Institution: University of Leeds

Unit of Assessment: 3

Title of case study: Reducing harm: improved identification and clinical application of pressure ulcer risk factors leading to reductions in pressure ulcer development

Period when the underpinning research was undertaken: 2000-2017

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:
Jane Nixon	Professor Tissue Viability and Clinical trials Research	2002-present
Julia M Brown (UoA2)	Professor Clinical Trials	1998-present
Susanne Coleman	Post-Doctoral Research Fellow	2009-present
Sarah Brown (UoA2)	Principal Statistician	2010-present

Period when the claimed impact occurred: 2014-present

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

1. Summary of the impact

Leeds researchers have driven a programme of research to establish key risk factors for pressure ulcer development. Work includes: large clinical research studies; risk factor systematic review; and development and validation of an evidence-based risk assessment instrument (PURPOSE-T). The work identified *skin status*, immobility and factors affecting tissue perfusion as the *primary* risk factors for pressure ulcer development.

The research provides 'Level A' evidence to support key recommendations in international guidelines with worldwide reach, and has influenced practice/improved clinical outcomes through: incorporation into international guidelines; implementation of PURPOSE-T; quality improvement projects; and public focused media, where skin status is now a focus in risk assessment practice.

2. Underpinning research

Pressure ulcers (PUs) represent a major burden to patients, carers and the healthcare system, affecting 7% and 5% of hospital and community patients, respectively. They occur in patients with reduced mobility when the skin and/or tissues are damaged by *sustained mechanical load* on areas of the body not adapted to pressure (e.g. buttocks/heels). PUs are classified according to the level of clinically assessed damage: non-blanching erythema (Category 1); loss of epidermis/dermis (Category 2); and deeper tissue destruction (i.e. fat, muscle and bone) (Category 3/4). Category ≥2 are reportable clinical incidents, and in 2004, associated annual NHS costs were estimated as between GBP1.4billion and GBP2.1billion – 4% NHS total budget.

Leeds researchers have driven a research programme that has made a significant contribution to the following PUs aspects.

RISK FACTOR RESEARCH SKIN STATUS: Using large representative populations and analysis methods, we were able to separate confounding effects. Our research has established that aspects of skin status – Category 1 (i.e. non-blanching erythema), alterations to intact skin, and localised skin pain – are independent risk factors associated with Category 2 PU [**1**,**2**,**3**].

Category 1 (non-blanching erythema): Three studies using logistic regression modelling have identified that Category 1 (non-blanching erythema) is independently associated with Category 2 PU development. First, in a small exploratory surgical study with 109 patients with wide

95% confidence intervals (CI) (Odds Ratio (OR) 7.02, CI 1.67-29.49, p=0.008) [**1**]. Second, in a large randomised controlled trial of 1,971 medical and surgical in-patients (OR 1.95, CI 1.31-2.91, p=0.001) [**2**], and third, in a large cohort of 634 acutely ill hospital/community patients (OR 3.25, CI 2.17-4.86, p=<0.0001) [**3**].

Alterations to intact skin: Two of the studies also identified that alterations to intact skin/skin trauma are independently associated with Category 2 PU development (OR 1.67, CI 0.999-2.80, p=0.05) [**2**], (OR 1.98, CI 1.30-3.00, p=0.0014) [**3**].

Pain: We are the first group worldwide to identify 'pressure-area related pain' as a possible risk factor through our qualitative research [**2**], quality of life systematic review [**4**] and multi-centre prevalence of 3,397 patients [**5**]. This informed our large cohort [**3**] where skin site multi-level modelling found significant evidence that localised 'pressure area related pain' is independently predictive of Category 2 PU (OR 2.25, CI 1.53-3.29, p<0.0001).

EVIDENCE-BASED RISK ASSESSMENT: Our systematic review [**5**,**6**] identified 54 eligible studies and classified key risk factor domains and sub-domains. For the first time, we identified skin status together with immobility and factors affecting tissue perfusion as the *primary* risk factors for PU development.

The systematic review [**6**] then underpinned the development of an evidence-based risk assessment instrument, using sequential consensus and validation studies involving service users and international experts. The consensus work led to conceptual framework development, theoretical causal pathway and design of a draft Risk Assessment Framework (PURPOSE-T). Validation included pre-testing and field testing to assess reliability, validity, data completeness and clinical usability [**5**].

