

<p>Institution: EaStCHEM</p>
<p>Unit of Assessment: 8; Chemistry</p>
<p>Title of case study: MIDAS: Monitoring and Decontamination of Hospital Medical Instruments; New Ultra-Sensitive Methods and New Government Guidelines</p>
<p>1. Summary of the impact Impact type: <i>Public Policy; Health (and related economic); Economic.</i> Significance: the research of the MIDAS (Medical Instrument Decontamination and Screening) group has been used to formulate Department of Health (DH) policy with respect to both the standard of contamination monitoring and the quality of instrument decontamination procedures. The Code of Practice CFPP 01-01, 2012 advocates the adoption of MIDAS's technology throughout the NHS. With effect from July 2012, this is contributing to reducing cancelled operations, 126,000 p.a., due to dirty instruments, minimising the risk of new cases of terminal, Transmissible Spongiform Encephalopathy (TSE) diseases, and reversal of the fear-driven, growing trend towards disposable instruments (at an estimated cost of ca £7bn worldwide). As a minimum estimate, this policy helps the work of 20,000 NHS sterile services hospital staff and contributes to the health and safety of all patients who now undergo surgery. Edinburgh Biosciences Ltd is employing four staff (2 PhD level) to manufacture and market MIDAS's new decontamination monitoring instrumentation. Research; date; attribution: Between 2002 and 2008 the Baxter and Jones groups developed and reported new methods to quantify and remove residual protein contamination on 'cleaned' hospital instruments. They set up MIDAS, the Medical Instrument Decontamination and Screening group, to develop and apply these methods for <i>in situ</i>, quantitative, ultra-sensitive detection of surface-bound, biological contamination on medical devices and for the removal of this contamination to levels below the limit of detection. Reach: The code of practice is currently in force at the UK level. Edinburgh Biosciences is commercialising decontamination monitoring systems for an international market.</p>
<p>2. Underpinning research Background: Effective instrument decontamination significantly reduces the unnecessary burden of cancelled surgical procedures and the waste generated by use of disposable items. Three per cent (ca. 126,000 operations) of all operations carried out annually in the UK have to be cancelled due to instrument cleaning/failure problems. In the US 34 million surgical operations are carried out each year, with a similar cancellation rate. There is currently great concern about healthcare-associated infection, and its negative impact on the public perception of the NHS. Lack of confidence in decontamination is leading to increased use of disposable surgical instruments. The global market for disposable hospital supplies is currently ca £7bn with expected 6 % annual growth. [GlobalData report, Mar 2013]. The inability of conventional instrument decontamination methods to inactivate prion proteins, the infective agents of Transmissible Spongiform Encephalopathy (TSE) diseases such as Creutzfeldt-Jacob Disease (CJD) has been a recent focus of public and professional concern. By 2009, there were 61 worldwide confirmed cases of iatrogenic CJD, i.e. that contracted by transmission during surgery, particularly in neuro- and eye-surgery. [http://www.patient.co.uk/doctor/Creutzfeldt-Jakob-Disease.htm; The National Creutzfeldt-Jakob Disease Surveillance Unit (NCJDSU)].</p>
<p>Research: Recognising that improvements in quality assurance and efficacy of cleaning of medical instruments would reduce hospital-acquired infections and cancelled operations the MIDAS (Medical Instrument Decontamination and Screening) project was set up by Baxter, Baxter, and Jones (all EaStCHEM) in 2002. With core funding from the Department of Health (DoH) its remit is the invention, evaluation and application of new methods for decontamination of medical devices and for the detection of biological material on surfaces.</p>
<p>The group carried out the first quantitative survey of protein contamination levels on 'cleaned' hospital instruments (DoH report December 2003; published 2006).[1] They then developed a</p>

