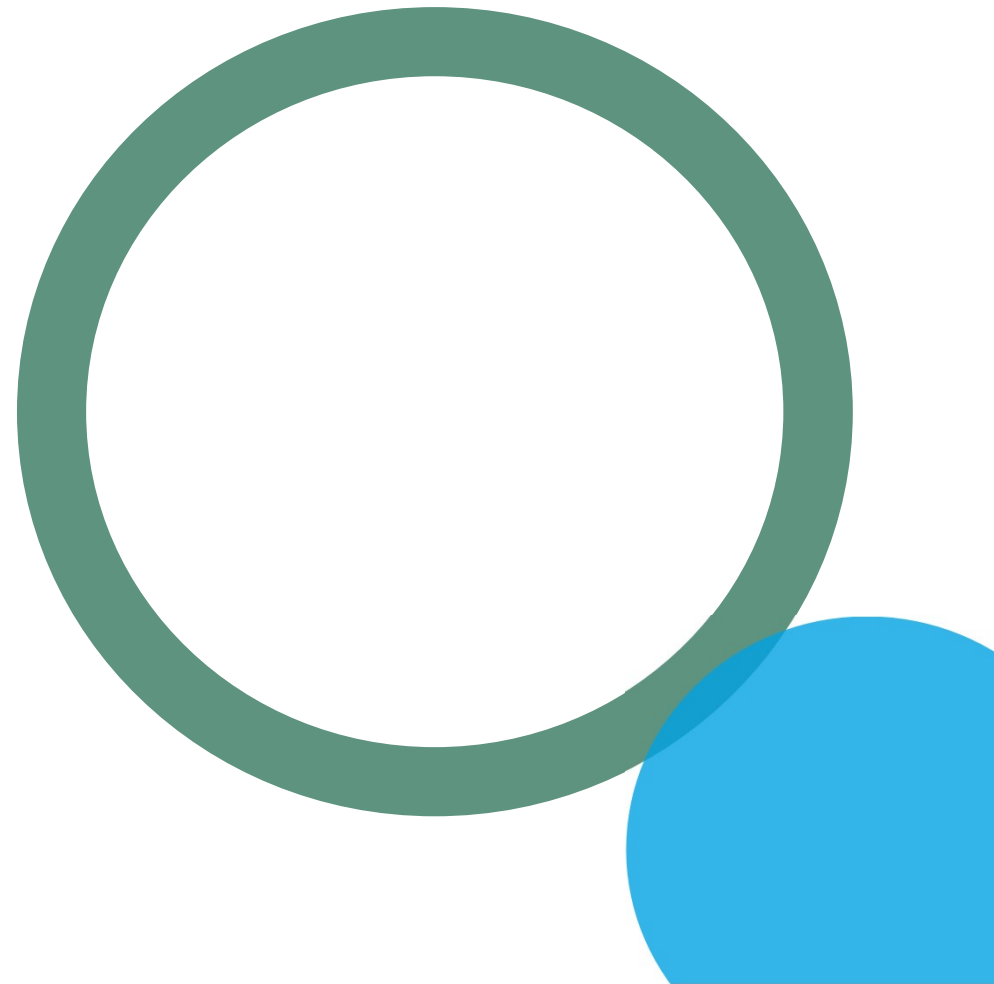
- If TSEs are particularly resistant to standard physical and chemical methods of inactivation and decontamination – What is best practice?



Revised guidance - Minimise transmission risk of CJD and vCJD in healthcare settings

Advisory Committee on Dangerous Pathogens (ACDP) May 2015

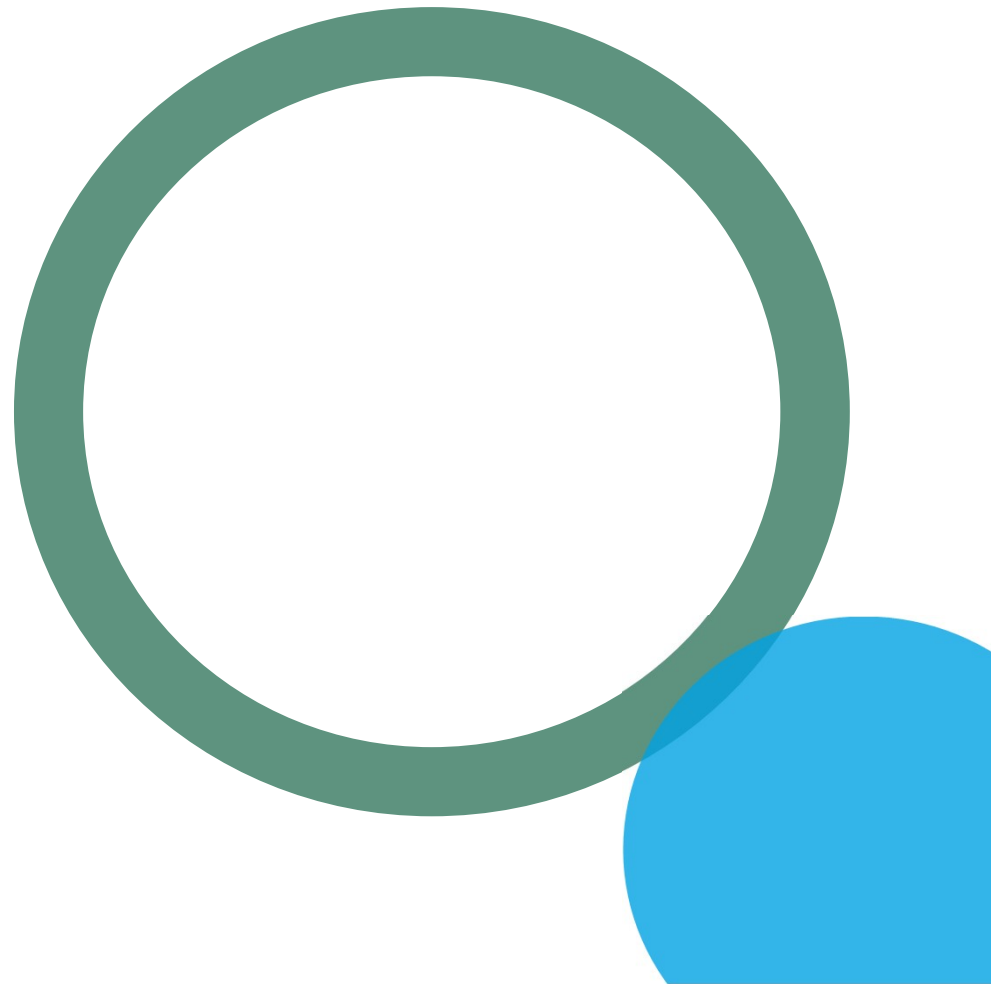
- If TSEs are particularly resistant to standard physical and chemical methods of inactivation and decontamination – What is best practice?
- **Effective cleaning is of great importance in the removal of these agents**
- Note: ACDP advised autoclaving can reduce infectivity but cannot be relied upon to completely eliminate infectivity. Even with the “Prion Cycle” with 134°C @ 18mins (referring to a Safety Action Notice for benchtop sterilisers)



