Waterlow risk assessment tool pdf free print

There are many pressure injury assent tools currently in use in the healthcare sector. The Waterlow pressure ulcer risk assessment/prevention policy tool was invented by Judy Waterlow MBE. The pressure care pioneer designed and researched her pressure ulcer risk assessment tool in 1985, while working as a Clinical Nurse Teacher.The Waterlow Score Card is applicable to all areas of care, from A&E to Residential Nursing Homes, but as the Waterlow website states: “It must be remembered that “Waterlow“, like all risk assessment scoring systems is a simplistic tool. Professional judgement must be used in determining the risk status of the patient/client. All assessments and, just as importantly, reassessments must be documented and the plan of care adjusted as necessary.”Find out more from the Waterlow website here: Waterlow Score Card The full revised Waterlow Score Card. The Waterlow pressure ulcer risk assessment/prevention policy tool is, by far, the most frequently used system in the U.K. and it is also the most easily understood and used by nurses dealing directly with patient/clients. Intended for use by nurses and carers at the patient/client interface. One side illustrates the risk assessment scoring system click here. The reverse side provides guidance on nursing care, types of preventative aids associated with the three levels of risk status, wound assessment and dressings click here. The separate sides of the card may be printed off/downloaded for Free. When people hand you a Moo MiniCard, they don't surreptitiously slip the business card into your hand; they splay out their set of cards and let you choose your favorite one. Then they tell you about the image on the back, whether it's a photo from a vacation, a product shot, an avatar or an innovative digital design. And though the pint-size cards may not fit neatly in your Rolodex--they're only half the size of traditional business cards--their colorful appearance and slick, high-quality feel make you take notice. Richard Moross, 30, came up with the idea for MiniCards late one night in 2003. As the strategic planner for a design firm, he was losing sleep thinking of a product idea. He thought about Coca-Cola's mission to have everyone in the world in arm's reach of a Coke and started running through the everyday items he had around. Moross looked close--to his pockets--and hit on business cards, realizing that when it came to people promoting their personal websites and blogs, they were still often scribbling their URLs on napkins or whatever else was at hand. Moreover, people were developing other aspects of their online identities, like MySpace pages and Flickr accounts, that didn't yet have a place in the physical world, and a traditional business card just seemed too stuffy to do the job. With MiniCards, Moross cuts away the blank space that makes up much of a business card and incorporates a personal image on the back. But when his design firm didn't have the means to develop the idea, Moross branched out and started Moo. When Moo finally launched MiniCards in 2006, funded by $5.5 million in venture capital, users could create their cards with images uploaded directly from their Flickr accounts, and they could use a different image on every card in their 100-card sets. Now users can upload photos from multiple social networking sites, like Bebo and Facebook, as well as directly from their computers. They can also order premade designs from about 40 artists.The cards quickly became popular with the Web 2.0 crowd that uses them as a supplement to traditional business cards. And since launch, there has been international demand, which Moross hadn't predicted. When the first batch of foreign-language cards was printed, they came out with question marks in place of text and Moross had to add support for multiple languages. The London-based company now translates its site into German, Italian, French and Spanish. Expanding beyond its signature MiniCards, Moo also offers sticker books, cards and postcards, and it just launched full-size business cards. The products have also created an aftermarket for accessories, like custom MiniCard holders, which Moo sells. Hand-made card holders made by Moo fans can also be found on craft site Etsy.com. Tapping into its enthusiastic community that posts photos of Moo products on Flickr, uses the prints for art projects and packaging design and even sends MiniCards out chain-letter style, Moo crowdsources some designs. Last holiday season, Moo hosted a Flickr competition for card designs and received more than 3,000 entries. "Within a month, we had more holiday cards than Hallmark," Moross says. The company continues to reach out to its community through a candid blog, parties, product development sessions and an "Overheard at Moo" Twitter stream, which all foster the company's fun, approachable and transparent culture. Moross also makes sure to listen. He has his entire team copied on customer service requests so they know of any problems, and he makes sure to monitor any mention of his company online. And mention it, they do. By encouraging customer communication and having a "blank canvas" product that inspires creativity, Moo benefits from organic word-of-mouth marketing. Its message is only helped along by the nature of the Moo product. "Everything we manufacture is handed from one person to another," Moross says. And by making his product's style stand out with distinctive shapes, heavy paper stock and a lustrous finish, even the most custom orders are recognizably Moo. Then there are the company's partnerships with social networking sites. Though Moo initially partnered only with Flickr, the company is now paired with Bebo, Facebook, Fotolog, LiveJournal and Vox, which collectively reach more than 100 million users. Moo has also opened up its API, so any other company that would like to design an integration can. It has already seen programs that generate 3D barcodes for stickers, create a MiniCard mosaic from a large image and import Flickr photos sorted by color. Though Moross declined to share sales figures, he did say that in 2007 Moo shipped 10 million MiniCards--which are sold in $20 packs of 100--to 180 different countries. The company has also tripled its work force from 11 to 30 since 2006. Now he's focusing on expanding his young company. "We had a really successful idea that was a single product," Moross says. "And we have to scale that out to multiple products." Can Rituals Fix Our Soulless Corporate Culture? A Ritual Designer Says Yes, But Some Fear Giving Even More of Themselves to the Office. Want to Increase Sales? Leverage This Brand Hack. These College Kids Bought a Custom T-Shirt Company With Their Bar Mitzvah Money. Now It's a $40 Million Business. 5 Streams of Income That Will Grow Your Wealth This Cult-Favorite Pottery Brand Was Founded by the Great-Grandson of Henri Matisse. Now, Its Factory Is an Experiment in Equitable Labor Practices. Is Your Digital Marketing Strategy Missing the Mark? Here's How to Tell. 'There's Often No Right Answer': A Famous Economist Explains the Smartest Way to Tackle Life's 'Wild Problems' Chapter written by Susanne Coleman, E Andrea Nelson, Isabelle L Smith, Sarah Brown, Julia M Brown, Lyn Wilson, Delia Muir, Justin Keen, Carol Dealey, Elizabeth McGinnis, Nikki Stubbs and Jane Nixon.Introduction: Increasing evidence makes it timely to reconsider which risk factors should be considered in pressure ulcer risk assessment and how to prompt an escalation of interventions for secondary prevention and treatment. The primary aim of the risk assessment work package of the programme was to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of a Risk Assessment Framework for use in clinical practice. The work package consisted of five phases incorporating a systematic review, a consensus study, conceptual framework development, design and pre-testing of the framework and clinical evaluation of the framework.Methods: (1) A systematic review of primary research to identify pressure ulcer risk factors; (2) a consensus study using a modified nominal group technique based on the RAND/UCLA (Research and Development, University of California in Los Angeles) appropriateness method, incorporating an expert group, review of the pressure ulcer evidence and the views of PURSUN UK to agree a draft pressure ulcer risk factor Minimum Data Set and develop a Risk Assessment Framework; (3) development of a pressure ulcer conceptual framework and theoretical causal pathway, building on the phase 2 consensus study; (4) design and pre-testing of the draft Risk Assessment Framework using cognitive pre-testing methods, to assess and improve its acceptability and usability with clinical nurses; and (5) clinical evaluation of the reliability, validity, data completeness and clinical usability of the Risk Assessment Framework through field testing of 230 patients by expert and community/ward-based nurses.Results: (1) The systematic review of primary research identified 15 risk factor domains and 46 related subdomains. The review indicated that there were three primary risk factor domains of mobility/activity, skin/pressure ulcer status and perfusion (including diabetes), but suggested that no single factor can explain pressure ulcer development. Other risk factor domains emerged less consistently. (2) The consensus study facilitated the agreement of risk factors and assessment items for the Minimum Data Set (including immobility, pressure ulcer and skin status, perfusion, diabetes, skin moisture, sensory perception and nutrition), allowing the development of a draft Risk Assessment Framework incorporating all Minimum Data Set items. (3) The new pressure ulcer conceptual framework incorporated five key components (mechanical boundary conditions, physiology and repair, mechanical properties of the tissue, geometry of the tissue/bone, and transport and thermal properties) and their impact on internal strains, stresses and damage thresholds. The theoretical causal pathway for pressure ulcer development identified direct causal factors, key indirect causal factors and other potential indirect causal factors for pressure ulcer development. (4) The design and pre-testing of the Risk Assessment Framework led to improved usability over the course of the three pre-test sessions, as 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’ for the assessment decision overall as determined by kappa. The percentage agreement for the assessment of ‘problem/no problem’ for the eight risk factors (mobility, skin, previous pressure ulcer, sensory perception, perfusion, nutrition, moisture and diabetes) ranged from 79.1% to 94.2% for inter-rater reliability and from 87.0% to 93.9% for test–retest reliability. Convergent validity, assessed by comparison with the same or similar constructs on other risk assessment scales (Braden and Waterlow), demonstrated moderate to high associations. In addition, field notes recorded by the expert nurses highlighted positive and problem aspects of using the tool in the clinical environment. A follow-up consensus process allowed consideration of evidence from the pain