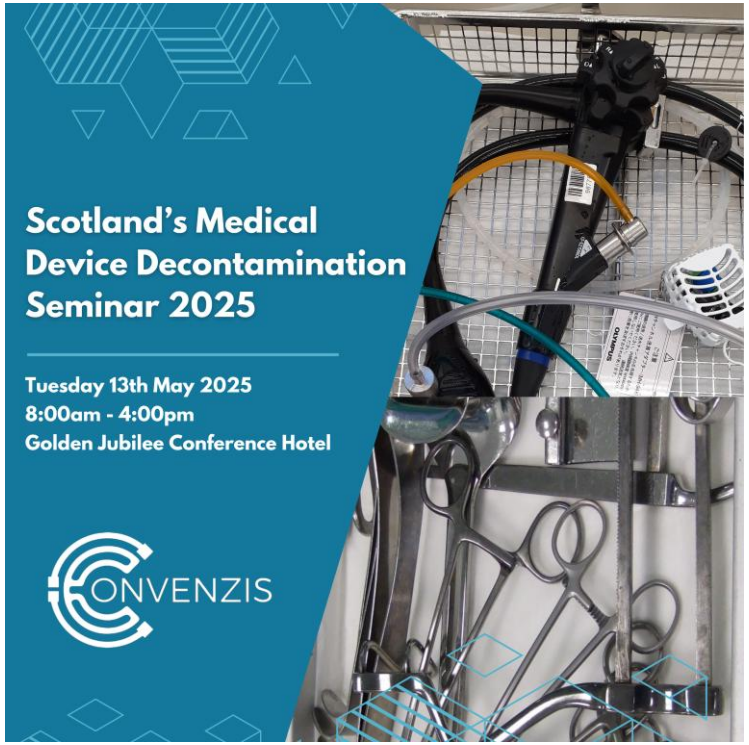
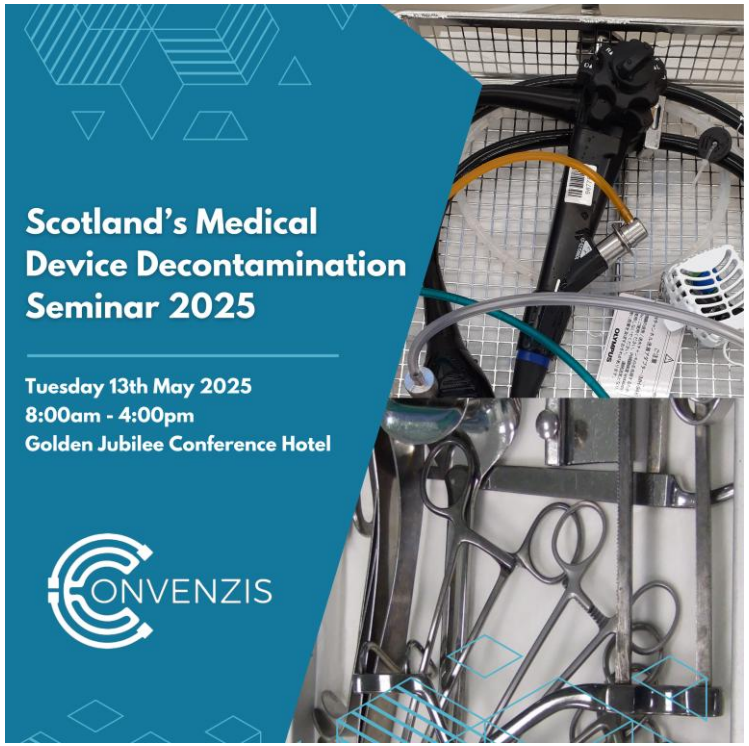
Welcome to Scotland's Medical Device Decontamination Seminar!

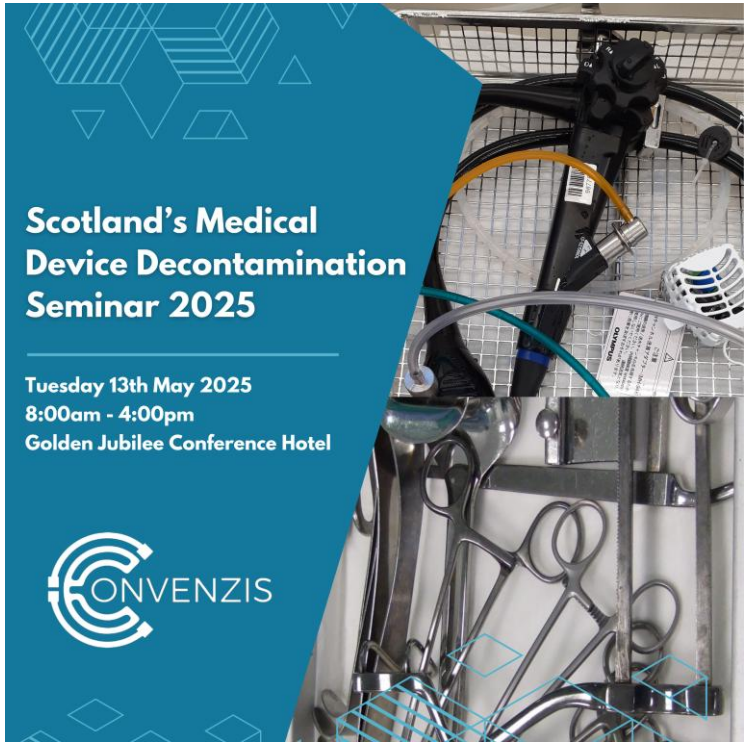


13th May 2025
Golden Jubilee Conference Hotel
Glasgow, G81 4SA



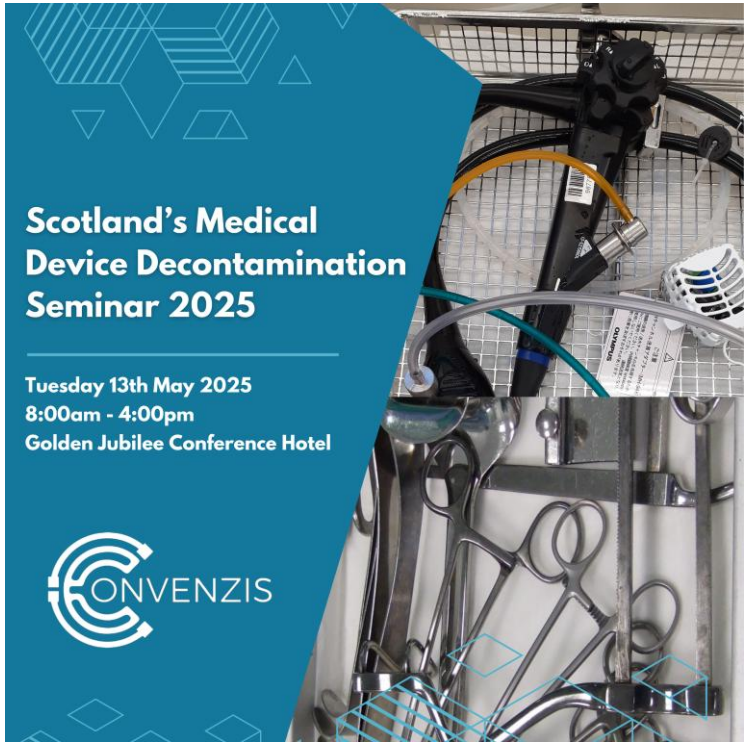
Chair Opening Address

Dr. Sulisti Holmes
Head of Decontamination and Incident Investigation Reporting Centre
NHS Scotland Assure



Keynote Presentation

Dr. Matthias Tschoerner
Head of Applications Department and Research and Development
Chemische Fabrik Dr. Weigert GmbH & Co.



Keynote Presentation

Alice Miller
Assistant Postgraduate Dental Dean
NHS Education for Scotland

Evolution not Revolution

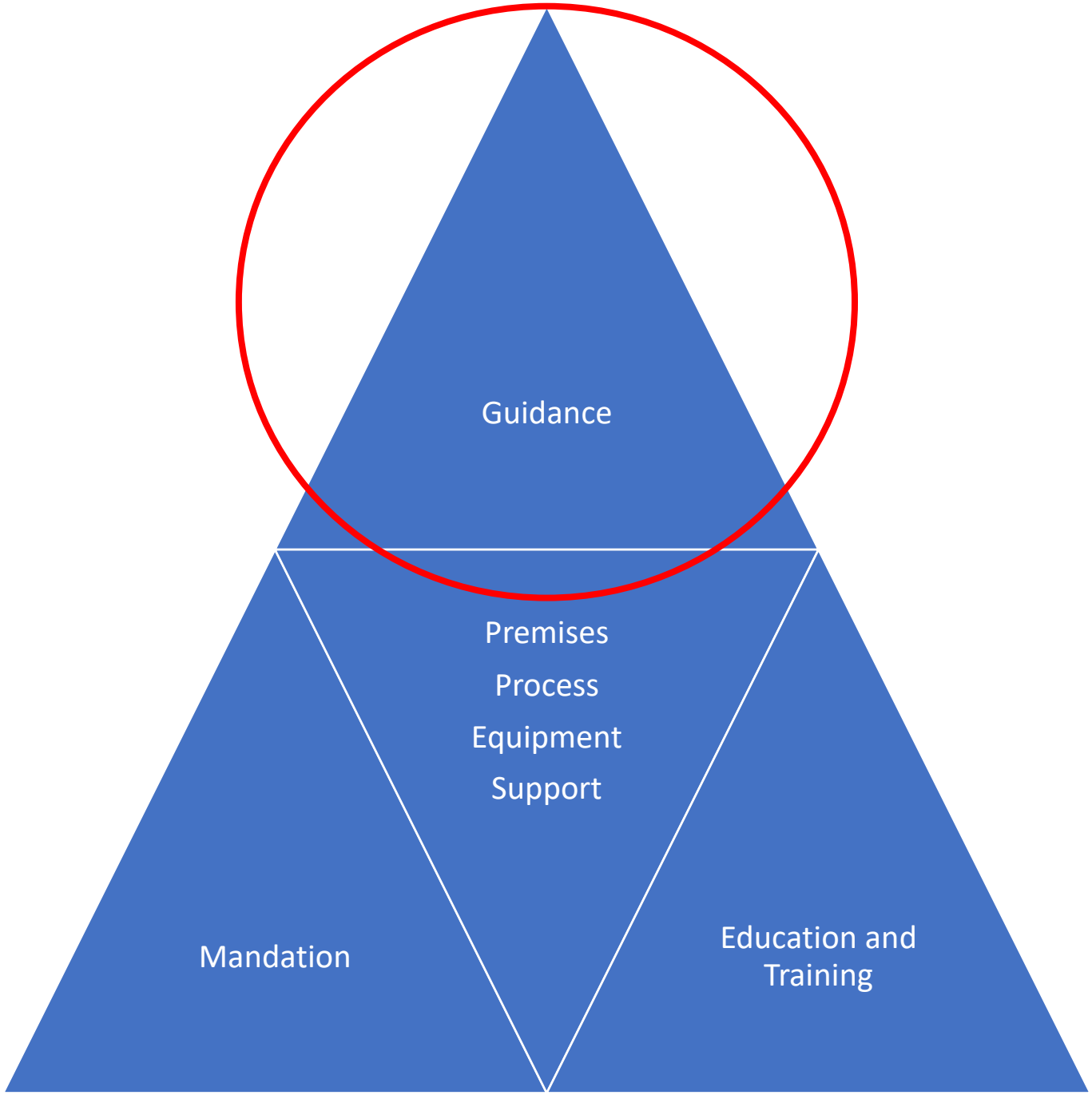
SHTM 01-05
and
LDUs in General Dental Practice (GDP)


PHILIPS
Calspar DP


MERCURY
SPILLAGE
KIT


WHIP
&
SADDLE


DUNS
DENTAL PRACTICE


Guidance
Premises
Process
Equipment
Support
Mandation
Education and
Training

Right Processes - GUIDANCE

Cleaning published March 2007

Sterilisation Published Dec 2011

Management (Online in PSM)
Published October 2014

- DDP DECON ROOM 2011

The Vision

‘To ensure accurate Infection Control / Decontamination information is disseminated widely and consistently in a form appropriate to the target audience and in a way which allows and encourages dentists and their teams to assess what they need to do to change their practices and improve patient safety’.

Irene Black, 2006

The Action Plan

Problem	Goal	Action Plan	Who's responsible		Monitoring Progress	Has the action been achieved
Wearing watches during clinical sessions	Watches are not worn during clinical sessions	When I change into my uniform then I will take off my watch [may also develop AP for buying and fixing clock to surgery wall] Reminder (if appropriate) Changing into uniform	All staff		e.g. how, who, when	Date_____ Always ☐ Sometimes ☐ Never ☐ Any comments/problems
			All dentists	X		
			All DCPs	X		
			All non-clinical staff			
			Other (names)			

- Decontamination in Dental Primary Care - An RCT of Two Educational Strategies

Research Question

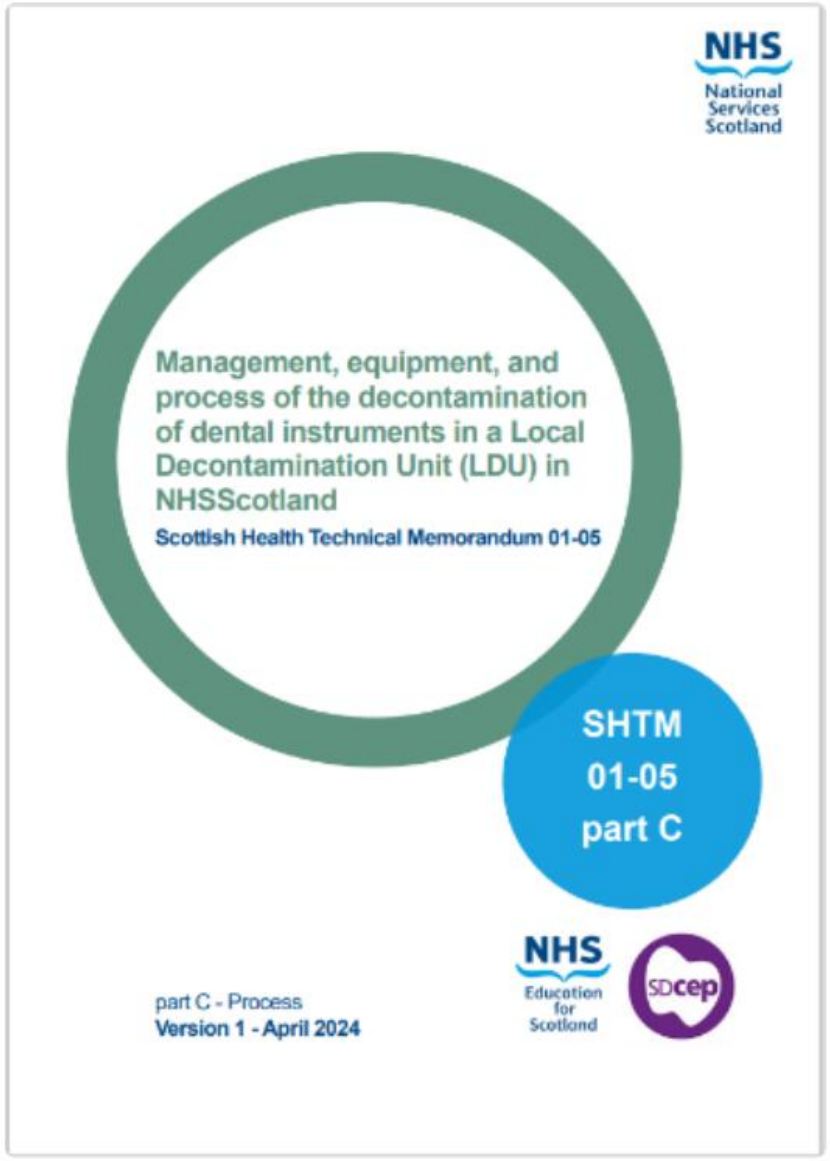
In comparison to postgraduate education alone, does the provision of postgraduate education coupled with theory-based, individualised, practice support visits lead to an effective and cost-effective increase in the implementation of postal guidance on the cleaning of dental instruments in dental primary care?

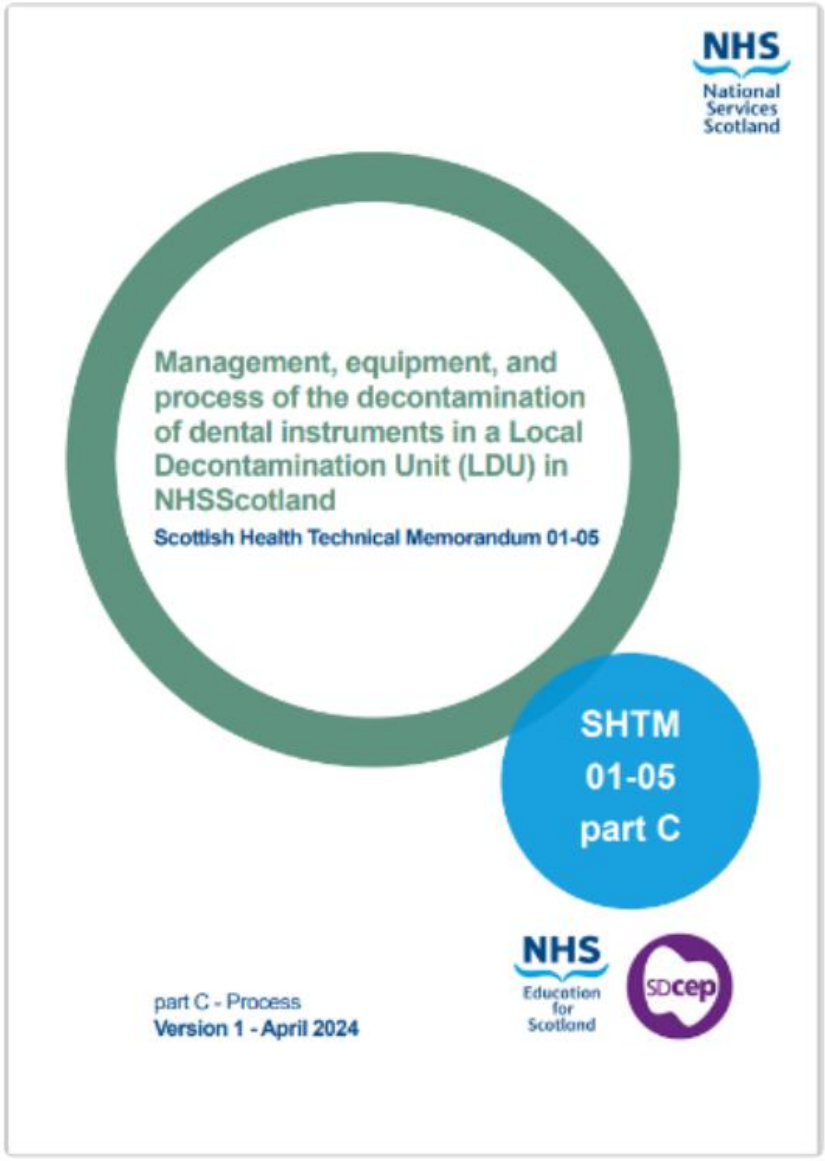
TRiaDS

Guidance

Management, equipment, and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland (SHTM 01-05)