Revised guidance - Minimise transmission risk of CJD and vCJD in healthcare settings

Improve on process – Research demonstrated leaving instruments to dry more than 15 minutes, can greatly increase the amount of residual protein contamination

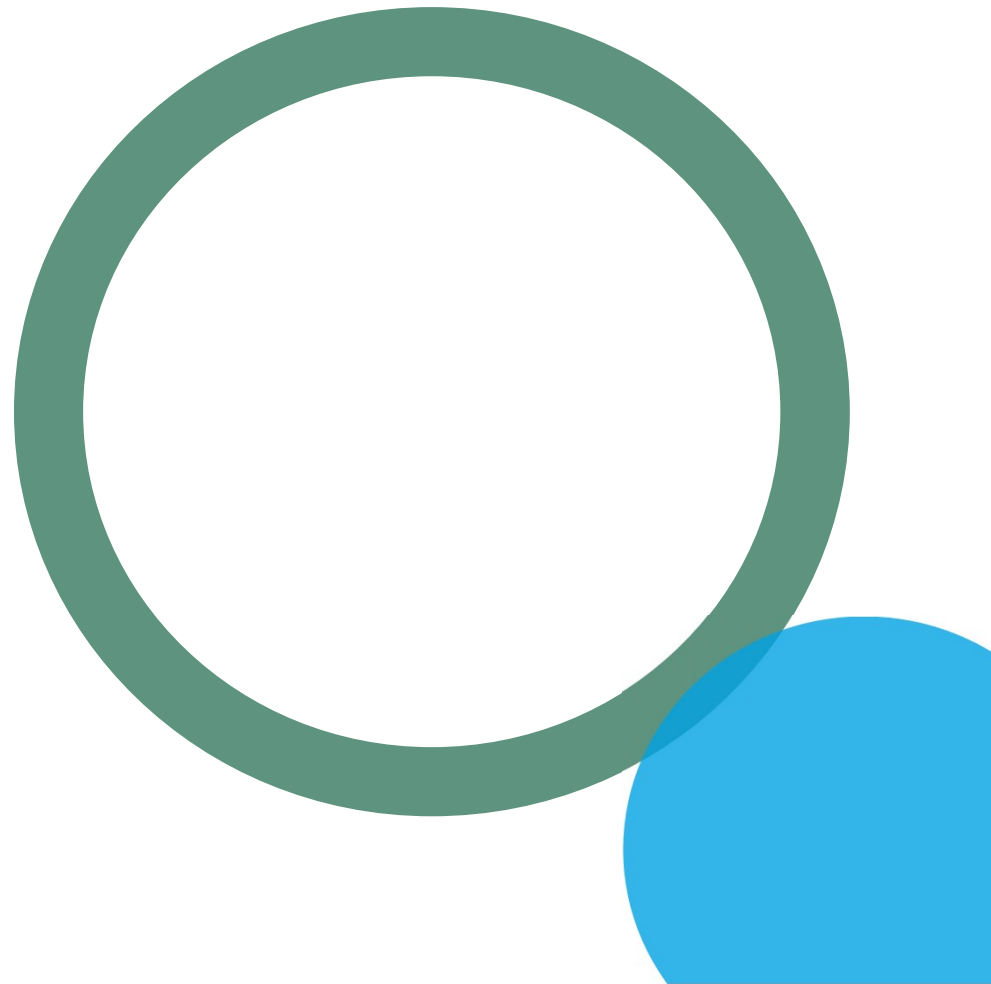
- **Transport instruments to CDUs as quickly as possible after use for cleaning & reprocessing**
- **Keep moist using appropriate methods**



Revised guidance - Minimise transmission risk of CJD and vCJD in healthcare settings

Improve on process – Cleaning Efficacy testing

- **ACDP introduced an acceptable upper limit for protein contamination after Washer Disinfector processing as 5ug per instrument side with a lower level for neurological instruments**
- **Various methods in the market such as high sensitivity protein test swabs, and ProReveal (a fluorescence based system to check presence of residual protein)**



Literature Review

Numerous studies with data on medical device residuals

Previous published literatures found residual protein in excess of $>100\mu\text{g}$ (Vassey / Baxter / Lipscomb)

