

Pressure UlceR Programme Of reSEarch (PURPOSE): using mixed methods (systematic reviews, prospective cohort, case study, consensus and psychometrics) to identify patient and organisational risk, develop a risk assessment tool and patient-reported outcome Quality of Life and Health Utility measures

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Dedication to Professor Donna Lamping: It was with great sadness that the team learned of Donna's illness in 2010 and her passing in 2011 at age 58. Donna was an international expert in the field of health psychology, health status and quality of life assessment. Educated and trained in centres of excellence in Canada and the USA, she moved to the London School of Hygiene and Tropical Medicine in 1992 where she established her position as an international leader in the field. Donna was an inspiration to the team, making a major contribution to the conception, design and gold standard evaluation of the Pressure Ulcer Quality of Life (PU-QOL) studies in her role as a grant co-applicant and through PhD supervision of Claudia Rutherford (née Gorecki). We feel privileged to have worked with her and dedicate this monograph to her memory.

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Scientific summary

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Scientific summary

Background

Pressure ulcers are a widespread, cross-speciality problem. They represent a major burden to patients and carers, having a detrimental effect on health-related quality of life (HRQoL), and are costly to the NHS.

Programme aims

The Pressure Ulcer Programme Of reSEarch (PURPOSE) was developed by a clinical–research collaborative. The work was organised into two themes with the following aims:

1. theme 1: to reduce the impact of pressure ulcers on patients through early identification of patients at risk of developing pressure ulceration
2. theme 2: to reduce the impact of pressure ulcers on patients through the development of methods to capture patient-reported HRQoLs and health utilities for routine clinical use and future research.

Patient and public involvement

We set up the Pressure Ulcer Research Service User Network (PURSUN UK) and with members have developed innovative patient and public involvement (PPI) methods to underpin programme development, delivery and dissemination. Examples of innovative activity include adaptation of the Patient Learning Journey preparation model for use in a research context; use of role play and video to facilitate PPI in the interpretation of qualitative data; integration of PPI into consensus methods; integration of service user narratives into dissemination materials; and the development of a live interview model to facilitate meaningful PPI at professional conferences and training events.

Rationale and aims

Theme 1 focused on improving our understanding of individuals' and organisational risk factors and on improving the quality of risk assessments (work packages 1–3). Theme 2 focused on developing patient-reported outcome (PRO) measures (work packages 4 and 5).

Work package 1: pain

Patients have reported that pressure ulcer pain is their most distressing symptom, that pain at 'pressure areas' was experienced before pressure ulcer manifestation and that their reports of pain are ignored by nurses. The primary aim of the research was to determine the extent of pressure area and pressure ulcer pain and explore the role of pain as a predictor of category 2 (and above) pressure ulcers in acute hospital and community populations.

Work package 2: severe pressure ulcers

There is good evidence that pressure ulcer risks are associated with patient health status but also suggestive evidence that the organisation of care can influence the risks. We aimed to describe and explain the ways in which the organisation of treatment and care influences the development of severe pressure ulcers and identify ways to improve root cause analyses.

Work package 3: risk assessment

Increasing evidence makes it timely to update pressure ulcer risk assessment and how to prompt an escalation of interventions for secondary prevention and treatment. The primary aim of the research was to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of an evidence-based Risk Assessment Framework to guide decision-making about the risk of developing pressure ulceration and the risk of progression to more severe ulceration.

Work package 4: quality of life

Patient-reported outcome instruments are used to inform patient care and compare treatment effectiveness. The principal aim of this work package was to develop a PRO measure of HRQoL specifically for people with pressure ulcers: the Pressure Ulcer Quality of Life (PU-QOL) instrument.

Work package 5: cost-utility

Cost-utility analysis is the gold standard for economic evaluation and, in some therapeutic areas, condition-specific utility measures are developed to provide assessment of the impact of conditions and a measure of treatment benefit. The aim of the study was to create a preference-based index (Pressure Ulcer Quality of Life – Utility Index; PUQOL-UI) that could be used to generate utility values suitable for use in cost-utility-based economic evaluations of pressure ulcer interventions.

Methods

The programme comprised 21 research studies, methodological substudies and projects as follows:

1. Pain: (1) multicentre acute hospital pain prevalence study; (2) multicentre community pain prevalence study incorporating (3) a comparison of case-finding methods; and (4) multicentre prospective cohort study.
2. Severe pressure ulcers: (5) retrospective case study; (6) patient involvement workshop with PURSUN UK; and (7) development of root cause analysis methodology.
3. Risk assessment: (8) systematic review; (9) consensus study; (10) conceptual framework development and theoretical causal pathway; (11) design and pretesting of the draft Risk Assessment Framework; and (12) field test to assess reliability, validity, data completeness and clinical usability.
4. Quality of life: (13) conceptual framework development (systematic review, patient interviews); (14 and 15) provisional instrument development; (16) pretesting of the provisional PU-QOL instrument using mixed methods; (17) field test 1 including (18) an optimal mode of administration substudy and item reduction with testing of scale formation, acceptability, scaling assumptions, reliability and validity; and (19) field test 2 – final psychometric evaluation to test scale targeting, item response categories, item fit, response bias, acceptability, scaling assumptions, reliability and validity.
5. Cost-utility: (20) time trade-off task valuations of health states derived from selected PU-QOL items and (21) validation of the items selected and the psychometric properties of the new PUQOL-UI.