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series of 'latent' fluorescent probes and protocols for *in situ* labelling of protein residues on surfaces. They developed a new epifluorescence scanning technique, EFSCAN, to measure these fluorescent, labelled residues, pushing the level of detection of proteins on surfaces down to ca. 100 attomoles mm⁻². [2] The new technique was fast and quantitative, and exceeded the sensitivity of the commonly used ninhydrin swab test by more than 5 orders of magnitude, and was patented. [5]

In parallel, the group developed RF gas-plasma methods for direct oxidation and elimination of proteins, including transmissible spongiform encephalopathy (TSE) infective tissue, from metal surfaces of medical instruments. [3] Recognising that this method is capable of eliminating the risk of iatrogenic CJD transmission between patients by surgery, this RF method was patented. [6]

The proven combination of gas plasma removal, and epifluorescence scanning to confirm decontamination, [4] led to the work with Edinburgh BioSciences to develop EFSCAN technology into a device.

Two further research projects were initiated in 2008 arising from funding from CONTEST, the UK Government's counter-terrorism strategy program on the detection and decontamination of toxins and biological agents: 'High-Level Decontamination using RF Gas-Plasma' and 'Ultra-sensitive Detection of Specific Biomolecules on Surfaces'. These provided robust evidence that toxins and biological agents can be detected and effectively cleaned from the surface of personal possessions and sensitive equipment in the context of CBRN (chemical, biological, radiological, and nuclear) clean-up, for example, the demonstration of *Bacillus spp* spore inactivation by gas-plasma treatment (2008).

People:

Prof R.L. Baxter, from 05/80 – 08/12 retirement; Dr H.C. Baxter, from 05/98 – 06/12 retirement; Prof A.C. Jones, from 01/89 to date: MIDAS PIs with complementary expertise in biological chemistry, transmissible spongiform encephalopathy (TSE), and spectroscopy research.

A.G. Whittaker, E.M. Graham, P.R. Richardson, G. Meek, G.A. Campbell, K. Grant, H. Halouani: PhD students, PDRAs, and research fellows in the research groups of the PIs. A. Aitken and M. Casey are collaborating medical experts at the University of Edinburgh, G. Meek is a collaborating Dental Surgeon, J.S. Barton, R. Maier and V.I. Kovalev are collaborators at Heriot Watt University, and G. DeLarge is an industrial collaborator in a RF gas plasma cleaning company (Plasma-Etch).

3. References to the research

The MIDAS group has been funded by a series of grants from the Department of Health, as well as funding from the Home Office. The journal articles, together with official reports, have informed Department of Health policy with regard to decontamination of surgical instruments.

Publications (*Underpinning research has been published in international, high-quality, peer reviewed, academic journals and receives citations from across the research area; A number of other (non-peer reviewed) articles have been published in the popular medical literature, accessible to a wide range of health professionals.*)

- [1] * Quantitative Analysis of Residual Protein Contamination on Reprocessed Surgical Instruments; R. L. Baxter, H.C. Baxter, G. A. Campbell, K. Grant, A.C. Jones, P.R. Richardson, A.G. Whittaker, *J. Hosp. Infection*, **2006**, 63, 439-44. doi:10.1016/j.jhin.2006.03.011. 25 cits, JIF 2.9.
- [2] *In Situ* Detection of Residual Protein Contamination on Surgical Instruments for On-the-Spot Monitoring of Decontamination. H.C. Baxter, A.C. Jones, R.L. Baxter, *Am. J. Infection Control*, **2012**, 40, e166-8. doi:10.1016/j.ajic.2012.04.296. 0 cits, JIF 2.7.
- [3] * Plasma cleaning of Dental Instruments; A.G. Whittaker, E.M. Graham, R.L. Baxter, A.C. Jones, P.R. Richardson, G. Meek, G.A. Campbell, A. Aitken, H.C. Baxter; *J. Hosp. Infection*, **2004**, 56, 37-41. doi: 10.1016/j.jhin.2003.09.019. 28 cits, JIF 2.9.
- [4] * Application of epifluorescence scanning for monitoring the efficacy of protein removal by RF gas-plasma decontamination. H.C. Baxter, P.R. Richardson, G.A. Campbell, V.I. Kovalev, R. Maier, J.S. Barton, A.C. Jones, G. DeLarge, M. Casey, R.L. Baxter. *New J. Phys.* **2009**, 11, 115028-42. doi:10.1088/1367-2630/11/11/115028. 3 cits, JIF 4.1.