work package and an extension of the pressure ulcer and skin status assessment items to include pressure area-related pain at the full assessment stage of the PURPOSE-T.Conclusion: The work package led to the development of a new Risk Assessment Framework, the PURPOSE-T, incorporating the Minimum Data Set; a screening stage to target assessment towards those in need; a full assessment stage; use of colour (rather than a score) to describe risk in terms of a personal profile to help in the planning of appropriate interventions; and decision pathways that make a clear distinction between patients with an existing pressure ulcer(s) (or scarring from previous ulcers) who require secondary prevention and treatment and those at risk who require primary prevention. The final PURPOSE-T framework has content, face and construct validity, with good inter-rater reliability and very good test–retest reliability.It is not appropriate to prevent pressure ulcers by subjecting all patients to resource-intensive interventions (such as repositioning by nurses or expensive mattresses) that may impact on their quality of life (e.g. by disturbing sleep) and cause harm by diverting nursing time from other areas, hence we must target care to those patients for whom it is likely to do more good than harm. Targeting patients for whom pressure ulcer prevention interventions are needed is achieved by considering the patients’ characteristics, a process known as risk assesssment. It is noteworthy that this is an individualistic approach to determining if someone is likely to develop a pressure ulcer, in contrast to the interaction/context-based explananations identified as also being important in our study of severe pressure ulcers (see Chapter 4). Regardless of context, risk assessment is widely accepted as being essential for pressure ulcer prevention1,14,23 as it allows ‘at-risk’ patients to be identified so that preventative interventions can be put in place to reduce the risk of ulcer development.In clinical practice, risk assessment scales are commonly used to give some structure to the assessment process, in preference to clinical ‘assessment’ or ‘judgement’ of risk. Nixon and McGough118 noted that there were > 40 pressure ulcer risk assessment scales, with the majority being developed from a literature review, expert opinion and/or adaptation of an existing scale. They noted that there were only seven ‘original’ scales. Many were developed in the 1970s and 1980s when the epidemiological evidence was limited by the primary research, including there being few studies considering the relative contribution of individual risk factors. This led to the inconsistent inclusion of risk factors between different scales, with the variables most frequently incorporated being continence/moisture, nutrition/appetite and mobility.118 This raises concern about the lack of agreement about what should be included in risk assessment scales to adequately identify risk and, as a result, the validity of those scales.118,119 In addition, existing scales tend to use ordinal scoring systems in which a comparison is made between the patient and a standard reference value to allocate a level of risk (e.g. high risk, moderate risk, at risk), with equal weighting usually given to included risk factors despite the fact that some may be more predictive than others. It has been argued that pressure ulcer risk assessment scales need to be developed on the basis of multivariable analyses to identify factors that are independently associated with pressure ulcer development118,120,121 and to advance our understanding of the relative contribution that different risk factors make to pressure ulcer development. Gold standard methods for the development of risk stratification tools include multivariable modelling (either from single studies or from meta-analysis from a number of studies) to identify items for a risk tool, with subsequent model testing on a ‘new’ prospective target population.122 This type of tool development has in the main been undertaken only in single-centre populations, with methodological limitations including inadequate sample sizes for both model derivation and testing.123–125From a practical perspective there are also issues with the use of existing risk assessment scales. Many were designed to identify risk status in patients without pressure ulcers, but in practice are often used for all patients, including those with and without pressure ulcers and do not distinguish between these groups. This is a limitation as nurses could discount an existing pressure ulcer in their clinical assessment and fail to instigate suitable secondary prevention and treatment interventions, which could lead to deterioration and the development of a more severe pressure ulcer.126 This resonates with findings from the severe pressure ulcer study (see Chapter 4). This is important as the pain cohort study (see Chapter 3) and a recent systematic review of pressure ulcer risk factors,46 conducted as part of this programme grant, indicated that the presence of a category 1 pressure ulcer is a key predictor of the subsequent development of a category 2 or above pressure ulcer, increasing the odds by two- to threefold.126Increasing evidence makes it timely to reconsider which risk factors should be considered in pressure ulcer risk assessment, how these should be assessed and the overall assessment process in the development of a Risk Assessment Framework. Furthermore, the systematic review46 conducted as part of this programme highlighted the need to agree a pressure ulcer risk factor Minimum Data Set and further develop a pressure ulcer conceptual framework. These would encourage the use of consistent factors across studies, facilitating meta-analysis, provide a standardised data set for case-mix adjustment and provide the fundamental components for pressure ulcer risk assessment in clinical practice.The overall aim of this work package was to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of a Risk Assessment Framework for use in clinical practice. (Note: as outlined in Chapter 1, Pressure ulcer development, the Risk Assessment Framework is not intended for the prevention or management of ulcers caused by medical devices as the primary risk factor for such ulcers is the presence of the device.)The methodological approach to the development of the Minimum Data Set and Risk Assessment Framework comprised five distinct phases: (1) developing the evidence base, (2) a consensus study, (3) conceptual framework development, (4) design and pre-testing and (5) clinical evaluation (Figure 11).To provide the foundation for the risk assessment work package and to ensure consideration of potential risk factors for inclusion in the Minimum Data Set and Risk Assessment Framework, a systematic review of primary research was undertaken to identify risk factors that are independently predictive of pressure ulcer development in adult patient populations.This Methods section has been largely reprinted with minor modifications from Int J Nurs Stud, vol. 50, Coleman S, Gorecki S, Nelson E, Closs S, Defloor T, Halfens R, et al. Patient risk factors for pressure ulcer development: systematic review, pp. 974–1003, 2013,46 with permission from Elsevier.The approach was based on the systematic review methods recommended for questions of effectiveness20,127 and adapted to identify risk factor studies, with consideration of the methodological limitations including bias and confounding associated with observational studies.83,85Methodological quality criteria were integrated into the inclusion and exclusion criteria of the systematic review, developed from principles of good research conduct in observational studies and randomised controlled trials that minimise bias.82,86,89,128Studies were included if they met the following criteria: primary research; adult study populations in any setting; outcome was the development of a new pressure ulcer(s); prospective cohort study, retrospective record review or a controlled trial; length of follow-up of at least 3 days, with the exception of operating room studies for which no minimal time period was set; outcome clearly defined as grade/stage 1 or above pressure ulcer23,129 or equivalent; multivariable analyses were undertaken to identify factors affecting pressure ulcer outcome; and the unit of analysis was the patient.Studies were excluded as follows: paediatric study populations; cross-sectional or case study designs; patient recall, patient self-report or an analysis of general practitioner records to assess outcome; or duplicate publications of a patient data set. Cohort studies (prospective and record reviews) were excluded from the review if > 20% of the study sample was excluded from analysis for reasons including withdrawal, death, loss to follow-up and missing records.82,83,86,89 Controlled trials were excluded unless the following minimum criteria applied: randomised allocation to treatment and intention-to-treat analyses.127,128 No language restriction was applied.Fourteen electronic databases were searched, from inception until March 2010: Allied and Complementary Medicine Database (AMED), British Nursing Index (BNI), MEDLINE, EMBASE, PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), The Cochrane Library, ProQuest, Networked Digital Library of Theses and Dissertations, International Theses in Progress, Theses Canada Portal, Australian Digital Theses Program, Russian Academy of Sciences Bibliographies and Index to Theses. The search strategy (see Appendix 14) sought to identify all published and unpublished research studies investigating risk factors for the development of pressure ulcers. The search strategy was designed with guidance from the collaborative team and included pressure ulcer search terms,130 Ovid maximum sensitivity filters for prognosis and aetiology or harm and an Ovid maximum sensitivity filter for randomised controlled trials.127In addition, we hand searched specialist journals and conference proceedings, contacted 13 experts, searched the UK national research websites and performed a citation search on all included studies and systematic reviews identified in the search (see Appendix 14).Abstracts were screened for relevance by one reviewer (CG) and checked by a second (JN). Articles assessed as potentially relevant were obtained in full and reviewed against the eligibility criteria by one reviewer (CG or SC) and checked by another (JN). When the statistical methods were unclear and eligibility could not be determined, statistical review was undertaken (JB). Disagreements were dealt with through consensus.When studies fulfilled the eligibility criteria data were extracted by a single reviewer (CG or SC) and checked by a second reviewer (JN). When data were missing from the publication, attempts were made to contact the authors. When duplicate publications of patient data sets were identified, the most detailed report was used for data extraction. Experts in the field were asked to review/data extract abstracts and articles not published in English (see Acknowledgements).There are no guidelines for the quality assessment of risk factor studies