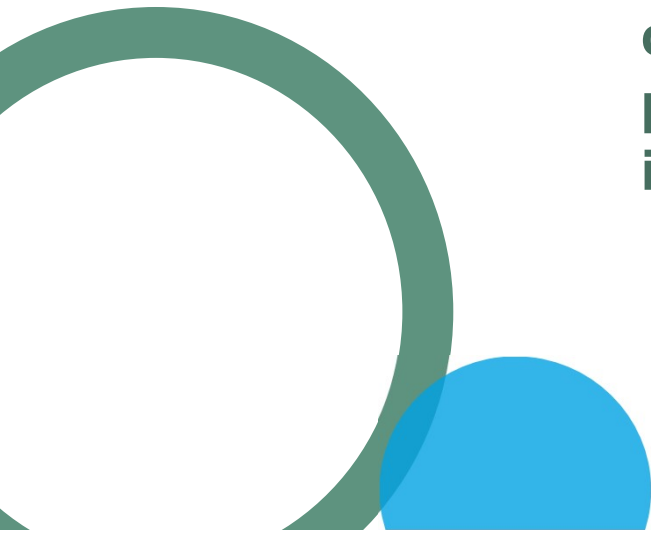
- Most of these studies omitted pertinent background information:
Equipment / Status of instruments



Aims and Objectives of the study

1 - Determine if 5 μ g residual protein limit can be achieved using current practices available

2 - To compare and establish which pre-cleaning method in addition to current AWD process performs best when reprocessing instruments of varying design



Methodology

Determine Cleaning processes:

- **Control Group – AWD (Automated Washer Disinfector)**
- **Group 2 – Pre-cleaning with Ultrasonic plus AWD**
- **Group 3 – Pre-cleaning with manual wash plus AWD**



Control Group – AWD, Belimed WD390 Tunnel Washer

Cycle Program:-

Prewash –	N/A °C for 6mins
Wash –	65 °C for 8mins
Rinse -	N/A °C for 2mins
Disinfect –	93 °C for 1min
Drying –	110 °C for 10mins
Detergent –	Serchem Maximum pH Plus, 125ml

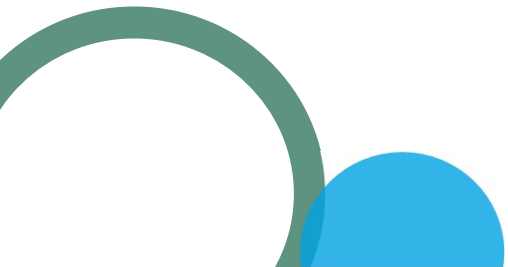


Pre-Clean Treatment Group 1 – Ultrasonic Bath plus AWD

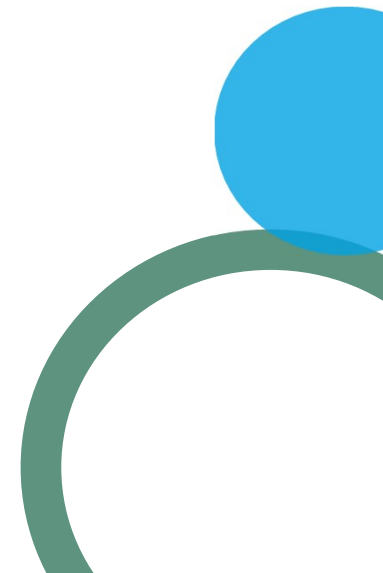
Ultrawave Hygea Cycle Program:-

**Cycle time – 32 °C for
10mins**

**Detergent – Ultrawave
Ultraclean
M2, 200ml**



Pre-Clean Treatment Group 2 – Manual cleaning plus AWD



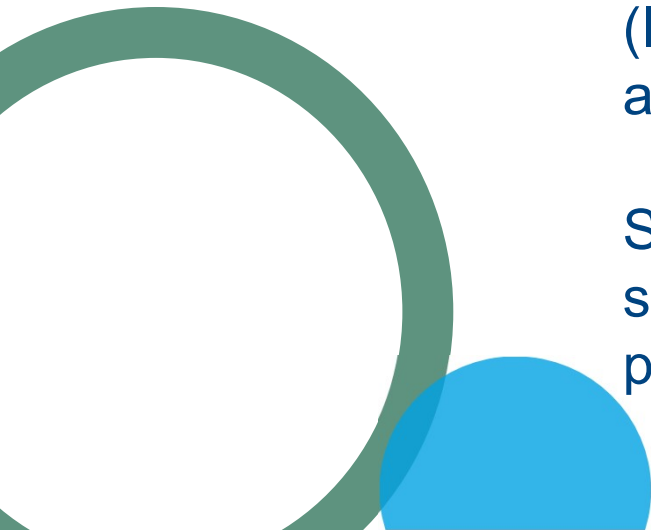
Instruments used

Select Instruments for study:-

Planar
Hinged
Box Jointed

(Instruments identified from previous studies and also CSSD staff as being difficult to clean)

Sample size based on previous data from similar studies, e.g. Vasseey, Lipscomb - 30 instruments per group

