Institution: University of Southampton		
Unit of Assessment: 03 Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: 03-02 New sustainable technologies, support tools and standards have improved the lives of people with incontinence		
Period when the underpinning research was undertaken: 2003 – 2019		
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:**
Mandy Fader	Professor of Continence Technology	July 2004 – present
Jacqui Prieto	Associate Clinical Professor, Infection Prevention	August 2004 – present
Cathy Murphy	Senior Research Fellow	July 2014 – present
Margaret Macaulay	Senior Research Fellow	August 2017 – present
Sandra Wilks	Lecturer in Medical Microbiology	November 2000 – present
Period when the claimed impact occurred: November 2013 – December 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

Globally, more than 200 million people with incontinence depend on technology to manage their condition. University of Southampton (UoS) research has led to novel sustainable continence products, online support tools and development of standards that have improved the lives of people with incontinence worldwide by:

Increasing user confidence in product choice and access to products: 1) The *Continence Product Advisor* website, co-created by UoS, has had more than one million visits worldwide and is a core component of a professional development massive open online course (MOOC) with users in 119 countries. 2) New International Organization for Standardization (ISO) and World Health Organisation (WHO) standards shaped by UoS research have given lower income countries sustainable access to products that were previously unavailable or too expensive.

Providing sustainable product choices for intermittent catheter users: Novel intermittent catheter cleaning methods have expanded options beyond single-use plastic catheters for users worldwide by enabling CE marking of 1) the first biodegradable, reusable intermittent catheter for women and 2) a biodegradable, biocidal wipe effective at decontaminating intermittent catheters.

Improving options for convenient, safe use of male incontinence devices: UoS researchers have designed a reusable penile compression device and produced evidence-based guidance to help thousands of men worldwide manage post-prostatectomy incontinence.

2. Underpinning research

Estimates of urinary incontinence in the UK alone indicate that as many as six million people are affected. People rely on continence products and devices to manage a condition that many find difficult to talk about, and it can be challenging to identify and access products that meet their physical and emotional needs. In recent years, single-use products, especially absorbent pads and urinary catheters, have become 'the norm' despite their significant environmental impact. Working with product users and carers, the Bladder and Bowel Management Group at UoS has used clinical trials, experimental methods, qualitative research and evidence syntheses to co-design and develop sustainable technologies to improve the quality of life of people living with incontinence.

Clinical trials and decision-aid methodology: Supporting product choice, decision-making and product development. Since 2006, Fader has led a series of trials to assess the performance of different continence product designs. A Medical Device Agency funded trial of absorbent products for men with light incontinence [**3.1**] showed substantial differences in performance between disposable and reusable products and between different designs, winning the International Continence Society best abstract award (Montreal, 2005). Building on this work, in 2008 Fader led a Health Technology Assessment (HTA) programme of three clinical trials [**3.2**] comparing the effectiveness of different absorbent continence product designs for men and women at home and in nursing homes. Her research showed, for the first time, important gender preferences and

highlighted the strengths and weaknesses of different designs of both washables and disposables for different needs.

Men's needs were investigated further in a Prostate Cancer Charity-funded cross-over trial comparing the effectiveness of four product designs for men with post-prostatectomy incontinence [**3.3**]. This was the first published study to compare different continence devices for men and showed the potential value (highly effective for leakage) and limitations (pain and discomfort) of the penile compression device (clamp), demonstrating the need for an improved design and, unlike for many existing clamps, clear user safety guidance. The research revealed that some device designs, when compared with pads, significantly improved men's quality of life and reduced the number of disposable pads used. Most men found a 'mix' of products to be more effective although they lacked information on which to base their product selection decision-making. In parallel, and to make this and other continence product research more accessible for clinicians and product users, Fader developed the concept of an evidence-based interactive website. This was based on the framework developed for the evidence synthesis chapter *Management with Continence Products* published by the International Consultation on Incontinence [**3.4**] and co-authored by Fader.