Published on 30 April 2024
From: NHSScotland Assure


NHS
National Services Scotland
Management, equipment, and process of the decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland
Scottish Health Technical Memorandum 01-05
SHTM 01-05 part C
NHS Education for Scotland
SDcep
part C - Process
Version 1 - April 2024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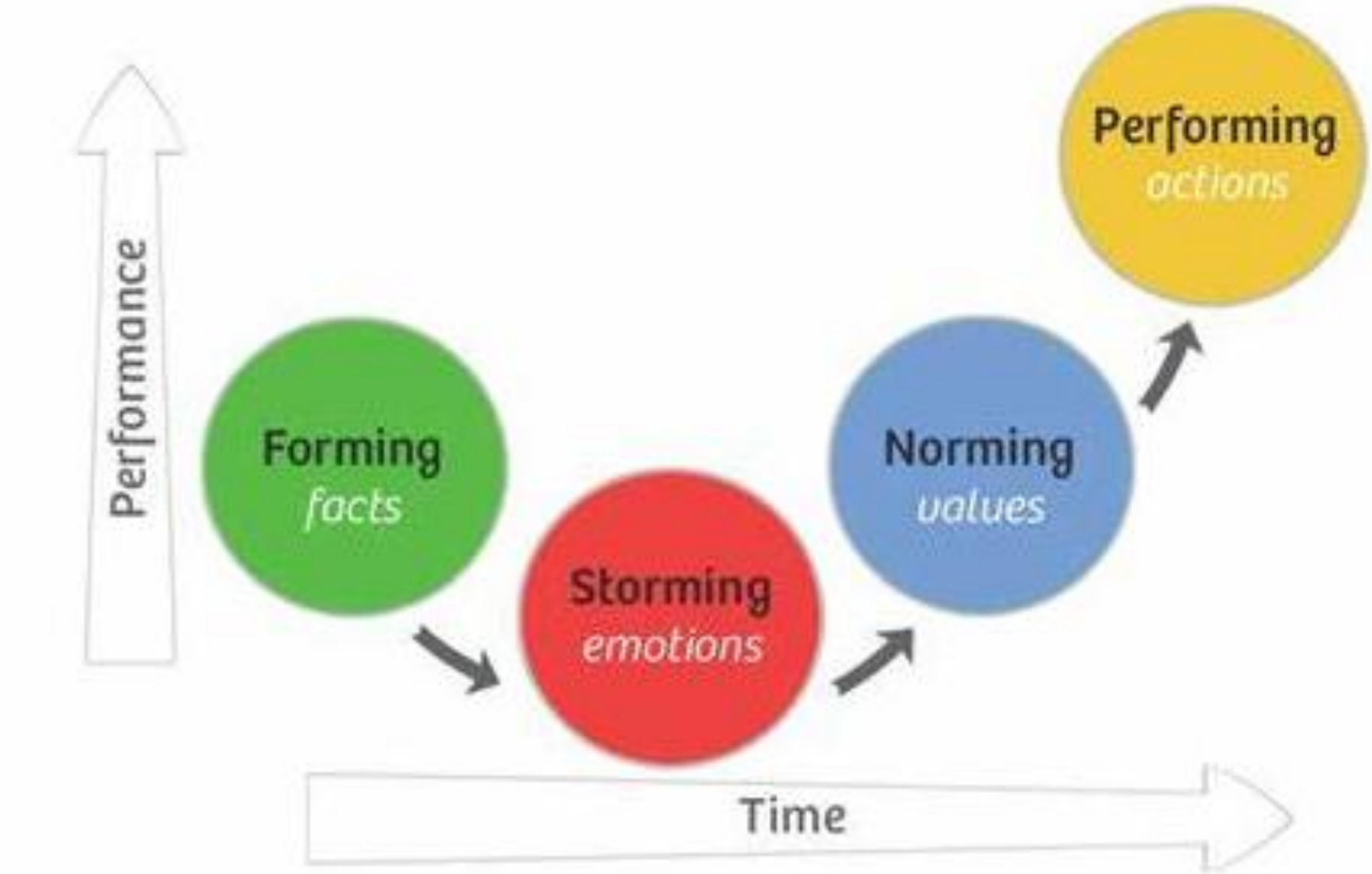
Version 1 - April 2024


Performance
Forming
facts
Storming
emotions
Norming
values
Performing
actions
Time

Current Challenges

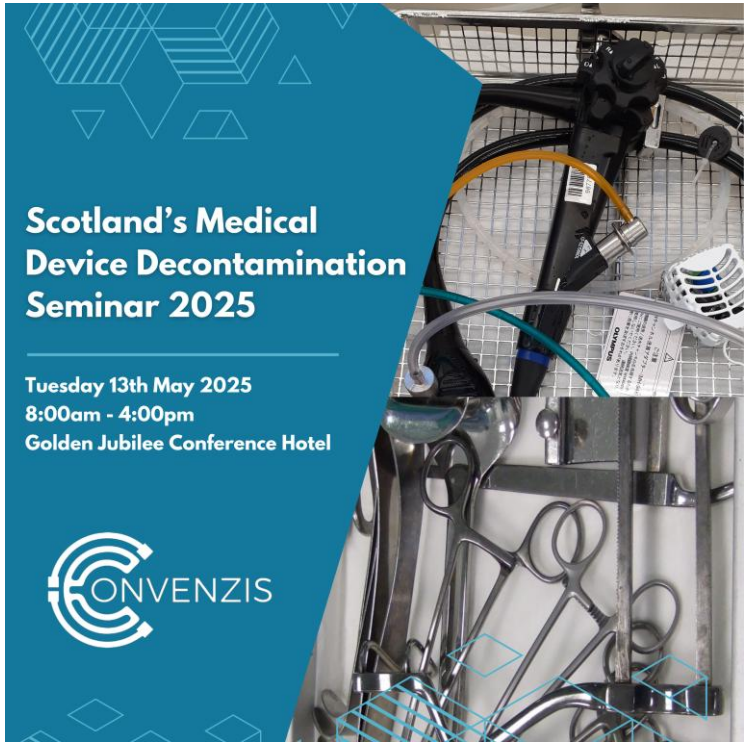
- Staff retention

  COVID burnout = high team turnover.

  Increased demand for training/keep process quality
- **S**HTM 01-05 getting confused with HTM 01-05

  Different content!
- Sustainability/ IPC not happy bed fellows

  SHTM 01-05 incorporated some principles



Keynote Presentation

Carol Colligan
Infection Control Manager / Decontamination Lead
NHS Shetland

MICROBIAL CONTAMINATION OF FINAL RINSE WATER FOR ENDOSCOPE WASHER DISINFECTORS

CAROL COLLIGAN, INFECTION CONTROL MANAGER/ DECONTAMINATION LEAD, NHS SHETLAND

SULISTI HOLMES, HEAD OF DECONTAMINATION AND INCIDENT REPORTING, NHS NATIONAL SERVICES, SCOTLAND

ROBERT ALLAN, AUTHORISING ENGINEER DECONTAMINATION, NHS NATIONAL SERVICES, SCOTLAND

PROFESSOR PETER HAWKEY, CONSULTANT MICROBIOLOGIST/ INFECTION CONTROL DOCTOR, NHS SHETLAND

THE BASICS

- FLEXIBLE ENDOSCOPES CANNOT WITHSTAND THERMAL PROCESSING
- HIGH LEVEL DISINFECTION & RINSING TO REMOVE CHEMICAL RESIDUES
- FINAL RINSE WATER NEEDS TO BE TESTED AS PER GUIDANCE AND STANDARDS

MICROBIAL TESTING

- TOTAL VIABLE COUNT (TVC) - LESS THAN 10 CFU/100 MLS
- ABSENCE OF *PSEUDOMONAS SP*

SOURCES

- SHTM 01- 06 – WEEKLY TESTS
- BS EN ISO 15883-4: 2018

POOR QUALITY RINSE WATER CAN REINTRODUCE CONTAMINANTS WHICH ADVERSELY AFFECT PATIENTS

THE INCIDENT - DEC 2019 SUDDEN RISE IN TVC LEVELS

HIIAT RISK ASSESSMENT UNDERTAKEN BY IPCT → RED/ HIIORT SUBMITTED TO HPS

THEATRE'S BCP PUT IN PLACE – REPROCESSING SUPPORT PROVIDED BY NHS GRAMPIAN

PATIENTS AFFECTED REVIEWED TO IDENTIFY ANY HIGH RISK FACTORS

PROBLEM ASSESSMENT GROUP (PAG) THEN INCIDENT MANAGEMENT TEAM (IMT) MEETINGS HELD

FIRST ACTION

ANOTHER SCOTTISH HOSPITAL WITH SAME MACHINES HAD RESOLVED THESE ISSUES BY INCREASING THE TEMPERATURE AND TIMING OF THE INCOMING RO WATER FEED FOR THE MACHINE SELF DISINFECTION CYCLES

SYNCHRONISATION OF CYCLES IMPLEMENTED → IMMEDIATE REDUCTION IN TVC LEVELS

MACHINES RETURNED TO SERVICE FOLLOWING AGREED SCHEDULE OF ACCEPTABLE TEST RESULTS

INCIDENT REVIEW SCHEDULED FOR MARCH 2020

FROM 30TH MARCH 2020

THREE SPIKES (50 -100 CFU/ 100MLS) OVER A PERIOD OF 16 WEEKS

PATTERN OF RESULTS FROM BOTH EWD WATER SAMPLES ALMOST IDENTICAL

FURTHER HIIORT SUBMITTED TO HPS (ARHAI)

PAG/ IMTS HELD – ALL RELEVANT PERSONNEL ATTENDED PLUS HEALTH FACILITIES SCOTLAND (HFS), EWD MANUFACTURER, UK REPRESENTATIVE FOR THE EWD MANUFACTURER & MANUFACTURER OF REVERSE OSMOSIS WATER SYSTEM

THEATRE'S BCP PUT IN PLACE – REPROCESSING SUPPORT PROVIDED BY NHS GRAMPIAN

PATIENTS AFFECTED REVIEWED TO IDENTIFY ANY HIGH RISK FACTORS

HFS CARRIED OUT A COMPLETE SITE AUDIT IN JULY 2020 TO DETERMINE ROOT CAUSE OF PROBLEM

OBJECTIVES

EXAMINE MAINTENANCE & SAMPLING OF COMPLETE SYSTEM

IDENTIFY CRITICAL POINTS WITHIN THE SYSTEM

PROVIDE PROPOSED CORRECTIVE ACTIONS

METHODOLOGY

SAMPLING IN THE HOSPITAL – SAMPLING & SANITATION PROCEDURES FOR SAMPLING PORTS/POINTS ETC.
CLEAR SCHEMATIC OF WHOLE SYSTEM & SAMPLING POINTS PREPARED TO UNDERSTAND INTERACTION OF EWDS WITH RO WATER SYSTEM

OFF ISLAND ACCREDITED LABORATORY– SAMPLE TRANSPORT/ HANDLING (COLD CHAIN/ PACKAGING), SAMPLE METHODOLOGY

RO AND WATER DISTRIBUTION SYSTEM – RO MANUFACTURER MAINTENANCE REPORTS, LOCAL MAINTENANCE RECORDS, SANITATION PROCEDURES, FILTER GRADES/ CONDITIONS, FREQUENCY OF FILTER CHANGES, POTENTIAL DEFICIENCIES/AREAS TO BE INVESTIGATED IN THE SYSTEM.
WEEKLY TVC WATER SAMPLES WERE TAKEN FROM BOTH EWDS, FROM DISTRIBUTION SAMPLING POINTS FOR THE COMPLETE RO WATER SYSTEM AND FROM EWDS BREAK TANKS

EWDS – MAINTENANCE REPORTS BY UK REPRESENTATIVE FOR EWD MANUFACTURER, PERIODIC TEST RECORDS, FILTER GRADES/ CONDITIONS, FREQUENCY OF FILTER CHANGES, POTENTIAL DEFICIENCIES/AREAS TO BE INVESTIGATED IN THE SYSTEM

WATER TEST RESULTS

Area Examined	Compliant
SOP including all routine tests	√
Staff training	√
Transport conditions – cold chain/ packaging	√
Laboratory Accredited for EWD water testing	√
Maintenance contract - EWDS / RO system	√
Water testing for RO water system	√

FINDINGS

- ALL COMPONENTS IN CONTACT WITH WATER HAD BEEN SUBJECTED TO REGULAR DISINFECTION PROCESSES APART FROM THE BREAK TANKS & TUBING LEADING TO TANKS
- HIGH TVCS DETECTED IN SAMPLES FROM EWD RINSE WATER & BREAK TANKS
- DESIGN OF THE PIPE AND BREAK-TANK WITHIN THE EWD WAS FOUND TO BE AN OPEN CIRCUIT EXPOSED TO AIR - POTENTIAL FOR BACTERIAL INGRESS & GROWTH
- NO WAY TO INSPECT LEVEL OF CLEANLINESS OF BREAK TANKS OR TO CHECK IF RESIDUAL WATER WAS LEFT IN THESE
- DRAWING HOT WATER FROM THE WATER TREATMENT & DISTRIBUTION SYSTEM DURING SYNCHRONISATION MIGHT NOT ALWAYS BE EFFECTIVE IF COLD WATER OR HIGH LEVELS OF BACTERIAL CONTAMINATION PRESENT IN PIPES OR BREAK TANKS

INCIDENT REPORTED TO INCIDENT REPORTING INVESTIGATION CENTRE (IRIC) ON 30TH JUNE 2020 - REF INV1817 OCC2151/ MHRA – REF 2020/006/023/487/014

BREAK-TANK

ACTIONS

- ROOT CAUSE FOR INCREASED TVC LEVELS COULD POSSIBLY BE LACK OF SANITATION OF THE INTERNAL BREAK TANKS
- BREAK TANK SANITISATION WAS NOT INCLUDED IN THE MANUFACTURER'S INSTRUCTIONS FOR THESE MACHINES/ NOT PART OF THE DAILY THERMAL DISINFECTION CIRCUIT
- EWD MANUFACTURER DEVELOPED A CHEMICAL SANITISATION SOP FOR BREAK TANKS
- FOLLOWING IMPLEMENTATION TVC LEVELS REDUCED TO LESS THAN 10 CFU/100ML
- CHEMICAL SANITISATION WAS A RISKY PROCEDURE FOR ESTATES STAFF
- BOTH EWDS REPLACED IN 2023 – GREATER ASSURANCE OF PATIENT/STAFF SAFETY, NO BREAK TANKS

LESSONS LEARNED

NHS SHETLAND UNAWARE ANY OTHER HOSPITALS WERE EXPERIENCING SIMILAR PROBLEMS

IMPROVED COMMUNICATION NEEDED BETWEEN BOARDS ABOUT ANY ISSUES & ACTIONS TAKEN TO REMEDY THESE

SUBSEQUENT ACTIONS TAKEN BY NHS SHETLAND

PILOT PROJECT COMMENCED TO TEST TVC'S FOR FINAL RINSE WATER AT GILBERT BAIN HOSPITAL LABS, NOT ACCREDITED FOR WATER TESTING

NSS OVERSIGHT & SUPPORT FROM NHS SHETLAND ICD/ MICROBIOLOGIST

WEEKLY TEST SAMPLES STILL SENT SOUTH TO ACCREDITED LAB

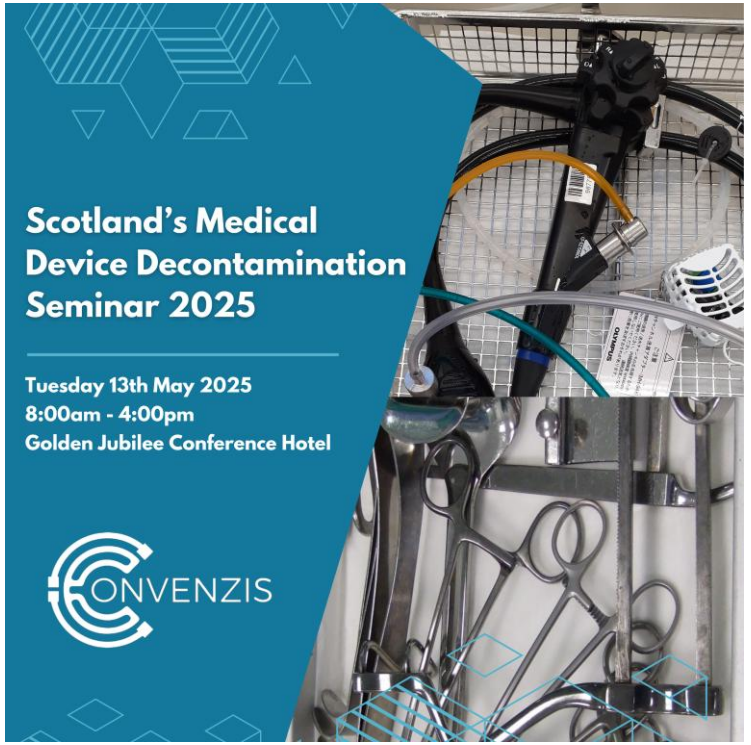
WILL CONTINUE UNTIL ASSURANCE THAT LOCAL TESTING IS AS RELIABLE AS OFF ISLAND TESTING

ACKNOWLEDGEMENTS

SULISTI HOLMES, HEAD OF DECONTAMINATION AND INCIDENT REPORTING, NSS

ROBERT ALLAN, AUTHORISING ENGINEER DECONTAMINATION, NSS

PROFESSOR PETER HAWKEY, CONSULTANT MICROBIOLOGIST/ICD NHS SHETLAND


Scotland's Medical
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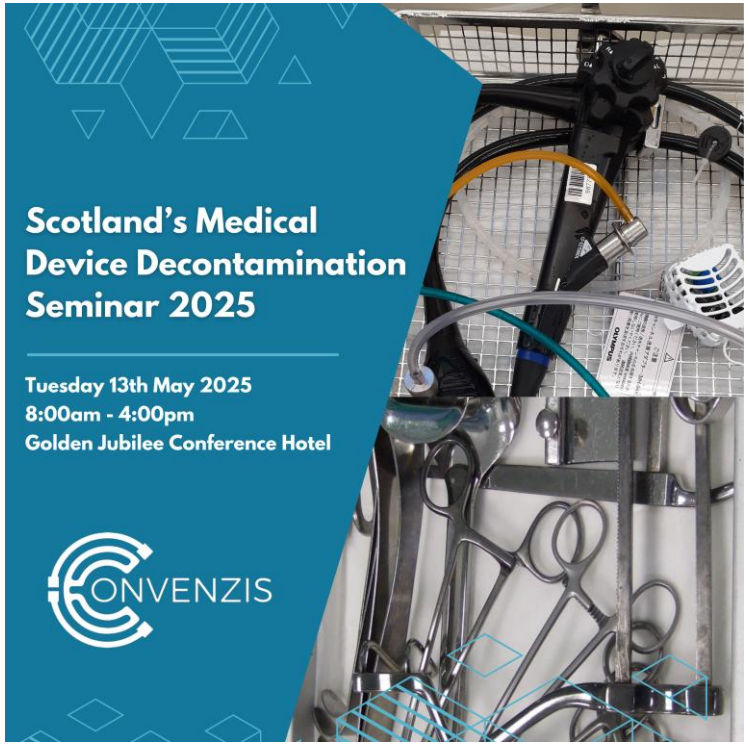
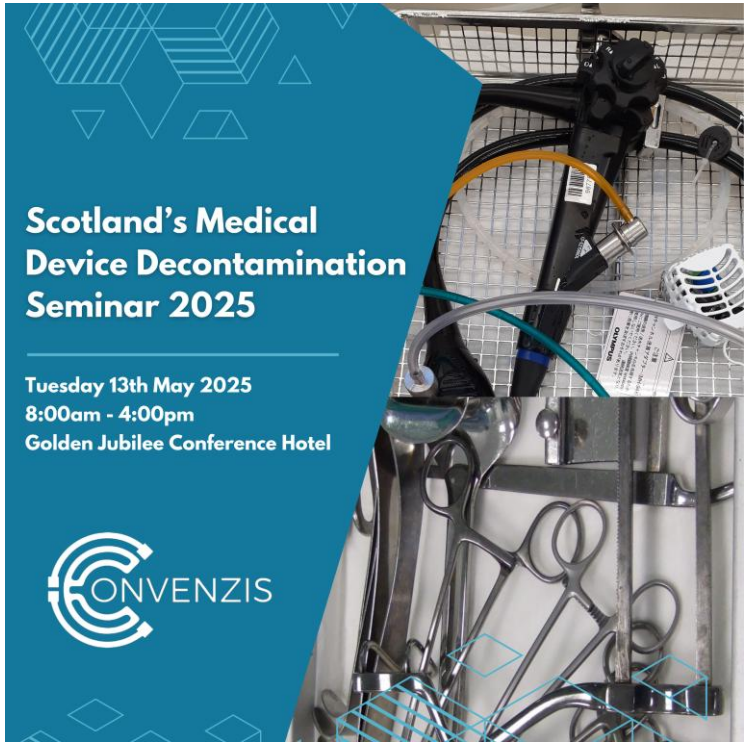
Q&A

