Institution: University of Huddersfield

Unit of Assessment: 3

Title of case study: Prevention and Management of Surgical Site Infections: Informing UK and International Standards and Improving Clinical Approaches

Period when the underpinning research was undertaken: 2010–2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Karen Ousey	Professor of Skin Integrity	2005-present
Barbara Conway	Professor of Pharmaceutics	2010-present
John Stephenson	Biomedical Statistician	2010-present
Steve Lui	Senior Lecturer	2010-present
Karen-leigh Edward	Visiting Professor	2015- present
David Leaper	Professor of Clinical Sciences	2013-2016

Period when the claimed impact occurred: 2014-2020

Is this case study continued from a case study submitted in 2014? No

1. Summary of the impact

At least one in twenty patients undergoing surgery acquire a surgical site infection (SSI), with a fatality rate of 4.5% in patients affected. More than one-third of post-operative deaths are related to SSI. Research at the University of Huddersfield (UoH) has changed policy and practice nationally and internationally for the prevention and management of SSI, through expert contribution to influential best practice statements and international consensus documents. Our research has generated a novel in-vitro test method assessing the fluid-handling properties of super-absorbent wound dressings, leading to increased revenue and a larger client base for Perfectus Biomed, a UK microbiology contract testing laboratory. The findings were also incorporated into an online training module which was taken by nearly 5,000 health care practitioners from 125 countries within a three-month period.

2. Underpinning research

Surgical site infection (SSI) occurs when microorganisms in a wound proliferate to a level that produces a local and/or systemic response. It can disrupt healing and weaken wound tissues. SSI therefore poses a serious post-surgery risk to patients and is a major concern worldwide: it accounts for 15.7% of all reported infections, with an estimated cost of £6,000–£11,000 per wound, a case fatality rate of 4.5% in patients who develop an SSI, and over one-third of case fatalities directly attributable to it. Research led by the University of Huddersfield (UoH) has reported new evidence to improve the prevention and management of SSI.

Ousey, Professor of Skin Integrity (at UoH since 2005), and **Conway**, Professor of Pharmaceutics (at UoH since 2010) were both leaders in their respective research fields prior to working together as part of the Institute of Skin Integrity and Infection Prevention (ISIaIP).

Research conducted by Conway in 2010-11, focused on formulation strategies to improve skin antisepsis. For [3.1], she and colleagues from Aston University and University Hospitals Birmingham conducted skin penetration studies using donor skin to examine what might improve the delivery of chlorhexidine digluconate (CHG), a powerful antiseptic, beneath the surface layers of the skin. Conway led on formulation strategy and testing. Findings showed that penetration to the lower layers of skin was significantly enhanced in the presence of eucalyptus oil. For [3.2], Conway and colleagues investigated the antimicrobial efficacy of CHG intravascular catheter gel against methicillin-resistant Staphylococcus aureus (MRSA) *in vitro,* using infected dressing and donor skin. The research demonstrated that the CHG intravascular catheter site gel had

detectable antimicrobial activity for up to seven days, which *in vivo* would reduce the risk of infection at the catheter insertion site. This work has greatly enhanced understanding of how broad-spectrum antiseptic agents can be better exploited to reduce SSI, and the unnecessary use of antibiotics.

In 2017, a systematic review and meta-analysis carried out by Ousey (as PI), **Lui** (provided systemic review expertise), Stephenson (provided statistical expertise) and **Leaper** (provided clinical expertise), with colleagues from Australia (Swinburne University and the Universities of Tasmania and Newcastle), demonstrated that ineffective patient warming after surgery can adversely affect wound healing [3.3].

In 2018, with a £98,000 Innovate UK grant, Ousey, in partnership with Perfectus Biomed (a microbiology contract testing laboratory) and Essity (a Swedish-based global company specializing in hygiene and health care products) developed an *in-vitro* test method assessing fluid handling properties of super-absorbent Polymer wound (SAP) dressings within an exuding wound model. Prior to 2018, no validated *in vitro* test method was available and therefore, clinicians had had to make treatment decisions based on marketing material and single case studies. The development, external validation, and accreditation of this method by United Kingdom Accreditation Service (UKAS), carried out within the ISO/IEC 17025:2005 guidelines (the international standard for testing and calibrating laboratories), provided an independent method for assessing SAP dressings that can be used worldwide and was awarded best pre-clinical research in the Journal of Wound Care awards (2018).