and so we developed an assessment framework based on guidelines for assessing quality and risk of bias in prognostic studies and on methodological considerations in the analysis, meta-analysis and publication of observational studies.81–89 Each study was appraised by two reviewers (JN, SC) and the following methodological limitations were noted when present: baseline characteristics not adequately described; inadequate measurement of risk factors (e.g. record review); inappropriate cut-points used for continuous data; and time-dependent covariates included in the analysis without appropriate adjustment.In addition, specific consideration was given to the following criteria:Is there a sufficient number of events (rule of thumb: ≥ 10 events per risk factor)?Are there sufficient data to assess the adequacy of the methods and analysis?Is the strategy for model building (i.e. inclusion of variables) appropriate and based on a conceptual framework?Is the selected model adequate for the design?Each of the four criteria was assessed to see whether or not they were met (yes/no/partial/unsure), which provided a structured approach for the classification of overall study quality. We classified studies as being of high, moderate, low and very low quality using the following criteria:high-quality studies: ‘yes’ for all criteriamoderate-quality studies: ‘yes’ for criterion 1 and at least two other criterialow-quality studies: ‘no’ for criterion 1 and ‘no’ or ‘partial’ for two other criteriavery low-quality studies: ‘no’ for criterion 1 and ‘no’ or ‘partial’ for all three remaining criteria.Meta-analysis of the data was not feasible for this review because of heterogeneity in the study designs, patient populations, risk factor descriptors, interventions used and outcomes reported. As the main aim was to identify risk factors rather than quantify the effect size of the relationship between these factors and pressure ulcer development, a narrative synthesis was carried out.127For each study, all factors entered into multivariable modelling and those that emerged as significant (p ≤ 0.05) were identified. For studies using stepwise regression, we included non-significant factors (p ≥ 0.05) if these were reported in the final model as being independently associated with pressure ulcer development.Risk factors were categorised into domains and subdomains by collating related factors from the source articles into a grouping (domain). An example of a domain and subdomain would be the domain of skin/ulcer status and the subdomains of stage/grade 1, existing pressure ulcer, previous pressure ulcer and general skin status. Evidence tables (see Appendix 15 for an example), were generated for each risk factor subdomain, with a summary narrative synthesis by subdomain and domain. For each subdomain, the total number of studies entering the variable, the total number of studies in which the variable emerged in the multivariable analyses and the quality of the studies are summarised. In the evidence tables (see Appendix 15 for an example), grade and stage of pressure ulcer are recorded as reported in individual studies.The numbers of studies considered and meeting the eligibility criteria are shown in the study flowchart (Figure 12). The 5437,57,60,79,80,125,131–178 included studies included 34,449 patients from acute and community populations.46The included studies comprised seven high-quality, 10 moderate-quality, 27 low-quality and 10 very low-quality studies (Table 29). The low- and very low-quality studies had inadequate numbers of pressure ulcers and other methodological limitations.The review identified 15 risk factor domains and 46 subdomains (Table 30). The number and quality of studies in which associated risk variables emerged in multivariable modelling and the number and quality of studies in which associated risk variables did not emerge are detailed in Table 30 [full evidence tables are available at: (accessed August 2015)]. The review highlighted three primary risk factor domains:Mobility/activity (immobility), with the subdomains of mobility subscales, mobility/activity, activities of daily living (ADL) and activity (bedfast/chairfast/immobile descriptors) emerging most consistently.Skin/ulcer status, with the subdomain of stage/grade 1 pressure ulcer emerging most consistently. General skin status was also found to be important but the diverse variables (e.g. dry sacral skin, mottled skin, unhealthy skin, skin redness, baseline skin trauma) made interpretation difficult.Perfusion, with the subdomain of diabetes emerging strongly in the high-/moderate-quality studies. Evidence from the large number of other perfusion-related variables suggests that factors that impair circulation increase the probability of pressure ulcer development but the evidence is limited by the large range of variable descriptors and study quality. Further research is needed in this area.Other risk factor domains that were less consistently associated with pressure ulcer development included nutrition, moisture, age, haematological measures, general health status, sensory perception and mental status. Additionally, only a small number of studies included body temperature and immunity and these factors require further research. Finally, the evidence related to race and gender as risk factors was equivocal.The review46 indicates that there are three primary risk factor domains of mobility/activity, skin/ulcer status and perfusion (including diabetes) but suggests that there is no single factor that can alone explain pressure ulcer development; rather, there is a complex interplay of factors that increases pressure ulcer probability. Although immobility is included in existing pressure ulcer risk assessment tools, the inclusion of skin/ulcer status and perfusion (including diabetes) is not universal. This highlights the need to reconsider the risk factors included in pressure ulcer risk assessment tools.It is noteworthy that there were a large number of potential risk factors –15 domains and 46 subdomains including over 250 named variables. Furthermore, there was a lack of comparable data fields for measurement of the same constructs and key risk factors were not routinely recorded in all studies.46 These limitations prevented meta-analysis to identify an item pool for a risk stratification tool and a key recommendation of the review was the development of a Minimum Data Set for pressure ulcer research and institutional cohorts to facilitate future large-scale multivariate analyses and meta-analysis.Although the systematic review46 provided a foundation for the ongoing work, there remained gaps in the evidence base and a lack of agreement over the key risk factors and data items to summarise patient risk. This highlighted the need to consult with experts in the pressure ulcer field about the relevance of the evidence to clinical practice and risk assessment and about other pertinent scientific (physiological and biomechanical) evidence that ought to be considered to agree the risk factors and items to be included in the Minimum Data Set and Risk Assessment Framework (see Appendix 16 for study protocol).The Aims and objectives, Methods and Results sections are largely reproduced, with amendments, from Coleman S, Nelson E, Keen J, Wilson L, McGinnis E, Dealey C, et al. Developing a pressure ulcer risk factor minimum data set and risk assessment framework, J Adv Nurs, with permission from John Wiley & Sons.126 © 2014 The Authors. Journal of Advanced Nursing. Published by John Wiley & Sons Ltd. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License.The aim of this study was to develop a draft pressure ulcer risk factor Minimum Data Set and Risk Assessment Framework for pre-testing and clinical evaluation.The objectives were to:agree a list of patient characteristics to form a Minimum Data Set suitable for routine collection of key risk factors in adult patient populationsdevelop a Risk Assessment Framework incorporating the Minimum Data Set with:a simple screening stage to quickly identify not-at-risk patientsa detailed full assessment stage for patients who are at potential/actual risk or who have an existing pressure ulcerdecision pathways [i.e. not currently at risk, primary prevention (at risk) or secondary prevention and treatment pathway (with pressure ulcer)].A consensus study using a modified nominal group technique based on the RAND/UCLA appropriateness method179 was used. This incorporated face-to face interaction and pre- and post-meeting questionnaire completion with an expert group, as well as face-to-face interaction with a service user group (PURSUN UK; see Chapter 2).The expert group comprised international clinical/academic leaders identified through their publication record in pressure ulcer or relevant research (see Acknowledgements). The involvement of international expert group members was facilitated by additional funding from a Leeds University World Universities Network grant. The group was purposively sampled to include the perspectives of nurses, doctors, bioengineers, epidemiologists and individuals with organisational development and decision science expertise. A multispecialty group was developed to take account of a wide range of opinions.180 Seventeen members were recruited to allow for attrition, as 12 was considered the optimum number in terms of preventing co-ordination problems whilst maximising reliability.181The service user group involved members of PURSUN UK (see Chapter 2). All members were invited to take part and seven people have been involved throughout the project. This includes people with experience of having a pressure ulcer or living with pressure ulcer risk as well as carers.The consensus process incorporated an initial expert group meeting and an initial PURSUN UK meeting followed by two consensus cycles. It was envisaged that the first consensus cycle would consider the Minimum Data Set and the second cycle would consider the Risk Assessment Framework; however, at the initial expert group meeting it was apparent that there were difficulties with considering the Minimum Data Set and Risk Assessment Framework separately as the two are interlinked. Discussion at the meeting highlighted the need to identify the key pressure ulcer risk factors and assessment items (i.e. the way in which the risk factors are measured) that would be included in the Minimum Data Set and incorporated in the Risk Assessment Framework. Therefore, the first consensus cycle focused on agreeing the risk factors to be included in the Minimum Data Set and Risk Assessment Framework and the second consensus cycle focused on the assessment items (Figure 13). The study was approved by the University of Leeds School of Healthcare Research Ethics Committee. Informed consent was gained from expert group members prior to participation (see Appendices 17–22 for participant information and consent forms).Reviewing the pressure ulcer risk factor evidence was an important element of the study and was integrated throughout all cycles of the consensus process.46 The systematic review46 provided evidence regarding the current state of knowledge surrounding pressure ulcer risk