Patents

- [5] R.L. Baxter, H.C. Baxter, A.C. Jones, G.A. Whittaker, G.A. Campbell, H. Halouani, P.R. Richardson, The University of Edinburgh: 'Latent Fluorescent Probes' 2008, WO/2008/047129.
- [6] R.L. Baxter, H.C. Baxter, The University of Edinburgh: 'Plasma Cleaning Methods for Medical, Surgical and Dental Instruments'. 2006, WO/2006/079801.

Grants Awarded (all peer reviewed)

- Cleaning and Monitoring of Protein Contamination of Surgical Instruments and Medical Devices (RL Baxter, HC Baxter, AC Jones & G Whittaker, Department of Health, 2002-6, £1,220k).
- Removal of Infective Protein Residues from Medical Instruments (RL Baxter, HC Baxter, AC Jones, Department of Health, 2006-7, £130k).
- Evaluation of gas-plasma decontamination for TSE inactivation (RL Baxter, HC Baxter, AC Jones, Department of Health, 2007-8, £72k).
- High-Level Decontamination using RF Gas-Plasma (RL Baxter, HC Baxter, AC Jones, Home Office, 2008-10, £120k).
- Ultra-sensitive detection of specific biomolecules on surfaces (RL Baxter, HC Baxter, AC Jones, Home Office, 2008-10, £120k).
- Assessment of EFSCAN technology for detection of residual protein contamination on surgical instruments (RL Baxter, HC Baxter, AC Jones, Department of Health 2011, £100k).

4. Details of the impact

Results of the MIDAS group on the quantification of contamination levels on 'clean' surgical instruments have been used to formulate, and are continuing to influence, government policy. As a minimum estimate, this policy helps the work of 20,000 NHS sterile services hospital staff and contributes to the health and safety of all patients who now undergo surgery, and the technology has been considered at an operation level at the Home Office for use in the aftermath of a CBRN incident. The new EFSCAN technology is in the final stages of commercialisation.

1. Public NHS policy: surgical equipment contamination monitoring and decontamination

The MIDAS group's research findings described in section 2 have been used in the formulation of 2012 Department of Health policy. The 2012/13 policy framework, CFPP-01-01 (Choice Framework for Local Policy Procedures for Decontamination) is the code of practice for the management and decontamination of surgical instruments that is adopted throughout the NHS, as required by the Health and Social Care Act 2008 with regard to NHS Decontamination (Sterile Services; Parts E and work acknowledged in Parts A and B) facilities.[S1]

CFPP-01-01 explicitly cites the researchers and describes the studies completed by the MIDAS group: Part A, see text on P8, paragraph 2.40 (section on 'Protein quantification using epifluorescence scanning'), p29, paragraph A1 (chapter on 'Inactivation of prions using novel technologies' describing 'instrument exposure to cold plasma' and further references on p38, paragraph A86. It also cites the report 'ESAC-Pr: New Technologies Working Group Report on Prion Inactivating Agents' written by the working group (2008), of which R. Baxter is a member.[S2] This report includes citations and references to the MIDAS research on pps 8,20,21,26,27,29.