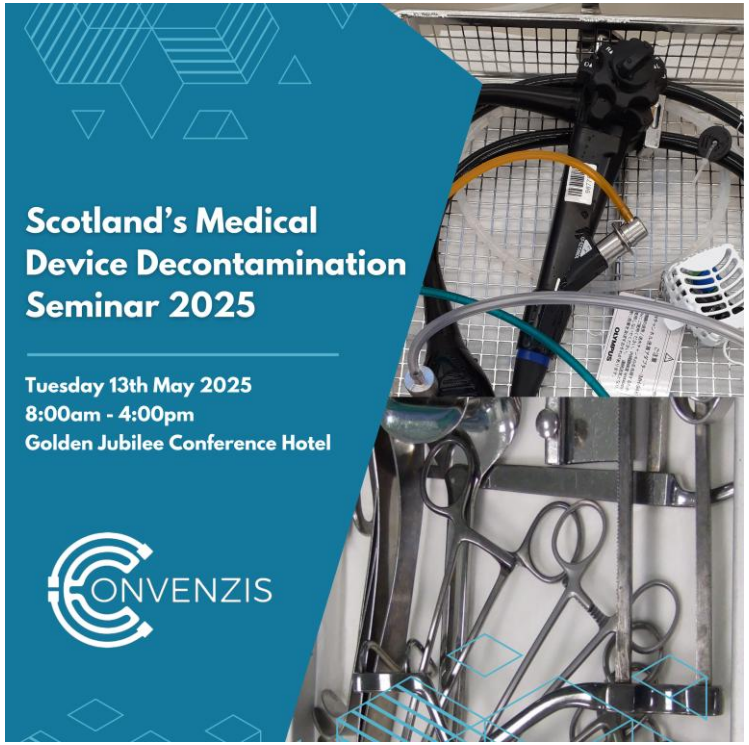


Refreshments & Networking



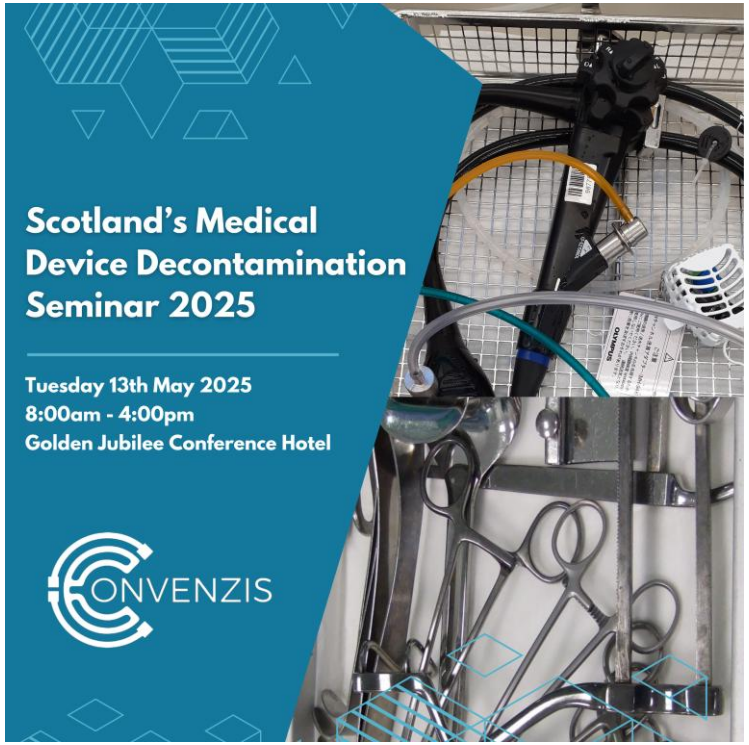
Chair Morning Reflection

Dr. Sulisti Holmes
Head of Decontamination and Incident Investigation Reporting Centre
NHS Scotland Assure



Keynote Presentation

Vanda Plecko
Consultant Microbiologist & Infection Control Doctor
NHS Highland



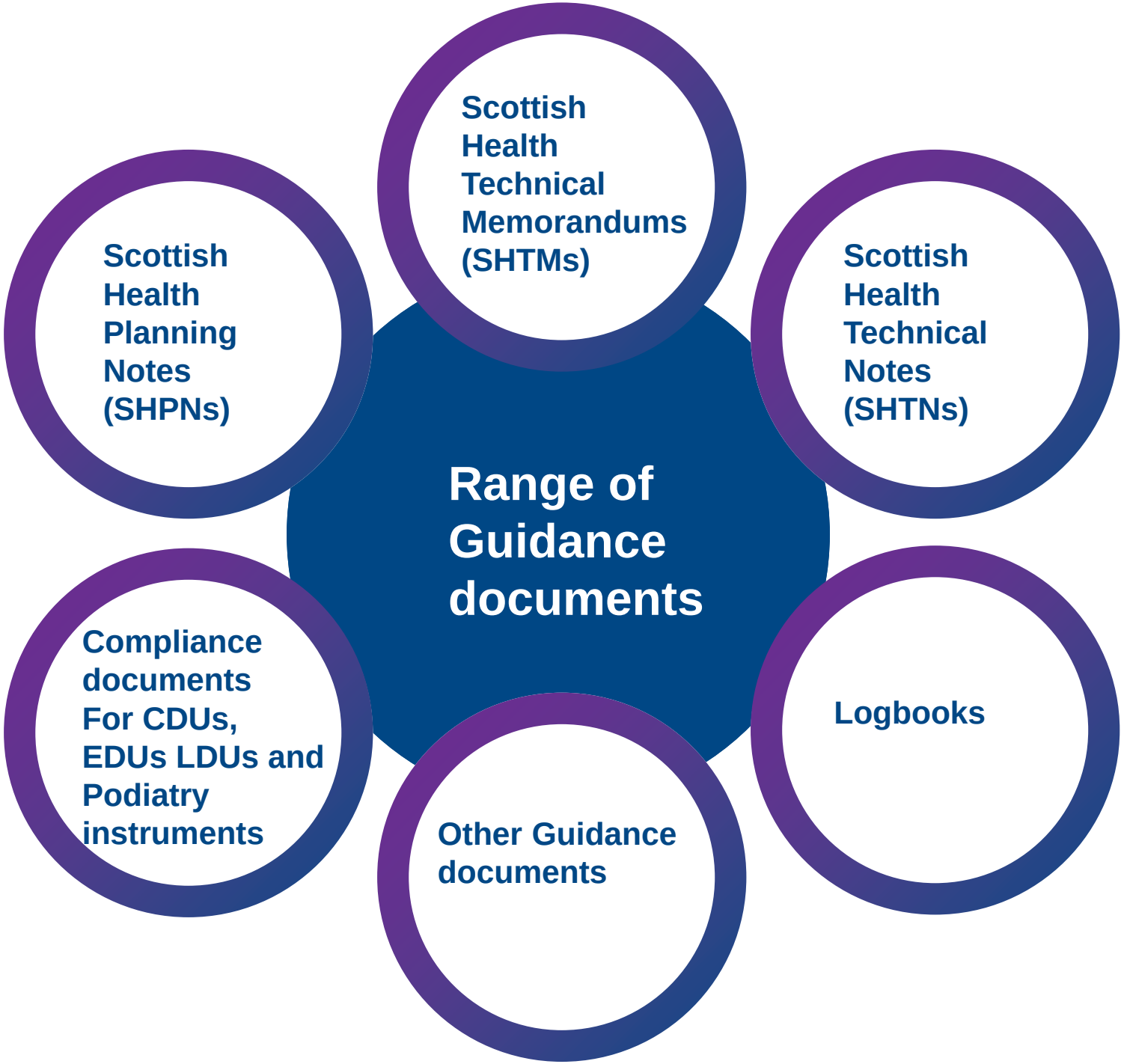
Keynote Presentation

Anne Campbell
Technical Advisor (Decontamination)
National Services Scotland

Anne Campbell
Technical Advisor (Decontamination)

NHSScotland Assure Decontamination Services Guidance

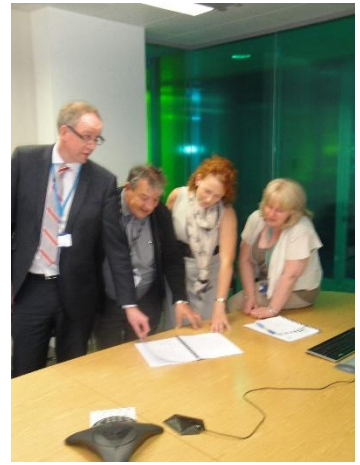
2025 Guidance update


Range of Guidance documents
Scottish Health Technical Memorandums (SHTMs)
Scottish Health Planning Notes (SHPNs)
Scottish Health Technical Notes (SHTNs)
Compliance documents For CDUs, EDUs LDUs and Podiatry instruments
Logbooks
Other Guidance documents

Reasons for change

Number of challenges since 2019

- **Some External**
  - Exit from European Union
  - New legislation
  - New British standards
- **Some internal**
  - Creation of NHSScotland Assure
  - Introduction of accessibility requirements
  - **Evidence and Lesson learns**
  - **Technology and Innovation**
  - **Stakeholder feedback**



Guidance currently under review

Scottish Health Technical Memorandum (SHTMs)

- SHTM 01 - 01: 2018 CDUs V1.0 - high priority - consideration of new technologies revised standards
- SHTM 01-02: Laboratory sterilizers: 2020 V1.0 – low priority

Scottish Health Planning Notes (SHPNs)

- SHPN 13 - 1 CDUs for publication 2025 - consideration of revised standards, BS 13485: 2021, BS EN 17141: 2020, detailed guidance on management/ planning of new build projects and new design layouts
- SHPN 13 - 3 EDU for publication 2025 - consideration of revised standards and updated BSG guidance

Guidance currently under review cont.

Other guidance

- SHTM 01-03 Cartridge of Dangerous goods in relation to used RMDs (pervious reference GUID 5006 – Updated regulations - UK transportation of dangerous goods:
- SHTN 01-08 On Loan RMDs - Roles and responsibilities - Changes to timelines
- Dental LDU, GUID 5005: 2019 – Updated references including SHTM 01-05
- Compliant Podiatry instruments, GUID 5007: 2020 – consideration of net Zero policy

All guidance to be evidence based and where available:

- include lessons learned from reported Incidents
- consideration of new technologies

Current published guidance not for review in 2025-2026

- Requirements for compliant CDU, GUID 5014: 2024
- Requirements for compliant EDU, GUID 5013: 2024
- SHTM 01-06: 2023 – Guidance for Decontamination of endoscopes and TOE probes V 1.0
- SHTM 01-05 Decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland V 1.0: 2024
- SHPN 13 - 2 LDU: 2008

In summary

Several new publication have been released in the last 2 years

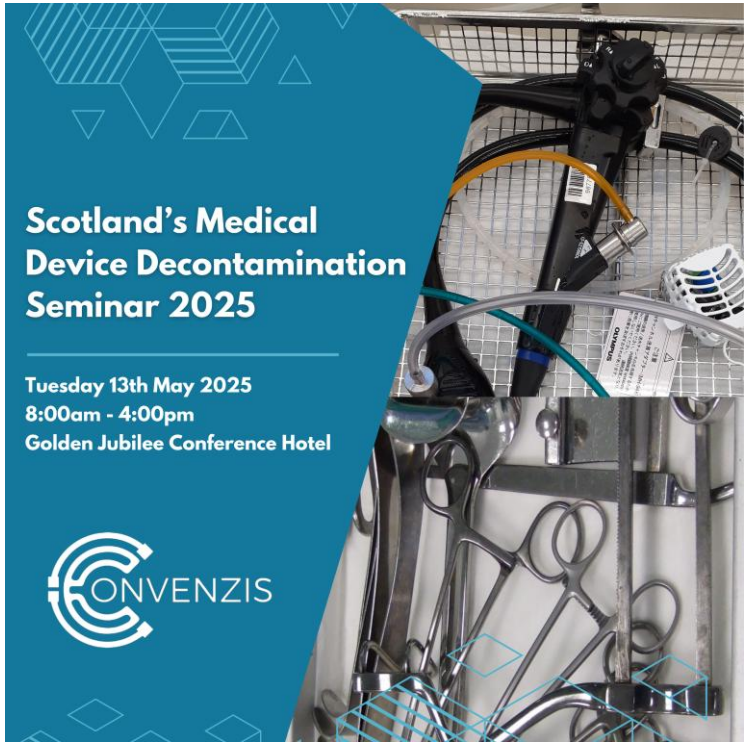
- Requirements for compliant CDU, (GUID 5014: 2024), EDU, (GUID 5013: 2024), SHTM 01-06: 2023 –Decontamination of endoscopes and TOE probes V 1.0
- SHTM 01-05 Decontamination of dental instruments in a Local Decontamination Unit (LDU) in NHSScotland V 1.0: 2024

- **What will be published soon?**
  - SHTM 01-03 Carriage of Dangerous Goods Regulations with respect to used Medical Devices – May 2025
  - SHTM 01-08 Decontamination Guidance Management of on Loan RMDs Roles & Responsibilities – June 2025
  - Requirements for compliant Dental LDUs and Podiatry instruments - Public consultation – June 2025
  - SHPN 13 -1 and 2 for CDUs and EDU design – Autumn 2025
- **What next? UK collaborative approach**
  - Greater collaboration with the other 3 nations in the UK to provide a consistent approach to Guidance and Technical Requirements

Thanks for Listening!

Thanks for all the fish

The answer to everything is 42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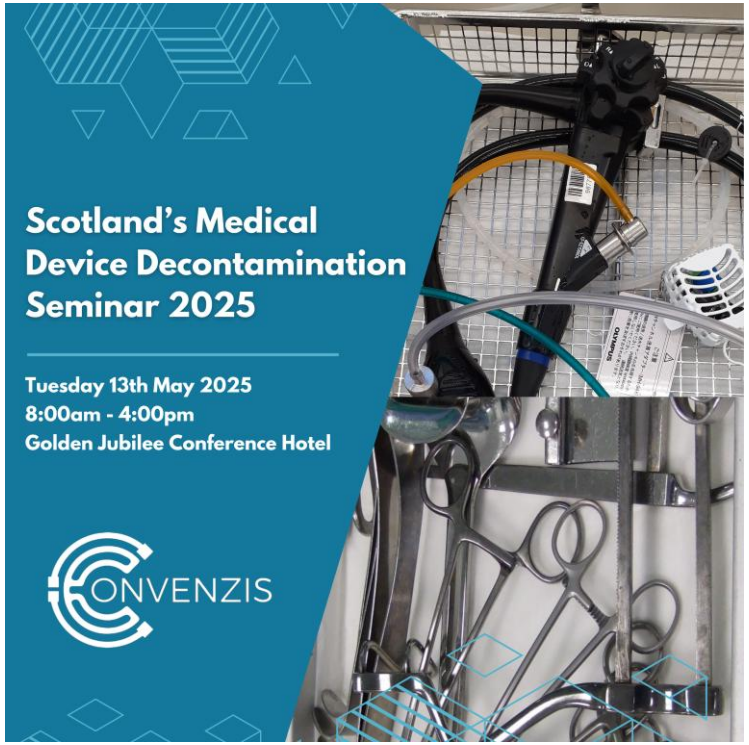
Case Study



Case Study

James Doherty
National Sales Manager
Wassenburg Limited

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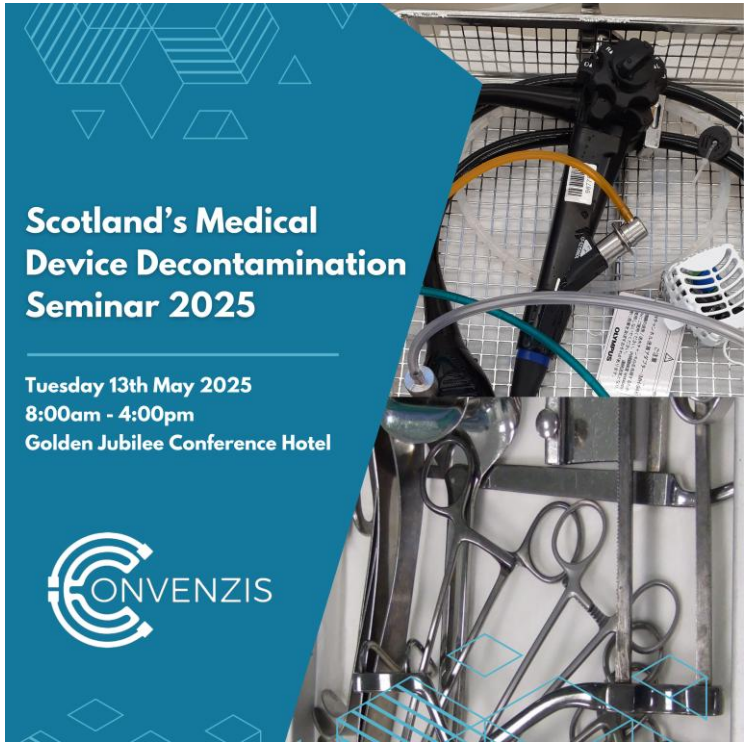
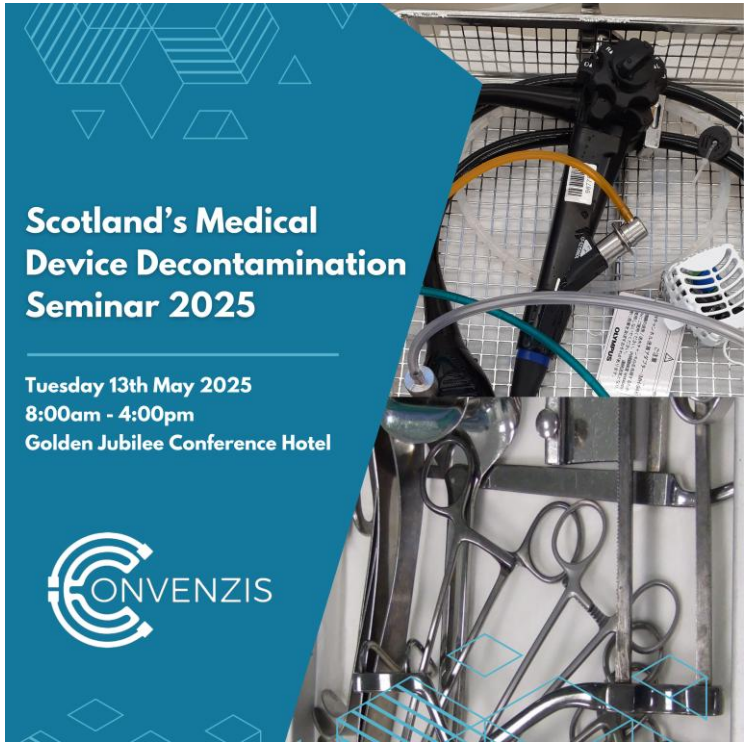


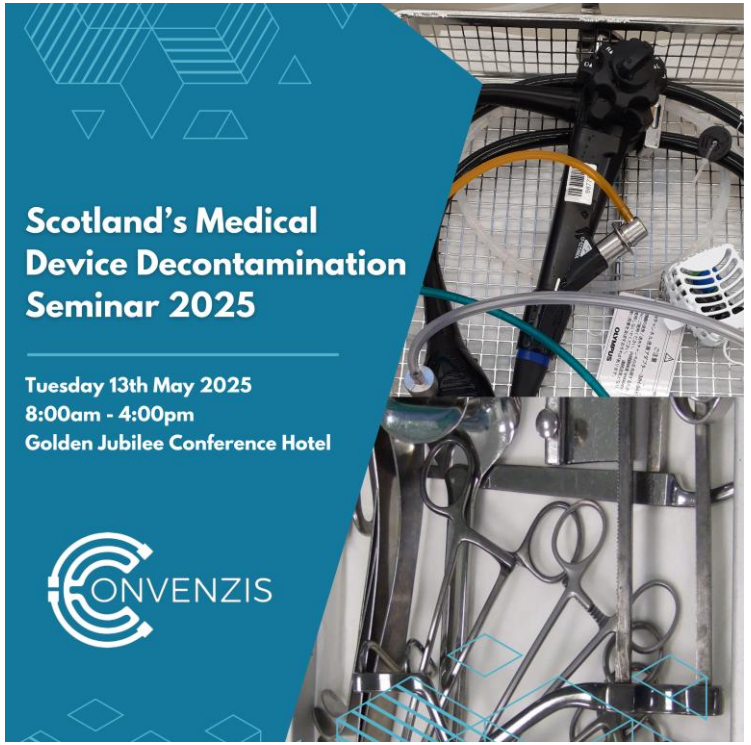
Case Study

nanosonics
Infection Prevention. For Life.