To enable users to select products most suited to their needs utilising the results of our research and to build on the findings of the male devices study [**3.3**], we were awarded a programme grant (GBP830,000) from Movember/Prostate Cancer UK. This included funding for the first evidence – based *Continence Product Decision Aid* which Fader and Dr Cathy Murphy developed using patient decision-aid methodology. We demonstrated that use of the tool improved user confidence in decision-making and reduced decision conflict [**3.5**] and it was incorporated into the *Continence Product Advisor.* In response to men's need for improved information and better products [**3.3**] a new prostate cancer section funded by this programme was built into the *Continence Product Advisor.* This programme also funded the development of a new clamp design as identified by our male devices study [**3.3**].

Experimental laboratory work: Developing novel reprocessing methods for intermittent catheterisation. In 2007, Fader co-authored a Cochrane review showing insufficient evidence for any catheter design or catheterisation technique affecting the rate of urinary tract infection [**3.6**]. This called into question the industry-driven, large-scale shift away from catheter reuse to single-use plastic catheters, which reduced user choice and had substantial cost implications. According to the Prescription Cost Analysis, NHS spend increased from GBP13m in 2008 to GBP104m in 2018. In England alone around 75,000 plastic intermittent catheters end up in landfill every year. The Cochrane findings underpinned the award to Fader of a GBP2.4m NIHR programme grant that included a randomised controlled trial comparing single-use catheters with 'mixed' use (single-use and multi-use) catheters. In preparation for the trial, Dr Sandra Wilks and Dr Jacqui Prieto developed, with patients, the first evidence-based, reliable and practical reprocessing method based on the Milton™ cold water sterilising method. When tested with catheter users, the UoS *Multicath Milton* method removed a range of common uro-pathogens from intermittent catheters when cleaned between uses and was acceptable to users. It allows the reuse of uncoated catheters repeatedly for up to 28 days [**3.7**] and led directly to the CE marking and marketing of the world's first reusable and biodegradable intermittent catheter (Emteva™) by UK company Hunter Urology. Interviews undertaken by Prieto with 40 catheter users highlighted the benefits of choice of catheter type to users who want the convenience of a disposable catheter but also the security of a reusable one.

3. References to the research

3.1 Fader M, **Macaulay M**, Pettersson L, Brooks R, Cottenden A. *A multi-centre evaluation of absorbent products for men with light urinary incontinence* (2006). Neurourol Urodyn. 25(7):689-95. https://doi.org/10.1002/nau.20259

3.2 Fader M, Cottenden A, Getliffe K, Gage H, Clarke-O'Neill S, Jamieson K, Green N, Williams P, Brooks R, Malone-Lee J. *Absorbent products for urinary/faecal incontinence: a comparative evaluation of key product designs* (2008) Health Technology Assessment. Jul;12(29): iii-iv, ix-185. https://doi.org/10.3310/hta12290 Grant holder: Fader; Funder: NIHR Health Technology Assessment Programme; GBP481,473; 2003 – 2007.

3.3 Macaulay M, Broadbridge J, Gage H, Williams P, Birch B, Moore KN and **Fader M**. *A trial of devices for urinary incontinence after treatment for prostate cancer* (2015). *BJU Int.* Sep;116