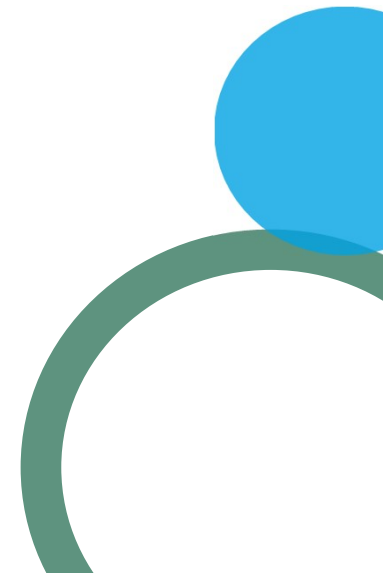


Planar Instruments

Retractor Initial Incision with Claws



Retractor Czerny

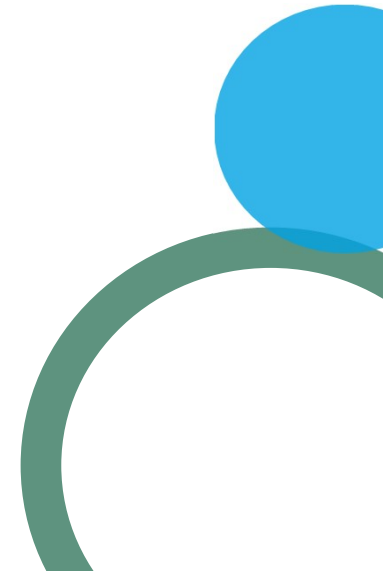


Hinged Instruments

Retractor Norfolk & Norwich



Forcep Dissecting Bonney with teeth

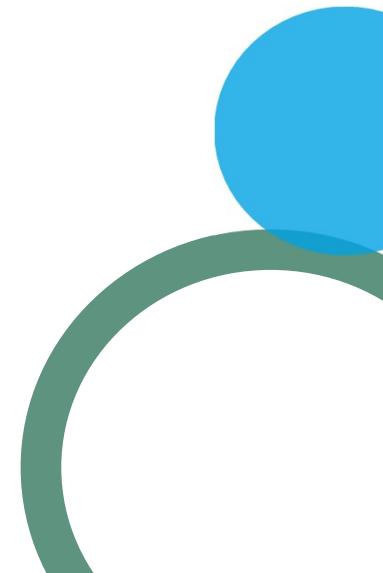
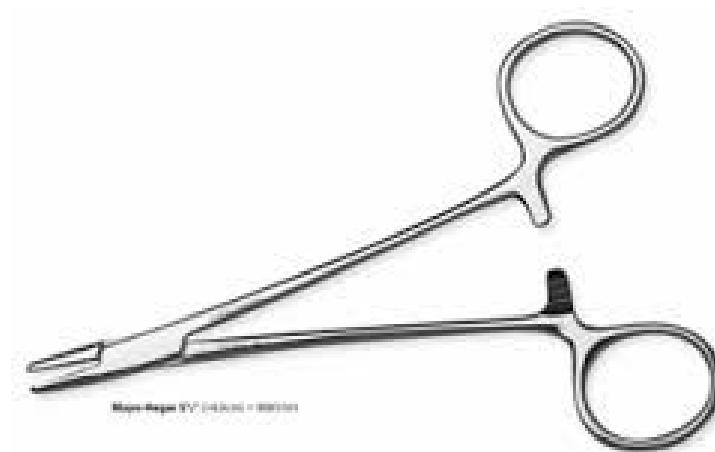


Box Jointed Instruments

Forcep Artery Kocher
½ teeth straight



Holder Needle Mayo
Hegar



Analysing Residual Protein

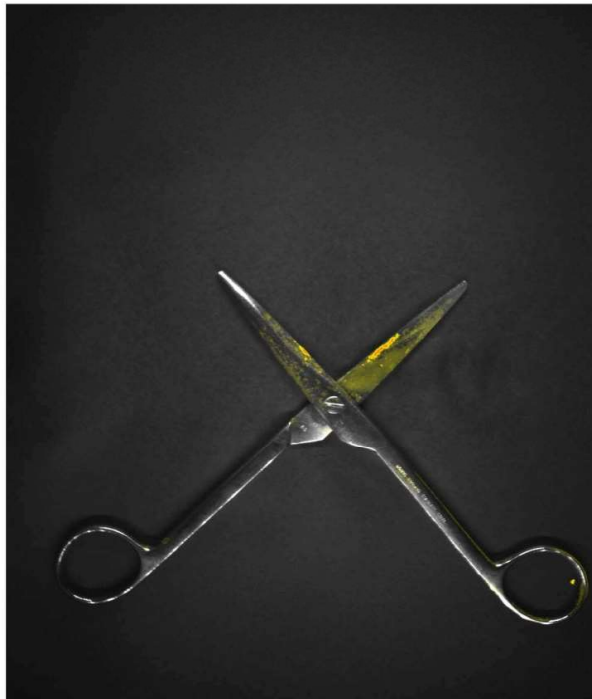
ProReveal®TM system

- A fluorescent based protein detection system capable of measuring down to less than 50ng.
- Rapid result < 5 mins
- Detects protein from instrument surface subjected to it, **therefore both sides of instrument presented for more accurate results**

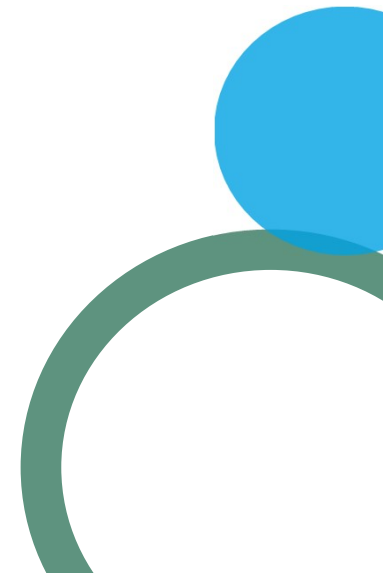


Typical ProReveal[®] TM Report

141124140632

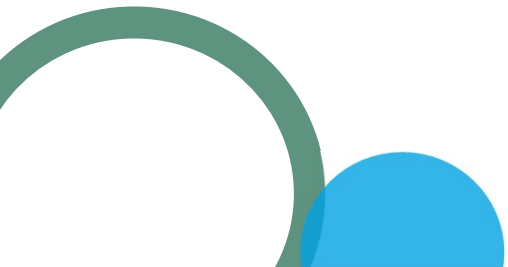


Dataset ID	141124140632
Site ID	01014
Capture Time	24/11/2014 14:06:32
Type	Measurement
User ID	Stephen Murphy
Contamination Limit	Signal Mass (µg)
Contamination Measurement	3.704 µg
Calibration XY Time	05/04/2013 12:52:01
Calibration Quantity Time	21/11/2014 13:37:25