Case Study

Ellie Wishart
Senior Medical Affairs Manager
Nanosonics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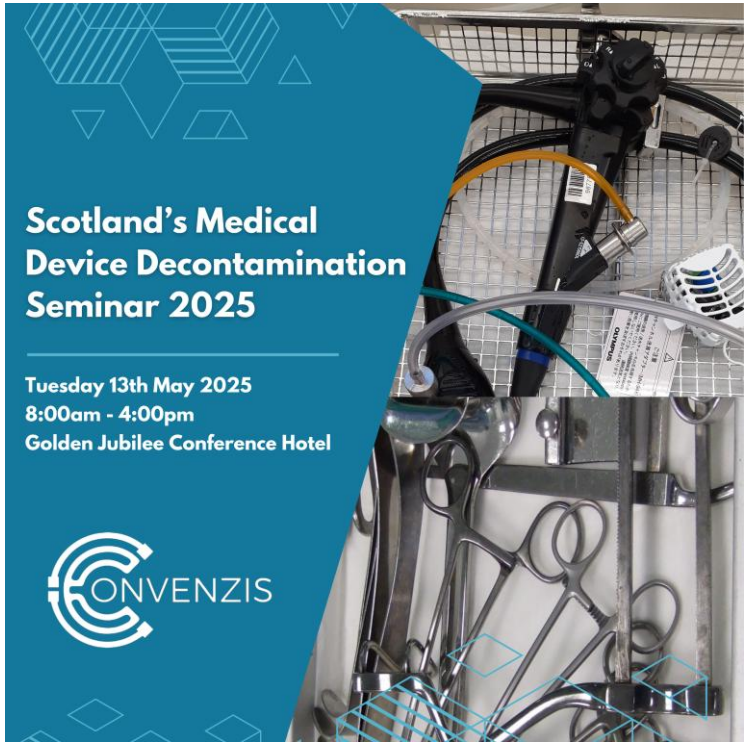
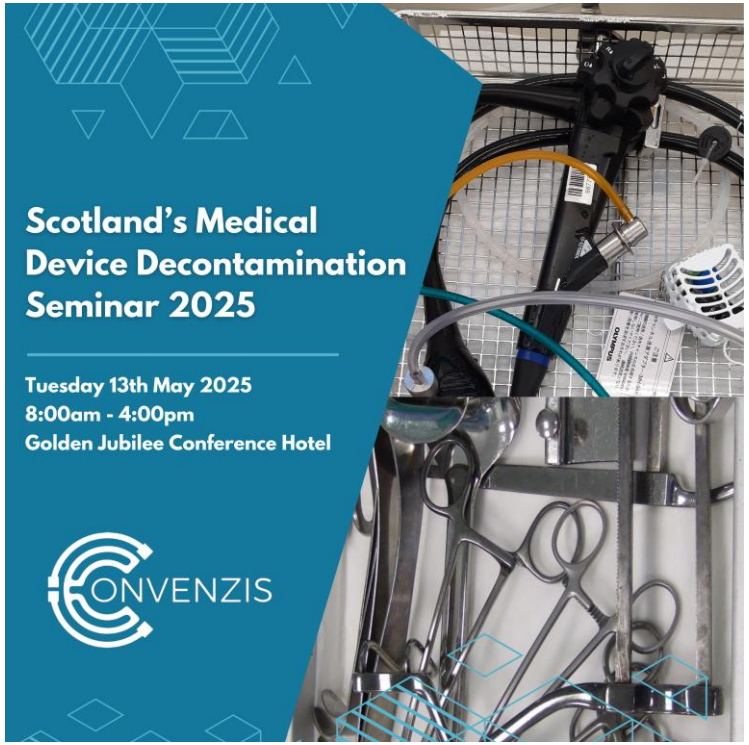
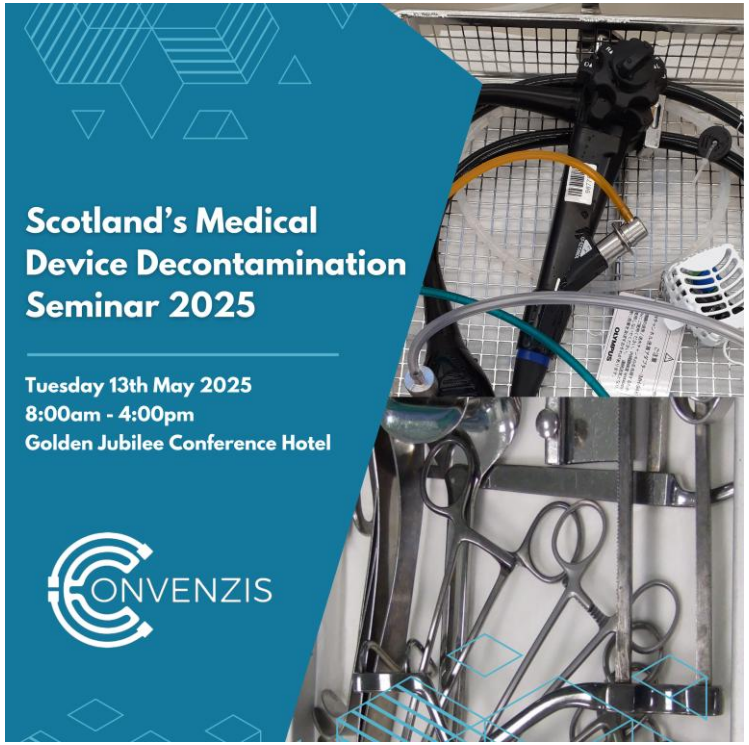


Lunch & Networking



Chair Afternoon Reflection

Vanda Plecko
Consultant Microbiologist & Infection Control Doctor
NHS Highland



Keynote Presentation

Gillian Cairns
Global Head of Microbiology
BSI

New PMS requirements for Great Britain

Gillian Cairns
Global Head of Microbiology

Jenifer Hannon
Post-market Surveillance Regulatory Lead

Vishal Thakker
Head of Approved Body

May 2025

Information presented within this presentation is based on our current understanding of the applicable legislations and information available

Agenda

01
Introduction and overview of the PMS regulations

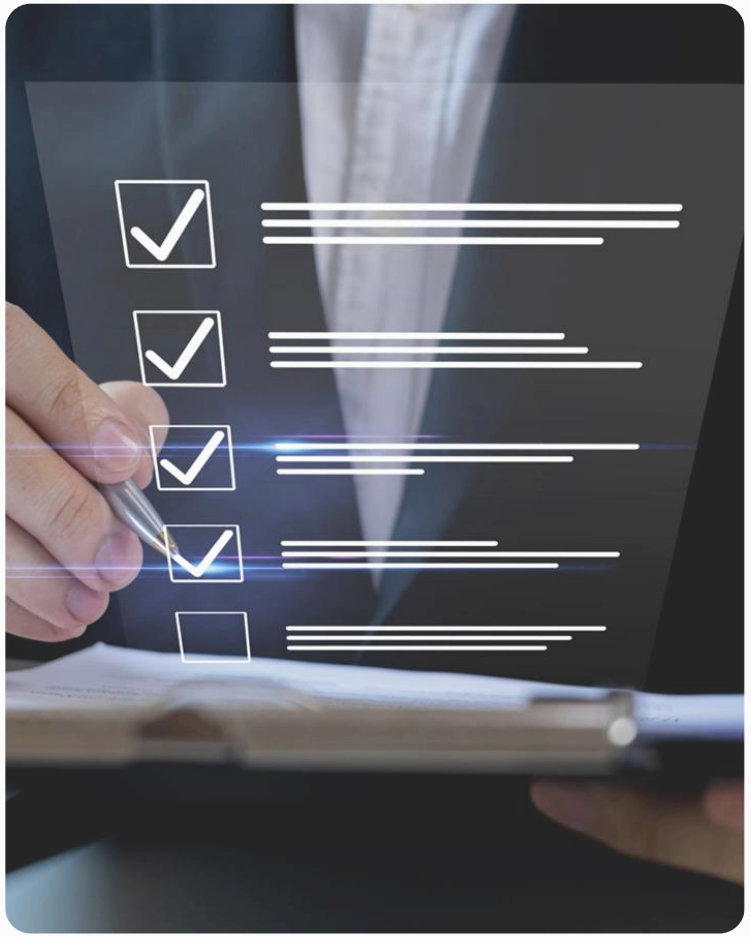
02
Timelines for implementation

03
PMS requirements relating to the QMS

04
Periodic safety update reports

05
A look to the future for the core UK MDR and HIE

06
Q&A session



Introduction

01

MHRA seeks to introduce regulatory reform in response to recommendations made by the Independent Medicines and Medical Devices Safety review (IMMDS review, 2018-2020)

02

Initial public consultation launched in 2021, other consultations are ongoing

03

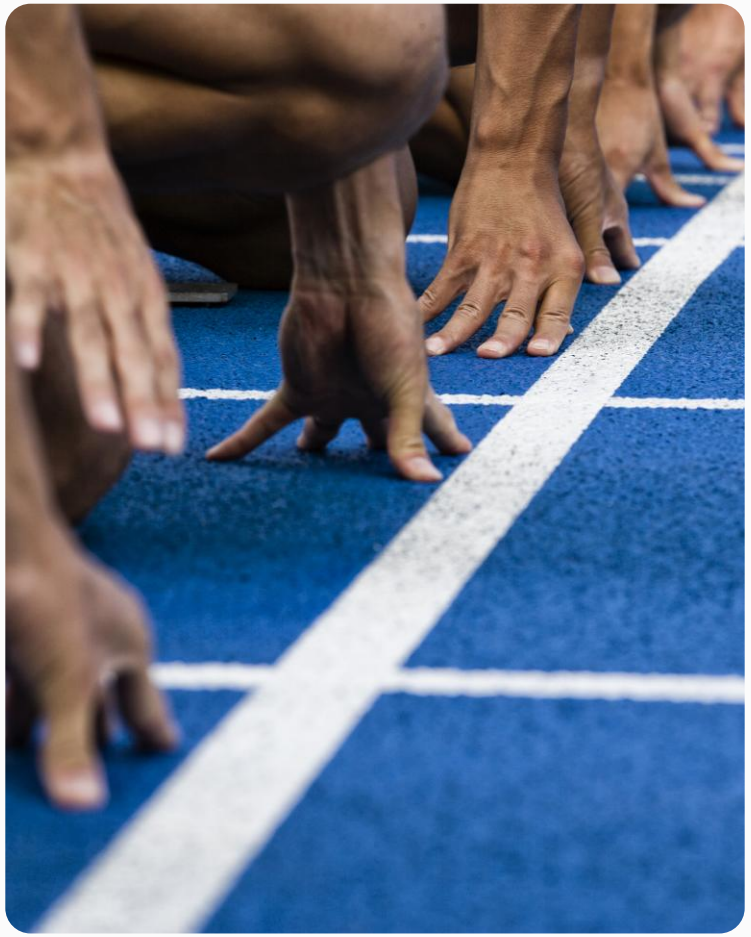
Post-market Surveillance Regulations are the first stage of strengthening regulatory requirements and aim to improve patient safety in Great Britain

04

Applies to all devices placed on the GB market or put into service, regardless of whether this is under the UKCA or CE scheme

05

Broadly mirrors the EU MDR/IVDR, some differences



Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 SI 2024/1368

Part 4A PMS

- Interpretation (definitions) (44ZC)
- Scope (44ZD)
- PMS System (44ZE)
- PMS Plan (44ZF)
- Preven
- Report
- FSCA a
- Post-m
- Periodi
- Trend R
- Reports received by Secretary of State (44ZO)
- Analysis of information received under Part 4A (44ZP)
- Retention of PMS documentation (44ZQ)
- Requests for PMS documentation (44ZR)

CE-marked devices must also comply!

Custom made devices are exempt from:

- FSCAs outside of Great Britain
- Post-market Surveillance Report
- Periodic Safety Update Report
- Trend Reporting

Complete exemption for:

- Devices for Clinical Investigation
- Devices for Performance Evaluation
- Device subject to an Exceptional Use Authorisation

Stakeholder responsibilities

Manufacturer

- PMS System and Plan
- CAPA
- Periodic reporting: PMSR, PSUR
- Serious Incident & FSCA reporting and investigation
- Trend reporting
- Co-operate with and provide information to MHRA upon request
- Retain PMS documentation

Approved Body

- Check manufacturers' compliance in surveillance audits
- Review CAPA notifications
- Review of PSURs, issue report when required
- Assess PMS Plans at initial application
- Provide information to MHRA upon request

UK Responsible Person

- Receive PSUR review reports
- Retain PMS documentation
- Co-operate with and provide information to MHRA upon request

MHRA

- Receive reports of Serious Incidents, FSCA and trends and monitor manufacturer's investigations
- Initiate separate investigations when necessary
- Identify trends, patterns and signals in information received & inform manufacturers
- Receive reports of incidents from healthcare professionals and the public and forward to manufacturers

Key new requirements

- **Preventive and Corrective Actions**: Notify UKRP, AB and MHRA and monitor
- **Serious Incident Reports**: 2 days, 10 days, **15 days**, defined content for initial and final
- **PMSR or PSUR**: Risk class dependent, updated regularly, defined content
- **Trend Reporting**: **all incidents** with significant increase in severity or frequency

Timelines for implementation

16 Dec 2024

- Regulation is passed into law by the UK government
- Impact assessment begins

Now!

- Conclude impact assessment
- Updates to QMS
- Updates to systems and tools
- Create or update device-specific PMS system and PMS plans

16 June 2025

- Regulation comes into force
- Compliance is required
- Implement PMS Plan
- Serious incident reporting aligns with EU
- Trend reporting

16 June 2026 and onwards

- 1st PSUR due within 1 year*
- 1st PMSR due within 3 years*

*does not apply to procedure packs except under certain circumstances

Impact assessment

01 Device

- Type
- Risk classification
- Lifetime

03 Geography

- Where am I placing the device on the market?

02 Certification

- CE (MDR/IVDR/Directives)
- UKCA (UK MDR 2002)

04 QMS

- Gap analysis to requirements 44ZE

05 Systems, procedures and documents

- Update
- New

PMS requirements related to the QMS

UKCA certified devices:

- PMS System which is device-specific and based on a PMS Plan
- Evidence of procedures which cover the requirements listed in Regulation 44ZE (3)
- **Evidence that the PMS System outputs feed into the technical and clinical documentation of the device as described in Regulation 44ZE (4)**

CE (Directives or MDR/IVDR) certified devices:

- PMS System which is device-specific and based on a PMS Plan
- Evidence of procedures which cover the requirements listed in Regulation 44ZE (3)

Periodic Safety Update Reports (PSURs)

Risk of device	Frequency of update under SI 2024/1368	Review by Approved Body?	For UKCA-devices: Standalone review or during ongoing surveillance?	Same as EU MDR/IVDR?
Class III device	Annual	**Only if the device has undergone UKCA conformity assessment by the approved body!**	Stand-alone	✓
Active Implant	Annual		Stand-alone	✓
Class IIb (implantable)	Annual		Stand-alone	✓
Class IIa (implantable)	Biennial		It depends!	✗
Class IIb (non-implantable)	Annual		Surveillance	✓
Class IIa (non-implantable)	Biennial		Surveillance	✓

Also applies to IVDs

Sterile procedure packs (Regulation 14)

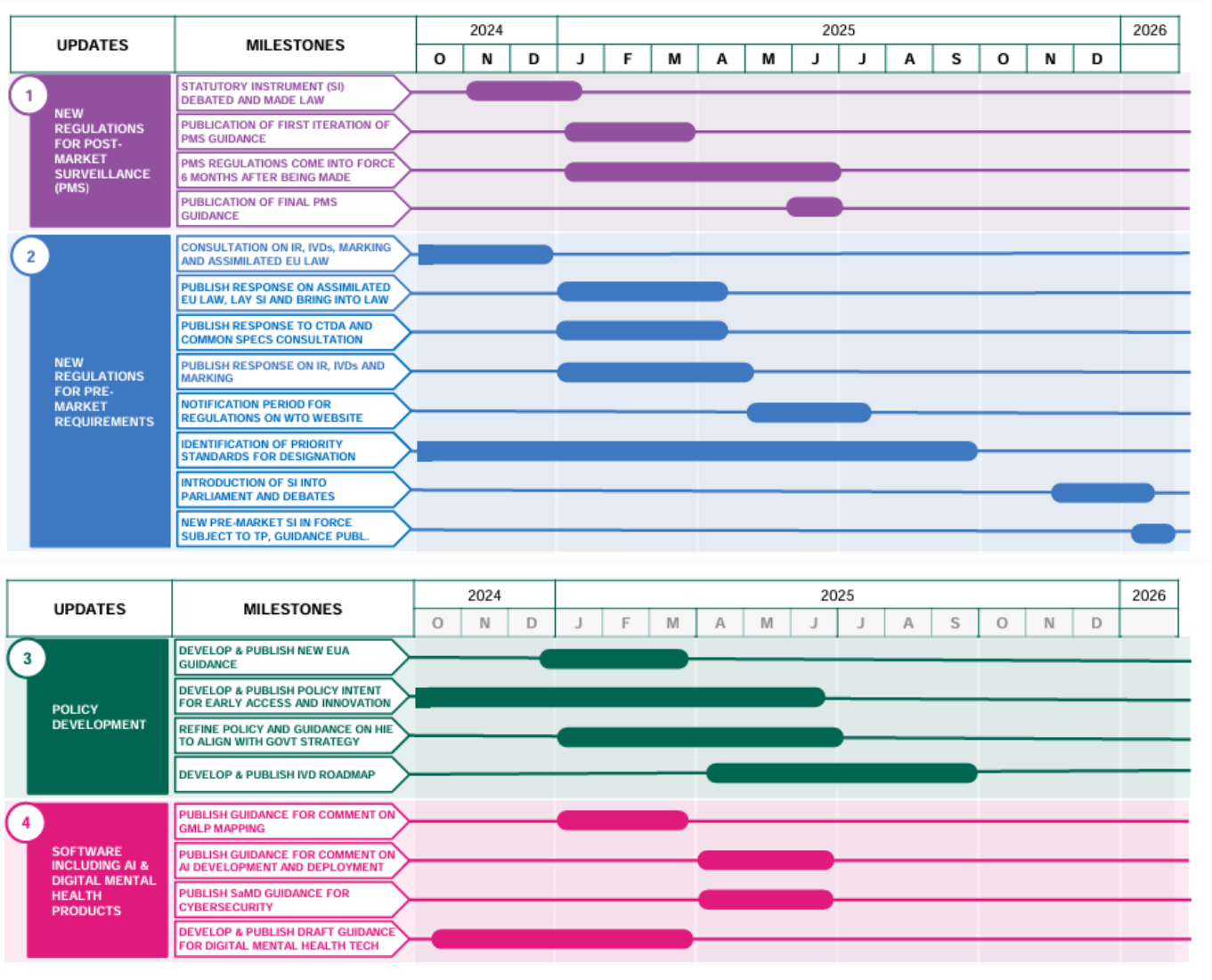
All PMS requirements apply to those manufacturers (e.g. hospitals) assembling the sterile procedure packs **except** for PMSR or PSUR obligations (Regulations 44ZL and 44ZM). However, under **certain** circumstances those regulations must be applied:

- If the system or procedure pack incorporates a medical device which does not bear a UKCA marking or a CE marking; or
- the chosen combination of medical devices is not compatible in view of their original intended use

In these cases the procedure packs shall be classified in line with accepted classification guidance, (e.g. intended use, highest classified device), and the PMSR/PSUR requirements apply.

In the case of system or procedure packs, the manufacturer placing these on the market or putting them into service should ensure they focus on gathering and analysing PMS information relating to the safety and performance of the **combined use of the devices** in the pack.

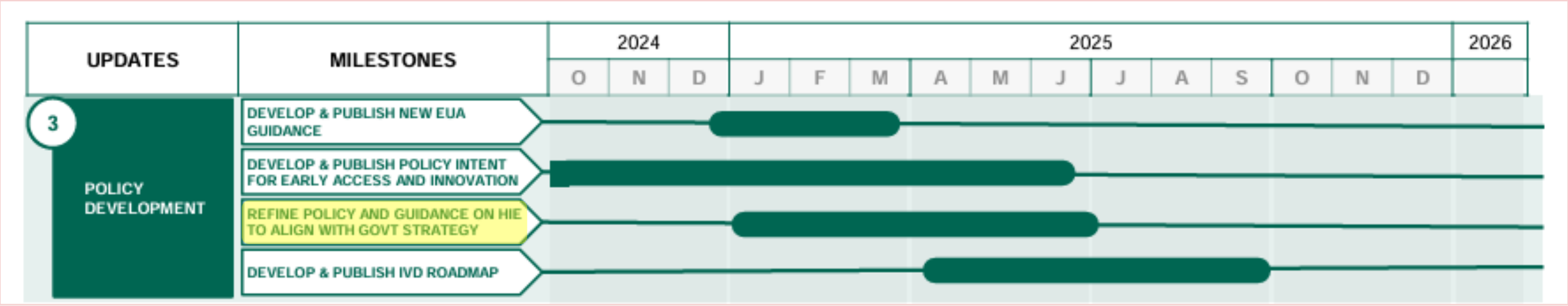
Future look at UK MDR 2002- Roadmap



Key Dates:

1. PMS SI- **In Force June 16th 2025**
2. New Updated regulations- **Draft-** Q3 2025 **In force-** Q1 2026
3. Current legislation to be accepted beyond July 2025

Future look at UK MDR 2002- Roadmap



HIE Policy currently under review

Future look at UK MDR 2002- Dec 2024 Consultation

International Reliance

- 4 Routes to market
- Covering EU MDR/IVDR, US FDA, CAN and AUS

Removal of UKCA Marking

- Physical UKCA Mark removed
- Introduction of UDI

IVD Reclassification

- Class B IVDs incl. self-test, Self-Declared + QMS certification

Assimilated EU Law

- Removal revocation dates for:
  - 2002/364- IVD Common Specs
  - 207/2012- eIFU
  - 722/2012- Tissues of Animal Origin
  - 920/2013- Designation and Supervision of ABs

Key Take Away Messages

01

PMS Regulation applies to the Great Britain market.

MDR & IVDR applies in Northern Ireland

02

Following a 6-month transition period, compliance with the regulation is required from 16 June 2025

03

Applies to all devices placed on the market or put into service in Great Britain, regardless of whether device is certified under the UKCA scheme or has CE certification

04

New reporting requirements for manufacturers:

- Shorter timelines to report serious incidents
- Trend reporting
- PMSR or PSUR for most devices

05

BSI will be looking to confirm manufacturers have updated their QMS to address the new PMS requirements during surveillance audits

Any Questions?