(3):432-42. Epub 2015 Apr 6. https://doi.org/10.1111/bju.13016 Grant holder: Fader; Funder: Prostate Cancer Charity 110841; GBP106,517; 2009 – 2013.
3.4 Cottenden A, Bliss D, Buckley B, **Fader M**, Gartley C, Hayder D, Ostaszkiewicz J, Wilde M. *Management Using Continence Products* (2013). Chapter 20 in *Incontinence* Edition 5. International Continence Society Eds. Abrams et al. ISBN 978-9953-493-21 (Quadrennial, international, systematic review of all continence product evidence, 2011 –13). Available on request.
3.5 Murphy C, de Laine C, **Macaulay M**, **Fader M**. *Development and randomised controlled trial of a Continence Product Patient Decision Aid for men post-radical prostatectomy* (2020) Journal of Clinical Nursing. 17.02.2020. https://doi.org/10.1111/jocn.15223 Grant holder: Fader; TrueNTH continence management programme; Funder: Movember/Prostate Cancer UK; GBP265,345 (of total GBP829,383); 2014 – 2019).
3.6 Moore KN, **Fader M**, Getliffe K. *Long-term bladder management by intermittent catheterisation in adults and children* (2007). *Cochrane Database Syst Rev*. Oct 17;(4) https://doi.org/10.1002/14651858.CD006008.pub2 (Cochrane systematic review)
3.7 Wilks SA, Morris N, Thompson R, **Prieto JA**, **Macaulay M**, Moore KN, Keevil CW, **Fader M**. *An effective evidence-based cleaning method for the safe reuse of intermittent urinary catheters: In vitro testing* (2020). Neurourology & Urodynamics. Mar;39(3):907-915. https://doi.org/10.1002/nau.24296 Grant holder: Fader; Development and clinical trial of a mixed (multi/single-use) catheter management package for users of intermittent catheterisation; NIHR Programme Grant for Applied Research programme RP-PG-0610 Amount: GBP2,374,857; 2013 – 2022.

4. Details of the impact

University of Southampton research designed to improve quality of life for people with incontinence has benefitted: a) patients, by increasing user confidence in and access to a wider and more sustainable range of continence products and devices, b) clinicians, supporting their practice through evidence-based online guidance, professional development training and the availability of new devices on prescription, and c) policymakers, through the development of new international standards and WHO product specifications that strengthen regulation of clinical devices and widen access to quality, cost-effective products in low-income countries.

Increased confidence in product choice and wider access to products for users, their informal carers and clinicians

We pitched the concept of the *Continence Product Advisor* website to the International Continence Society, the foremost, international, multi-disciplinary organisation for incontinence education and research (3000+ members worldwide), who invested in the technical expertise to build and launch the website in November 2013. This website is the first evidence-based, comprehensive and independent (i.e. not industry-driven), multimedia resource for patients and clinicians, utilising our research [**3.1-3.3,3.5**] to support continence product selection and use. It is the only evidence-based source of continence product advice listed on the NHS website for patients, with more than 1 million visits from men and women from more than 190 countries worldwide over the impact period. It averages more than 10,000 visitors per month. More than 890 product queries and 240 user tips have been submitted by users, informal carers and clinicians, each answered by an expert nurse [**5.1**]. The website is maintained by the International Continence Society and it is a valued resource for its international membership and their patients. Its former Secretary General states: "*The value of the website is inestimable … I find the website incredibly helpful to guide both patients and caregivers in the selection of appropriate products*." [**5.2**] Online surveys show that most users found the website 'very helpful' (74%), gaining confidence in product selection and use (66%) [**5.3**]. Representative feedback included: "*It is … very informative, helped me realise there are many more options to manage incontinence than I thought"* and for men preparing for surgery, *"Forewarned is forearmed … takes away some of the fear … helps you to deal with your situation more easily and confidently"*.

The *Continence Product Advisor* is the core component of a new education programme (MOOC) *Understanding Continence Promotion* [**5.4**], launched in February 2019 by the UK Association for Continence Advice (ACA), a membership organisation for all health and care professionals, including NHS Trust continence service leads, with an interest in bladder and bowel health. The course, which

offers training on how to support self-management of continence conditions, is free to ACA members and can count as a professional development credit – although informal carers and people living with incontinence have also completed it. It has been run six times over the REF impact period, training 3622 people from 119 countries; 100% of responders to a post-course survey reported gaining knowledge or skills and online reviews posted on the FutureLearn site gave an average rating of 4.7 out of 5.0. [**5.4**]