In collaboration with Sheffield Hallam University, Ousey (who as Co-Investigator provided expertise on infected and non-infected wounds), and Stephenson (who provided statistical expertise) focused on the use of non-invasive infrared thermography (IRT), performed pre- and post-operatively, to predict the risk of SSI in obese women following caesarean section (CS). Wound infections and surgical wound dehiscence [6] are not uncommon with obesity. Prior to the research, no independent wound assessment technology was available to stratify women to low or high risk of SSI. The findings demonstrated that IRT imaging of wound and abdomen in obese women undergoing CS is more effective than visual (subjective) wound assessment. These findings support precision and performance of IRT as an independent SSI prognostic tool and pave the way for future technology to aid decision-making in antibiotic prescribing ([3.4], 2019).

In order to achieve international consensus on the clinical indicators for a chronic wound, Ousey and three colleagues from Australia undertook an online Delphi consensus process involving international key opinion leaders in infection. Consensus was reached on clinical indicators of wound chronicity, wound infection and biofilm presence, as well as agreement that the term "critical colonisation" (the point when the patient's immune system is no longer able to control the colonising bacteria in a wound) was lacking evidence for use and should no longer be used in wound assessment (2019) [3.5].

3. References to the research

[3.1] Karpanen TJ, **Conway** BR, Worthington T, Hilton AC, Elliott TS, Lambert PA. Enhanced chlorhexidine skin penetration with eucalyptus oil. BMC Infectious Diseases. 2010;10(1):278. doi.org/10.1186/1471-2334-10-278

[3.2] Karpanen TJ, Casey AL, **Conway** BR, Lambert PA, Elliott TS. Antimicrobial activity of a chlorhexidine intravascular catheter site gel dressing. Journal of Antimicrobial Chemotherapy. 2011;66(8):1777-84. doi.org/10.1093/jac/dkr191

[3.3] **Ousey** K, Edward KL, **Lui** S, **Stephenson** J, Walker K, Duff J, Leaper D. Perioperative, local and systemic warming in surgical site infection: a systematic review and meta-analysis. Journal of Wound Care. 2017;26(11):614-24. doi.org/10.12968/jowc.2017.26.11.614

[3.4] Childs C, Wright N, Willmott J, Davies M, Kilner K, **Ousey** K, Soltani H, Madhuvrata P, **Stephenson** J. The surgical wound in infrared: thermographic profiles and early stage test-accuracy to predict surgical site infection in obese women during the first 30 days after caesarean

section. Antimicrobial Resistance & Infection Control. 2019;8(1):7. doi.org/10.1186/s13756-018-0461-7
[3.5] Haesler E, Swanson T, **Ousey** K, Carville K. Clinical indicators of wound infection and biofilm: reaching international consensus. Journal of Wound Care. 2019;28(Sup3b):s4-12. doi.org/10.12968/jowc.2019.28.Sup3b.S4

Evidence of quality of the research: The publications all add to the body of knowledge and have been integral in enhancing clinical practice through international, peer reviewed journals. The new *in vitro* test method assessing fluid handling properties of super-absorbent wound (SAP) dressings was awarded best pre-clinical research in the Journal of Wound Care awards in 2018.

4. Details of the impact

The research described in this case study has been included in guidance and best practice documents for health care practitioners in the UK and internationally. It has informed the practice of health care professionals worldwide, benefited a commercial company and influenced global educational practice in the field of wound infections.

Much of the impact was due to the dissemination of the research findings [3.1 – 3.6] achieved through Ousey's internationally leading role in her research area, through bodies including the International Wound Infection Institute (IWII, of which she was elected chair in 2017), the International Surgical Wounds Complications Advisory Panel (ISWCAP – Vice President since 2019) as well as the European Wound Management Association (EWMA). Thanks to Ousey's international reputation in her field, UoH's ISIaIP was invited to join the World Union of Wound Healing Societies (WUWHS) as a sister organization, the only university to be awarded this honour, with Ousey in the role of Chair of the core expert working group.