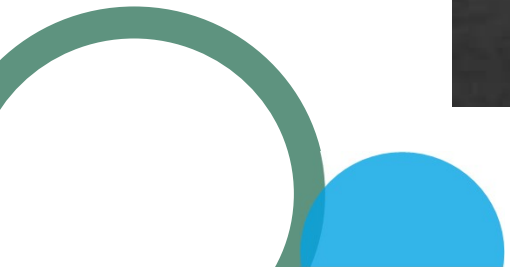
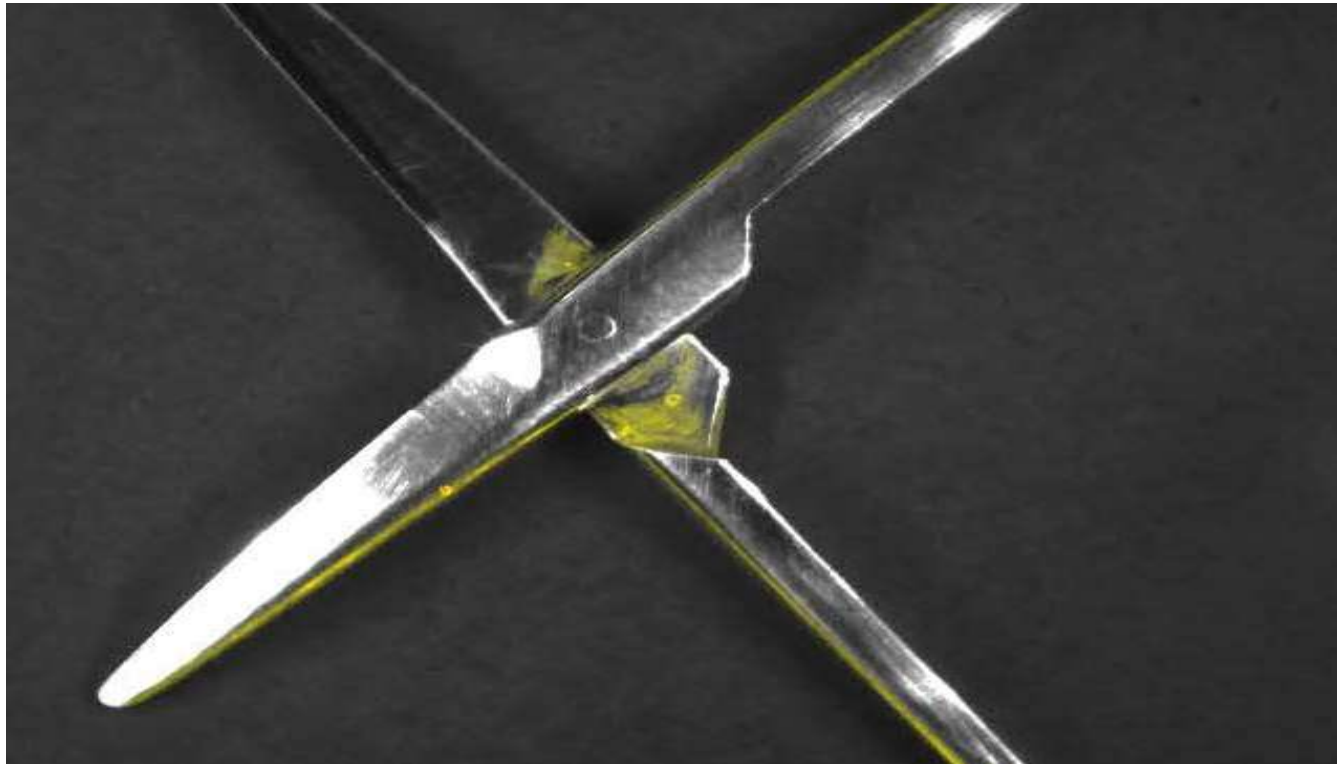


