NB: This study protocol (version 2, dated 14 September 2010) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, funding, and publication policy are available upon request

4.1 Study aims

This study aims to:

1. Agree a Pressure Ulcer Minimum Data Set (PU-MDS)
2. Develop an evidence based Pressure Ulcer Risk Assessment Framework (PURAF) for use in clinical practice.

5 STUDY DESIGN

5.1. Overview of Study Design

This study will utilise structured consensus methods and will be underpinned by a PU risk factor systematic review (Nixon et al) and emerging evidence from the PURPOSE studies.

5.2 Overview of Consensus Process

ASPECT		Month	Event	Activity
PU-MDS		Sept 2010	Working Group	Pre nominal group work-up: • Identify specific issues to be examined • Methodologist review and synthesis research evidence • Develop and pilot questionnaire #1A
PU-MDS		Oct/ Nov 2010	PU-MDS Nominal Group (Meeting 1)	Pre-meeting: NG members complete questionnaire #1A
PU-MDS		Nov/ Dec 2010		At meeting • Present results of review of evidence synthesis • Presentation of results of questionnaire #1A

				• Exploration of areas of disagreement
PU-MDS		Dec 2010		After meeting • Revise questionnaire (#1A →#1B) and NG members complete questionnaire #1B
PU-MDS		Jan/ Feb 2011	Consultation	Wider international completions of questionnaire #1B by a sample of approximately 200 researchers and clinicians recruited via PU/ Wound care Organisations.
	PURAF	March 2011	Working Group	Pre nominal group work-up: • Identify specific issues to be examined • Methodologist review and synthesis research evidence • Develop and pilot questionnaire #2A
PU-MDS		March 2011	PU-MDS Nominal Group (Meeting 2)	Pre-meeting: collate results of questionnaire #1B
PU-MDS		May 2011 (same day as 1st PURAF meeting)		At meeting • Presentation of results of questionnaire #1B • Exploration of areas of disagreement • Agreement of final PU-MDS
	PURAF	April 2011	PURAF Nominal Group (Meeting 1)	Pre-meeting: NG members complete questionnaire #2A
	PURAF	May 2011 (same day as 2nd PU-MDS meeting)		At meeting • Present results of review of evidence synthesis • Presentation of results of questionnaire #2A • Exploration of areas of disagreement
	PURAF	May/ June 2011		After meeting • Revise questionnaire (#2A →#2B) and NG members complete #2B
	PURAF	June/ July 2011	Consultation	Wider international completions of questionnaire #2B by a sample of approximately 200 researchers and clinicians recruited via PU/ Wound care

				Organisations.
	PURAF	August –Nov 2011	PURAF Nominal Group (Meeting 2)	Pre meeting: Collation of results of questionnaire #2B
	PURAF	Nov/ Dec 2011		At meeting • Presentation of results of questionnaire • Exploration of areas of disagreement • Agreement of final PURAF

5.3 PU-MDS Development

Using the evidence from the PU risk factor systematic review (Nixon et al) and emerging evidence from the other PURPOSE programme studies a questionnaire will be developed by the working group to elicit the views of the PU-MDS nominal group members in relation to data items for inclusion in the PU-MDS. The nominal group will comprise 12-14 key stakeholders/ experts in the area of PU risk / development / research / practice and they will be asked to complete the questionnaire (#1A) after reviewing a summary of the PU risk factor systematic review.

The PU- MDS nominal group will then have a series of two face to face meetings which will be carefully led by experienced facilitators and will be observed, audio taped and transcribed to allow thematic analysis of issues affecting final ratings. The terms of reference will be fully articulated at each meeting.

The first meeting will allow the initial questionnaire (#1A) results to be presented to the group and areas of disagreement discussed and explored. The questionnaire will be revised following the meeting (#1B) and the nominal group members will be invited to re-complete the questionnaire privately which will determine the levels of consensus within the group in relation to the criteria for inclusion in the PU-MDS. The purpose of the questionnaire is to find out what items experts think are required in a minimum data set (MDS), using the systematic review data as the initial list of possible items.