Key findings**Theme 1****Work package 1: pain**

Pressure area-related pain prevalence was 16.3% (327/2010) in the hospital population. Of 1769 hospital patients with no observable pressure ulcers, 12.6% (233) reported pressure area-related pain. The prevalence of pressure area-related pain in patients with pressure ulcers was 43.2% (104/241) in hospital patients and 75.6% (133/176) in community patients. A detailed pain assessment of 197 patients identified pressure area-related pain on skin areas assessed as normal as well as on pressure ulcers. The distribution of pain intensity was similar for all grades and both inflammatory and neuropathic pain were observed. The community trusts utilised different methods of case ascertainment and different pressure ulcer prevalence rates were observed (locality 1 = 0.77 and locality 2 = 0.40 per 1000 adult population).

The prospective cohort study of 632 acutely ill hospital and community patients identified significant evidence that the presence of pain at a skin site is an independent predictor for developing a category 2 or above pressure ulcer in four multivariable models as follows: (1) a priori logistic regression, (2) overdispersion logistic regression model and (3) an Accelerated Failure Time model for analyses conducted on a patient level, and (4) a multilevel logistic regression model for the analysis conducted on a skin-site level.

Work package 2: severe pressure ulcers

For seven of eight patients the best explanation of the evidence was that the general organisational context played a significant role in severe pressure ulcer development. In four accounts, specific events contributed to development. One patient's ulcer was deemed unavoidable. Severe pressure ulcers were more likely to develop in contexts in which clinicians failed to listen to patients/carers or recognise/respond to high risk or the presence of an existing pressure ulcer and services were not effectively co-ordinated. Service users found the interactive workshop format and the use of a 'simulated patient' account valuable. Including novel components (interviews with patients/carers) and sensitivity to the contexts within which health professionals work in root cause analysis can improve the quality of the insights captured.

Work package 3: risk assessment

1. The systematic review identified 15 risk factor domains and 46 subdomains, with three primary risk factor domains of mobility/activity, skin/pressure ulcer status and perfusion (including diabetes). It suggests that no single factor can explain pressure ulcer development.
2. The consensus study facilitated agreement of risk factors/assessment items for the Minimum Data Set (including immobility, pressure ulcer and skin status, perfusion, diabetes, skin moisture, sensory perception and nutrition), and draft Risk Assessment Framework [subsequently named Pressure Ulcer Risk Primary or Secondary Evaluation Tool (PURPOSE-T)] development.
3. The new conceptual framework incorporates five key components [(1) mechanical boundary conditions, (2) physiology and repair, (3) mechanical properties of tissue, (4) geometry of tissue/bone and (5) transport and thermal properties] and their impact on internal strains, stresses and damage thresholds. The theoretical causal pathway identifies direct, key indirect and other potential causal factors for pressure ulcer development.
4. The design and pretesting of the draft PURPOSE-T led to improved usability over the course of three pretest sessions, demonstrated by increased data completeness and appropriate pathway allocation.
5. The field test demonstrated that inter-rater and test-retest agreement for the PURPOSE-T was 'very good' (kappa) for the assessment decision overall. The inter-rater and test-retest percentage agreement for 'problem/no problem' ranged from 79.1% to 94.2% for the main risk factors. Convergent validity demonstrated moderate to high associations. Field notes highlighted positive and problem aspects in relation to using the PURPOSE-T in the clinical environment.
6. A follow-up meeting of experts and service users allowed consideration of the pain cohort study results and led to revisions of the PURPOSE-T and inclusion of pressure area-related pain.
7. The final PURPOSE-T has the following features: Minimum Data Set, screening stage to target assessment towards those in need, full assessment stage, use of colour to weight risk factors, and decision pathways that distinguish between patients with an existing pressure ulcer or scarring who require secondary prevention and treatment and those at risk who require primary prevention.

Theme 2

Work package 4: quality of life

Our conceptual model includes four HRQoL domains [(1) symptoms, (2) physical functioning, (3) psychological well-being, and (4) social participation] divided into 13 subdomains. The final PU-QOL instrument consists of 10 scales to measure pain, exudate, odour, sleep, vitality, mobility/movement, daily activities, emotional well-being, self-consciousness and appearance, and participation. We established that self-administration is not suitable for hospital inpatients with pressure ulcers and it is intended for administration following a user manual. Respondents rate the amount of 'bother' attributed on a 3-point scale. The final PU-QOL instrument mostly satisfies psychometric criteria for acceptability, reliability and validity.

Work package 5: cost-utility

Seven items were selected from the PU-QOL instrument for inclusion in PUQOL-UI on the basis of best practice psychometric and Rasch methods. Of the large number of potential health states constructed from the items and response option variants, 52 were valued by the general population, with the remaining health state values being predicted using ordinary least squares and random-effects regression models. Although both models exhibited satisfactory predictive power and acceptably low levels of error, the random-effects model is recommended for use. The secondary study analysis indicated that item selection for the PUQOL-UI was appropriate and acceptable to patients and that items had adequate levels of validity.