The final PURPOSE-T [**5**] differs from pre-existing instruments. It has a screening stage to quickly identify patients who are clearly not at risk of PU development. It incorporates *primary* risk factors – immobility, skin status and perfusion. It stratifies patients using skin status, making a distinction between patients with no existing PUs requiring primary prevention and those with a Category ≥1 PU who require escalation in care/treatment [**5**].

3. References to the research

1. Nixon J, Cranny G and Bond S. (2007) Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients. Int J Nurs Stud 44(5): 655-663. DOI: 10.1016/j.ijnurstu.2006.02.010

2. Nixon J, Nelson EA, Cranny G, Iglesias C, Hawkins K, Cullum N, et al on behalf of the Pressure Trial Group. (2006) Pressure relieving support surfaces: a randomised evaluation. Health Technol Assess 10(22). DOI: 10.3310/hta10220

3. Smith I, **Brown S**, McGinnis E, Briggs M, **Coleman S**, Dealey C, Muir D, Nelson E A, Stevenson R, Stubbs N, Wilson L, **Brown J, Nixon J**. (2017) Exploring the role of pain as an early predicator of category 2 pressure ulcers: a prospective cohort study. BMJ Open 7(1). DOI: 10.1136/bmjopen-2016-013623

4. Gorecki C, **Brown JM**, Nelson EA, Briggs M, Schoonhoven L, Dealey C, Defloor T, and **Nixon J** on behalf of the European Quality of Life Pressure Ulcer Project Group. (2009) Impact of pressure ulcers on quality of life in older patients: a systematic review. J Am Geriatr Soc 57(7): 1175-1183. DOI: 10.1111/j.1532-5415.2009.02307.x

5. Nixon J, Nelson EA, Rutherford C, **Coleman S**, Muir D, Keen J, McCabe C, Dealey C, Briggs M, **Brown S,** Collinson M, Hulme C, Meads D, McGinnis E, Patterson M, Czoski-Murray C, Pinkney L, Smith I, Stevenson R, Stubbs N, Wilson L, **Brown JM.** (2015) Pressure UlceR Programme Of reSEarch (PURPOSE). NIHR Journals Monograph 3(6). DOI: 10.3310/pgfar03060

6. Coleman S, Gorecki C, Nelson EA, Closs J, Defloor T, Halfens R, Farrin A, **Brown J M**, Schoonhoven L and **Nixon J.** (2013) Patient Risk Factors for Pressure Ulcer Development: Systematic Review. International Journal of Nursing Studies 50 (7): 974-1003. DOI: 10.1016/j.ijnurstu.2012.11.019

Associated grants:
2. NIHR HTA GBP1 million Randomised controlled trial comparing alternating pressure overlay and alternating pressure replacement mattresses, including qualitative sub-study **Nixon** clinical lead and **Brown J** statistical/design lead, both co-applicants.

3,**5**,**6.** NIHR PGfAR: PURPOSE GBP2.1 million comprised 10 clinical studies (6,735 patients accrued), 8 methodological studies and 3 systematic reviews across 5 Work Packages including: Chapter 3 pain and Chapter 5 systematic review and the development and validation of an evidence-based risk assessment framework (PURPOSE T). **Nixon** PI, **Brown J** Co-applicant, **Coleman** Work Package Lead Risk Assessment.

4,**6.** Smith and Nephew Foundation GBP109,280 Post-Doctoral Research Fellowship **Nixon** PI.

4. Details of the impact

Changes to PU risk assessment impacts thousands of patients daily. Guidelines advocate risk assessment to be undertaken on admission for all hospital/community facilities to identify 'at risk' patients and initiate preventive/management measures [**A**,**B**]. The reach of the Leeds research is extensive due to its incorporation within international guidelines and clinical practice, and significant due to the contribution of large high-quality studies with low risk of bias [**A**,**B**].

INTERNATIONAL GUIDELINES: The most wide-reaching guidelines are international guidelines produced jointly for the first time with a worldwide platform in 2014 [**A**] and 2019 [**B**] through USA, European and Pan-Pacific collaboration. The guideline is used by healthcare professionals worldwide. **Nixon** and **Coleman** are recognised internationally for their research and led the appraisal and drafting of the guideline risk factor chapter [**A**,**B**].