Prior to the second nominal group meeting the PU-MDS questionnaire #1B will be administered, via a web-based survey tool to a wider representative group to test the consensus views of the nominal group in relation to the factors for inclusion in a PU-MDS.

We aim to recruit 200 researchers and clinicians to be involved in this part of the study. Participants will have access to the PU a summary of the systematic review as well as the nominal groups' views.

At the second nominal group meeting the results of questionnaire #1B, the wider PU-MDS consultation will be presented and discussed and the final PU-MDS will be agreed.

5.4 PURAF Development

Using evidence from the PU risk factor systematic review (Nixon et al), emerging evidence from the other PURPOSE programme studies and the results from the PU-MDS wider consultation the working group will develop a PURAF questionnaire to elicit the views of the PURAF nominal group members in relation to the value of key risk factors in both PU risk screening and detailed PU risk assessment. A similar staged process detailed as above will be adopted. The nominal group will complete questionnaire #2A in advance of the first PURAF nominal group meeting.

The first PURAF meeting will allow the initial questionnaire (#2A) results to be presented to the group and areas of disagreement discussed and explored. The questionnaire will be revised following the meeting (to form questionnaire #2B) and nominal group members will be invited to re-complete the questionnaire privately which will determine the levels of consensus within the group in relation to the components and format for PURAF.

Prior to the second nominal group meeting the PURAF questionnaire #2B will be administered via a web-based survey tool to a wider group to test the consensus views of the nominal group in relation to the components and format for the PURAF. We aim to recruit 200 researchers and clinicians to be involved in this part of the study. Participants will have access to the PU risk factor systematic review summary report as well the nominal groups' views.

At the second nominal group meeting the results of the wider PU-MDS consultation will be presented and discussed and the final PURAF will be agreed.

6 STUDY PARTICIPANTS

6.1 Nominal Group Membership

Nominal group members will be purposively sampled ensuring representation of researchers and clinicians with expertise in the following areas:

- Vascular/ perfusion/ diabetes
- Nutrition
- Biomedicine
- Dermatology
- Minimum Data Set
- Psychology
- Pressure ulcer research
- Tissue Viability
- Statistics
- Organisational Development
- Software engineering

The role of the PU-MDS nominal group is to agree a PU-MDS. The role of the PURAF nominal group is to develop an evidence based PURAF.

6.2 Working Group Membership

The working group will comprise of PURPOSE PU academic and clinical leaders including Jane Nixon (Chief Investigator), Susanne Coleman (Project Lead/ researcher), Andrea Nelson (multi-centre health services research) Carol Dealey, Lyn Wilson, Elizabeth McGinnis, and Nikki Stubbs (clinical expertise) and Michelle Collinson and Julia Brown (statistical expertise). The role of this group is to support the nominal group to identify specific issues to be examined, to develop questionnaires and to synthesis research evidence for consideration.

6.3 Wider Consultation Participants

The wider consultation participants will include individuals with similar expertise of the nominal group members as well as clinical users. They will not be required to attend face to face meetings. This group will allow the consensus views of the nominal groups to be tested by a larger group

7 RECRUITMENT AND CONSENT PROCEDURES

7.1 Nominal Group Participant

Potential PU-MDS and PURAF nominal group participants will be identified via the literature pertaining to pressure ulcers and/or membership of pressure ulcer related professional organisations, including the Tissue Viability Society, European Pressure Ulcer Advisory Panel, the National Pressure Ulcer Advisory Panel, Japanese Society of Pressure Ulcers and the Australian Wound Management Association. They will be approached by email and sent a nominal group participation information sheet and asked if they would be interested in participating in the research. This will be followed up by further email correspondence or a telephone discussion if required by the potential participants where they have any questions he/ she would like the researcher to answer regarding the implications of the research. After this should they wish to participate they will be asked to provide consent by returning a Word Document containing their electronic signature. They will be free to withdraw their participation at any time including before, during or after nominal group meetings and before, during or after questionnaire completion.