Further Reading

MHRA Publications

- Statutory Instrument laid in Parliament sets out first steps in delivering Medical Device Regulatory Reform and strengthening patient safety - GOV.UK
- Implementation of the future regulations - GOV.UK

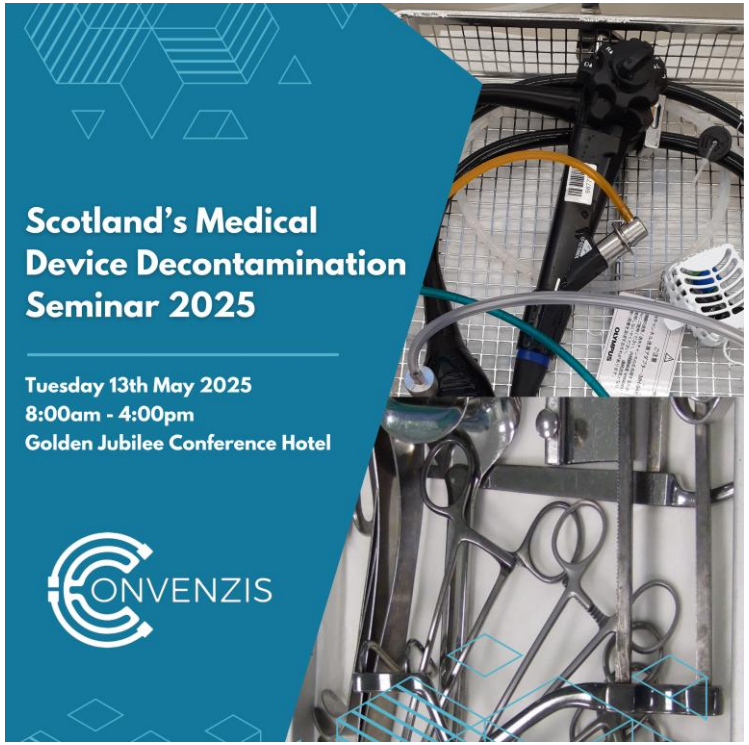
Draft Legislation

- The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 (Draft being debated in UK Parliament)
- https://hansard.parliament.uk/Lords/2024-11-28/debates/C0F23A0F-30D3-4C40-A26F-06FD5282493B/MedicalDevices(Post-MarketSurveillanceRequirements)(Amendment)(GreatBritain)Regulations2024 (Transcript of the debate of the legislation in the House of Lords – UK Parliament)

Other publications

- the Independent Medicines and Medical Devices safety Review

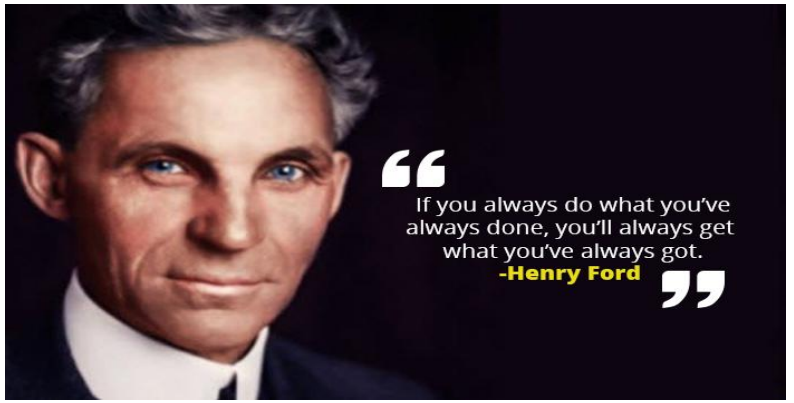
Thank you for your Attention!



Keynote Presentation

John Prendergast
Principal Engineer
NHS Wales Shared Services Partnership/Specialist

Decontamination Challenges – Pioneering The Future



John Prendergast AE(D),MIHEEM, IDSc (Chtd)

Medical Device Decontamination Seminar

NHS Scotland

May 2025

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
Shared Services Partnership

John Prendergast

Principal Decontamination Engineer

NHS Wales Shared Services Partnership – Specialist Estates Services (Cardiff UK)

Short Bio:

- Member Institute of Healthcare Engineering and Estates Manager (UK)
- Chartered Member Institute of Decontamination Sciences (UK)
- Chairperson – Central Sterilising Club (Commenced 2024)
- Chairperson – All Wales Decontamination and Sterilization Advisory Group
- Chairperson – Board of AE(D) Registration – IHEEM
- IHEEM Registered AE(D)

Disclaimer

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

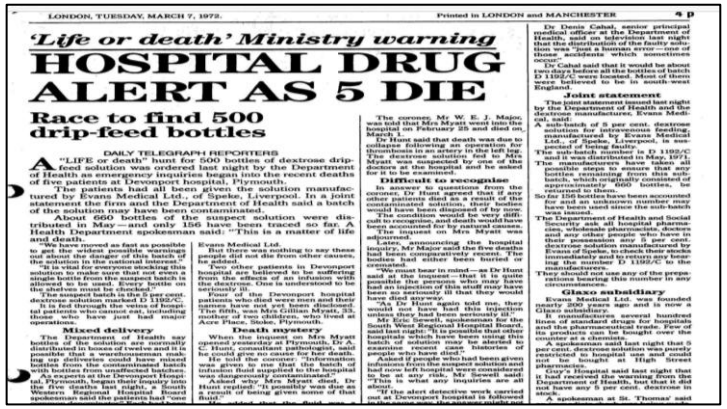
This presentation is to promote continual improvement, discussion, education and is delivered in the best interests of patient safety.

Objectives

- Where we have been
- Medical Device Evolution
- Advancement in Reprocessing Methodologies
- Single Use v Re-usable?
- Sustainable Practises
- Validation/Testing

There are many challenges ahead. Several obstacles and directives that we may not have encountered previously.

Background



LONDON, TUESDAY, MARCH 7, 1972. Printed in LONDON and MANCHESTER 4p

'Life or death' Ministry warning

HOSPITAL DRUG ALERT AS 5 DIE

Race to find 500 drip-feed bottles

DAILY TELEGRAPH REPORTERS

A "LIFE or death" hunt for 500 bottles of dextrose drip-feed solution was ordered last night by the Department of Health as emergency inquiries began into the recent deaths of five patients at Devonport hospital, Plymouth.

The patients had all been given the solution manufactured by Evans Medical Ltd., of Speke, Liverpool. In a joint statement the firm and the Department of Health said a batch of the solution may have been contaminated.

About 660 bottles of the suspect solution were distributed in May—and only 156 have been traced so far. A Health Department spokesman said: "This is a matter of life and death.

"We have moved as fast as possible to get the widest possible warnings out about the danger of this batch of the solution in the national interest."

Hospitals are warning patients using the solution to make sure that not even a single bottle from the suspect batch is allowed to be used. Every bottle on the shelves must be checked.

The batch number is D 1102/C. Per cent. dextrose solution marked D 1102/C.

It is fed through the veins of hospital patients who cannot eat, including those who have just had major operations.

Mixed delivery

The Department of Health say bottles of the solution are normally distributed in boxes of twelve and it is possible that a warehouseman making up deliveries could have mixed bottles from the contaminated batch with bottles from unaffected batches.

As experts at the Devonport Hospital, Plymouth, began their inquiry into the five deaths last night, a South Western Regional Hospital Board spokesman said the patients had "one

The coroner, Mr W. E. J. Major, was told that Mrs Myatt went into the hospital on February 25 and died on March 1.

Dr Hunt said that death was due to collapse following an operation for thrombosis in an artery in the left leg.

Mrs Myatt was admitted to one of the doctors at the hospital and he asked for it to be examined.

Difficult to recognise

In answer to questions from the coroner, Dr Hunt agreed that if any other patients died as a result of the contaminated solution it might be very difficult to recognise them.

The condition would be very difficult to recognise, and death would have been accounted for by natural causes.

The inquest on Mrs Myatt was adjourned.

Later, announcing the hospital inquiry, Mr Major said the five deaths had been compared with a list of patients had either been buried or cremated.

"We must bear in mind—as Dr Hunt said at the inquest—that it is quite possible that other patients who have had an injection of this stuff may have been so seriously ill that they would have died anyway.

"As Dr Hunt again told me, they would not be alerted to anything unless they had been seriously ill."

Mr Eric Sewell, spokesman for the South West Regional Hospital Board, said last night: "It is possible that other people who have had injections from a batch of solution may be alerted to examine recent case histories of people who have died."

Asked if people who had been given injections from the batch of solution that had now left hospital were considered to be at any risk, Mr Sewell said: "This is what any inquiries are all about."

Dr Denis Cahal, senior principal medical officer at the Department of Health, said on television last night that the mistake made in this solution was "just a human error—one of those accidents which sometimes occur."

Dr Cahal said that it would be about a week before all the bottles of batch D 1102/C were located. Most of them were believed to be in south-west England.

Joint statement

The joint statement issued last night by the Department of Health and the drug manufacturer, Evans Medical, said:

A sub-batch of 5 per cent. dextrose solution for intravenous feeding, manufactured by Evans Medical Ltd., of Liverpool, is suspected of being faulty.

The sub-batch number is D 1102/C and it was distributed in May, 1971.

The manufacturers have taken all possible steps to recover the bottles remaining from this sub-batch, which originally consisted of approximately 660 bottles, be returned to them.

So far 504 bottles have been accounted for and an unknown number may have been used since the sub-batch was issued.

The Department of Health and Social Security has sent all hospital pharmacies, wholesale pharmacists, doctors and any other people who have in their possession any of the dextrose solution manufactured by Evans of Speke, to check their stocks immediately and to return any bearing the number D 1102/C to the manufacturers.

They should not use any of the preparations bearing this number in any circumstances.

Glaxo subsidiary

Evans Medical Ltd. was founded nearly 200 years ago and is now a Glaxo subsidiary.

The company produces several hundred lines of standard drugs for hospitals and the pharmaceutical trade. Few of its products can be bought over the counter by the public.

A spokesman said last night that 5 per cent. dextrose solution was purely restricted to hospital use and could not be bought at High Street pharmacies.

Guy's Hospital said last night that it had received the warning from the Department of Health, but that it did not have any 5 per cent. dextrose in stock.

A spokesman at St. Thomas' said

Hospital exposes 18 patients to risk of human form of 'mad cow' disease because surgical tools were not sterilised properly

- Tools had been used on man suspected of having Creutzfeldt-Jakob Disease
- Not subjected to enhanced sterilisation procedures in possible cases of CJD
- North Carolina hospital apologises to patients and their families over blunder
- Brain disease causes blindness and kills 90% of sufferers within one year

By SIMON TOMLINSON
PUBLISHED: 16:05, 11 February 2014 | **UPDATED:** 16:44, 11 February 2014

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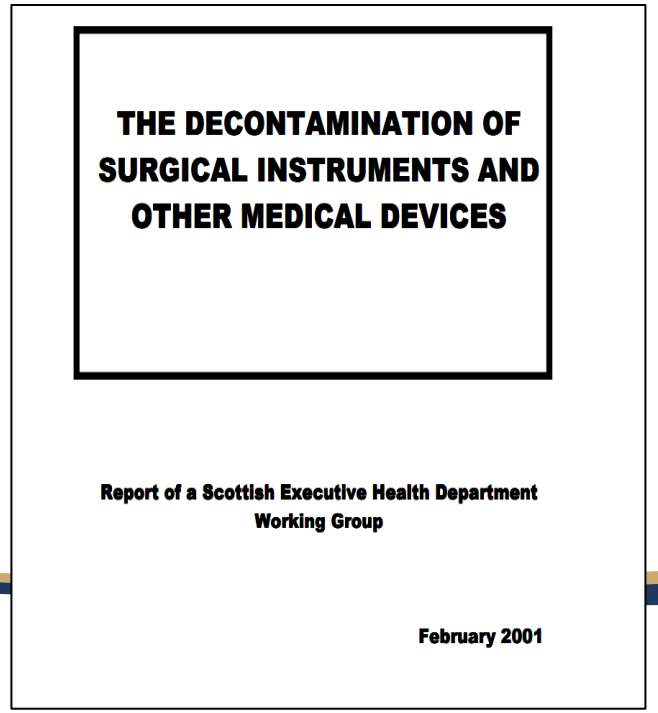
8 View comments

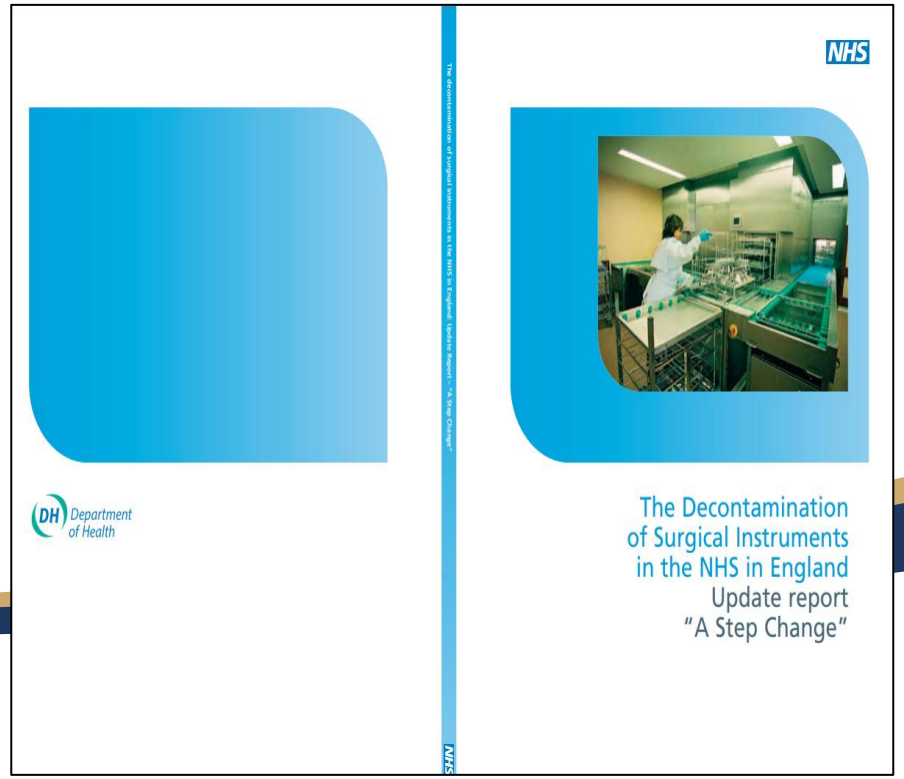
Eighteen patients in North Carolina may have been exposed to a fatal brain disorder similar to 'mad cow' disease after undergoing surgery with instruments that had not been properly sterilised.



THE DECONTAMINATION OF SURGICAL INSTRUMENTS AND OTHER MEDICAL DEVICES

Report of a Scottish Executive Health Department Working Group

February 2001



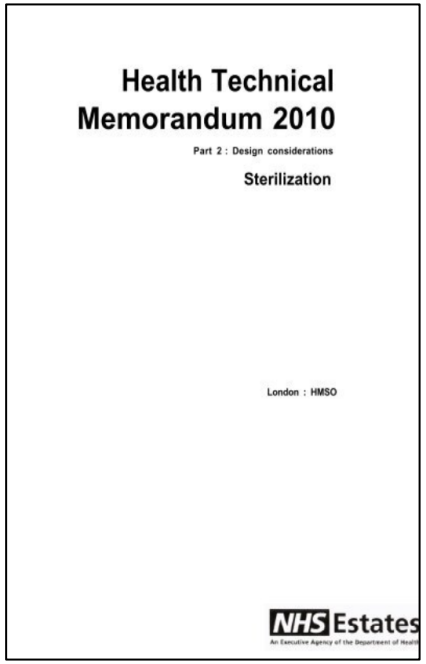
DH Department of Health

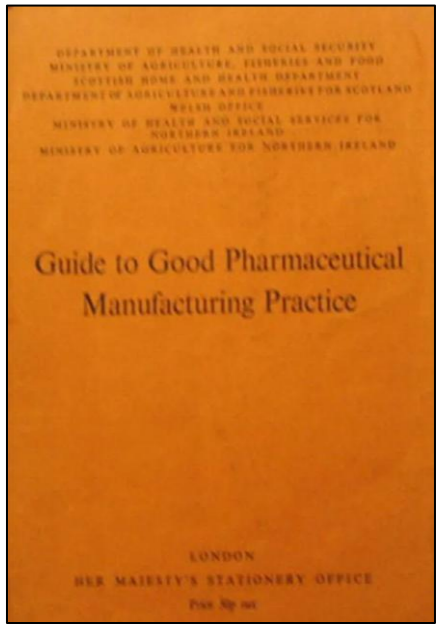
NHS

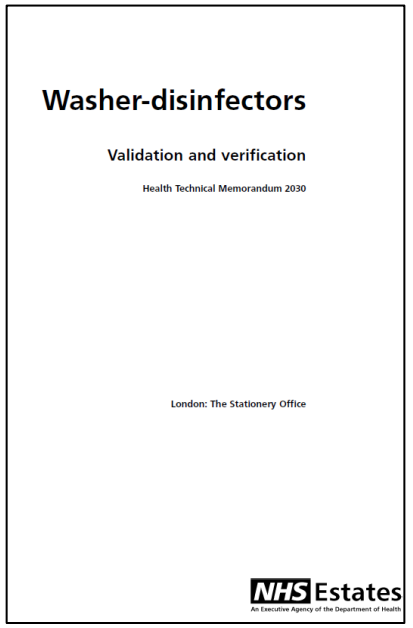
The Decontamination of Surgical Instruments in the NHS in England Update report "A Step Change"

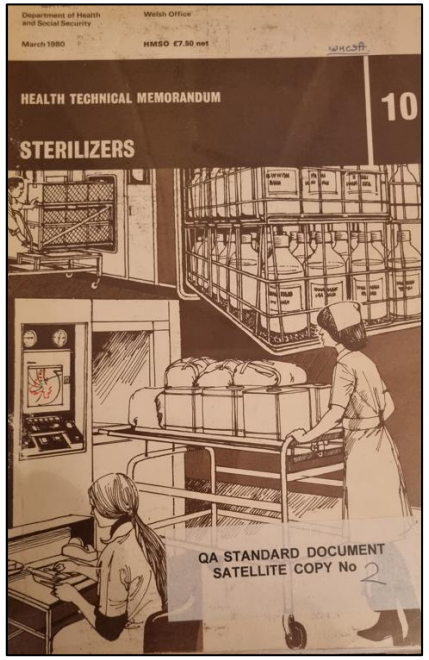
Partneriaeth Cydwasanaethau
Shared Services Partnership

Background









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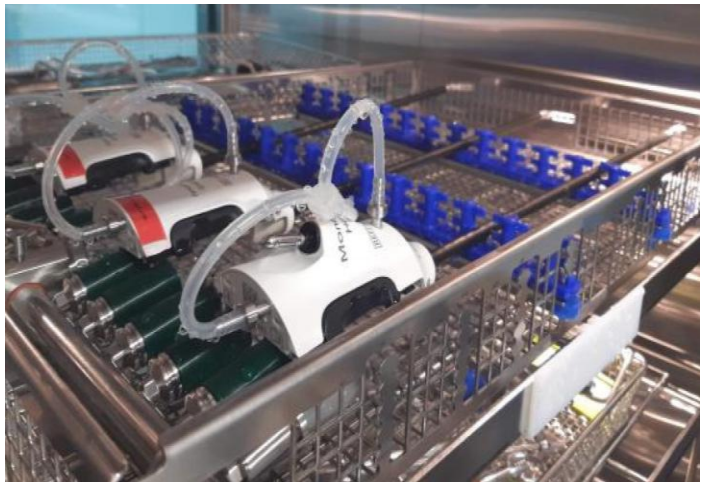
Partneriaeth Cydwasanaethau
Shared Services Partnership

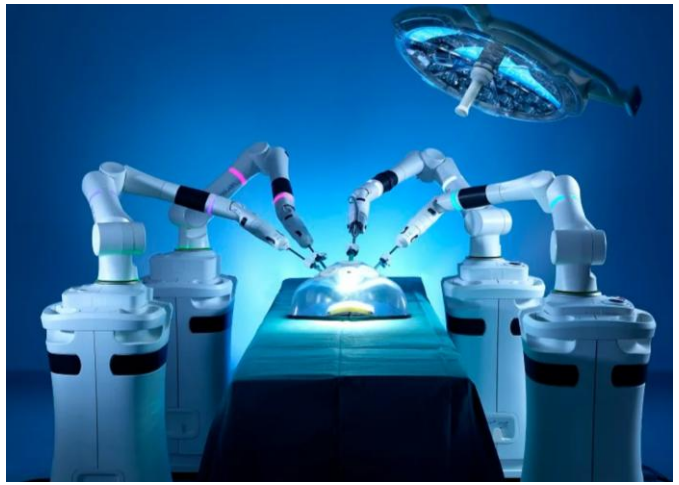
Medical Device Evolution

The evolution of medical devices used for surgical intervention, enhances surgical safety, effectiveness and patient recovery. Is decontamination given the necessary consideration when designing such innovation?

The future will include greater use of precise robotic systems, smart devices and 3D printing.

Medical Device Evolution





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Shared Services Partnership

How Does Decontamination Evolve?

Many of our existing Decontamination systems have not been developed for differing material compositions of modern devices (steam/chemistry/mechanical cleaning).

Our equipment/systems may damage the devices.

Can we assemble/disassemble the devices for decontamination?