2. Health

MIDAS has extended the technology through research trials currently underway with Edinburgh Royal Infirmary, Ninewells (Dundee), Glasgow Dental Hospital. The consultant microbiologist, leading the work says "*The introduction of new detection technology, such as EFSCAN, is essential to drive improvements in the standards of decontamination of medical instruments throughout the Health Service*".[F1] Data obtained in these projects will inform supplements to CFPP-01-01[S1] with regard to defining maximum permissible levels of protein contamination on reprocessed surgical devices and driving the adoption of new detection technology (such as EFSCAN) when commercial systems become available. A letter of support from a DoH Senior Principal Research Officer states "*We will continue to use the outputs from this study as we develop aspects of the CFPP in future and anticipate that successful commercialisation of your technology for assessment of instrument decontamination will make it available to NHS Trusts for their surgical sterilisation departments*".[F2]

The CONTEST funded research demonstrated the efficacy of the EFSCAN technology for both

detection and decontamination of material from possessions and equipment clean-up after a CBRN incident. In a corroborating letter, the DoH CBRN Research Manager states "*There is a clear concept of use of the research findings, namely to detect contamination and provide clean possessions and other sensitive items in the aftermath of a CBRN incident... results from the projects have been considered at an operational level at the Home Office*".[F3]

3. Economic: commercialisation of EFSCAN for detection of contamination

Through Edinburgh Research Innovation, MIDAS exploited the IP developed in the 2002-8 research. Working with Edinburgh Biosciences, a proof-of-concept EFSCAN instrument for hospital Sterile Services Departments use was constructed in 2011-12. In early 2013, Edinburgh BioSciences was awarded a SMART:SCOTLAND grant of £100k by Scottish Enterprise to develop and bring the EFSCAN system to market by the end of 2013. Edinburgh Biosciences UK has four salaried people now developing the EFSCAN proof-of-concept design into commercial prototypes for manufacture and marketing. Two are PhD level engineers, one Masters (mechanical engineering); and an electronic engineer (honours degree). The Edinburgh Biosciences CEO said "*Following the successful development of a proof-of-concept instrument, Edinburgh Biosciences Ltd. sees commercial exploitation of this instrument as a key element of its business launch plan. As the reliability and performance characteristics of the system are confirmed, marketing and sales of the instrument will expand internationally from a UK base. The US is a target market given that awareness of the problems of contamination of surgical instruments is already in the public domain*".[F4]

A portable 'hand-held' fluorescence detector for fast detection of biomolecules on surfaces, in the context of homeland security, has also been developed.

The press (Telegraph, Guardian, Scotsman newspaper articles; BBC News and radio, and specialist publications) note the value to public and the profession, and cite MIDAS's work directly. Examples include BBC reports,[S3],[S4] and an Association for Perioperative Practice report which cites [S1], stating "*The prevention of infection is one of the fundamental principles of patient care...The effective decontamination of surgical instruments is critical in the management of healthcare associated infection and patient safety; therefore it is essential that practices and processes applied to thorough decontamination of all surgical instruments is of the highest quality and reflects modern day standards*".[S5]

5. Sources to corroborate the impact

[S1] Choice Framework for local Policy and Procedures (CFPP) 01-01. March 2013 – 'Management and decontamination of surgical instruments used in acute care'.

<https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care>. (Section E as well as acknowledgements in Section A and B)

[S2] 'ESAC-Pr: New Technologies Working Group Report on Prion Inactivating Agents' (August 2008. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_086803.pdf).

[F1] A corroborating letter is provided by the microbiology consultant, based at Glasgow Dental Hospital, responsible for decontamination in NHS Glasgow and Clyde Hospital, who led the study using EFSCAN on "Reducing the risk of vCJD by improving the cleaning of neurosurgical instruments", funded by the Scottish Government.

[F2] A corroborating letter from the Senior Principal Research Officer, Department of Health Policy Research Programme.

[F3] A corroborating letter from the CBRN Research Manager, Research & Development Division, Department of Health.

[F4] A corroborating letter from the CEO of Edinburgh Biosciences.

[S3] Surgery patients at risk from CJD, 2011: <http://www.bbc.co.uk/news/health-12898082>.

[S4] Unsafe surgical instruments delay Glasgow operations, 2013: <http://www.bbc.co.uk/news/uk-scotland-21760110>.

[S5] Report from the Association for Perioperative Practice (<http://www.afpp.org.uk/news/resources/decontamination>).