factors but the group also considered wider scientific evidence that was drawn from the expertise of the group. The relevance of the evidence to clinical practice, as well as the practicalities of pressure ulcer risk assessment, were also considered by the group.Questionnaires were completed by all expert group members privately before and after the cycle 1 and 2 meetings (see Figure 13). In each questionnaire, participants were asked to rate their level of support for statements (relating to the inclusion of risk factors/assessment items in the Minimum Data Set and Risk Assessment Framework) on a 9-point Likert scale, with 1 indicating strong disagreement and 9 indicating strong agreement. Each statement was preceded by a relevant summary of the pressure ulcer systematic review evidence, as well as a summary of expert group discussions, a summary of PURSUN UK group discussions (as applicable) and follow-up/explanatory notes (as applicable). Electronic links to the full systematic review evidence tables and the full summary of the preceding expert group discussions were also available within the questionnaires. This allowed the research team to identify areas of agreement, uncertainty and disagreement before each meeting and to schedule the discussion agenda accordingly. The completion of the questionnaire after the meeting allowed individuals to change their ratings in light of discussions and/or when necessary allowed questionnaire items to be clarified and amended.Questionnaires were administered and completed using a commercial online survey platform. Participants were asked to complete the questionnaire within 2 weeks of initial posting. One or two reminders were sent (and on one occasion, because of a holiday period, a third reminder was sent) to participants who had not completed the questionnaire within the allotted 2-week period. The surveys were closed to response at 10 weeks following initial posting.All expert group meetings were led by trained facilitators and were audiotaped. Unlike a traditional RAND/UCLA method in which the first face-to-face meeting occurs following questionnaire completion, an initial face-to-face meeting was undertaken to review the pressure ulcer evidence and consider the views of the group to inform the development of the cycle 1 risk factor questionnaire.182 At cycle 1 and 2 expert group meetings (see Figure 13), the pre-meeting collective questionnaire responses were anonymously fed back to the group. Members were also provided with a reminder report of their individual questionnaire responses and a copy of the summary of the discussions of the previous expert group meeting. The questionnaire results highlighted areas of agreement and areas of uncertainty and disagreement, which provided a focus for the group discussions to ascertain whether there was genuine uncertainty or disagreement or if there was ambiguity in the wording of the questionnaire.As pressure ulcer risk assessment practice is part of routine care there was a need to explore the acceptability of proposed risk assessment elements to patients and carers; this was undertaken through facilitated PURSUN UK meetings. PURSUN UK members’ views were fed back to the expert group at the subsequent meeting (cycles 1 and 2) and through the cycle 2 pre-meeting questionnaire.The researcher (SC) listened to the audio tapes of the expert group meetings and read the associated transcripts in total to ensure completeness. The data were then coded, with categories based on the pressure ulcer risk factor systematic review, in keeping with a directed content analysis approach.183 As new themes emerged from the expert group discussions further codes were added. A summary report of each meeting was generated by the researcher. The report was reviewed by the facilitators and members of the working group (subgroup of the expert group that comprised the local team and incorporated three academic nurses, three clinical nurses, one PPI officer and one member with organisational development expertise) to ensure that it reflected group discussions.Careful notes were taken throughout the PURSUN UK meetings and a summary of the discussions was written by the researcher (SC). The summary was circulated to the facilitator and group participants to ensure that it reflected the discussions at the meeting.Questionnaire statements were summarised using the median group response as a measure of central tendency. In keeping with the RAND/UCLA appropriateness methods and other studies179,184–186 Likert-scale group median responses for each statement were categorised into three tertiles. For this study, the categories were 1–3, disagree; 4–6, uncertain; and 7–9, agree. Within-group agreement was measured using the RAND disagreement index,179 which considers the dispersion of individual scores and identifies areas of disagreement (when panellists rate at both ends of the Likert scale). An index of > 1 indicates disagreement.Using the group median response and the disagreement index for each statement (regarding risk factors/assessment items) the following principles were applied following post-meeting questionnaire completion:group medians of 1–3 without disagreement would be excludedgroup medians of 7–9 without disagreement would be includedwhen the disagreement index was > 1 or when the median was 4–6, group medians would be excluded but noted as potential areas for further research.The expert group comprised nine female and eight male participants. There was 100% (n = 68/68) completion of questionnaires, with 77.9% (n = 53/68) completed within the 2-week allotted time period [13.2% (9/68) were completed up to 1 week late; 2.9% (2/68) up to 4 weeks late; 1.5% (1/68) up to 6 weeks late; 1.5% (1/68) up to 7 weeks late; and 2.9% (2/68) up to 8 weeks late]. In total, there was 86.3% attendance at the face-to-face meetings (17/17 attended the first meeting, 13/17 attended the second meeting and 14/17 attended the third meeting). The results concerning the risk factors (cycle 1) and assessment items (cycle 2) of the Minimum Data Set and Risk Assessment Framework are detailed in the following sections.The expert group agreed that three risk factors should be incorporated into the screening stage of the Minimum Data Set and Risk Assessment Framework for the assessment of all patients: immobility, existing pressure ulcer and previous pressure ulcer. Table 31 shows the changes in questionnaire responses between the pre-meeting questionnaire and the post-meeting questionnaire.The expert group agreed that 11 risk factors, namely immobility, existing pressure ulcer, previous pressure ulcer, general skin status, perfusion, skin moisture, dual incontinence, diabetes, sensory perception, nutrition and albumin level, should be incorporated into the full assessment stage of the Minimum Data Set and Risk Assessment Framework for patients who were considered to be at potential/actual risk or who have an existing pressure ulcer identified at the screening stage. Table 32 shows the changes in questionnaire responses between the pre-meeting questionnaire and the post-meeting questionnaire. A summary of the key discussion points relating to uncertain (group median 4–6) risk factors is detailed in Table 33. After reviewing the evidence, the post-meeting questionnaire was revised and blood pressure, smoking and cardiovascular disease were combined into a general category of ‘perfusion’.Using the decision rules highlighted in the methods section, the Minimum Data Set and Risk Assessment Framework comprised only those risk factors for which there was agreement (group median 7–9 without disagreement). The progression of risk factors through the consensus study is detailed in Figure 14 (see also Tables 31 and 32). This shows that of the original 15 risk factor domains and 46 subdomains identified in the systematic review,46 26 risk factors were considered to potentially warrant inclusion in the Minimum Data Set and Risk Assessment Framework and progressed to consensus cycle 1.The risk factors for inclusion were mainly agreed in the cycle 1 post-meeting questionnaire but there were some refinements of the risk factors in the cycle 2 pre-meeting questionnaire. The expert group had agreed that albumin should be included at the second stage of the assessment (see Table 32). However, at a subsequent PURSUN UK meeting, concern was raised about the need to undertake an additional blood test for the assessment of albumin. In light of this, expert group members were asked whether there was a clinical indication for undertaking an additional blood test to measure albumin for patients to establish the level of pressure ulcer risk and it was concluded that this was unnecessary. The expert group also concluded that skin moisture and dual incontinence could be combined into one measure.There was support (group median 7–9 without disagreement) for all statements in the cycle 2 questionnaire concerning the assessment items of the Minimum Data Set and Risk Assessment Framework. However, following discussion at the cycle 2 meeting, the expert group felt that some changes should be made to specific items. As the group were content with the majority of the pressure ulcer risk factor Minimum Data Set items highlighted in the cycle 2 pre-meeting questionnaire, the post-meeting questionnaire focused on items that required adjustment. The agreed assessment items for the screening and full assessment stage are detailed in Table 34. In addition, the expert group agreed that the Risk Assessment Framework would facilitate the identification of a risk profile for each patient, rather than condense the risk from different aspects into a single score. This would support care planning, with interventions selected in response to specific risk factors.Using the results from cycle 1 and 2 of the study, an initial draft of the Risk Assessment Framework was produced (see Appendix 23) incorporating the screening and full assessment stage and decision pathways of the assessment process. This underwent further graphic design prior to pre-testing.The Aims and objectives, Methods and Results sections are largely reproduced, with amendments, from Coleman S, Nixon J, Keen J, Wilson L, McGinnis E, Dealey C, et al. A new pressure ulcer conceptual framework, J Adv Nurs, with permission from John Wiley & Sons.187 © 2014 The Authors. Journal of Advanced Nursing. Published by John Wiley & Sons Ltd. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License.By bringing together the relevant fields of enquiry and clarifying key risk factors for pressure ulcer development, the consensus study provided an opportunity to undertake an additional piece of work to review and enhance the pressure ulcer conceptual framework.1 This was to bridge the gap between the epidemiological, physiological and biomechanical evidence and enhance our understanding of the role of individual risk factors in pressure ulcer development. This was not part of the programme outline initially but emerged as an additional output of the work.The aim was to develop a new pressure ulcer conceptual framework. Specific objectives were to:review and update the biomechanical elements of the NPUAP/EPUAP 2009 conceptual frameworkdevelop a theoretical causal pathway for pressure ulcer developmentmap risk factors identified in the consensus study to the updated conceptual framework.The expert group reconvened in an additional facilitated meeting which was planned so that members had access to the outcomes of the consensus study, the evidence of the systematic review46 and risk factor/causal factor terminology before the face-to-face meeting. Familiarity with the risk factor/causal factor terminology allowed us to explore the role of the risk factors in the pressure ulcer causal pathway. This was facilitated by consideration of definitions from Brotman and colleagues:188risk factor – a variable with a significant statistical association with a clinical outcomeindependent risk factor – a risk factor that retains its statistical association with the outcome when other established risk factors for the outcome are included in a statistical modelnon-independent risk factor – a risk factor that loses its statistical association with the outcome when other established risk factors for the outcome are included in a statistical model.Brotman and colleagues188 suggest that a causal factor is a risk factor that has a causal relationship with a clinical outcome and is defined experimentally (known to affect outcome) rather than statistically. They make a distinction between direct and indirect causal factors:Direct causal factor – directly impacts the outcome (or the likelihood of the outcome).Indirect causal factor – impacts the outcome (or affects its likelihood of occurrence) by changing a direct causal factor. If the direct causal factor is prevented from changing then changes in the outcome will not be produced.In our work we further categorised indirect causal factors into key indirect causal factors (for which the epidemiological/wider scientific evidence and/or clinical resonance was stronger) and other indirect causal factors. Meeting discussions were audio recorded and transcribed, allowing key themes to be identified.In addition to considering the outcomes of the consensus study (see Phase 2: consensus study), the researcher (SC) listened to the audio tapes of the conceptual framework expert group meeting discussions and read the associated transcripts in total to ensure completeness. The analysis allowed the researcher (SC) to draft the new pressure ulcer conceptual framework and theoretical causal pathway, which was circulated to the expert group by e-mail to ensure content validity.The expert group discussions led to amendments to the existing NPUAP/EPUAP conceptual framework,1 as illustrated in Figure 15. Most notably, it was recognised that, although mechanical properties of the tissues and geometry (morphology) of the tissues and underlying bones impact on the internal strains and stresses (as an example, subjects who are either very emaciated or very obese will have enhanced strains and stresses within the soft tissues), their impact was considered to be more relevant to the susceptibility of the individual (i.e. impacting on the damage threshold). Furthermore, transport (perfusion and lymphatic drainage) also impacts on the damage threshold of the individual and this would also be affected by temperature in terms of vasodilation/vasoconstriction, thereby affecting tissue perfusion. The underlying physiology of an individual will also have an impact on his or her repair capacity and this was an important consideration that was captured in the amended conceptual framework (see Figure 15).The theoretical schema of a proposed causal pathway for pressure ulcer development detailing the direct, key indirect and other potential indirect causal factors is illustrated in Figure 16. Table 35 shows the mapping of the direct causal factors and key indirect causal factors against the key components of the enhanced 2009 NPUAP/EPUAP conceptual framework. Although it was recognised that the presence and weighting of specific risk factors may vary in relation to the anatomical site of the pressure ulcer, it was not possible to delineate the evidence to skin site-level risk factors.Three characteristics were classified as direct causal factors: immobility, skin/ulcer status and perfusion. Immobility is a necessary condition for pressure ulcer development and is therefore considered a direct causal factor (see Figure 16); through its impact on mechanical boundary conditions (see Table 35) it directly impacts the outcome (or the likelihood of the outcome). Of note is that friction and shear is not specified as a patient characteristic but rather as a characteristic of the mechanical boundary condition (see Table 35).Identifying whether skin/ulcer status (incorporating existing and previous pressure ulcers and general skin status) and poor perfusion represent a direct or indirect risk factor is less straightforward. It could be assumed that they are indirect factors as without some degree of immobility a pressure ulcer would not develop. However, this is not in keeping with the definitions of causal factors and oversimplifies the complex interplay of factors required to lead to tissue damage. There is strong epidemiological/wider scientific evidence that poor perfusion and skin/ulcer status reduce patients’ tolerance to pressure and increase the likelihood of pressure ulcer development, suggesting that they are direct causal factors, and this may explain why some immobile patients develop pressure ulcers whereas others do not.Further insight was gained by mapping skin/ulcer status and poor perfusion to the conceptual framework; it was apparent that they were clearly implicated in the susceptibility and tolerance aspect of the framework (see Table 35). Skin/ulcer status mapped to the individual geometry (morphology) of the tissue and bones, the mechanical property of the tissues, the transport and thermal properties and the physiology and repair aspects of the framework. Perfusion mapped to the individual transport and thermal properties and the physiology and repair elements of the framework and is related to factors that impair circulation. Within the expert group it was recognised that oxygen-carrying capacity was important in maintaining healthy tissues, although it was also recognised that other factors such as the delivery of nutrients and waste removal were important, and at present it is difficult to determine the most important factors relating to perfusion. Further confirmatory research is needed to more clearly ascertain the aetiological mechanisms of importance.Moisture, sensory perception, diabetes, low albumin level and poor nutrition were considered key indirect causal factors as they impact the outcome (or affect its likelihood of occurrence) by changing a direct causal factor (see Figure 16).The theoretical conceptual schema (see Figure 16) was further developed to include other indirect causal factors to illustrate the potential relationships and the impact of diverse factors that may be involved in the causal pathway. However, it is recognised that the inter-relationships among potential and key indirect causal factors are complex and require further elucidation. Other potential indirect causal factors include those with weak or limited epidemiological/wider scientific evidence but which are thought to impact on key indirect and direct causal factors. These include age, medication and pitting oedema as well as other factors relating to general health status including infection, acute illness, raised body temperature and chronic wound.Having considered the causal pathway for pressure ulcer development (see Figure 16) and mapped the direct and key indirect causal factors for ulcer development against the components of the enhanced conceptual framework (see Table 35), a new conceptual framework is proposed that enables the epidemiological evidence to be linked to the conceptual framework (Figure 17). The new framework shows that there is a relationship between the mechanical boundary conditions and the susceptibility and tolerance of the individual. The risk factors that impact the mechanical boundary conditions and the susceptibility and tolerance of the individual are detailed in the framework and are based on the direct causal factors of immobility, skin/ulcer status and poor perfusion as well as on the key indirect causal factors of poor sensory perception and response, diabetes, poor nutrition, moisture and low albumin level.For simplicity, the risk factors are represented under the elements that they predominantly affect (either mechanical boundary conditions or susceptibility and tolerance of the individual), but the broken line running under the risk factors indicates that some risk factors may have an effect on both sides of the framework, which is more clearly articulated in the theoretical schema (see Figure 16) and risk factor mapping (see Table 35). The absence of risk factors on either the individual susceptibility and tolerance or the mechanical boundary conditions side of the framework would affect the likelihood of pressure ulcer development [i.e. a patient with good perfusion may be able to tolerate higher levels of immobility (without developing a pressure ulcer) than a patient with poor perfusion].The consensus study identified the risk factors and assessment items and suggested a structure for the Risk Assessment Framework (incorporating the risk factor Minimum Data Set). With these elements agreed we engaged the support of a graphic designer (see Acknowledgements) to develop the new Risk Assessment Framework in a way that would facilitate ease of use. This incorporated the use of colour to aid clinical decision-making. To ensure that clinicians/nurses understood and were able to use the Risk Assessment Framework, the next study of the work package was undertaken – pre-testing of the Risk Assessment Framework (see Appendix 24 for study protocol).The aim was to assess and improve the acceptability, usability, format, design, clarity, comprehension, language and data completeness of the draft Risk Assessment Framework (incorporating the risk factor Minimum Data Set) with clinical nurses.Cognitive pre-testing methods were used to evaluate how clinical nurses interpreted questions, response categories and instructions while using the draft Risk Assessment Framework.189 This was conducted over three pre-test sessions and incorporated three focus groups and 12 ‘think out loud’ interviews, estimated as the number required for data saturation. It was anticipated that focus groups with nurses in similar roles (e.g. staff nurses, senior nurses) would facilitate greater understanding of the usability of the Risk Assessment Framework, allowing group members to ‘spark ideas off one another’, which might lead to greater disclosure.190In addition, one-to-one think out loud interviews191 were undertaken to allow the researcher (SC) to identify specific problems with the risk assessment tool that would be amenable to resolution by modification. The study was conducted to allow analysis of and adjustment to the Risk Assessment Framework to be undertaken between pre-test sessions so that three different versions of the tool could