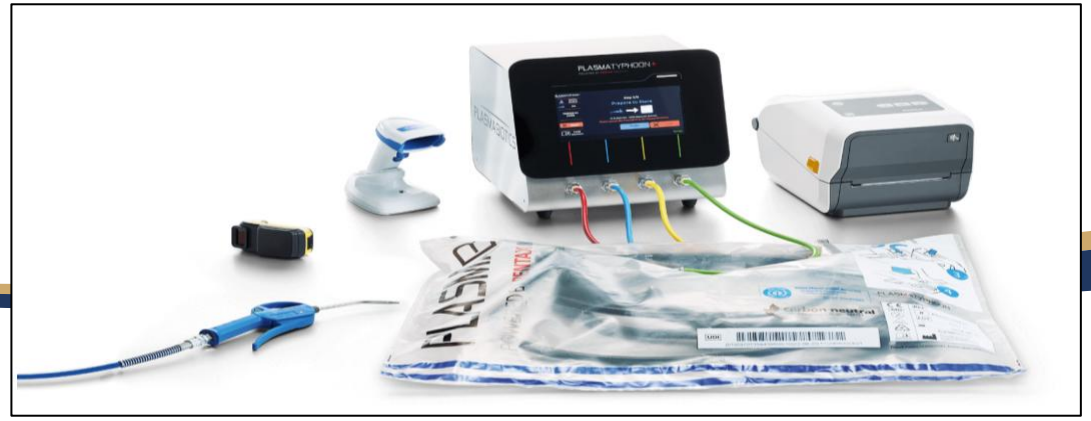
Have we got the correct racks to present devices to the W/D?

Sterilization compatibility?

Contradiction of IFU's

Are Decontamination professionals involved when purchasing?

How Does Decontamination Meet Evolution?



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Partneriaeth Cydwasanaethau
Shared Services Partnership

Evolution – Endoscope Decontamination

Decontamination of Endoscopes – Manual Cleaning of Scopes – Use of Automated technology?

Sterilization – should all high risk scopes be sterilized? Should all scopes be sterilized?

Drying of endoscopes – is the 3 hour rule accurate? Are systems presenting a ‘dry’ endoscope?

Chemical Disinfection or greater use of cold plasma, ozone and other Nano technologies?

Monitoring cleanliness of Endoscopes – QC (less emphasis than water)?

Single use endoscopes (Bronchoscopes/Cystoscopes etc)

Patient Surveillance!

Redesign of endoscopes – surfaces to repel proteins and microbes?

Evolution – Sterile Services

Sterile Service Provision – Cycle configuration, must be based upon product families we are decontaminating, not just generic guidelines.

Use of Configured racks?

Sterile Barrier Systems will dictate cycle configuration, its not one size fits all – Containers/Disposable/Linen

Use of ultrasonics/solutions to flush/irrigate

Monitoring of protein on devices?

Sustainable?

Single Use v Reusable?

Single Use – Pro's

Single-use devices minimize the risk of cross-contamination and surgical site infections.

No need for cleaning, inspection, sterilization, or functional testing, which saves time and resources.

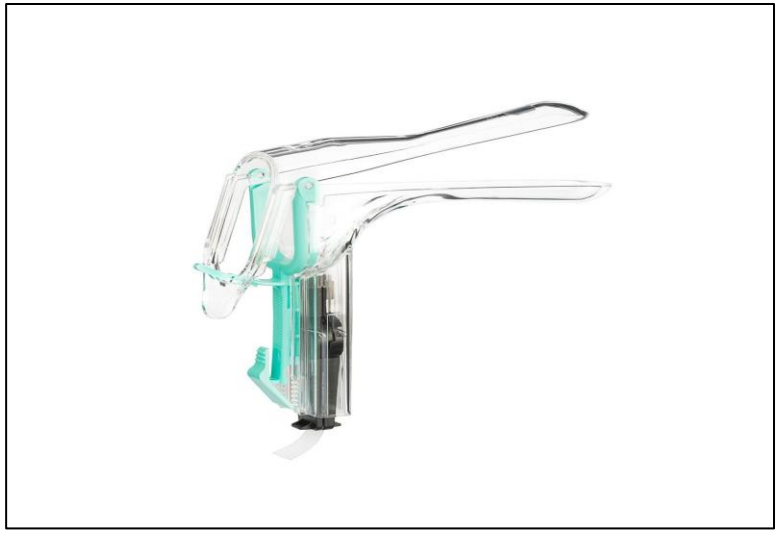
Reusable – Pro's

Reusable devices can be more cost-effective in the long run, especially when considering the cost of purchasing new single-use devices.

Environmental Sustainability: Reusable devices reduce waste generation and lower the environmental impact of medical practices.

Potential for Reduced Carbon Footprint: Reusing devices can reduce the energy and material consumption associated with manufacturing new products.

Single Use v Reusable?



Sustainability – Marmite?

Sustainable medical device decontamination focuses on using environmentally friendly methods for cleaning and disinfecting reusable medical devices while maintaining patient safety and hygiene. This includes minimizing the use of harsh chemicals, reducing waste, and promoting sustainable practices throughout the decontamination process. Patient Safety?

Are we a utility heavy process?

Are we a sustainable process?

Quicker Fixes?

Sustainability

Can we work more efficiently?

Steam generation/Water Purification – Efficient options

Rinse Water – can we re-use FRW, can we re-use RO reject water?

Recycle – Do we reuse/recycle as we should?

Circular Economy – Minimising Waste/Compostable materials!

Sterile Barrier Systems

- Containers – Reusable – Can we accommodate?
- Linen – Reusable – What are consequences at Laundry?
- Single Use – Disposable – Can we recycle?

PPE – Compostable rather than re-use!

Testing/Validation/Monitoring

System were developed when equipment was controlled, manufactured and operated in a different manner.

Are HTM's/SHTM's/WHTM's – an obstacle to change?

Testing/Validation/Monitoring

Are are wasting time and resources with current HTM/SHTM/WHTM protocols?

System were developed when equipment was controlled, manufactured and operated in a different manner.

Is it time to review?

Are control/monitoring systems providing the required verification?

Technology is available

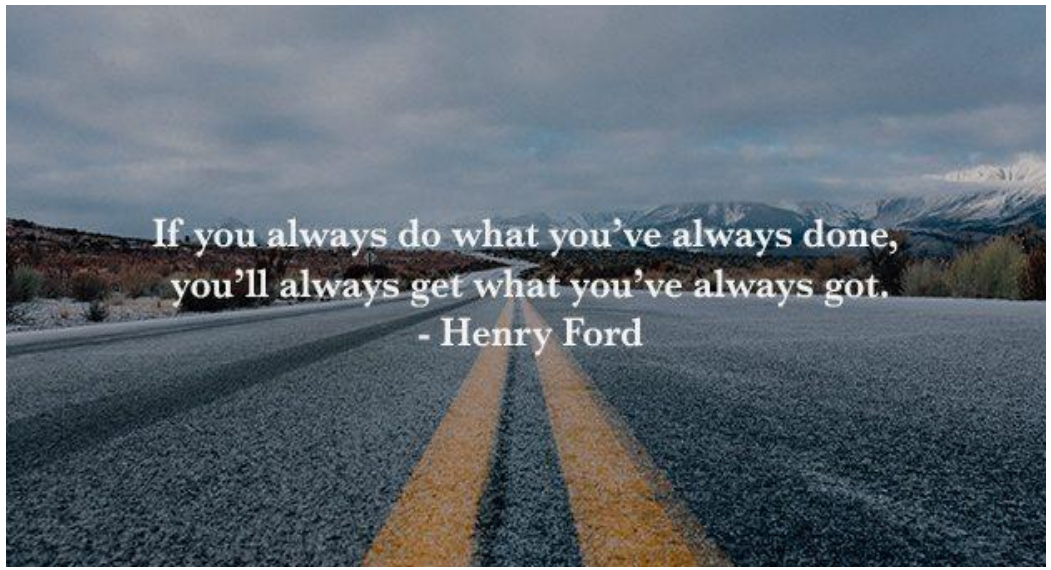
Continuous Monitoring

Process Verification

Use of data logger technology

Encrypted and repeatable

Your Thoughts – Be Smart with Change!



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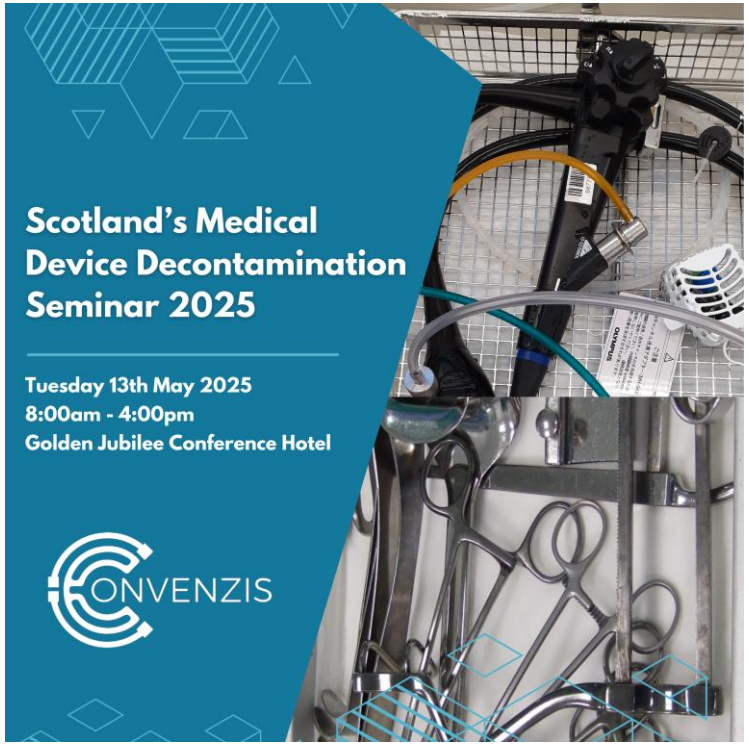


Keynote Presentation

Ms Lydia Robb
Scottish Clinical Leadership Fellow, Plastic Surgery Trainee
Centre for Sustainable Delivery

Steven Chawk
Project Manager
National Green Theatres Programme, Centre for Sustainable Delivery

National Green Theatres Programme

Centre for Sustainable Delivery

NHS SCOTLAND

Lean Surgical Trays

Lydia Robb
Scottish Clinical Leadership Fellow,
Plastic Surgery Registrar
&
Steven Chawk
Project Manager, National Green Theatres Programme

Background

The national Green Theatres Programme is a key element of the Scottish Government's Climate Emergency and Sustainability Strategy 2022 – 2026.

It aims to reduce the carbon footprint of theatres across NHS Scotland and enable more environmentally sustainable care by:

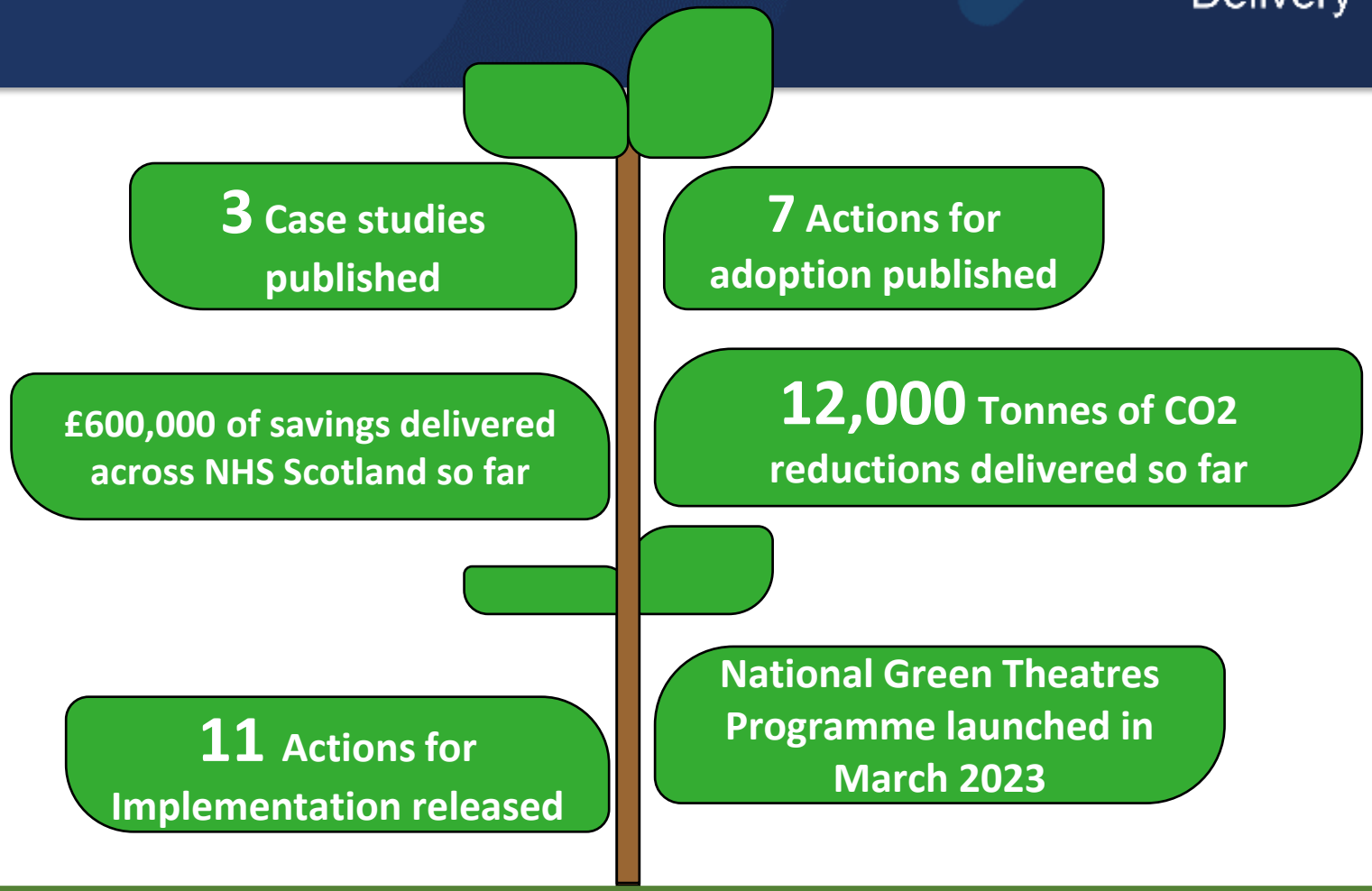
- Working with clinicians and professionals to develop actions that reduce carbon emissions.
- Supporting Boards to implement, measure and report on these improvements.
- Cost savings / cost neutral initiatives

Our journey so far

Centre for Sustainable Delivery

NHS SCOTLAND

Green Theatres Speciality Delivery Group



NHS Scotland's Climate Emergency and Sustainability Strategy

NHS Highland's Green Theatres Project

Green Anaesthetists Group

Our Aim

Centre for Sustainable Delivery

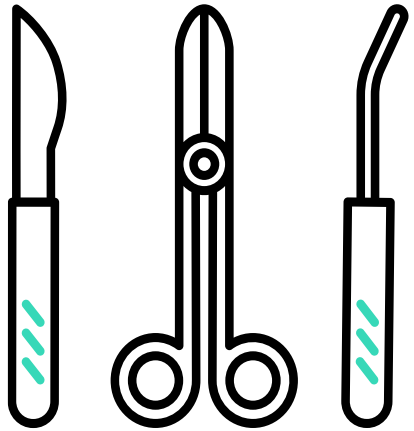
NHS SCOTLAND

The objective is to achieve a 20% reduction in the overall number of surgical trays in circulation across NHS Scotland by March 2026.

Lean Trays - Why is this important?

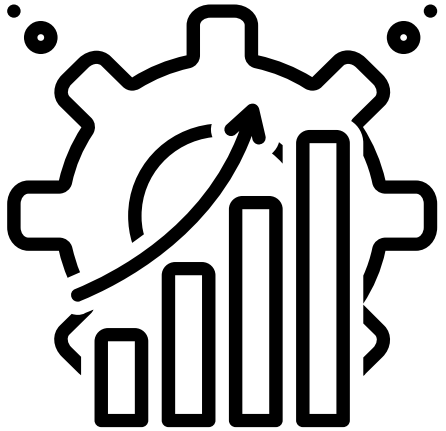
Centre for Sustainable Delivery

NHS SCOTLAND



75%

75% of Surgical Instruments are not being used



90%

Central Decontamination Units are working at near full capacity

Collaborate. Redesign. Innovate. Transform.

1]Avansino, J.R.; Goldin, A.B.; Risley, R.; Waldhausen, J.H.; Sawin, R.S. Standardization of operative equipment reduces cost. J. Pediatr. Surg. 2013, 48, 1843–1849.

2] Van Meter, M.M.; Adam, R.A. Costs associated with instrument sterilization in gynecologic surgery. Am. J. Obstet. Gynecol. 2016, 215, 652.e651–652.e655.

3] van Nieuwenhuizen, K. E., van Trier, T., Friedericy, H. J., Jansen, F. W., Dankelman, J., & van der Eijk, A. C. (2024). Optimising Surgical Instrument Trays for Sustainability and Patient Safety by Combining Actual Instrument Usage and Expert

Benefits of Lean Trays

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Instrument Lifespan

This will be achieved by removing unused instruments from surgical sets, reducing the number of times instruments are processed, hence, extending the lifespan of the instruments

Reduction in Tray Size

By auditing and streamlining surgical sets this will create the conditions for clinical teams to reduce the size of their surgical trays, less instruments, less space required to store them and process them.

Environmentally Friendly Practice

Auditing instrument usage will identify instruments that may benefit from being migrated into standard sets as opposed to sitting as a supplementary item

Reusable Alternatives

Creating space on surgical sets will allow conversations to take place with clinicians and the relevant stakeholders to investigate current single use instruments to determine if there is merit in migrating certain instruments to reusable alternatives.

Theatre Efficiencies

Surgical sets place significant load on the SSD, portering and theatre staff who must transport, handle and maneuver these sets. A reduction in the volume and weight will reduce the risk of musculoskeletal injuries.

MSK Injuries

With fewer trays and instruments to count and check before, during and after surgery, theatre staff would spent less time on this task allowing for greater efficiencies peri-operatively.

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Working life of Surgical Instruments

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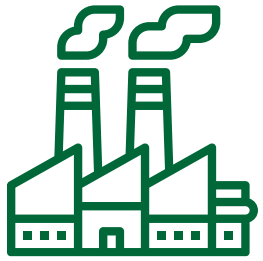
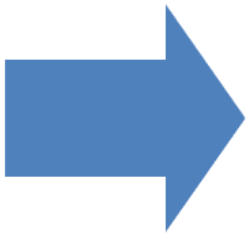
Service helped to deliver on 275,000 planned operations in the last year

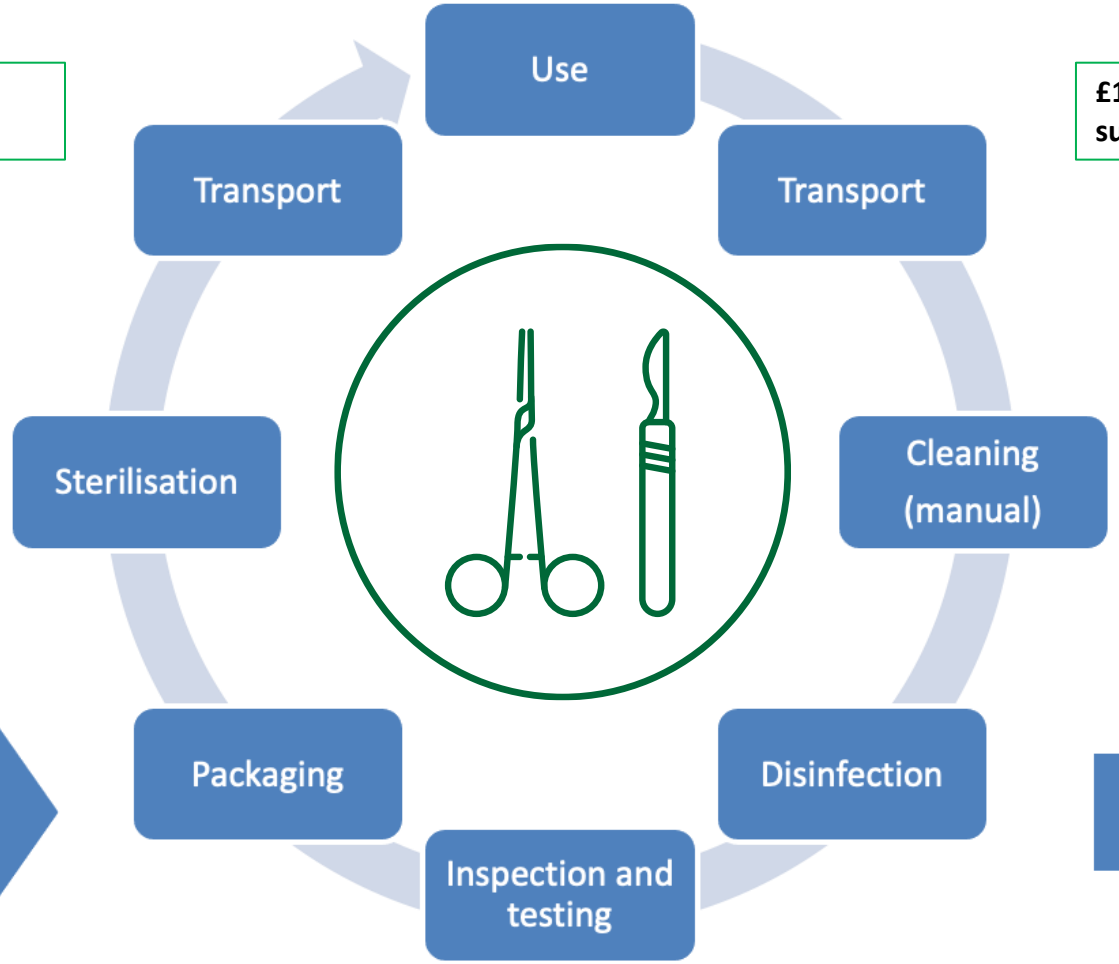
38 million instruments processed annually in NHS Scotland

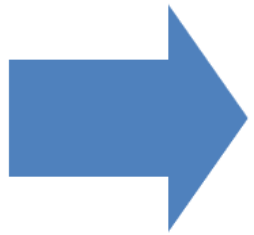
£1.23 = total cost to process a singular surgical instrument

Estimated carbon footprint of over 2,000 tonnes









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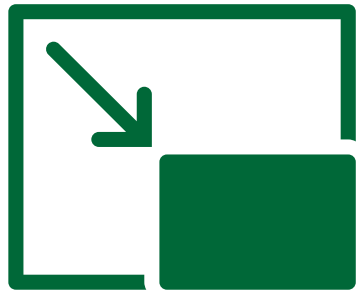
What can we do?