Limitations

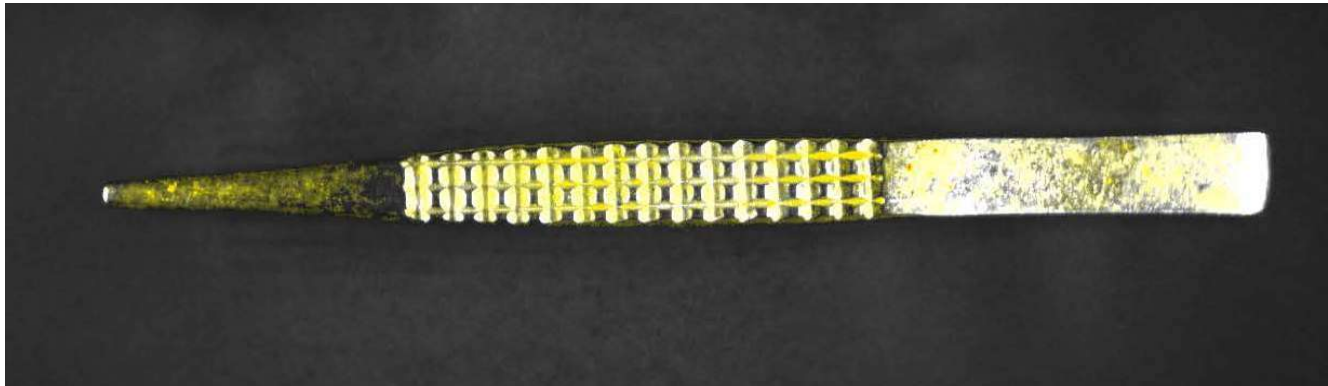
- **Time Frame / Work around demanding schedules / Disruption to staff**
- **Not every instrument type could be assessed**
- **Site specific equipment (Other AWD / U/S may produce different results)**
- **ProReveal – Size of instrument, no lumens, material (e.g. polymer handle)**



Scissor Mayo Post Manual & AWD processing



Forcep Dissecting Bonney – Post AWD



Residual protein (yellow hue) shown to be present not only in working area of instrument but also handling areas

Statistical Analysis

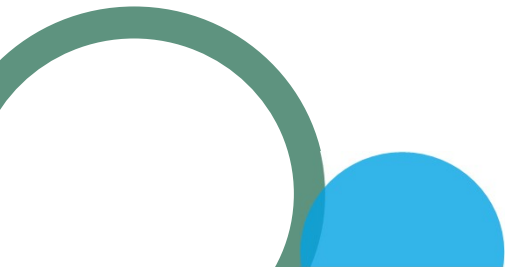
- **ANOVA**

 - (used to compare sample means between groups)

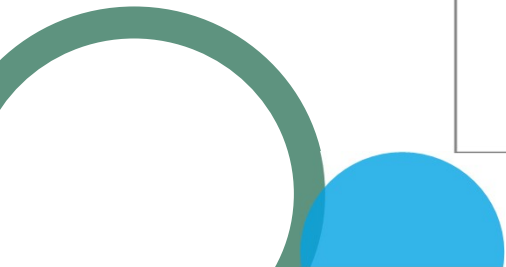
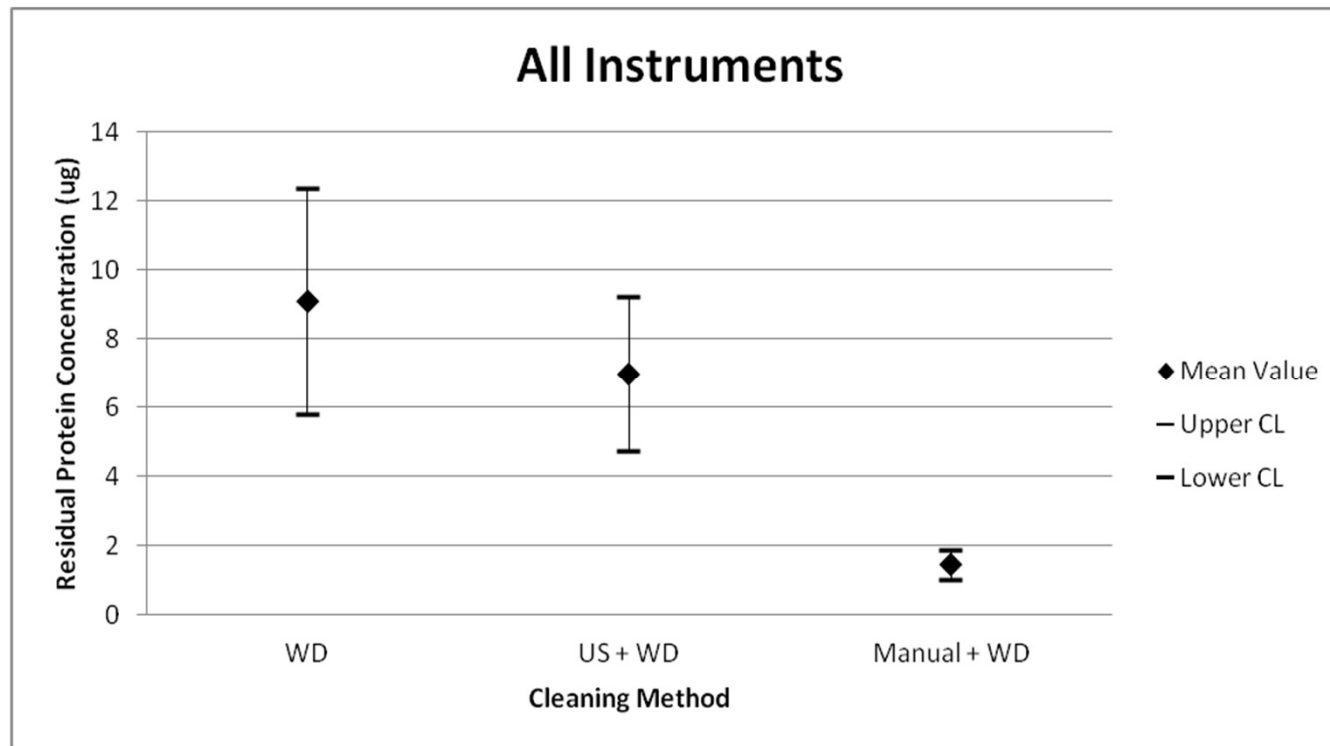
- **Bonferroni & Tukey HSD Post Hoc tests**

 - (to determine which groups differed from each other and limit the statistical type 1 errors)