Representative feedback included: "*I think it would great if all nurses could have this introduction to what continence means, the effects it has on individuals … made me reflect on my current practice*" (Nurse of 12 years). "*Made me feel like taking up nursing again*" (Informal carer). "*It has enlightened me on how to treat and take care of my bowel and if there's incontinence occurrence how to control and treat it*" (Person living with incontinence). [**5.4**] Professor Jo Booth, MOOC Lead stated: "*Without access to this unique resource (Continence Product Advisor) we would have had great difficulty in delivering the comprehensive, independent information our students need.*" [**5.5**]

New international standards to improve product quality, strengthen device regulation and increase access to cost-effective, reliable continence products in low-income countries

As a result of her role in *Management with Continence Products* [**3.4**] and the clinical trials [**3.1-3.3**], in 2016 Fader was invited by the International Continence Society to lead an international group of experts to develop standardised terminology for absorbent products [**5.6**]. Absorbent incontinence products come in a wide range of different designs, but the variety of synonyms used to describe them are confusing for product users, clinicians, manufacturers and purchasing agencies. A new standard was needed to better reflect current product design and aid decision-making. The outcome of the work was a new recommended terminology for all designs of single use absorbent products [**5.7**]. Fader's research influenced the International Organization for Standardization (ISO) when the ICS terms were adopted by ISO. Jesper Nordlinder, ISO Aids for Ostomy and Continence Committee Lead stated: "*ISO standards are highly influential documents which are used worldwide by industry (manufacturers of the products specified) and key institutions involved in the procurement of products including the UK Supply Chain … Professor Fader's research [has] provided her with unique expertise on the use of a wide range of products, both from a clinical and academic standpoint. Therefore, as a consequence of the close working between the two committees, her expertise influenced the ISO terminology*." [**5.8**].

Fader was subsequently invited by the WHO in 2016 to develop assistive product specifications (APS) for disposable and washable absorbent continence products [**5.9**] which utilised the new standards. The WHO Global Cooperation on Assistive Technology (GATE) had launched the Priority Assistive Products List, selected on the basis of widespread need and impact on people's lives. APSs underpin the priority assistive product lists and provide a set of standards that regulate the procurement of absorbent continence products in low-income countries. They are used by government procurement officers to guide tendering processes and inform the UNICEF catalogue. In Tajikistan for example, absorbent pads have been highlighted as the fifth most needed assistive product group. The APS developed by Fader et al was adopted onto Tajikistan's new assistive products list in 2019 [**5.10**]; this enabled procurement agencies in Tajikistan, for the first time, to purchase clinically effective, sustainable and cost-effective continence products. Describing the UoS research contribution as '*essential*', WHO's GATE lead said: "*The inclusion of the specifications for absorbent continence products, developed by Professor Fader, is an important advancement for the millions of people managing incontinence with limited access to essential products*." [**5.9**] This has recently led to Fader and Murphy being commissioned by WHO to research the provision and use of washable absorbents in low income countries (GBP60,000).

Provision of sustainable, reusable and effective options for intermittent catheter users

Fader has highlighted the shortcomings of catheter design and the need for innovation in design and methods for use in various media interviews, including live appearances on BBC Breakfast and Radio 4 *Today* in 2015. The UoS group subsequently worked with a company developing a biodegradable, reusable intermittent catheter in order to reduce the use of single use plastics. The UoS *MultiCath Milton* cleaning method [**3.7**] was essential in enabling the first reusable and biodegradable intermittent catheter, Emteva™ (Hunter Urology), to become CE marked for sale in the EU and available for patients via the UK drug tariff. Prior to Emteva, the estimated 20,000+ female intermittent catheter users in the UK alone were confined to single use catheters. The

availability of a reusable intermittent catheter to use alongside single use ones has been reported by catheter users to provide optimal choice for their physical and lifestyle needs. The CEO of Hunter Urology stated: "*The work done by Professor Fader's team at the University of Southampton has been essential in enabling the reusable Emteva catheter to become available to catheter users.*" [**5.11**]. Around 36,000 Emteva catheters have been prescribed in England alone since 2016 benefitting approximately 9,000 women [**5.12**]; they are also sold internationally, including in Denmark and Australia [**5.11**]. The estimated annual cost per user for single-use intermittent catheters is GBP2,190 (based on typical usage of 4 catheters per day at a mean intermittent catheter cost of GBP1.50). If one Emteva is substituted for all daily catheterisations, this equates to an annual saving for all female intermittent catheter users in the UK of more than GBP32,000,000 and a 100% reduction in plastic catheters being thrown away.