be pre-tested and improvements made in an interative process.For the pre-test we recruited nurses from a large acute teaching hospital trust, a district general hospital and two primary care trusts. Purposive sampling was undertaken to ensure that tissue viability nurses, staff nurses and sisters from hospital and community settings were recruited from each of the four participating sites. Participants included those who had an interest in tissue viability (e.g. a link nurse or member of a local pressure ulcer or wound care working group). The study was approved by the University of Leeds School of Healthcare Research Ethics Committee. Informed consent was obtained prior to participation in the study (see Appendices 25 and 26 for the patient information leaflet and consent form).The three facilitated pre-test sessions were undertaken away from the clinical environment and involved 8–12 nurses from the four participating sites, who were grouped by job role (staff nurse, sister/charge nurse and tissue viability nurse specialist/research nurse) to facilitate openness, as the use of heterogeneous groups can lead to inhibition in raising issues that do not seem to be shared by others.190 This was thought to be particularly important for this group as a hierarchy might have stifled disclosure (e.g. a staff nurse might not want to disagree with the views of his/her ward sister). Having nurses from different centres minimised familiarity, which can lead to participants relying on ‘taken for granted’ assumptions.190 At the pre-test session, the nurses were trained in how to use the Risk Assessment Framework and were then randomly allocated to either a focus group or a one-to-one think out loud interview.Training involved a short presentation and demonstration on how to use the draft Risk Assessment Framework with a simulated patient. Each nurse then completed the draft Risk Assessment Framework using case studies and vignettes (see Appendix 27) that were accompanied by photographs of pressure areas and ulcers. The vignettes were appropriate to the nurses’ area of practice (i.e. community nurses used vignettes of community patients). The vignettes were co-developed by the project lead, the project team and members of PURSUN UK to ensure that they were realistic and clinically relevant. Nurses were encouraged to ask questions throughout the training session.The sessions were planned to ensure that four to eight nurses192 per pre-test were assigned to the focus group. Each was asked to complete the Risk Assessment Framework again, using three case studies relevant to their area of practice. Nurse participants were encouraged to highlight any areas of the Risk Assessment Framework form that they found confusing. A co-facilitator assessed data completeness and listed areas where data items were not completed or were not completed as required, as well as areas noted by the nurses as confusing. The focus group meeting then convened to discuss the use of the Risk Assessment Framework. The meeting was moderated by two facilitators and audio recorded. The moderator promoted group interaction and guided discussions using a topic guide (see Appendix 28), which considered the usability of the Risk Assessment Framework and any areas of confusion regarding its use. This was informed by the data completeness assessment.Up to four nurses from each session were assigned to the one-to-one think out loud interviews. A topic guide (see Appendix 29) was used and the researcher first guided the nurses though the think out loud technique. Once the nurse were content with the approach, they were asked to complete the Risk Assessment Framework again in the presence of the researcher using three vignette case studies appropriate to their area of practice. The researcher encouraged the nurses to vocalise their thoughts as they completed the Risk Assessment Framework. This allowed specific issues relating to difficulty in interpreting items or confusion about aspects of the Risk Assessment Framework to be identified. The interviews were audio recorded.Data completeness of the Risk Assessment Framework forms was undertaken by calculating the percentage of item-level missing data, the percentage of decision pathways allocated and the percentage of item-level missing data for those for whom a decision pathway was allocated. The appropriateness of the allocated decision pathway was also assessed based on the decision rules of the Risk Assessment Framework and the item responses for each assessment.The focus group meetings and the think out loud interviews were audiotaped and transcribed. The researcher listened to the audio tapes and read the transcripts to ensure accuracy and to ensure that a good overview of the discussions had been achieved. The data were then coded, which was directed by the risk factor items of the Risk Assessment Framework, using a directed content analysis approach.183 The emphasis was on identifying themes across the focus groups and think out loud interviews that impacted on the application of the Risk Assessment Framework in clinical practice. A summary report of each meeting was reviewed by the facilitators to ensure that it reflected the discussions that had taken place. The report was considered by a working group (consisting of clinical and academic leaders in the pressure ulcer field) and adjustments were made to the draft Risk Assessment Framework, which was pre-tested at the subsequent session in an iterative process. Following pre-testing, the Risk Assessment Framework was also reviewed by PURSUN UK and the consensus study expert group.The pre-test sessions were well attended by 34 nurses from acute (n = 16) and community (n = 18) settings. Over the three pre-test sessions, 101 Risk Assessment Framework assessments were undertaken using vignette case studies by 11 tissue viability/research nurses (n = 32 Risk Assessment Framework assessments), 12 staff nurses (n = 36 Risk Assessment Framework assessments) and 11 sisters (n = 33 Risk Assessment Framework assessments). At each pre-test session, four nurses undertook the think out loud interviews and seven or eight nurses attended the focus groups. Table 36 details the level of data completion for each pre-test session, which can be seen to improve as the Risk Assessment Framework was amended over the three pre-test sessions.An inappropriate decision pathway was allocated when an assessment detailed the presence of a ulcer and the case–study patient should have been allocated to the ‘pressure ulcer category 1 or above or scarring’ pathway but was allocated to the ‘at-risk’ pathway. Uncertainty about the appropriateness of the allocated pathway related to missing data, for example a patient was allocated to the ‘not currently at risk’ pathway but the skin assessment items were not fully completed and hence there was a possibility that a higher pathway was appropriate.Figure 18 illustrates how the levels of missing data decreased over the three pre-test sessions overall and when a decision pathway was allocated. Figure 19 illustrates how the number of decision pathways allocated increased notably from the first to the second pre-test. Table 37 presents the appropriateness of the decision pathways allocated according to the decision rules of the Risk Assessment Framework and the item responses for each assessment.Changes made to the Risk Assessment Framework between pre-test sessions in response to the analysis of data completeness, think out loud interviews and focus groups are summarised in Figure 20 and related to three main areas: flow and format, decision support and wording of specific items. An example of the changes made to these main areas between pre-test sessions is shown in Figures 21–23 in relation to step 1 of the assessment. It should be acknowledged that, following these changes, some nurses still completed the step 1 skin/ulcer items despite not needing to. This could be related to the use of case studies in the pre-test sessions in which information on skin/ulcer status was readily available, whereas in clinical practice this information may be less obvious.Other notable changes made over the course of the pre-test session relate to the move from landscape to portrait orientation to improve the flow of the tool and the development of specific items (e.g. the terminology relating to ‘bedfast’ and ‘chairfast’ in the step 1 mobility items was found to be confusing and there was a need to incorporate an element of frequency to the items, which were subsequently amended and tested at the next session). The think out loud participants from the first pre-test also highlighted that items for which a positive response indicated that the patient did not have a problem were confusing. This related to step 1 mobility items and the step 2 sensory perception item and changes were made to the Risk Assessment Framework used at subsequent sessions.The first pre-test focus group felt that there should be some provision within step 1 of the Risk Assessment Framework to enable nurses to use their clinical judgement in terms of other significant risk factors (which may be exceptions to the rule) that they should take into account when considering if a patient should progress to the more detailed step 2 assessment. This could relate to the severity of a risk factor (e.g. terminally ill patients, severe diabetes, perfusion problems and severe nutritional problems). Having ‘other items’ at step 1 was considered by the working group but there was concern that the screening stage could become too large. Taking into account the causal pathway for pressure ulcer development, it was decided that a ‘vulnerable skin’ item would be included instead to focus the assessment on the potential impact that other medical conditions might have on the skin, rather than on the presence or absence of many different conditions.The data completeness assessment (see Table 36 and Figure 18) showed poor decision pathway allocation in the first pre-test. The corresponding focus group discussions highlighted confusion over where to indicate the pathway allocation; some nurses had attempted to indicate a pathway on the form although they were clearly unsure of where to do this. This alerted us to a significant omission and lack of clarity within the Risk Assessment Framework and the need to include a response box within the ‘not currently at risk’ pathway at the first stage of the assessment and to make the pathway allocation tick boxes at stage 2 of the assessment more obvious. In addition, the think out loud interviews in the first pre-test session highlighted an issue relating to the ordering of the decision pathway boxes in the first draft Risk Assessment Framework, that is, the first pathway (left) being the blue ‘not currently at risk pathway’, the second pathway (middle) being the orange primary prevention pathway and the third pathway (right) being the red secondary prevention/treatment pathway, and the resultant possibility of ticking the primary prevention pathway before getting to the secondary prevention/treatment pathway. It was suggested that, as ‘red trumps orange’, the boxes should be reordered so that the red one was