Institution: King's College London

Unit of Assessment: UoA3 - Nursing

Title of case study: Improving the experience of living with extensive chronic wounds: innovative products and methodologies for wound care in patients with epidermolysis bullosa

1. Summary of the impact

Adults with epidermolysis bullosa have extensive chronic wounds that seriously compromise their quality of life. Research at King's College London (KCL) has led to the development and commercialization of an innovative range of dressing retention garments, Skinnies WEB™, which radically improve patient experience and significantly reduce costs. KCL work has also generated a range of novel methodologies for research including a validated n-of-1 design for proof of concept tests, a validated model for engaging users in the design and development of medical devices and the TELER clinical notemaking system for wound care, which has been adopted internationally. This work has generated new business opportunities (product lines and roll-outs) for four UK companies.

2. Underpinning research

Initial research at King's College London (KCL) by Dr Patricia Grocott (Research Fellow/ Senior Research Fellow, 2001-2007; Reader in Palliative Wound Care, 2007-present) and Professor Dame Sarah Cowley (Lecturer/Senior Lecturer, 1992-97; Professor of Community Practice Development, 1997-2012) with people with non-healing cancerous wounds revealed that wound dressing products were ineffective because manufacturers lacked understanding of patients' needs (Ref 1). The first project we established to address this problem – Woundcare Research for Appropriate Products (WRAP) – was an innovative model of non-competitive collaboration between academic researchers, clinicians and industrial partners. WRAP (2001-2004) was led by KCL in collaboration with the University of Birmingham, Oxford Radcliffe NHS Trust, Bradford NHS Foundation Trust, Guy's and St Thomas' Hospital Trust (GSTT) and 12 industrial partner companies. WRAP focused on developing replicable methodologies and tools to support the translation of patient needs into effective wound care products. WRAP outputs included a standardised method of testing fluid uptake into dressings and a 3D imaging system for measuring how skin moves under dressings, which helps explain why dressings fail (Ref 2).

Through adapting a clinical note-making system originally developed by a mathematician, Mr AA Le Roux, for use in the fields of physiotherapy and stroke rehabilitation, we established a novel methodology for evaluating clinical outcomes in complex wound care, based on patient recorded outcome measures. The TELER system developed and validated in WRAP enables practitioners to easily evaluate precise clinical changes in wounds undergoing treatment, for example by measuring control of exudates, and a range of other physiological attributes typical for wound healing and management (Ref 3).

The next phase of wound care research, led by KCL from 2005-8, was undertaken as part of the MATCH (Multidisciplinary Assessment of Technologies Centre for Healthcare) project, in collaboration with the Universities of Brunel, Birmingham, Nottingham and Ulster, GSTT and four industrial companies. Our investigation of ways to engage users in research on medical devices resulted in a replicable model for engaging users in wound care device user engagement in wound care device development (Ref 4).

Insights gained from research participants about patient experience of wound care and methodologies developed in WRAP and MATCH underpinned our next project, focusing on people with epidermolysis bullosa (EB). EB is a rare inherited skin condition affecting an estimated one in 17,000 people in the UK and those with EB represent a group whose needs epitomize the considerable struggle that people with extensive wounds have with their dressings. The Woundcare for Epidermolysis Bullosa (WEB) project ran from 2009-2012 and was led at KCL in collaboration with St John's Institute of Dermatology at GSTT, Debra (the charitable foundation that supports people with EB worldwide), Longhand Data Limited, a fashion designer and knitwear manufacturer and adults with EB (Refs 5, 6 and 7). Through a series of workshops involving adults

with EB, their carers, and specialist nurses, we identified a range of limitations of current dressings and bandages, including problems with dressing fit, stability, comfort, temperature and exudate. The WEB project focused on finding new solutions to the challenge of containing and holding in place patch-worked dressings for extensive wounds.

In WEB we also developed the digital application of TELER for EB, including an EB Deficit Index that measures the impact of EB on individual wellbeing and functioning, and an automated system for calculating index numbers.

