Institution: University of Leeds

Unit of Assessment: UOA3 (Allied Health Professions, Dentistry, Nursing & Pharmacy)

Title of case study: Case study 4. Identification of risk factors and better prevention of pressure ulcers in hospital patients

1. Summary of the impact)

Research in Leeds has identified independent risk factors associated with pressure ulcer development and made a significant contribution to the evidence base for choosing the most cost-effective mattress to prevent pressure ulcers. Through publication and subsequent integration into systematic reviews/ practice guidelines, and membership of committees the research has been disseminated to policy makers and practitioners. Leeds evidence is now included in international guidelines in at least 17 languages. This has led to a change in clinical and purchasing practice with likely reduction in the number of pressure ulcers and health service cost.

2. Underpinning research

Pressure ulcers occur in patients with reduced mobility when the skin is damaged by sustained mechanical load on areas of the body not adapted to pressure (e.g. sacrum, buttocks, or heels). Pressure ulcers affect one in ten hospital patients, are a major burden to healthcare services and patients, and can be fatal. Pressure ulcers involving superficial skin loss, blistering or worse damage (reaching fat, muscle and bone) are reportable clinical incidents and a key NHS quality indicator. In the United Kingdom the total cost of pressure ulcers has been estimated at £1.4 - £2.1 billion annually or 4% of the National Health Service expenditure (Miller PS. In economics as well as medicine prevention is better than cure. *Age Ageing*. 2004;33(3):pp217–8). Preventing pressure ulcers depends on accurate identification of people at risk, and use of effective prevention strategies, the most important of which is the bed or mattress.

Our Research

Leeds Researchers **Jane Nixon** (Professor Tissue Viability and Clinical Trials Research, Leeds 2002-present), **Julia Brown** (Professor Clinical Trials Research, Leeds 1998-present) and **Andrea Nelson** (Professor in Wound Healing, Leeds 2005-present) have identified the risk factors associated with pressure ulcer development, and provided evidence of clinical and economic effectiveness for mattresses.

1. Risk factors during surgery and in the early post-operative recovery period

Our analysis of data from a randomised controlled trial (RCT) with 446 surgical patients (with blinded outcomes) identified risk factors associated with pressure ulceration in the immediate post-operative period. We (**Nixon, Brown**) identified increased risk associated with low intra-operative blood pressure / low core temperature and reduced mobility/activity on the first day post-op [1]. Our cohort study (**Nixon**) identified the importance of non-blanching erythema and skin alterations as being important risk factors for the development of pressure ulcers [2].

2. Risk factors in hospital patients

The PRESSURE trial, the largest mattress trial in the field (**Nixon, Nelson**), identified that older age, acute versus elective admission, diabetes, and skin vulnerability (presence of a chronic wound, alteration to intact skin or non-blanching erythema) were each independently predictive of ulceration [3, 4]. This was led by University of York (Cullum was PI: Nelson led on qualitative aspects, Nixon on trial design and conduct, risk factors and outcomes assessment).

In summary, our pressure ulcer risk factor research has established independent patient factors associated with increased risk of developing a pressure ulcer using large representative populations and analysis methods able to separate out effects of confounding, e.g. association of age with other potential risks.

3. Support surface effectiveness

Early work [5] (**Nixon, Brown**) established the ability of an operating table overlay to reduce pressure ulcer incidence in people undergoing elective, major general, gynaecological or vascular surgery (supine or lithotomy). The relative reduction in the incidence of postoperative pressure ulcers was 47% associated with using the polymer pad (relative risk 0.53; 95% confidence interval 0.33 to 0.85; in 446 patients).

The PRESSURE trial (co-applicants **Nixon, Brown, Nelson**) [3, 4, 6] has set the standard for pressure ulcer research in providing robust evidence for clinicians and care providers. PRESSURE was a large multicentre, rigorous RCT with allocation concealment, an *a priori* sample size estimate and intention-to-treat analysis, comparing the clinical and cost effectiveness of alternating pressure (AP) mattress overlays versus AP mattress replacements in the prevention of pressure ulcers. Clinical and health economics results were published as twin papers by the British Medical Journal (BMJ) [3, 6] and were the subject of the Editorial, unprecedented in the field.

PRESSURE (with 1971 patients from 11 centres) showed higher tolerance for AP replacements than AP overlays (patient request to change 19% vs 23%), and an 80% probability that AP mattress replacements are cost saving (despite higher purchase cost). Furthermore, there was no evidence of a difference in the total number of new pressure ulcers with AP mattress overlays versus AP mattress replacements (OR 0.94, 95%CI 0.68 to 1.29).