first, and this was undertaken for the second pre-test (see Figures 21–23).The review of the Risk Assessment Framework by PURSUN UK and the expert group (following pre-testing) led to a final change to the Risk Assessment Framework. Although members of PURSUN UK felt that the Risk Assessment Framework was clear and understandable, they raised concern about the wording of the sensory perception item; this related to the ‘ability to feel and respond’ aspect of the item. The group agreed that the patient might be able to fulfil only one of these requirements, which should be considered a problem, but the wording suggested that it would be a problem only if the patient could not do both. They felt that the terminology should be ‘feel and/or respond’. This led to the wording of the sensory perception item being reconsidered at the subsequent expert group meeting and amendments being made.The pre-test facilitated the development of the preliminary Risk Assessment Framework (see Appendix 30), which was easily understood by clinical nurses. The Risk Assessment Framework was subsequently named the PURPOSE-T and will be further evaluated in clinical practice.To enable the provisional Risk Assessment Framework (PURPOSE-T) to be used with confidence in clinical practice, the fifth phase of the work package examined the fundamental properties of the instrument. This involved a field test to assess its reliability, convergent validity and clinical usabilty (see Appendix 31 for the study protocol).The aims of field test 1 were to assess the:data completeness and clinical usability of the PURPOSE-Tinter-rater and test–retest reliability of the PURPOSE-Tconvergent validity and known groups validity of the PURPOSE-T.The PURPOSE-T was evaluated through field testing using observational descriptive methods. Hospital inpatients and community nursing patients were invited to participate. Demographic characteristics were collected and individual pressure ulcer risk was assessed for all patients. Paired assessments were undertaken simultaneously using the PURPOSE-T, one by a ward/community nurse and one by an expert nurse, with each nurse remaining blind to the corresponding assessment. A blinded retest was undertaken by the same expert nurse at a follow-up visit.In addition, the expert nurses involved in data collection kept field notes of their experience of using the PURPOSE-T in clinical practice and comments from ward/community nurses during their use of the PURPOSE-T. The field notes were summarised and used to inform design amendments and issues of importance for implementation.The PURPOSE-T (field test version) incorporates a three-step assessment process:step 1 – screening assessment of mobility and skin statusstep 2 – full assessment of analysis of independent movement, sensory perception, detailed skin assessment, previous pressure ulcer history, perfusion, nutrition, moisture and diabetesstep 3 – assessment decision of ‘no pressure ulcer not currently at risk’, ‘no pressure ulcer but at risk’ and ‘pressure ulcer category 1 or above or scarring from previous pressure ulcer’.The tool is colour coded as follows to facilitate decision-making:blue – ‘no problem’ with risk factoryellow – ‘problem’ that may impact on pressure ulcer riskorange – ‘problem’ that puts the patient at risk and requires primary preventionpink – patient has a pressure ulcer or scar from a previous pressure ulcer and requires secondary prevention/treatment.The assessment decision is also colour coded using the RAG (red/amber/green) rating as follows:red – ‘pressure ulcer category 1 or above or scarring from previous pressure ulcer’amber – ‘no pressure ulcer but at risk’green – ‘no pressure ulcer not

currently at risk’.At step 1 there are four mobility options with ‘tick all applicable’ instructions. If only the blue-coded criterion ‘walks independently with or without walking aids’ is ticked the instructions are to progress to step 1 skin status. If any other mobility criteria (which are all coded yellow) are ticked, the instructions are to progress to step 2 (see Appendix 30).The step 1 skin status item also has four options with ‘tick all applicable’ instructions. If only the blue-coded ‘normal skin’ option is ticked the instructions are to allocate the patient to the green assessment decision – the ‘no pressure ulcer not currently at risk’ pathway. If any other skin status options are ticked (coded yellow and pink), the instructions are to progress to step 2 full assessment (see Appendix 30).Step 2 includes assessment of the following:analysis of independent movement: five options, including four coded orange (with varying limitations to frequency and extent of independent movement) and one coded yellow (making major position changes frequently)detailed skin assessment of 13 skin sites (with the option for ‘other’ skin sites), with three options for each, including ‘normal skin’ coded blue, ‘vulnerable skin’ coded orange and ‘pressure ulcer category 1’ coded pinkprevious pressure ulcer history: two options, including ‘no known pressure ulcer history’ coded blue and ‘pressure ulcer history’ coded yellow, with presence of scar (if applicable only) coded pinksensory perception: two options, including ‘no problem’ coded blue and ‘patient is unable to feel and/or respond to discomfort from pressure’ coded orangeperfusion: three options, including ‘no problem’ coded blue and two options coded orange: ‘conditions affecting central circulation, for example shock, heart failure and hypotension’ and ‘conditions affecting peripheral circulation, for example peripheral vascular/arterial disease’nutrition: five options, including ‘no problem’ coded blue and four options coded yellow: ‘unplanned weight loss’, ‘poor nutritional intake’, ‘low BMI’ and ‘high BMI’moisture: three options, including ‘no problem/occasional’ coded blue and two options coded yellow: ‘frequent’ and ‘constant’diabetes: two options, including ‘not diabetic’ coded blue and ‘diabetic’ coded yellow.Step 3 involves allocation of an assessment decision as outlined in Table 38.A nurse was defined as an expert if he or she was a member of the participating trusts’ tissue viability teams (tissue viability nurse consultant/specialist/clinical research nurse). Participating expert nurses attended an initiation training day at which the PURPOSE-T was presented, the instruction manual was provided and they used the PURPOSE-T through vignettes and role play until they were confident in how to use it. In practice, all expert nurses involved in recruitment and data collection were clinical research nurses with specialist tissue viability knowledge gained through their role in other PURPOSE programme research projects.The expert nurses in the acute sector identified a range of wards, sought verbal permission from ward managers to undertake the research and arranged a mutually convenient date with a qualified member of the ward team to undertake training and patient assessment. In the community sector the expert nurses sought volunteers from the community nursing service and arranged a mutually convenient time to undertake training and patient assessment.All participating ward/community nurses underwent training in the use of the PURPOSE-T from the expert nurses. This included a full explanation of the PURPOSE-T and the instruction manual followed by an invitation to undertake an assessment using the same vignettes that were used by the expert group nurses in their training, so that they were familiar with the instrument. Either the ward/community nurse or the ward/community team budget received a per-patient or a per-hour payment to cover the funding required to release the ward/community nurse from usual clinical duties.Inclusion criteriaInpatient in the acute setting or community nursing patient in the community setting.Provide written informed consent/verbal witnessed consent/consultee agreement.Expected to be available for the PURPOSE-T retest.Exclusion criteriaPatients in obstetric, paediatric, day case surgery or psychiatric settings (acute or community).Patients deemed by the attending health-care professional to be too unwell to be approached and/or complete the study assessment schedule.Patients were purposively sampled ensuring a similar number of hospital and community patients and representation of patients across four broad levels of risk (as defined by their mobility and ulcer status) as follows:no mobility restrictionssome mobility/activity limitationsbedfast/chairfastpressure ulcer category 1 or above.Each ward/community nurse was asked to identify four patients on his or her caseload, one from each of the four broad levels of risk when possible.Ward-/community-based nurses identified suitable patients from their area of practice. A full verbal explanation of the study and a patient information leaflet (see Appendix 32) were provided by the attending clinical staff or a member of the tissue viability team and assenting patients were then invited to provide informed, written consent (see Appendix 33). When patients were capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent was obtained (see Appendix 34). In addition, to ensure that the study population was representative of the clinical population assessed in the course of usual care, when patients lacked capacity ethical approval was given for consultee agreement (see Appendices 35 and 36). Assessment of eligibility and informed consent was undertaken by a member of the tissue viability team. Patients who both were eligible for study participation and provided informed consent/consultee agreement were registered centrally using the CTRU automated 24-hour telephone registration system.Each patient recruited to the field test was assessed by only one pair of assessors.At baseline, demographic and clinical data were recorded for each patient by the expert nurse. Baseline data included type of NHS facility (hospital/intermediate care/community nursing team), type of admission/referral (e.g. elective/acute), ward specialty (hospital patients only), date of birth, gender and ethnicity. Clinical assessment included the subscales of the Braden scale51 and the Waterlow scale.50At baseline the PURPOSE-T was completed and recorded by a member of the ward/community team and the expert nurse, blind to each other’s assessment. This incorporated the detailed skin assessment and, when applicable, pressure ulcer classification.1 The blinding was maintained through the design of a sealable research form. Both nurses were instructed to complete their assessment and seal the form prior to collection.Finally, the expert nurse undertook a second visit and completed the PURPOSE-T and recorded clinically relevant changes to the patient’s condition since the baseline assessment. The PURPOSE-T assessment was carried out blind to the baseline assessment, again maintained through the sealed research form.The length of the test–retest interval was planned to be short enough to ensure that clinical change in the pressure ulcer was unlikely to occur but sufficiently long to ensure that the expert nurse did not recall his or her responses from the first assessment. Nurses were asked to plan their retest