Impact on international clinical guidance and practice

Based on the body of work described in Section 2, Ousey co-authored the 2016 updated edition of the International Consensus on Wound Infection in Clinical Practice [5.1], which offers practical information on wound infection for health care practitioners. The international guidance was revised and the evidence-base strengthened based on new insights from Ousey's research [3.5]; additional content was added about the role of biofilm in wound healing and redundant concepts and terminology removed ("critical colonisation"). The importance of a holistic approach to patients with active wound infection was also highlighted. The document was developed in association with the International Wound Infection Institute (IWII), an international committee of world leading experts representing expertise in prevention and management of wound infection globally. By the end of December 2020, the document had been downloaded 4,700 times, and 4,000 hard copies had been distributed. A Chinese translation resulted in a further 1,254 downloads and 1,000 hard copies being distributed.

In the UK, the document has led to significant clinical benefits, providing, according to a Vascular Nurse Consultant at the Mid Yorkshire Hospitals NHS Trust, "a standard template of approach to wound infection across the nations" and helping to "standardise approaches within England". It has helped clinical service at many levels to change practice and has led to a reduction in unnecessary antimicrobial and antibiotic use. By June 2020, the changes in the consensus document had also changed local policy informing, according to the same source, "the whole of the acute and community NHS workforce", as well as the education and training of the clinical workforce [5.2a].

The document has also been used by leading wound care companies, including ConvaTec, an international medical products and technologies company: "The document is well respected and a key reference tool to support the appropriate use of ConvaTec brands" (Global Clinical and Medical Strategy Director, ConvaTec) [5.2b].

Publication of this document resulted in health care practitioners across the world removing the term 'critical colonisation' from their infection policies and replacing it with 'overt and covert signs

of infection'. Wounds Australia, a charity dedicated to the suffering caused by wounds, reported in June 2020 that it had used the contents of the document in presentations at practitioner conferences in the United States of America (US), Australia, the United Kingdom (UK), Canada, Denmark and China, and that it had influenced generalists and specialists in providing everyday care [5.2c]. Kuala Lumpur Hospital in Malaysia, the largest tertiary hospital in South East Asia, confirmed that it had been using the document in its daily practice and removed "critical colonisation" from its training. "The document has a huge impact", wrote a Senior Consultant Wound Care Physician. "There will be a big change in clinical settings for the wound care teams in the 146 centers (sic) [across Malaysia, Singapore, Myanmar and Thailand]" (June 2020) [5.2d].

Ousey's appointment in 2018 as Chair of a Core Expert Working Group for WUWHS (which represents over 90% of wound care experts worldwide) was a key factor that influenced the development of another consensus document. Surgical Wound Dehiscence (SWD): Improving Prevention and Outcomes (2018) [5.3] cites Ousey's previous work (2017) [3.1], which identified the risk of SWD. By the end of 2020, the consensus document had been downloaded 2,820 times, and 4,000 hard copies had been distributed in the UK and internationally. The document aims to improve outcomes for patients and carers and has been implemented into clinical areas in the US, Australia, New Zealand, Malaysia and the UK. A Senior Research Fellow at the University of Western Australia wrote in July 2020 "The document is used in clinical practice and has improved the clinicians' ability to correctly diagnose the category of wound dehiscence, which leads to appropriate therapeutic management of this type of wound…This document is being used at St John of God Health Care, Midland, and is currently undergoing implementation at multiple sites in Perth and across Australia." [5.4a].

Early feedback from Australian clinicians was extremely positive, with many commenting how much the document was needed and how it would improve clinical assessment and patient healing outcomes [5.4a]. In Malaysia, Kuala Lumpur Hospital confirmed that the document provided an evidence-based foundation for the training of wound teams in different hospitals, and that teams in Orthopaedics, Plastic and Reconstructive Surgery and other areas had used it as a reference guide. "It has good impact especially in Asia," wrote a Senior Consultant Wound Care Physician, "as we are using more evidence-based medicine." [5.4b].

By July 2020, Smith and Nephew, a leading international medical technology company headquartered in Watford, UK, had distributed 1,000 hard copies of the document to clinicians at key congresses and educational meetings, receiving what the company called very positive feedback on its value. Smith and Nephew's Senior Global Marketing Manager added that, "This consensus continues to help shape and impact the material I am producing for our teams as part of our dedication to practice development and consistency." [5.4c].