3. References to the research

1. **Nixon J,** McElvenny D, Mason S, **Brown J**, and Bond S (2000). Prognostic factors associated with pressure sore development in the immediate post-operative period*. International Journal of Nursing Studies,* **37**: 279-89.

First prospective study to use multivariate analyses to identify factors independently predictive of pressure ulcer development in the in the intra and immediate post-operative period. This was funded by a NHS Northern and Yorkshire Region R&D grant (£85,048)

2. **Nixon J**, Cranny G, Bond S (2007). Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: A cohort study. *International Journal of Nursing Studies*, **44**: 655-63.

Cohort study showing that non-blanching erythema is an important and independent risk factor for the development of new Category 2 pressure ulcers. This was funded by a NHS Northern and Yorkshire Region R&D grant (£10,000), Tissue Viability Society Training Fellowship (£6,000) and a Smith & Nephew Foundation Doctoral Nursing Fellowship (£30,000).

3. **Nixon J,** Cranny G, Iglesias C, **Nelson EA,** Hawkins K, Phillips A, Torgerson D, Mason S, Cullum N (2006). Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (Pressure Relieving Support Surfaces) trial. *British Medical Journal*, **332**: 1413–15.

This remains the largest randomised controlled trial in the field setting the standard for pressure ulcer research. It was published simultaneously with a cost effectiveness analysis [6] and was the subject of a BMJ editorial. This was funded by the NIHR HTA Programme (£1 million).

4. **Nixon J, Nelson EA,** Cranny G, Iglesias C, Hawkins K, Cullum N, et al on behalf of the Pressure Trial Group (2006). Pressure Trial: Pressure RElieving Support SUrfaces: a Randomised Evaluation. *Health Technology Assessment,* **10** (22).

This is the trial report published as part of the renowned HTA monograph series. This trial was funded by the NIHR HTA Programme (£1 million)

5. **Nixon** J, McElvenny D, Mason S, **Brown J,** Bond S (1998). A sequential randomised controlled trial comparing a dry visco-elastic polymer pad and standard operating table mattress in the prevention of post-operative pressure sores. *International Journal of Nursing Studies,* **35**:193-203*.*

This is the largest trial of operating table overlays. It was highlighted on p17 in the Cochrane Review [A] for its quality. Funded by a NHS Northern and Yorkshire Region R&D grant (£10,000), Tissue Viability Society Training Fellowship (£6,000) and Smith & Nephew Foundation Doctoral Nursing Fellowship (£30,000).

6. Iglesias C, **Nixon J**, Cranny G, **Nelson EA**, Hawkins K, Phillips A, Torgerson D, Mason S, Cullum N (2006). PRESSURE Trial Group. Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis. *British Medical Journal,* **332**: 1416-18.

Analysis showing that despite the higher unit cost of alternating pressure mattress replacements, there is a higher probability that alternating pressure mattress replacements are cost saving. Funded by NIHR HTA (£1 million)

Note: Leeds researchers are in **bold**. Copies of publications are available from the HEI on request.

4. Details of the impact

Impact on health and welfare

Well-designed and high quality research undertaken by Leeds has directly influenced clinical practice and is now incorporated into systematic reviews [A-B] and international [C] and national guidelines [for example, D] for use by nurses, doctors and allied healthcare professionals in countries around the world. The most wide-reaching guidelines are the Pressure Ulcer Prevention and Treatment Clinical Practice Guidelines [C] produced by the joint US National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP), which was published in 2009, and cites all six Leeds studies [1-6] and has been translated into 17 languages by national pressure ulcer prevention organisations across Europe, Asia and South America who recommend adoption [C]. The reach of the Leeds research is extensive due to its incorporation in international and national guidelines, and significant due to its forming a large proportion of the high quality (low risk of bias) evidence in the systematic reviews and clinical guidelines.

Impact in systematic reviews for clinicians, policy makers and guideline developers

The PRESSURE trial [3, 4, 6] was incorporated into the 2008 and 2011 Cochrane systematic review and BMJ Clinical Evidence systematic review of mattress support surfaces for pressure ulcer prevention [A, B]. These reviews provide the foundation for the development of national and international guidelines. Our trial provided approximately 80% of the data for the comparison of alternating pressure devices in [B]: PRESSURE provided data on 207 events in 1971 people, four other trials provided data on 26 events in 243 people.