Conclusions

The PURPOSE programme supported the development of a network of 30 acute and community NHS trusts and accrual of a total of 6735 patients to the National Institute for Health Research portfolio. The PURPOSE programme has provided important insights for pressure ulcer prevention and treatment and the involvement of service users in research and development, with implications for PPI, clinical practice, quality/safety/health service management and future research.

Implications for patient and public involvement in research

1. Patient and public involvement requires explicit commitment to involving service users and their perspectives throughout every aspect of the research process.
2. Presenting research data in live and interactive formats can make the interpretation process more engaging and accessible to service users and can support meaningful dialogue between service users and professionals.

Implications for clinical practice development

1. Front-line health-care professionals should respond to patient symptoms including pain (soreness and discomfort), alterations to intact skin and category 1 pressure ulcers and instigate/escalate care provision.
2. Patients with pressure ulcers should have pain assessment, including type of pain, to inform treatment.
3. In circumstances in which clinicians do not have the skills necessary to address needs, patients should be referred to appropriate colleagues.
4. Some clinicians blamed patients for the development of severe pressure ulcers. In circumstance in which the provision of effective pressure ulcer prevention interventions is impacted by a patient's mental capacity or physical disability, advice (consultation) should be sought from colleagues with appropriate multidisciplinary specialist expertise and a problem-solving approach adopted.
5. Development of an electronic version of PURPOSE-T in health-care settings would facilitate large-scale multivariable modelling and the refinement of PURPOSE-T.
6. The implementation of key research findings may be facilitated through the use of the active monitoring model of care – Pressure Ulcer Prevention Pathways (PUPPs) – which incorporates risk assessment using the PURPOSE-T (including skin status and pain), the allocation of patients to primary and secondary prevention pathways and active monitoring of individual patients' skin responses to preventative interventions. It details required actions and escalation in response to deterioration and pressure ulcer development.

Implications for quality, safety and health service management

1. To maximise learning, root cause analysis could be extended in two ways:
 - i. interview patients and carers to capture their accounts of events
 - ii. increase awareness of the possibility that staff are working in contexts in which risky practices are tolerated and be able to assess whether or not this is the case.
2. It is important to co-ordinate services effectively so that pressure ulcer risks are communicated to everyone involved (patients, carers, all members of the multidisciplinary team).
3. Service reconfiguration/ward reorganisation planning needs to ensure continuity of clinical leadership and oversight/delivery of clinical care to high-risk patients.
4. A standardised case ascertainment method in the community setting should be developed.

Implications for future research

Pain

1. Replication of the pain cohort study is required.
2. The impact of including pain as an indicator for the escalation of preventative interventions requires investigation.

Severe pressure ulcers

1. The severe pressure ulcer study is the first of its kind and the findings should be confirmed by further empirical research.
2. There may be merit in studying 'best practice' settings to better understand how patients' and organisational risks are identified and effectively acted on.

Risk assessment

1. Development of objective measurement methods of mechanical boundary conditions, individual susceptibility and tissue tolerance, and early indicators of damage.
2. Further evaluation of the PURPOSE-T is required including sensitivity and specificity in different patient populations, impact on decision-making/processes of care and effectiveness in reducing pressure ulcer incidence in practice.
3. The pressure ulcer risk factor Minimum Data Set should be incorporated into future research.
4. Development of appraisal methods for risk factor research.
5. Development of a lay version of PURPOSE-T that can be used by patients and carers to facilitate self-assessment.
6. The impact of including skin status as an indicator for the escalation of preventative interventions requires investigation.

Quality of life

1. The PU-QOL instrument requires further evaluation through assessment of responsiveness to provide evidence to support score interpretation and to explore utility in routine practice.
2. The PU-QOL can be used in pressure ulcer research on the proviso that studies undertake parallel psychometric analysis to assess the performance of the scales in future samples.
3. The PU-QOL instrument requires translation and validation for international utilisation.

Cost–utility

1. The PUQOL-UI can be used in pressure ulcer prevention/treatment trials to enable cost–utility analyses.
2. Further research is required to determine the responsiveness of the PUQOL-UI.
3. Further research is required to establish the benefits of the PUQOL-UI (and other condition-specific utility measures) over generic utility measures; this must take into consideration the impact that condition-specific utility measures may have on decision-making and efforts to achieve allocative efficiency.
4. Further research is required to determine the extent to which patients completing HRQoL measures consider (and are able to consider) ‘disease attributable’ impact only.

Access to PURPOSE tools and instruments

1. PURPOSE-T: <http://medhealth.leeds.ac.uk/accesspurposet> (accessed July 2015).
2. PUPPs: <http://medhealth.leeds.ac.uk/accesspurposet> (accessed July 2015).
3. PUQOL: <http://medhealth.leeds.ac.uk/puqol-ques> (accessed July 2015).
4. PUQOL-UI: <http://medhealth.leeds.ac.uk/puqol-ui> (accessed August 2015).

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