NHS outcomes have improved through the UoH research, with eight free-to-attend international conferences in the UK, US and Canada between 2016 and 2020, and online in July 2020 at which Ousey and Conway shared their findings [3.1 – 3.5] and best practice in both skin integrity and infection prevention with over 2,500 clinical practitioners. Feedback indicated participants' intention to use the research outcomes in their clinical practice: "Conference presentations helped with personal reflection and hence this is how one can polish up and improve delivery of care" (UK delegate) [5.5]. "As a Practice Nurse these wound care updates are very relevant to ensure I am using evidence-based practice. This will ensure my patients get good care which prioritises their care and ensures I work effectively. Thank you for this informative week of wound updates" (UK delegate) [5.5]. There was also positive feedback from outside the UK: "The use of antimicrobials and the TIME chart was very helpful. I will be incorporating some of these issues and treatments into my facility" (US delegate) [5.5]. "I find wounds daunting sometimes. After the webinar I feel more confident about why it's so important to manage the biofilm and be aggressive managing it. The curetting was really interesting and something I will take back to my colleagues. I have informed them about the webinar and suggested they watch it" (US delegate) [5.5].

Impact on commercial companies

Ousey's research with Perfectus Biomed into super-absorbent wound dressings enabled the company to offer testing of such dressings to manufacturers, which according to the company significantly increased their reputation, revenues and client base: "The research has [also] allowed

Perfectus to expand their service offer to current and future clients and therefore increasing [sic] revenue. As a result of the project, Perfectus have gained an additional 5 clients who have commissioned the test method" [5.6]. Although confidentiality agreements with those clients do not allow them to be named, Perfectus emphasize that the clients have benefited from the new *in vitro* test method through the de-risking of costly clinical trials.

3M, a multinational company operating in the health care field (amongst others) used the research into super-absorbent wound dressings to add a chlorhexidine digluconate intravenous (CHG i.v.) securement dressing to their product range, with the research [3.2] cited on their website in evidence [5.7].

Impact on education and NHS practice: antimicrobial stewardship in wound management

Ousey's research on Antimicrobial Stewardship (AMS, [3.6]) led to her being approached by the European Wound Management Association (EWMA) to develop a global online education module, AMS in Wound Care [5.8a], which launched in October 2019 for a three-month period. 4,929 people from 125 countries enrolled, including over 1,300 from the UK. Feedback demonstrated how participants intended to use their new knowledge to inform their own practice to improve patient outcomes: "I am more motivated than ever to embrace AMS in my practice" (Medical Officer, Nigeria); "Will share with my working colleagues" (practitioner, Malta); "Has definitely changed parts of my practice" (participant); "I now feel motivated to challenge practice within my area. To promote change and improve patient outcomes" (participant) [5.8b]. A senior community nurse from Orkney wrote: "Ultimately I hope to share this learning within my community nursing team. Being so rural often means clinicians play a very generic role as specialist support is not readily available" [5.8b]. 75% of learners reported that they had applied what they had learned from the module in their clinical practice [5.8b]. Due to the success of the course, the EWMA decided in March 2020 to translate it into Spanish. The Spanish language version went live in Autumn 2020.

EMWA asked Ousey to create the European SSI best practice statement (BPS) [5.9], launched in January 2020 and distributed to 2,000 professionals; Ousey was subsequently asked to be an international expert panel member [5.9, 5.10]. The document incorporates Ousey's work on peri-operative warming, aiming to provide evidence-based best practice recommendations for SSI management in hospitals, community and primary care across Europe.

5. Sources to corroborate the impact

[5.1] www.woundinfection-institute.com/wp-content/uploads/2017/03/IWII-Wound-infection-in-clinical-practice.pdf

[5.2] Testimonials a – d, evidencing impact of [5.1].

[5.3] www.woundsinternational.com/resources/details/consensus-document-surgical-wound-dehiscence-improving-prevention-and-outcomes

[5.4] Testimonials evidencing impact of [5.3].

[5.5] Conference evaluations

[5.6] Perfectus Biomed testimonial

[5.7] Web page from 3M website offering CHG i.v. securement dressings and quoting the research www.3m.co.uk/3M/en_GB/company-uk/3m-products/~/3M-Tegaderm-CHG-Chlorhexidine-Gluconate-I-V-Securement-Dressing/?N=5002385+3293188878&rt=rud

[5.8] Evidence of AMS in Wound Care online teaching module: (a) module www.futurelearn.com/courses/antimicrobial-stewardship-in-wound-management (b) evaluation documents

[5.9] Wounds UK (2020) Best Practice Statement: Antimicrobial stewardship practices in wound care. London, Wounds UK. Available at: www.wounds-uk.com

[5.10] Wounds Week 2020 online conference