Rationalise instruments being used

- Stops unnecessary cleaning and transport of unused items
- Space for reusable items to be considered

Reduce the NUMBER of the Trays in a set

- This means more trays can be processed in each cycle of the washer
- Consider conversion or complex trays or sets



Reduce the SIZE of the Tray

- Smaller din baskets means more trays can be processed in each cycle of the washer

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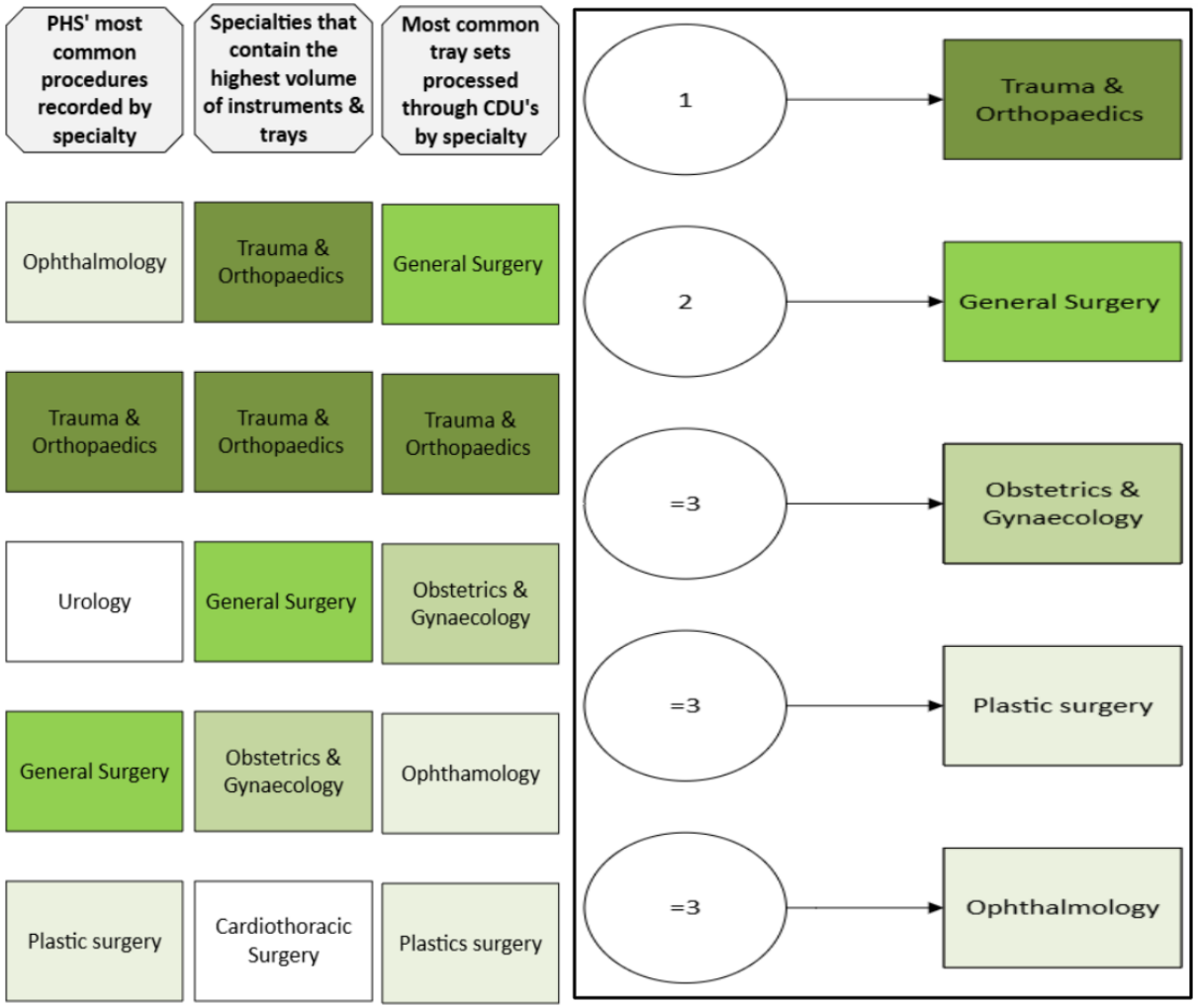
Lean Trays- Our Plan

- Identified high volume high impact areas to target first
- Worked with CDU’s and conducted a comparative analysis with Public Health Scotland's Data on most common elective procedures
- Recommendation to initially focuses on the these top 5 specialties
- NGTP will engage with these specialties through existing Specialty Delivery Groups



LEAN TRAY TOOLKIT

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The Toolkit

OUR NETWORK

NGTP
The National Green Theatre Programme have developed this toolkit for distribution and use across NHS Scotland

Lean Tray Stewards
Identify Lean Tray Steward within each specialty, and a Champion in local boards to coordinate the work

CDU Contact
The programme has identified a key contact within each CDU that will support the work.

Engage Suppliers
Some trays will require supplier input for redesign process, such as consignment trays. Contact them early.

SharePoint
All resources can be found on our SharePoint site. Including data and local success stories

DIGITAL LEANING PROCESS

1 Identify Tray
Tray identification can be based on:
- High volume/ high impact trays
- Large tray sets
- Procedure specific
- Generic Trays

2 Planning
You will need:
- Instrument List
- Tray Photograph

Template Workbook is provided for your project planning.

EXCEL TEMPLATE

3 Data Collection
Distribute your form or excel template. All consultants who use the tray set should be consulted.
Ask your colleagues to rank instrument utilisation as: Always Used / Often used / Rarely Used / Never Use

4 Implement
Identify instruments to:
- Keep / Remove
- Add supplementaries
- Consider conversion / complex tray

Design a leaned tray in consultation with your CDU point of contact
Capture tray photograph.

5 Feedback
Gather feedback from Lean tray champion should monitor for any issues and adjust as necessary.
Template available below

FORM TEMPLATE

OPTIONAL

Generic Trays
Generic trays are often used for many procedures within the specialty or shared by specialties

Additional Data
Gathering additional data may benefit the lean process by auditing instrument use in real time, capturing a range of procedures and surgeons

Template
A template form is linked allowing teams to Audit and Re-audit instrument use.

FORM TEMPLATE

Distribution
Generate a QR code for your audit form and display in your theatres. Ask the team to complete the form at every tray use

Template
Combine the Audit data with your Digital Leaning Process to design your Leaned Tray

MEASUREMENT

What to measure?
Record all trays leaned, including the overall reduction in trays, size, instruments and supplementaries

Local
Lean Tray Champions should record their teams progress and feedback to their Specialty Steward

National
Stewards are invited to update our national spreadsheet outlining progress across specialties

LINK

SDG
Your teams progress with the Lean Trays Project will be discussed as part of the SDG

Share Your Trays
Share examples of good practice or successful leaned trays through the SDG or SharePoint

Version 1 - Created January 2025 by the National Green Theatre Programme Team, CfSD

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The Workbook - Example

Lean Tray - Tayside Plastics - Minor

Search for tools, help, and more (Alt + Q)

File Home Insert Share Page Layout Formulas Data Review View Automate Help Draw

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E30

Process for leaning surgical trays

Identify Procedure	Establish how many different tray sets are used in your health board	Collate a list of the instruments within the set	Distribution	Collation & Leaning conversations	Embed & Report	Monitor
Identify the procedure that your team intends to streamline.	This will require liaising with Central Decontamination Unit (CDU) colleagues. For key contacts within your CDU please see the 'Key Contacts' sheet. This is a good opportunity to discuss the upcoming changes.	This information can be found on the tray list and can be obtained via CDU colleagues. List all instruments in the 'Responses' sheet of this excel document. This will populate all subsequent sheets with identical information Add images of the tray set to the 'Outcome Report' sheet	Share this spreadsheet with clinicians who perform this operation. Ask that they complete their own tab with this excel document. **TIP: Rename the 'Clinician' sheets to reflect the clinicians name**	Each response recieved will populate within the 'Responses' sheet. This will provide an overview of the frequency of use of each instrument. Use this data to inform leaning conversations with colleagues	Liaise with CDU colleagues to embed the changes. Where appropriate, ask if your tray size can be reduced. Record results on the 'Outcome Report' sheet. Include image of leaned set alongside the new instrument set list. **IMPORTANT: Share this workbook with the lean tray steward to capture and share team successes.**	The lean tray champion should monitor for any issues and adjust as neccessary.
1	2	3	4	5	6	7

IF YOU ARE A CLINICIAN TAKING PART IN THE LEANING PROCESS PLEASE FIND YOUR NAME AT THE BOTTOM OF THIS EXCEL SHEET AND NAVIGATE TO THAT SHEET. YOU WILL THEN USE A DROPDOWN OPTION TO IDENTIFY THE FREQUENCY OF USE FOR EACH INSTRUMENT

Reporting data

- Health Board
- Hospital Site
- Tray set name
- Number of sets in circulation
- Number of trays in set - before leaning
- Number of instruments - before leaning
- Number of trays in set - post leaning
- Number of instruments - post leaning
- Reduction in tray size, if applicable

Terminology

Lean tray steward	Identified colleague who will support and collate lean tray results for their surgical specialty and liase with the National Green Theatres Programme
Lean tray champion	Identified colleague who is co-ordinating the local streamlining of a specific set/tray

Instructions Key Contacts Outcome Report Responses Leaned Tray BM AL SW SJ MH MN DAM DJ Clinician 9 Clinician 10

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The Workbook - Example

Lean Tray - Tayside Plastics - Minor

Search for tools, help, and more (Alt + Q)

File Home Insert Share Page Layout Formulas Data Review View Automate Help Draw

Cut Copy Format Painter Paste Undo Clipboard

Calibri (Body) 11 Font

Wrap Text Merge & Center Alignment

General Number

Conditional Formatting Format As Table Cell Styles Styles

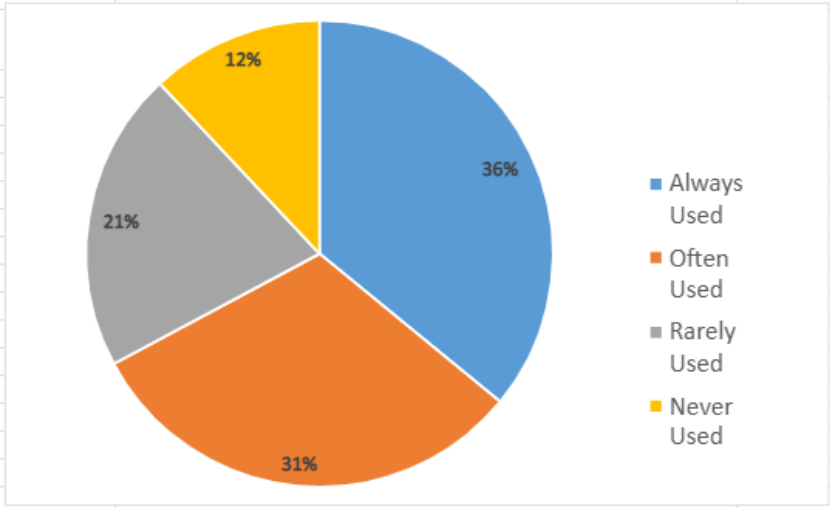
Insert Delete Format Cells

AutoSum Clear Sort & Filter Find & Select Editing

Add-ins Add-ins

U15

	A	B	C	D	E	F	G	H	I	J	K	L
1												
2												
3	Tray_Name	Instrument_description	Always Used	Often Used	Rarely Used	Never Used	Decision Outcome	Keep / Remove / Supplementray / Conversion Tray / Other				
4		Towel Clip (x4)	1	4	3	0	Keep	reduce ?				
5		Scalpel BP	3	4	1	0	Keep					
6		Scalpel Barrons	4	3	1	0	Keep					
7		Addison Forceps	8	0	0	0	Keep					
8		Gilles Forceps	1	3	3	1	Keep					
9		Mcindoe foreceps (non toothed)	0	3	3	2	Keep					
10		Scissors (sharp point)	5	1	1	1	Keep					
11		Scissors Tenotomy	4	3	0	1	Keep					
12		Curved Scissors Strabismus	1	2	3	2	Remove					
13		Kilner Straight scissors	0	3	4	1	Remove					
14		Mayo Straight scissors	2	2	4	0	Remove	Consider reducing size?				
15		Mosquito artery forceps (x5)	1	4	3	0	Other	Reduce to ? 4				
16		Sinus Lister curved (x2)	0	1	2	5	Remove					
17		Needle Holder Halsey	7	1	0	0	Keep					
18		Needle Holder Foster Gillies	2	2	3	1	Keep	****				
19		Pen Somerlad	0	1	0	7	Remove					
20		Gillies Skin Hooks Large (x2)	3	3	1	1	Keep					
21		Gillies Skin Hooks Small (x2)	3	3	2	0	Remove					
22		Rake Kilner (Cats Paws) (x2)	4	3	1	0	Keep					
23		Bipolar	8	0	0	0	Keep			Example:		
24		Quiver	4	4	0	0	Keep			Tray_Name	Instrument_description	Always Use
25		Kidney Dish (8 inch)	3	3	2	0	Keep			SJOP011 CATARACT SET	WRAP QUICK CHECK H400 91CM x 91CM	3
26		Gallipot 60mls x1	2	3	2	1	Remove				BOX STERILISING	1
27		Gallipot 250mls (x3)	3	4	1	0	Other	reduce to 2			FORCEPS SPONGE HOLDING RAMPLEYS 7 WITH SPONGE"	4
28			0	0	0	0					SCISSORS IRIS STRAIGHT SHARP POINTED 3.5	1
29			0	0	0	0					FORCEPS ARTERY HALSTEADS MOSQUITO CURVED 9CM	0
30			0	0	0	0					NEEDLEHOLDER CASTROVIEJO 216mm	0
31			0	0	0	0					NEEDLEHOLDER LIMS ROUND BODIED	3
32			0	0	0	0					HANDLE BARD PARKER No 3 5	0
33			0	0	0	0					MANIPULATOR TRIPLE CHOPPER & MUSHROOM 0109308 or A2302 or 6-08	3
34			0	0	0	0					HOOK CLAYMAN S/E A2300 OR D4020	1
35			0	0	0	0					HOOK MALTZMAN FENZL S/E A2305	0
36			0	0	0	0					FORCEPS SUTURE & CONJUNCTIVAL LISTER B951/D401/A5502	3
37			0	0	0	0					FORCEPS MOORFIELDS 0101543/A5500/0101542	1



Instructions Key Contacts Outcome Report Responses Leaned Tray BM AL SW SJ MH MN DAM DJ Clinician 9 Clinician 10

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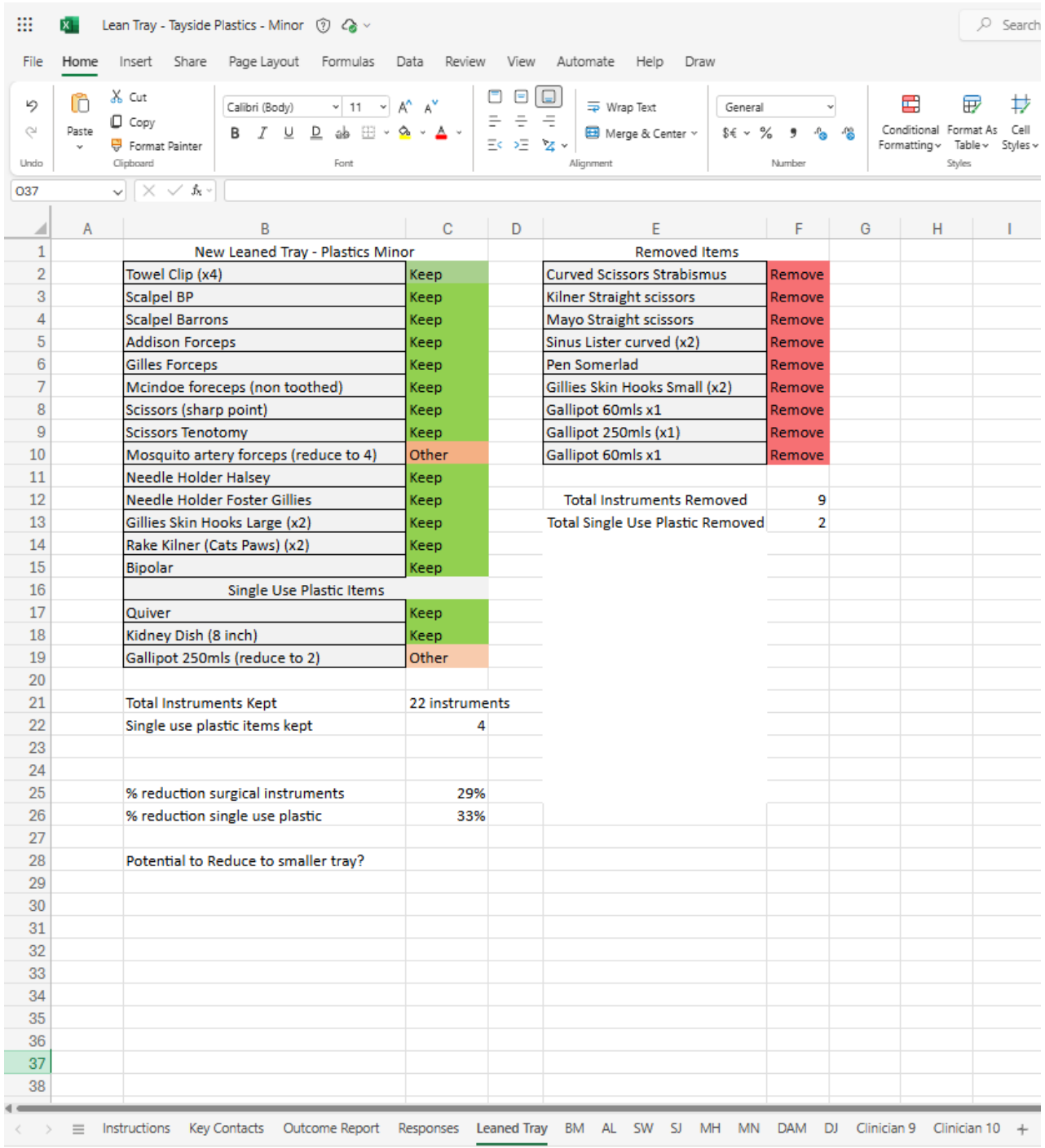
The Workbook - Example



	A	B	C	D	E	F	G	H	I
1		New Leaned Tray - Plastics Minor			Removed Items				
2		Towel Clip (x4)	Keep		Curved Scissors Strabismus	Remove			
3		Scalpel BP	Keep		Kilner Straight scissors	Remove			
4		Scalpel Barrons	Keep		Mayo Straight scissors	Remove			
5		Addison Forceps	Keep		Sinus Lister curved (x2)	Remove			
6		Gilles Forceps	Keep		Pen Somerlad	Remove			
7		Mcindoe foreceps (non toothed)	Keep		Gillies Skin Hooks Small (x2)	Remove			
8		Scissors (sharp point)	Keep		Gallipot 60mls x1	Remove			
9		Scissors Tenotomy	Keep		Gallipot 250mls (x1)	Remove			
10		Mosquito artery forceps (reduce to 4)	Other		Gallipot 60mls x1	Remove			
11		Needle Holder Halsey	Keep						
12		Needle Holder Foster Gillies	Keep		Total Instruments Removed	9			
13		Gillies Skin Hooks Large (x2)	Keep		Total Single Use Plastic Removed	2			
14		Rake Kilner (Cats Paws) (x2)	Keep						
15		Bipolar	Keep						
16		Single Use Plastic Items							
17		Quiver	Keep						
18		Kidney Dish (8 inch)	Keep						
19		Gallipot 250mls (reduce to 2)	Other						
20									
21		Total Instruments Kept	22 instruments						
22		Single use plastic items kept	4						
23									
24									
25		% reduction surgical instruments	29%						
26		% reduction single use plastic	33%						
27									
28		Potential to Reduce to smaller tray?							
29									
30									
31									
32									
33									
34									
35									
36									
37									
38									

The Workbook - Example

Lean Tray - Tayside Plastics - Minor

Health_Board	Hospital_Site	Tray_set_name	Pre_leaning_data>>	No_of_sets_in_circulation	No_of_trays_in_set	No_of_instruments_in_set	Post_leaning_data>>	No_of_leaned_sets_in_circulation	No_of_trays_in_set.	No_of_instruments_in_set.	Were you able to reduce tray size (Yes/No)	How many trays were reduced in size?
Tayside	Ninewells	Plastics Minor		21	1	31		10	1	22	Yes	1

1.531 kgCo2e per procedure*

Total instruments reduced: 9

Total reduction in surgical trays: 0

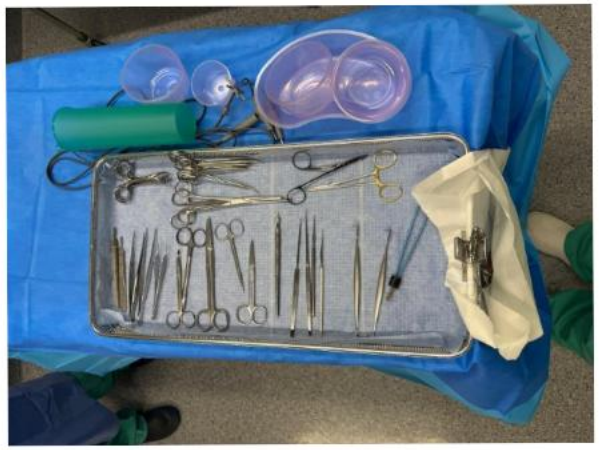
Total surgical trays reduced in size: 1

*Carbon savings based on Rizan et.al (2021) paper that calculates the carbon associated with the decontamination of a surgical tray with an average of 29 instruments as 1.532kg/Co2e

**Carbon savings are approximate and will vary depending on efficiency of machine loading within CDU's

*Assumed carbon saving of 0.052kg/Co2e per instrument as part of a set.