Based on the findings in **3.7**, Wilks was awarded a Small Business Research Initiative grant (GBP530,000; NIHR) to develop and test a biodegradable, biocidal, impregnated wipe to offer a quick, discreet alternative or complementary cleaning method to Milton. This was designed to further increase the uptake of reusable intermittent catheters. A partnership with JVS Products Ltd developed a biocidal wipe that was shown to be effective at cleaning reusable catheters 'on the go'. Having achieved its Class I CE mark in 2020, JVS temporarily pivoted the product towards the surface cleaning market in response to the Covid-19 pandemic, achieving more than 150,000 in sales up to December 31, 2020 [**5.13**].

Improved options for safe penile compression device use and development of the 'Southampton clamp'

Having identified through their research [**3.3**] a need among men for an effective, reusable clamp to enable physical activity and reduce reliance on disposable, plastic-backed pads, the UoS group, together with clamp users, co-designed a new clamp that is more effective, more comfortable/less painful and easier to use than existing designs. The 'Southampton clamp' [**5.14**] provides a reusable (and therefore sustainable), discreet and secure way of preventing leakage after prostatectomy. A preliminary user trial showed that men felt the design is discrete and looks good, and is easy to put on and take off, compared with the best of the currently available clamps. A new industry partner will support prototype development, licensing (CE marking) and commercialisation of the clamp (and other newly developed products) via internet sales and the Drug Tariff [**5.15**]. Currently manufacturers' guidance provided with several clamp brands is not based on evidence, which places users at risk of pressure-related skin damage. Working with clamp users, UoS research also enabled the development and publication of evidence-based generic clamp guidance on the *Continence Product Advisor*.

5. Sources to corroborate the impact

5.1 Analytics data: Continence Product Advisor visitor data, 01.11.13 – 31.12.2020
5.2 Testimonials: Letter from Professor Adrian Wagg, former General Secretary of the ICS; video from healthcare professionals and product users https://www.youtube.com/watch?v=2QshQfoJlJc
5.3 *Continence Product Advisor* feedback survey data to 20.11.2020. PDF uploaded or link to survey data: https://www.surveymonkey.com/results/SM-J5PCYYCTL
5.4 MOOC reviews. PDF uploaded or link to reviews: https://www.futurelearn.com/courses/understanding-continence-promotion
5.5 Testimonial letter from Dr Jo Booth**,** former ACA Education Officer.
5.6 Testimonial from Professor Bernard Haylen, Chair of ICS standardisation committees
5.7 Report: ICS standardisation of terminology.
5.8 Testimonial from Jesper Nordlinder, Chair of ISO/TC173/SC Aids for ostomy and incontinence.
5.9 Testimonial letter from Wei Zhang, Technical Officer, Global Co-operation on Assistive Technologies, World Health Organization.
5.10 Report: Assistive Technology in Tajikistan: Situational Analysis WHO, 2019. Page 66. https://apps.who.int/iris/bitstream/handle/10665/312313/9789289054102-eng.pdf
5.11 Testimonial letter from Gary Hunter, CEO, Hunter Urology.
5.12 Emteva UK Drug Tariff sales 2016-2018 from Prescription Cost Analysis data. PDF uploaded.
5.13 Testimonial from Rob Scoones, Director, JVS Products Ltd.
5.14 International patent app PCT/GB2018/052733 (published April 2019 as WO/2019/063994).
5.15 Letter of support from Eakin R&D Ltd.