3. References to the research

Ref 1 Grocott P, Cowley S. The palliative management of fungating malignant wounds – generalising from multiple-case study data using a system of reasoning. *International Journal of Nursing Studies* 2001;38(5):533-45. Doi: http://dx.doi.org/10.1016/S0020-7489(00)00098-5. (Scopus citations 18)
Ref 2 Cowley S, Grocott P. Research design for the development and evaluation of complex technologies: an empirical example and critical discussion. *Evaluation* 2007; 13(3):285-305. Link: http://evi.sagepub.com/content/13/3/285.short. (Scopus citations 3)
Ref 3 Browne N, Grocott P, Cowley S, Cameron J, Dealey C, Keogh A, Lovatt A, Vowden K, Vowden P. Woundcare Research for Appropriate Products (WRAP): validation of the TELER method involving users. *International Journal of Nursing Studies* 2004; 41(5):559-71. Link: http://www.sciencedirect.com/science/article/pii/S0020748903002098. (Scopus citations 13)
Ref 4 Grocott P, Weir H, Bridgelal Ram M. A Model of User Engagement in Medical Device Development *International Journal for Health Care Quality Assurance* 2007; 20(6):484-93. Link: http://www.emeraldinsight.com/journals.htm?articleid=1626575&show=abstract. (Scopus citations 9)
Ref 5 Grocott P, Blackwell R, Currie, C, Pillay E, Robert G. Co-producing novel wound care products for epidermolysis bullosa; an empirical case study of the use of surrogates in the design and prototype development process *International Wound Journal* 2012 Apr 9. Doi:10.1111/j.1742-481X.2012.00972.x. (Scopus citations 0)
Ref 6 Grocott P, Blackwell R, Weir H, Pillay E. Living in dressings and bandages: findings from workshops with people with Epidermolysis bullosa. *International Wound Journal* 2012 Apr 4. Doi:0.1111/j.1742-481X.2012.00973.x. (Scopus citations 0)
Ref 7 Grocott P. Blackwell R, Currie C, Pillay E, Clapham J, Graham-King P, Hon J, Snelson K. Woundcare research for epidermolysis bullosa: designing products with users. *Dermatological Nursing* 2013;12(1):30-5. (No Scopus data)

Supporting grants

- *Enhancing current skin and wound care and patient outcomes for epidermolysis bullosa (WEB Case Study)* Guy's and St Thomas' Charitable Foundation G090706 (Grocott PI) £115,000, 2010-12.
- *Web Case Study* KCL Innovation and Futures Fund Award for prototype development and evaluation (Grocott PI) £40,000, 2009.
- *Multidisciplinary Assessment of Technologies Centre for Healthcare* EPSRC (Grocott Co-Investigator and KCL lead) £300,000 to KCL (of £6.3m total funding), 2005-08.
- *Woundcare Research for Appropriate Products (WRAP)* EPSRC (Cowley PI; Grocott Co-Investigator) £1,077,037, 2001-04.

4. Details of the impact

An innovative range of dressing retention garments

Work at King's College London (KCL) on the WRAP and MATCH projects revealed the negative impact that extensive non-healing wounds can have on daily life for people with life-long conditions like epidermolysis bullosa (EB). These studies highlighted the critical role of wound dressings and the extreme inadequacy of bandages as a method for holding patch-worked dressings in place

over extensive wounds. Patient participants identified the development of a replacement for bandages as a key unmet need. These findings led to the Woundcare for Epidermolysis Bullosa (WEB) project, which produced an innovative range of dressing retention garments that will hold wound dressings in a more stable system (Ref 7). These garments, designed in collaboration with CLC Design Consultancy Limited, were commercialised in 2012 as a new product line, Skinnies WEB™ (Source 1A), under an exclusive licence from KCL with Skinwear Limited, and are now marketed worldwide by Dermacea Limited.

People who have used the garments report a range of benefits including comfort, healing of wounds that had persisted for years, improved ability to wear clothes and shoes and enhanced self-esteem and confidence. The following quotes are examples from participants in the WEB project (Source 2C):

"Absolutely amazing! It has improved my quality of life because it keeps my dressings firmly in place, without needing to use so much tape, which itself causes injuries. The wounds on my trunk are 30% due to tape."

"A week ago I forgot to wash the garments...my regular carer put bandages on my back ... [and I thought] oh my god, I don't want to go back to that again."