- **95% confidence intervals**

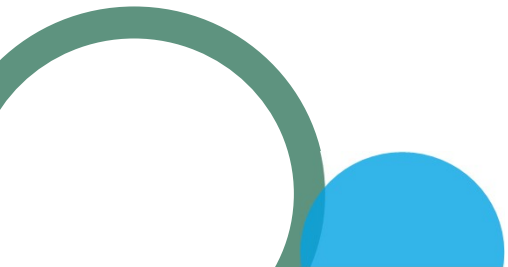


Results – Graph plotting residual protein for all instruments against cleaning methods

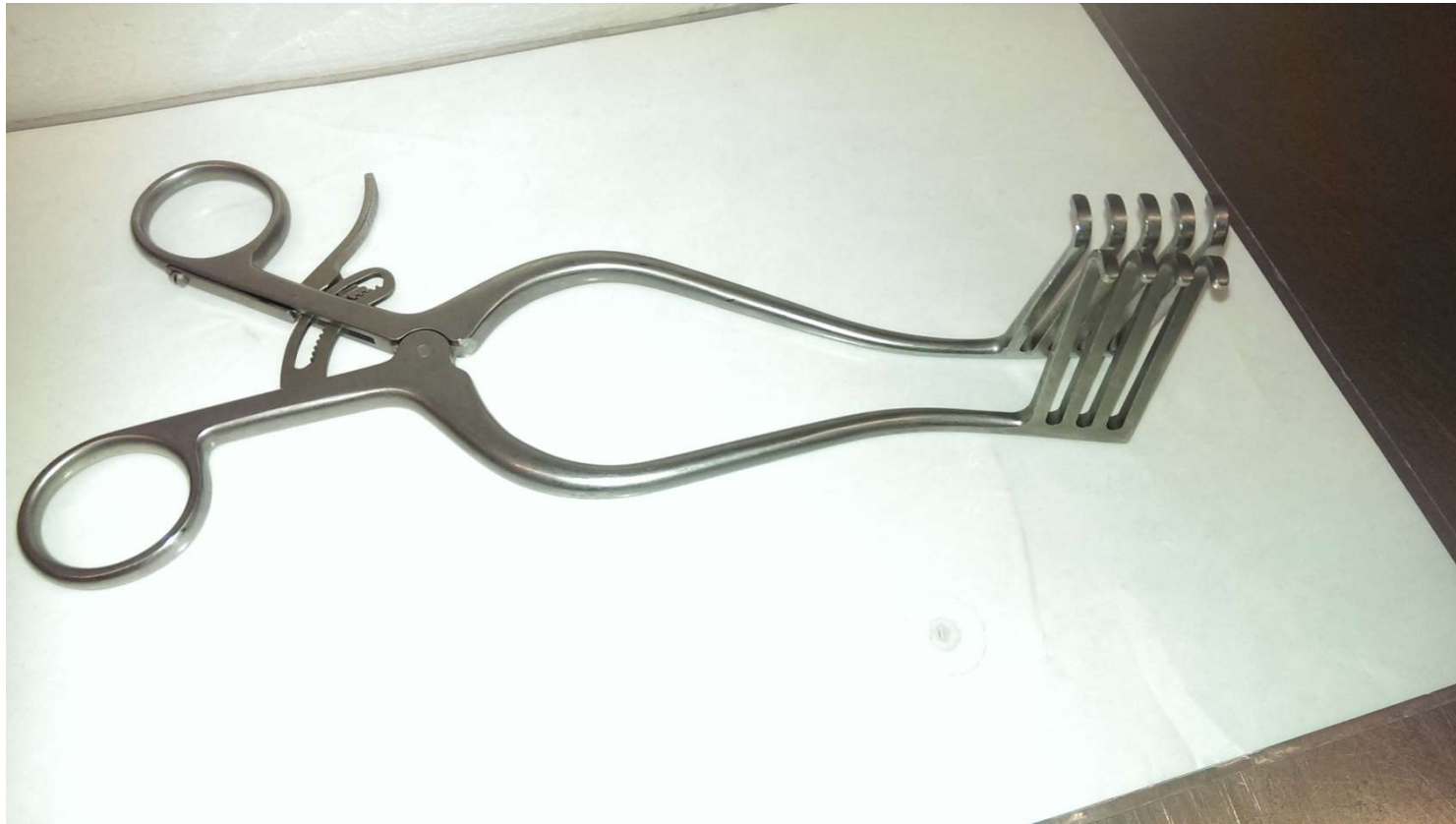


Manual cleaning - Points of interest

- **Not a validated process**
- **Open to varying results depending on operator manual cleaning technique**
- **Currently instruments targeted for manual cleaning will be the ones that ‘visually’ appear to be heavily contaminated.**