INSERT IMAGES OF ORIGINAL TRAY SETS BELOW:

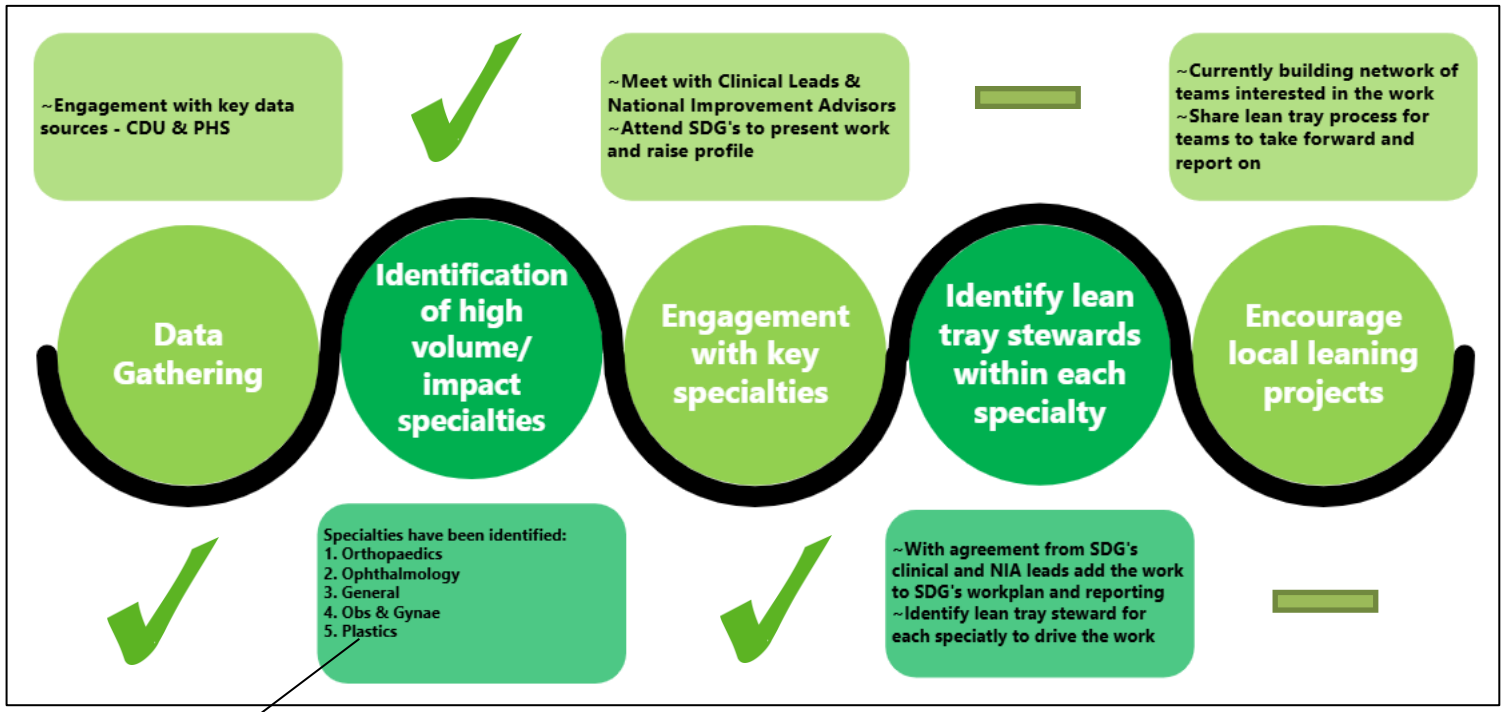


INSERT IMAGES LEANED TRAY SETS BELOW:

PLEASE INCLUDE LIST OF ITEMS IN LEANED SURGICAL SET

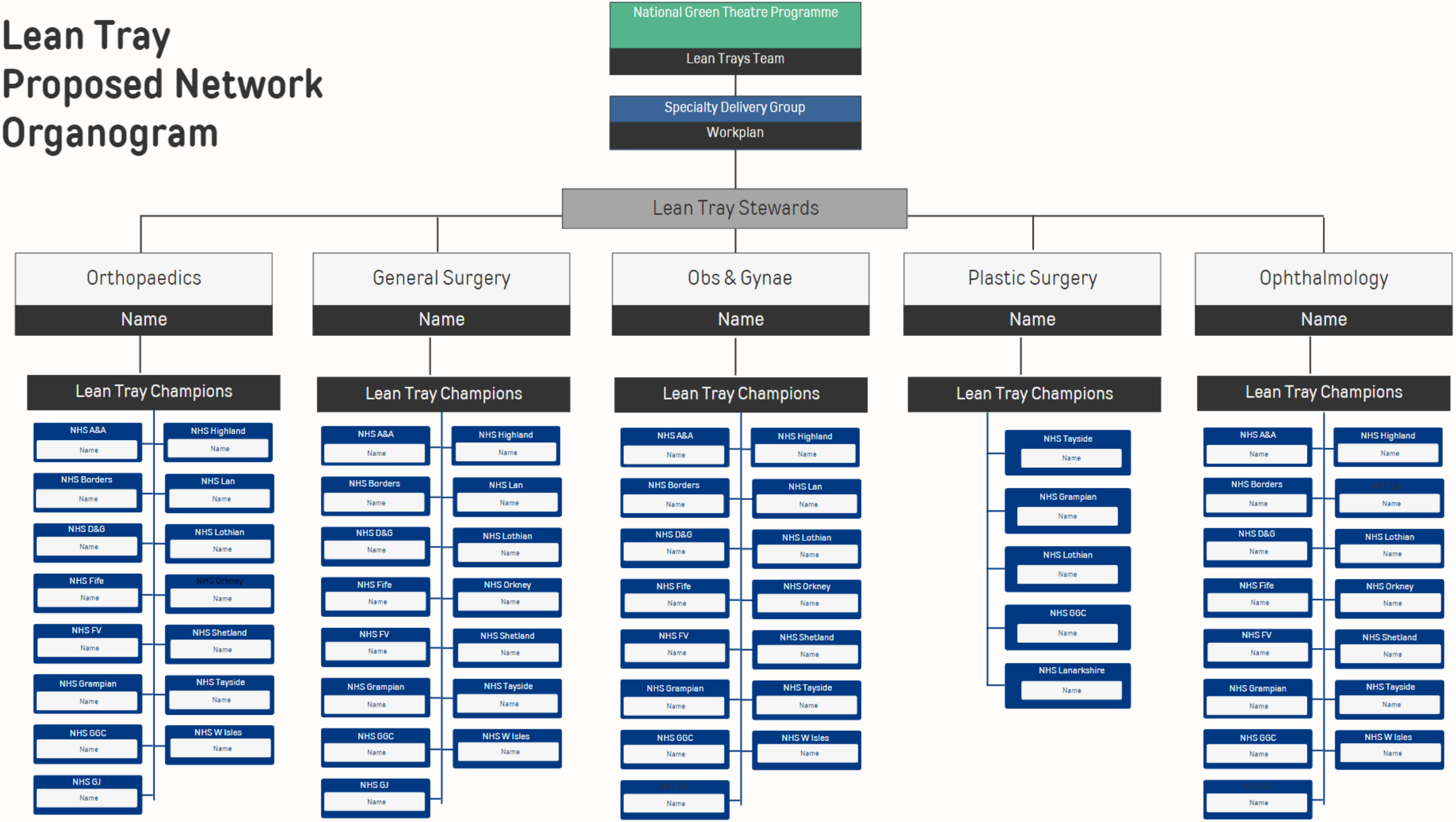
Instructions | Key Contacts | Outcome Report | Responses | Leaned Tray | BM | AL | SW | SJ | MH | MN | DAM | DJ | Clinician 9 | Clinician 10

Progress & Next steps…



Plastics does not have an SDG but our clinical fellow is a plastics registrar.
Andy Maylon (Medical Devices & Legislation Unit, SG) provided details of all plastics clinical leads.

Lean Tray Proposed Network Organogram



Clinical Engagement

- Adopt this project into your departments as Lean Tray Champions
- Identify your high volume high impact surgical trays
- Identify a Lean Tray Steward within the SDG to take forward the work integrating into the SDG workplan for 25/26

Case Examples Across Scotland

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Orthopaedics

C.Gee Golden Jubilee
RA- TKA

Tray Reduction
20%
5 to 4

Instrument Reduction
30%
52 to 36

Conversion Tray
4%

Orthopaedics

P.Moses Forth Valley
TKA

Tray Reduction
38%
4 to 2.5

Plastic Surgery

D.Jordan Tayside
Lumps and Bumps

Tray Size Reduction
50%
30x60 to 30x30

Instrument reduction
59%
27 to 11

Ophthalmology

Borders
Cataract Trays

Reduced Tray Size
from 2x2 to 2x1

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Pilot Centre

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NHS Tayside
Plastic Surgery Dept

Trialed Lean Trays methodology on three highest use trays

1- Plastic Minors [1462]
2- Plastic Basic [801]
3- Hand Tray [63]

Plastic Minor Tray

Instrument Reduction 29%
31 to 22

Single Use Plastic Reduction 33%

Tray Size reduction 50%
From 60x60 to 30x60

Associated Cost Avoidance
£32,208 Annually

Associated Carbon Avoidance
1249 kg/CO2e

Plastic Basic Tray

Instrument Reduction 39%
61 to 37

Single Use Plastic Reduction 33%

Tray Size – n/a

Associated Cost Avoidance
£23,796 Annually

Associated Carbon Avoidance
1094 kg/CO2e

Hand Tray*

Instrument Reduction 38%
47 to 29

Single Use Plastic Reduction 33%

Tray Size – n/a

Associated Cost Avoidance
£1411 Annually*

Associated Carbon Avoidance
72 kg/CO2e*

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The Challenges : Clinical View

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- Clinical engagement difficult due to workload and commitments
- Lack of clinician understanding of decontamination processes and capacity
- Departmental consensus on 'Leaned Tray' : team majority with adjustments
- Time consuming process for clinical team which risks no or minimal leaning achievable

Next Steps

- Continue clinical engagement with decontamination support
- Upcoming workshops – Specialty specific, Board Specific
- Grow network of Lean Tray Stewards and Champions across specialties

Resources

- NHS Scotland – Lean Tray Project Website
- CfSD National Green Theatres Programme: Actions for Implementation- Lean Tray Resources
  - Workbook
  - Toolkit
  - Action for Implementation
- National Green Theatre Programme. Lean Tray Project Group
  - lydia.robb@gjnh.scot.nhs.uk
  - steven.chawk2@nhs.scot

Next Steps

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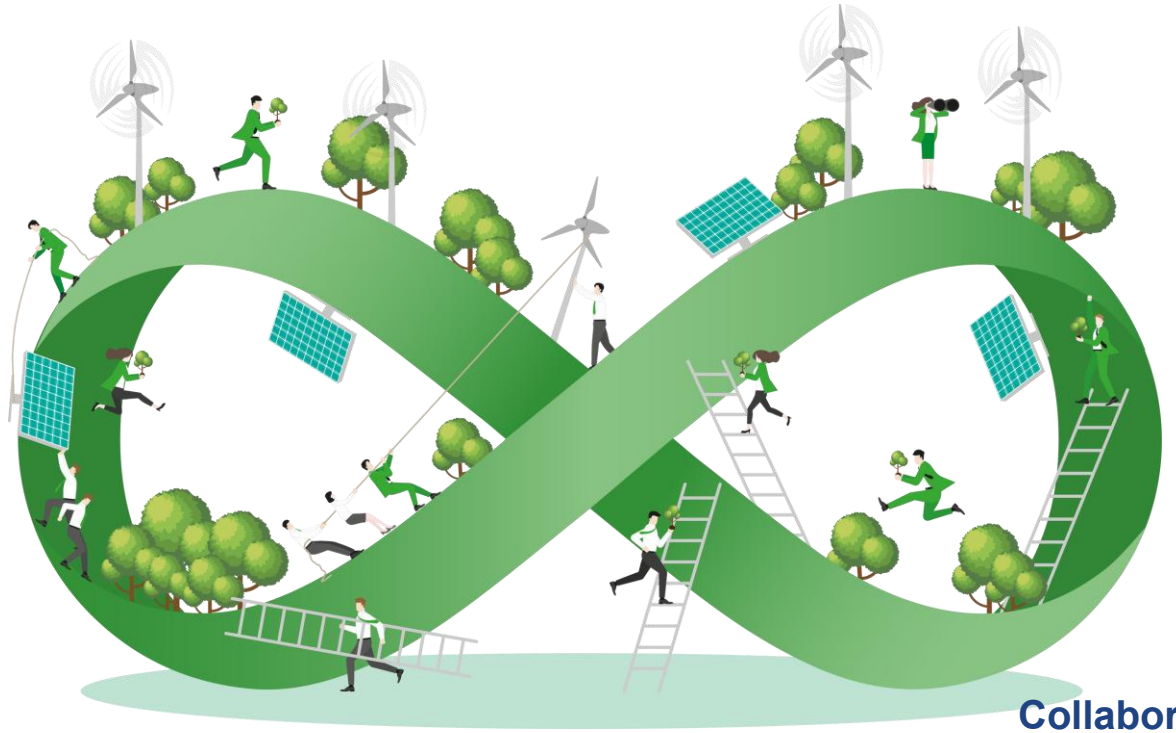
Contact the NGTP Lean Tray Implementation Team for further information



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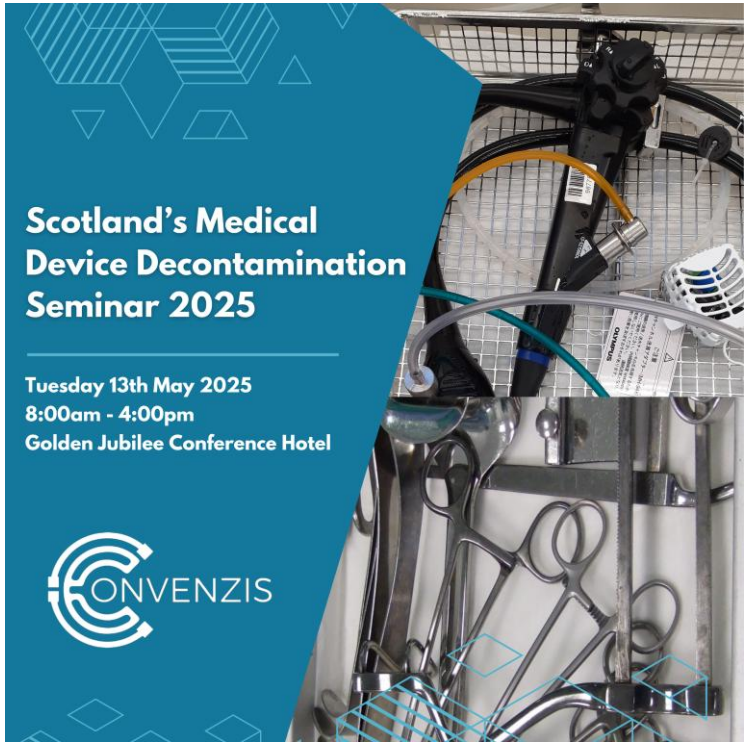
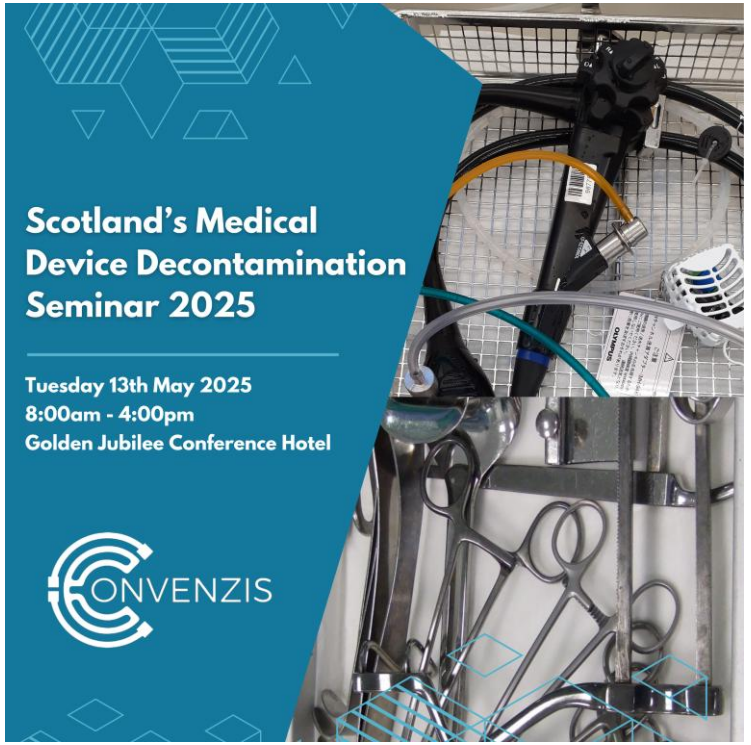


Keynote Presentation

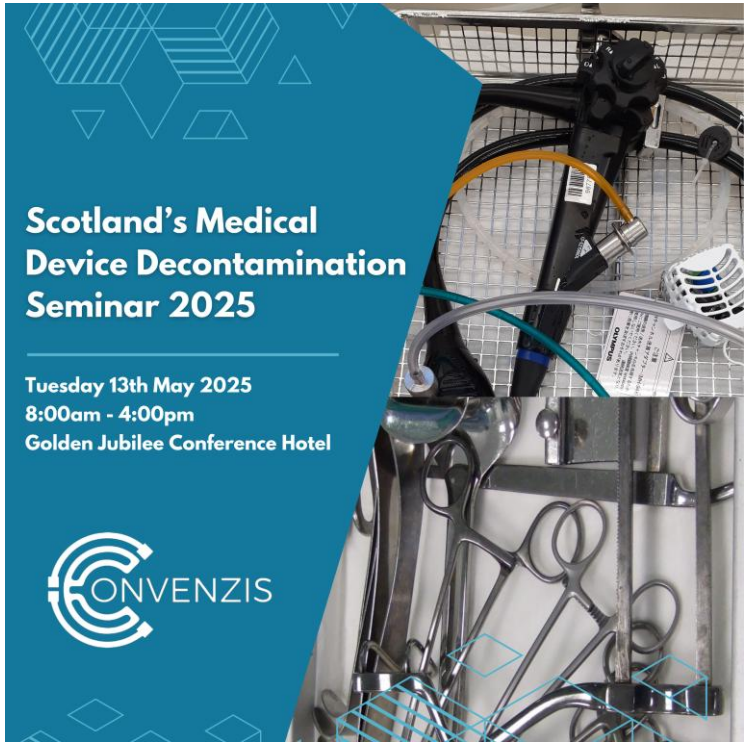
Dr. Sulisti Holmes

Head of Decontamination and Incident Investigation Reporting Centre

NHS Scotland Assure


Scotland's Medical
Device Decontamination
Seminar 2025
Tuesday 13th May 2025
8:00am - 4:00pm
Golden Jubilee Conference Hotel
CONVENZIS

Q&A



Closing Remarks