Leeds research has directly influenced the guidelines in three ways:
a) pathophysiological mechanisms explained using our risk factor conceptual framework [**5**], which were reproduced with permission [**A** Figure 2, **B** Figures 2.1 and 4.1].
b) risk factor guideline sections adopted our systematic review methodology and structured the evidence and recommendation hierarchy using our conceptual framework and domain/sub-domain classification [**6**].
c) Evidence for specific guideline statements including Level A evidence for Category 1 PUs are tabulated:

Guideline Statement	2014 [**A**] Leeds data	2019 [**B**] Leeds data
*'Consider individuals with a Category/Stage 1 pressure injury **to be at risk** of progression or new Category/Stage 2 pressure injury'*	**Recommendation** **Strength of Evidence B**. 2/4 studies 2,068/5,125 patients 222/665 PU events) [**1**,**2**].	**Recommendation** **Strength of Evidence A*** 3/6 studies 2,670/6,337 patients 374/852 PU events [**1-3**].
*'Consider **the potential impact** of alterations to skin status over pressure points on pressure injury risk'*	*N/A*	**Good Practice Statement** 2/14 studies 2,573/7,883 patients 359/1,262 PU events [**2**,**3**].
*'Consider **the potential impact** of pain at pressure points on pressure injury risk'*	*N/A*	**Good Practice Statement** 1/1 studies 602 patients 152 PU events [**3**].

*Note that strength of evidence increased from B to A due to Leeds research.

Guideline reach and revenues: The international guidelines have been distributed and translated as tabulated, with associated profits of USD293,790 divided between the three collaborating organisations to support ongoing developments in the field [**C**,**D**]:

	2014		2019	
	Full Clinical Guideline	**Quick Reference Guide**	**Full Clinical Guideline**	**Quick Reference Guide**
Paper and electronic copies purchased	4,543		4,599	
Free downloads		200,000		36,000
Printed with permission		2,272		723
Language translations [D]		**13**		**13**
Revenues	USD480,741		USD477,171	

PURPOSE-T CLINICAL IMPLEMENTATION: Our risk factor [**1**-**3**], pain [**2**,**3**,**4**] and systematic review [**6**] underpinned the development of our evidence-based risk assessment instrument - PURPOSE-T [**5**] with a focus upon skin assessment (including presence of Category 1, alterations to intact skin and localised skin pain), mobility and perfusion.

Intellectual Property: PURPOSE-T is copyrighted and accessed through a 'permission to use' function [**E**]. Since its 2014 launch, it has had 965 'permission to use' requests from healthcare providers and individuals [**F**] and the paper version has been coded into 4 electronic NHS records systems including: SYSTEM 1/EMIS (community) and PPM/EVOLVE hospital by 8 NHS Trusts[**F**].

Clinical implementation: Nixon and **Coleman**, who are members of the NHS England Stop the Pressure Programme, are supporting national implementation in England and have ongoing dialogue with the All Wales Tissue Viability Nurses Forum who agreed a national Wales roll-out [**F**]. Clinical implementation requires a major commitment by healthcare organisations (consultation, changes to local policies, guidelines and nursing documentation, training large numbers staff etc.). To date PURPOSE-T has been fully/partially implemented in at least 16 acute Trusts/Health Boards, 3 combined community/acute and 17 community Trusts, 8 hospices and 1 nursing home, impacting thousands of patients daily [**F**].

Clinical outcomes: early adopters of PURPOSE-T have reported positive outcomes on care processes including improved rates of risk assessment and clinical outcomes (i.e. reduced PU prevalence) [**G**]. For example, 4 consecutive annual prevalence studies in a large teaching hospital(circa 1,400 patients) indicates:

a) sustained reduction in Category ≥1 hospital acquired PUs – 8.02% (2012), 7.6% (2013)pre-implementation and 4.91% (2014), 3.81%(2015) post implementation,
b) improved proportion of patients assessed on admission – 80% (2012), 78% (2013) pre-implementation and 80% (2014), 91% 2015) post implementation,
c) improved proportion of those at risk with a care plan – 74% (2012), 86% (/2013) pre-implementation and 92% (2014), 90% (2015) post-implementation [**G**c].