Manual cleaning – Retractor Norfolk & Norwich

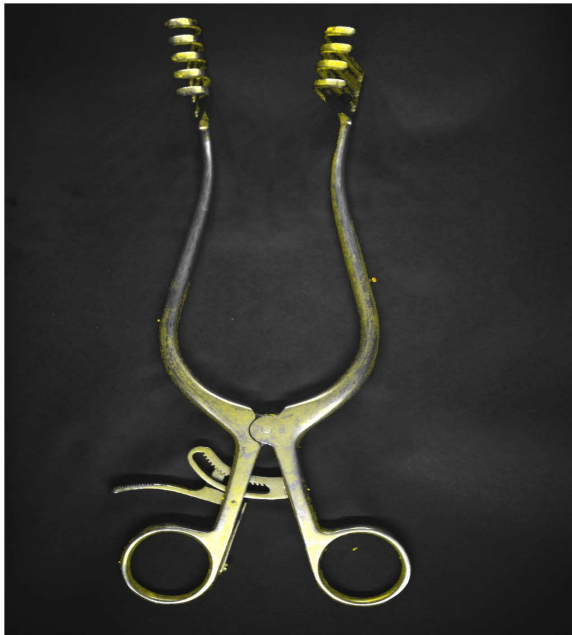


Manual cleaning – Retractor Norfolk & Norwich

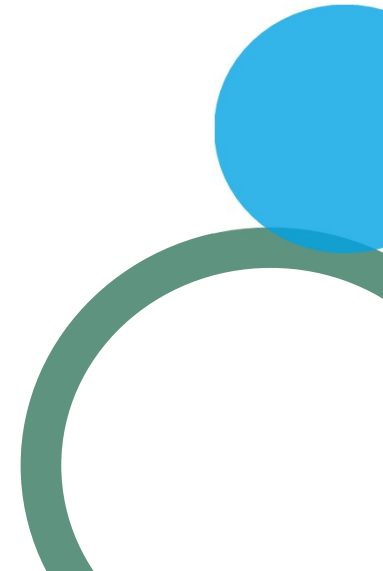
141126114423



253506033574001401014141126114423

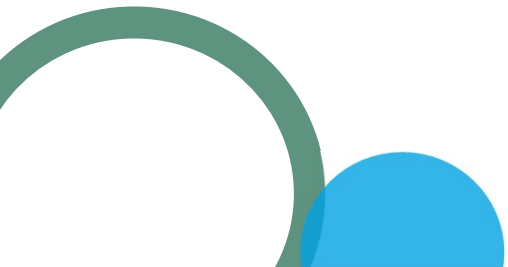


Dataset ID	141126114423
Site ID	01014
Capture Time	26/11/2014 11:44:23
Type	Measurement
User ID	Stephen Murphy
Contamination Limit	Signal Mass (µg)
Contamination Measurement	10.639 µg
Calibration XY Time	05/04/2013 12:52:01
Calibration Quantity Time	21/11/2014 13:37:25



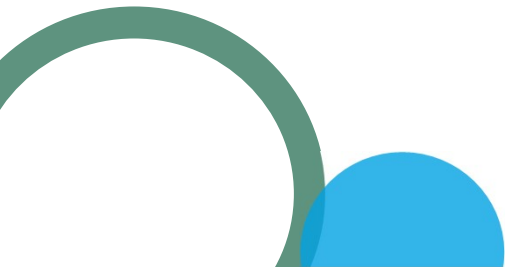
Conclusion 1

- **Manual cleaning plus AWD methodology was a significantly more effective method of decontamination for surgical instruments**
- **Impossible to manually clean all instruments due to high throughput**



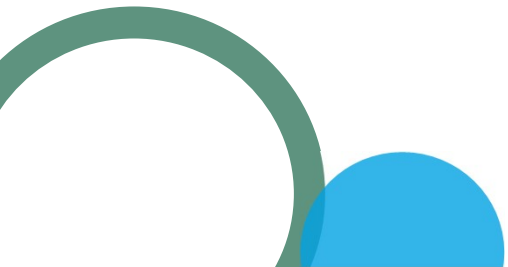
Conclusion 2

- **5µg limit is achievable (but may impact on washer disinfectant cycles being altered / Operational practices and validation methods revised)**
- **Analysing results from other AWD's / Ultrasonic baths and complex instruments may provide different results**



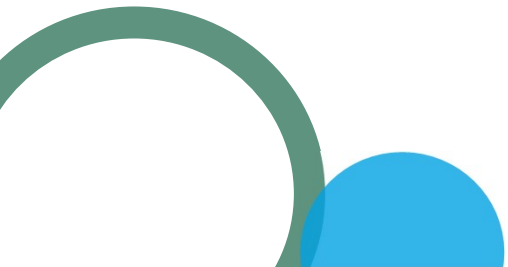
Important factors affecting efficacy

- **Equipment maintenance**
 - ❖ Spray arms / Load Carriers
- **Loading**
 - ❖ Overloading / Shadowing
 - ❖ Open instruments
- **HTM01-01 and revision of SHTMs recognise:**
 - ❖ Time from use to reprocessing
 - ❖ Keeping instruments moist
 - ❖ Continuous monitoring and improvement



Feedback and Improvements

- **Various trusts and managers in particular Ninewells have been appreciative and acknowledged the information will help them to become more aware and improve the service**
- **New studies are being carried out (Pre cleaning, more effective detergents)**
- **New technologies for monitoring protein levels being made available / Instrument coatings**



Acknowledgements

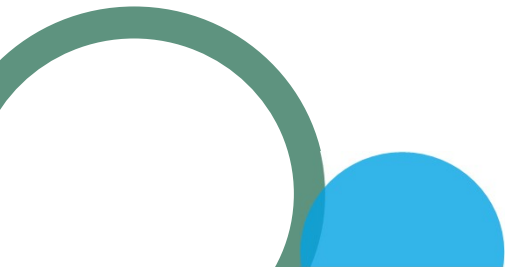
National Services Scotland / Health Facilities Scotland for funding and allowing time to undertake the study

All staff at Ninewells Hospital, particularly Billy Alexander & Nancy Gray for their instrument guidance and input

Dr Sulisti Holmes in her role as dissertation supervisor for her patience, assistance and guidance

Mr Norman McLean and Mr David Hill for the opportunity to complete the MSC Medical Device Decontamination

Peskett Solutions, Synoptic Health & Dolby Medical for providing support and consumables



Up Helly Aa - Fighting the good fight



Thank you

stephen.murphy2@nhs.scot

Tel: 07917086649