visit between 1 and 3 days after the baseline visit for hospital patients and between 1 and 7 days after the baseline visit for community patients, taking into account the anticipated recovery/deterioration/stability of each patient’s condition and, for hospital patients, length of stay.The expert nurses involved in data collection also kept field notes of their experience of using the PURPOSE-T in clinical practice.The PURPOSE-T identifies three groups of patients: those patients who are not currently at risk of developing a pressure ulcer, those patients who have no pressure ulcer but who are ‘at risk’ and require primary prevention and those patients with an existing pressure ulcer/scar who require secondary prevention/treatment. For the purposes of describing the study population and to assess convergent validity with other risk assessment tools, ‘at risk’ is defined as all patients ‘who have no pressure ulcer but who are at risk’ and all patients who have a ‘pressure ulcer category 1 or above or scarring from previous pressure ulcers’. A patient is therefore defined as ‘not at risk’ if his or her outcome within the raw data was recorded as ‘no pressure ulcer not currently at risk’. The cut-point used to identify patients at risk was ≤ 18 for the Braden scale193 and ≥ 10 for the Waterlow scale.50In the study population we aimed to recruit approximately 25% of patients ‘not at risk’ and 75% ‘at risk’. In a two-rater study, the numbers of subjects required to detect a statistically significant kappa (two-sided p-value ≤ 0.05) with 90% power and 75% assessed as being ‘at risk’, assuming a null hypothesis value for kappa, are given in Table 39.To establish whether the tool gives a high degree of beyond-chance agreement, we tested against a null value of 0.6. With 90% power, 199 patients were required. To allow for withdrawal/non-compliance in paired assessments of 15%, we aimed to recruit 230 patients.No examples of formal sample size estimation methods for the evaluation of screening instruments were identified in the literature. Therefore, literature relating to the psychometric evaluation of rating scales was considered. The ‘rule of thumb’ recommendation of 5–10 patients for every item in a questionnaire was used to estimate the sample size of 115–230 patients.194,195 The proposed sample size of 230 to assess the inter-rater reliability of the instrument, with > 95% expert nurse data compliance (based on previous research experience), was expected to provide a sufficient number of patients to assess the validity of the risk assessment instrument.Data completeness was assessed for each element of the PURPOSE-T including the percentage of missing item-level data and risk categories allocated.We produced kappa (with 95% CI), prevalence-adjusted bias-adjusted kappa (PABAK) and the maximum value of kappa (κmax.) statistics to assess the inter-rater and test–retest reliability for agreement of risk status overall (i.e. at risk/not at risk); cross-tabulations of overall risk status by rater/retest were produced. We also examined the extent of agreement for individual PURPOSE-T items using cross-tabulations by type of rater/retest. In addition, we produced kappa (with 95% CI) and weighted kappa statistics to assess the inter-rater reliability for agreement of the PURPOSE-T outcome on the 3-point scale (no risk, at risk, current pressure ulcer or pressure ulcer scarring) and produced cross-tabulations of PURPOSE-T outcome by type of rater/retest. We used guidelines to interpret kappa analysis as detailed in Table 40.196,197Table 41 details the psychometric tests undertaken. Convergent validity assesses the degree to which constructs (or scores on a measure) expected to be related are, in fact, related. The degree to which assessment of ‘at risk’ and ‘not at risk’ is related to risk assessment status as assessed using the Braden and Waterlow risk assessment scales was determined, using cross-tabulations.In addition, cross-tabulations of corresponding items between the PURPOSE-T and the Braden scale and/or the Waterlow scale were produced and correlation coefficients were calculated. The Spearman rank correlation coefficient was used when each of the items being compared had more than two levels, for example the Braden activity and Braden mobility subscales each have four levels and were both compared with the PURPOSE-T analysis of independent movement (which had been reduced to a 3-point scale). The phi correlation coefficient was calculated when dichotomous variables were compared, for example risk status on the Braden scale compared with risk status on the PURPOSE-T. For exploratory purposes, the following hypotheses were used as guides to the magnitude of correlations, as opposed to pass/fail benchmarks: high correlation r > 0.7; moderate correlation r = 0.3–0.7; low correlation r 90%. The inter-rater and test–retest agreement was ‘very good’ for the assessment decision overall as determined by kappa. The percentage agreement for the assessment of ‘problem/no problem’ for the eight risk factors (mobility, skin, previous pressure ulcer, sensory perception, perfusion, nutrition, moisture and diabetes) ranged from 79.1% to 94.2% for inter-rater reliability and from 87.0% to 93.9% for test–retest reliability. Moderate to high associations were demonstrated for convergent validity, assessed by comparison with the same or similar constructs on other risk assessment scales (Braden and Waterlow). A known group comparison was not possible because of the small number of patients recruited from elective wards. In addition, field notes recorded by the expert nurses highlighted positive and problem aspects of using the tool in the clinical environment. Negative aspects included difficulties in assessing some of the PURPOSE-T items and concerns about reliability, but these were not evidenced in the formal evaluation of inter-rater and test–retest reliability.It is of note that both expert and ward/community nurses allocated the majority of patients (> 95%) to the ‘not at risk’ category, with only ‘yellow’ and ‘blue’ boxes completed (see Tables 45–47). This means that these patients did not have skin, sensory perception, perfusion or major mobility problems but were characterised by minor mobility limitations with or without nutritional deficits, moisture problems or a history of previous pressure ulcers (with no scar). This is interesting because these factors do not emerge consistently in multivariable modelling (see Phase 1: Systematic review of patient risk factors for pressure ulcer development, Emerging risk factor domains/subdomains), were still judged to be important in the consensus development process, but colour coded as ‘yellow’ (i.e. requiring clinical judgement). It may be that in practice they are judged to be not important in the absence of the other key risk factors. The next stage of the development process will involve the dissemination of the PURPOSE-T into routine NHS care and this will facilitate large-scale multivariable modelling and predictive validity testing, allowing further refinement of the tool.The main differences between the PURPOSE-T and other widely used risk assessment tools are as follows:a risk factor Minimum Data Set is incorporated to facilitate multivariable modellinginvolves a screening stage for all patients and a full assessment stage for those at potential/actual risk or with an existing pressure ulcer. This allows those who are obviously not at risk to be quickly identified, preventing the need for a more detailed full assessment, which will save time in clinical practicea risk profile is identified for each patient (rather than a score condensed from different aspects of risk) to support care planning, with interventions selected in response to specific risk factorsthere is incorporation of the symptom of pain as a risk factorcolour is used to aid decision-makingthere is a clear distinction between primary and secondary prevention: patients with an existing pressure ulcer or scarring from a previous ulcer are allocated to a secondary prevention and treatment pathway. This has the potential to facilitate escalation of interventions to prevent deterioration in existing pressure ulcers and promote healingdevelopment was based on a systematic review of the risk factor evidence and the pain cohort studydevelopment involved international and interdisciplinary experts in the fieldthe tool was developed in partnership with service users.Pressure Ulcer Research Service User Network UK members have been involved at various stages throughout this work package:involvement in the consensus study (with particular emphasis on the acceptability of pressure ulcer risk assessment elements for patients)contribution to the development of the case studies for the Risk Assessment Framework pre-test studyreviewing the Risk Assessment Framework following the pre-testsupporting the development of the Risk Assessment Framework clinical evaluation study, particularly relating to the development of patient information leaflets.This project has provided some specific examples of the impact of PPI. The impact can be clearly seen in changes that were made to the Risk Assessment Framework as a direct result of PURSUN UK members’ input, such as the exclusion of albumin, the inclusion of pain and a previous severe pressure ulcer and changes to the wording of the sensory perception domain. PURSUN UK members also highlighted the need to adapt the Risk Assessment Framework so that it can be used by patients and carers at home. This is being incorporated into our next programme of work.The risk assessment work package comprising a systematic review of pressure ulcer risk factors, consensus study, conceptual framework development, design and pre-test and clinical evaluation led to the development and validation of a new Risk Assessment Framework, the PURPOSE-T [see (accessed July 2015)], with an underpinning risk factor Minimum Data Set. The PURPOSE-T comprises two stages of assessment, the screening stage for all patients and the full assessment stage for patients at potential/actual risk or with an existing pressure ulcer. It facilitates the identification of a risk profile rather than a condensed score and allows patient to be allocated to a not currently at risk, primary prevention (at risk) or secondary prevention and treatment pathway (existing pressure ulcer or scarring from a previous pressure ulcer). The next stage of the development process will involve dissemination of the PURPOSE-T into routine NHS care, which will facilitate large-scale multivariable modelling and predictive validity testing, allowing refinement of the tool. The conceptual framework also provides a foundation for a programme of bioengineering and translational research to develop improved assessment techniques with greater precision for clinical use. The work package makes a key contribution to the pressure ulcer field and has the potential to directly impact risk assessment in clinical practice. The research methodologies utilised may also have a broader application to other relevant areas of health-care research.

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