International guidelines

The extent to which the NPUAP/EPUAP guidelines [C] draw upon Leeds research is shown in the following sections, with recommendations explicitly based on our work **in bold**:

Patients in the operating room (page 41). "*Refine risk assessment of individuals undergoing surgery by examining other factors that are likely to occur and will increase risk of pressure ulcer development, including: …, **b) Increased hypotensive episodes intraoperatively, c) Low core temperature during surgery, d) Reduced mobility on day one postoperatively**.'*

Risk assessment practice (page 25-26) . *"Use a structured approach to risk assessment… Consider individuals with **alterations to intact skin** to be at risk of pressure ulcer development. …. 'In addition, the presence of **non-blanching erythema** also increases the risk of Category/Stage II pressure ulcer development'*). And *"Consider the impact of the following factors..including **diabetes** increase the risk of pressure ulcer development."*

Support surfaces (page 39) *"**Alternating-pressure active support overlays and replacement mattresses have a similar efficacy in terms of pressure ulcer incidence (strength of evidence = A)**."*

It is noteworthy that only seven of 83 guideline statements have strength of evidence A (the highest level). The clear finding of no clinical difference, but better tolerance and increased probability for cost saving is important for evidence-based care. Other international summaries prepared for commissioners of services and clinicians use our research and specifically note its quality [D].

Pressure ulcer prevention is an important element of patient safety and care quality for clinicians, managers and commissioners. Our research has extensive reach and impact on these groups due to its being a significant part of high quality evidence in international guidelines [E,F].

Impact upon economy

Our research [3, 4, 6] has impacted purchasing of mattresses for pressure ulcer prevention. After the publication of PRESSURE, which showed a greater patient acceptance of and cost-effectiveness associated with alternating pressure (AP) mattress replacements (which have a higher unit purchase cost than AP mattress overlays) there was a decrease in the proportion of AP mattress overlays being purchased. Prior to trial publication 42% of powered AP mattresses were overlays, and after trial publication this fell to 33-34% in years 2007/8 and 2009 [G].

Impact upon policy

Nixon and **Nelson** are active members of National and International collaborative and Policy Groups on the basis of their work. NIXON led the Risk Assessment Guideline Development Group in the development of the NPUAP/EPUAP (2009) guidelines, which led to consideration of our high quality Leeds research. Nelson and Nixon were both part of the Scottish Preliminary Pressure Ulcer Risk Assessment (PPURA) development team, on behalf of the Scottish Executive (Healthcare Improvement Scotland) Guidance for Policy and Practice. We advised on the development of pressure ulcer screening and our risk factor research influenced the development of this component to the risk assessment process including assessment of skin condition [H].

Impact on the public

Information prepared for members of the public at risk of pressure ulcers [I] notes the role of operating table overlays and this is derived from the Cochrane Review [A] where the PRESSURE trial [5] is the largest trial and noted as being of high quality (p5 of the pdf of the review)

5. Sources to corroborate the impact

A. McInnes E, Jammali-Blasi A, Bell-Syer SEM, Dumville JC, Cullum N et al. Support surfaces for pressure ulceration Cochrane Library 2011 Issue 4 http://bit.ly/TJW7dx. (accessed 22/10/13). Our trials [3,5] and their quality/low risk of bias mentioned on p15 and p17 of pdf.

B. Reddy M. Pressure Ulcers - Clinical Evidence 2011;05:1901, available at http://clinicalevidence.bmj.com/x/index.html (accessed 22/10/13). Our PRESSURE trial[3] and accompanying economic analysis [6] referred to on p10 of pdf.

C. National Pressure Ulcer Advisory Panel & European Pressure Ulcer Advisory Panel. Pressure Ulcer Prevention and Treatment Clinical Practice Guideline 2009: http://www.npuap.org/online-store/product.php?productid=17585&cat=3&page=1. Multiple references to our research.

D. Pressure Ulcer Prevention: An Evidence-Based Analysis Ontario Health Technology Assessment Service. 2009;9(2): 1–104. Published online 2009 April 1. Available from http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/ (accessed 27/09/13).

E. Corroboration from Nurse Advisor, Quality & Safety, Auckland District Health Board.

F. Corroboration from International Leader, SSiS, Karolinska University Hospital, Sweden.

G. Corroboration from Group Clinical Services Director, Arjo Huntleigh (commercial in confidence data). Letter dated 23/10/13.

H. Health Improvement Scotland (2010) Preliminary Pressure Ulcer Risk Assessment (PPURA) Scottish risk assessment guidelines incorporating screening of immobility, nutrition, continence and skin condition. http://www.healthcareimprovementscotland.org/programmes/patient_safety/tissue_viability/key_resources/pura_pressure_ulcer_assessment.aspx (accessed 22/10/13).

I. Clinical Evidence - Patient information. Pressure sores (19 February 2013) http://clinicalevidence.bmj.com/x/systematic-review/1901/patient-information.html (accessed 22/10/13). Overlay mentioned on p2 of pdf.

Copies of all corroboration are available on request from the HEI.