BELGIUM QUALITY IMPROVEMENT PROJECT: Based upon our risk factor systematic review evidence [**6**], Smet and colleagues developed a risk assessment approach for Belgium, involving assessment of only two risk factors of skin status (i.e. presence of Category ≥1 PU) and immobility/inactivity [**H**,**C**].

They introduced the Belgium tool into Ghent and Leuven hospitals and reported:
a) increased compliance with daily risk assessment from 50% to 85%,
b) similar proportions of patients identified as at risk (i.e. no additional resource implications but with improved clinical outcomes including: annual prevalence in Ghent hospital was 5.27% in 2015, 4.01% in 2018 – relative reduction 23.9%; and annual incidence in Leuven hospital was 0.62% in

2015, 0.45% in 2018 – relative reduction 27.4%) [**H**].

PUBLIC FOCUSED MEDIA: In 2018, the European Pressure Ulcer Advisory Panel launched a video for use by healthcare professionals, patients and the public [**I**]. The content is based upon our research and systematic review evidence that skin status and immobility are key indicators of risk [**1**-**3**,**6**] [**C**,**I**]. The video has subtitle/sound translations into 13 languages with over 16,000 views.

5. Sources to corroborate the impact

A. 2014 Guidelines. Pressure Ulcer Prevention and Treatment Clinical Practice Guideline. National Pressure Ulcer Advisory Panel (USA), European Pressure Ulcer Advisory Panel and Pan-Pacific Pressure Injury Alliance, including:
a) Full Clinical Practice Guideline,
b) Quick Reference Guide
c) Evidence tables http://internationalguideline.com/static/pdfs/NPUAP-EPUAP-PPPIA-PUGuideline-TechDoc-DataExtract-2014.pdf

B. 2019 Guidelines. Pressure Ulcer Prevention and Treatment Clinical Practice Guideline. National Pressure Injury Advisory Panel, European Pressure Ulcer Advisory Panel and Pan-Pacific Pressure Injury Alliance, including:
a) Full Clinical Practice Guideline
https://guidelinesales.com/store/ViewProduct.aspx?id=15036954;
b) Quick Reference Guide: https://guidelinesales.com/store/ViewProduct.aspx?id=15037122
c) Evidence tables http://internationalguideline.com/static/pdfs/risk_factors-data_table.pdf

C. Letter from President European Pressure Ulcer Advisory Panel confirming:
a) EPUAP guideline sales, research underpinning EPUAP video based, and research underpinning Belgium Risk Assessment instrument

D. Guideline translations https://www.epuap.org/pu-guidelines/#2014qrgtranslations

E. PURPOSE-T https://ctru.leeds.ac.uk/purpose/purpose-t/

F. PURPOSE-T downloads and implementation
a) Tabulated summary of evidence source for implementing organisations
b) Survey PURPOSE-T registrants
c) Emails/letters from implementing organisations
d) Permission to use registrations

G. PURPOSE-T Process and Clinical Outcomes
a) Pennine Acute Hospitals NHS Trust, https://epostersonline.com/wnds2015/node/296?view=true
b) Lincolnshire Community Health Services,
https://epostersonline.com/wounds2016/node/487?view=true
c) Leeds Teaching Hospitals NHS Trust, email and 4 year prevalence spreadsheet
d) Leeds Community Healthcare NHS Trust, https://www.epuap.org/21-st-european-pressure-ulcer-advisory-panel-societe-francaise-de-lescarre-joint-annual-meeting-2019/

H. Belgium Risk Assessment Project Smet S, de Graff A, Bernaerts K, Casaer MP and Beeckman D. (2019) The Belgian pressure ulcer risk assessment project: Is assessing mobility and skin status a more accurate, reliable, and feasible approach to assess pressure ulcer risk in hospitalised patients? Int Wound J 16(6): 1577-1578. DOI: 10.1111/iwj.13240

I. European Pressure Ulcer Advisory Panel Educational Video
https://www.epuap.org/ with YouTube links to English and 13 European and Asian languages:
https://www.youtube.com/watch?v=KGpuWztuQJo
https://www.youtube.com/channel/UCWxoqLQU4HOyccyrBZskLvw/videos?view_as=subscriber