The use of these garments also significantly reduces costs. Whereas bandages for EB patients need to be cut off after a single use because of heavy soiling, the Skinnies WEB™ garments can be reused 30-40 times. In the WEB study, the average annual cost of wound care per participant (including labour, time taken to do dressings and wound care products used) was £85,118. Using the garments instead of bandages resulted in an average annual saving of £10,943, approximately 13% of total wound care costs (Ref 7).

One in four people with EB have a type of disease called dystrophic EB. The use of Skinnies WEB™ gloves offers specific clinical benefits for people with dystrophic EB, preventing the webbing of fingers associated with that condition and thereby reducing the frequency of need for surgery. The impressive performance of the gloves led study participants and hand therapists to request a bespoke glove service, and in 2013 this was introduced at Guy's and St Thomas' NHS Foundation Trust by the Senior Hand Therapist to supply the Skinnies WEB™ webspacer gloves to delay disease progression and finger webbing in dystrophic EB patients.

Data from the WEB study on the benefits of the new garments supported a successful application to the Prescription Pricing Authority for listing on the Drug Tariff (Source 1B) and patient access. The Skinnies WEB™ garment range is also listed in the International Best Practice Guidelines for EB wound care (Source 1C). The WEB project won the 2013 Guardian University Award in the 'Outstanding Research' category (University Awards Ideas Bank) (Source 2B). Debra, the charitable foundation that supports people with EB and their families worldwide has highlighted Skinnies™ in its news stories (Source 2A).

The TELER clinical note-making system

Following an introduction made by the KCL research team in 2009, the intellectual property of TELER was sold by Mr Le Roux in January 2012 to Longhand Data Limited, specialists in digital data capture and processing. This has resulted in TELERwoundcare - a sophisticated system of digital data capture, processing and analysis customised for routine clinical care, telemedicine and research (Source 3A). The system also incorporates a standard NHS referral process to which a photograph of a wound can be added. Tissue viability nurses receiving data submissions from care homes or field-based nurses can then triage the patient and respond appropriately. The system allows data to be submitted through an iPad as well as directly through a PC or using a mobile phone linked to a digital pen and paper recording system.

TELERwoundcare is being adopted nationally and internationally in wound care applications and telemedicine, licensed from Longhand. The system has been adopted by the National Wound

Healing Centre in Eastbourne, where a team of tissue viability nurses are providing any qualified provider (AQP) services in wound management to the NHS, and a number of NHS organisations in the Yorkshire and Humber region and beyond have also expressed interest in the system. TELERwoundcare has been adopted by IBERWounds, a wound-healing clinic based in Lisbon that has developed an AQP-type woundcare support service and will triage and supervise the treatment of wounds in 150 residential care homes across Portugal, with Longhand providing data collection and management services (Source 3B). Woundcare4heroes are setting up a telehealth care system providing intensive and follow up wound care for wounded servicemen and veterans, following discharge from the Royal Centre for Defence Medicine at University Hospitals NHS Foundation Trust (Source 3C). Longhand Data Limited is providing TELERwoundcare for this service.

5. Sources to corroborate the impact

1) Skinnies™ WEB Dressing Retention Garment Style Range
   A. http://www.skinniesuk.com/category/eb-adult
   B. Listing on the Drug Tariff from 2013-05-01 http://www.ppa.org.uk/edt/June_2013/mindex.htm
   C. Inclusion in International Guidelines: http://www.woundsinternational.com/pdf/content_10609.pdf

2) Skinnies™ in the news and patient feedback
   A. Debra news report: http://www.debra.org.uk/index.php?mact=News,cntnt01,detail,0&cntnt01articleid=105&cntnt01origid=15&cntnt01returnid=29
   B. Guardian University Awards Ideas Bank: http://www.guardian.co.uk/higher-education-network/2013/feb/26/research-impact-winner-kings-college
   C. Woundcare for Epidermolysis Bullosa Report, includes patient accounts of their experiences with the garments (pdf available)

3) The TELERwoundcare system
   A. http://www.longhanddata.com/teler-measuring/what-is-teler.html
   B. http://www.medipex.co.uk/news/latest-news/tele-wound-management-goes-live-in-eastbourne
   C. http://www.woundcare4heroes.org.uk/mission