7.2 Wider Consultation Participants

Wider participants will volunteer their participation in the study in response to a general advert. Professional organisations will be approached and their associated journal editors and asked if they are able to advertise the research through their email contacts lists and journals. In addition, flyers and posters will be used at relevant conferences subject to organisational approval. The research will be advertised through a simple email communication, journal advertisements and presentations to professional/network groups Professional organisations including the UK Tissue Viability Society, European Pressure Ulcer Advisory Panel, the US National Pressure Ulcer Advisory Panel, Japanese Society of Pressure Ulcers and the Australian Wound Management Association. They will be approached by email correspondence through their usual ‘contact us’ mechanism and at no time will access to organisational membership be provided to the research team. Direct communication with members will be undertaken by the respective organisations using their local policies and procedures. Advertising materials will include a brief description of the study and a web link to the web-based survey platform which will host the participant information sheets, the summary PU risk factor systematic review and the questionnaire. Wider participants will be free to withdraw their participation at any time including during and after questionnaire completion.

8 DATA COLLECTION

8.1 Questionnaire Data Collection

Questionnaires will be completed via a commercial online survey platform. Nominal group participants and wider consultation participants will be sent an email link to the web-based questionnaire with supporting evidence and user friendly instructions of how to complete the questionnaire, as well as the timescale within which this should be undertaken. Following guidance from the HTA (2001) the questionnaire will be developed to comprise of generic risk factor stem questions preceded by related specific questions. The response options will utilise a 9 point Likert scale where 1 indicates strong disagreement and 9 indicates strong agreement, as well as a don't know option. The questionnaires will be tested prior to launch.

8.2 Nominal Group Meeting Data Collection

Nominal Group meetings will be observed, audio-taped and transcribed to allow thematic analysis of issues affecting final ratings.

9 STATISTICAL CONSIDERATIONS

Statistical analysis is the responsibility of the project lead. The analysis plan outlined in this section will be reviewed and a final statistical analysis plan will be written before any data summaries or analyses are performed. The analysis plan will be written in accordance with current CTRU Standard Operating Procedures and will be finalised and agreed by the following people: the study Statistician and Supervising Statistician, the Chief Investigator and the project lead. Any changes to the final analysis plan and reasons for change will be documented.

Nominal group and wider group participant ratings will be calculated by using the median response for each factor. Factors will be rated on the nine point Likert scale where 1 indicates strong disagreement and 9 indicates strong agreement. The extent of within group agreement for each group will be measured using the mean absolute deviation from the median. Participant demographics for both the nominal group and wider participants will be summarised using simple descriptive statistics.

10.2 Ethical Considerations

This study will recruit PU experts and clinicians. The related ethical issues are minimal and mainly relate to the time taken to complete questionnaire and/or attend audio-taped Nominal Group Meetings. There are no other forseen risks to participants. Informed consent will be obtained prior to nominal group participation in the study. The right of a potential participant to refuse without giving reasons will be respected. The patient will remain free to withdraw at any time from the study without giving reasons.

The study will be submitted to and approved by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC). The CTRU will provide SHREC with a copy of the final protocol, participant information sheets, consent forms and all other relevant study documentation.

16 REFERENCES

Bennet G, Dealey C, Posnett J (2004) The cost of pressure ulcers in the UK. age and Ageing. 33(3): 230-235

Cullum N, Deeks J, Fletcher A, Long A, Mouneimne H, Sheldon T, et al. 1995. The prevention and treatment of pressure sores: How effective are pressure-relieving interventions and risk assessment for the prevention and treatment of pressure sores? *Effective Health Care Bulletin.* 2(1) pp1-16.

Dalkey N and Helmer D. 1963. An experimental application of the Delphi method to the use of experts. Management Science 9, 458-467

Delbecq A and Van de Ven A. 1972. The Nominal Group as a Research Instrument for Explanatory Health Studies. Exploratory Health Studies.

Department for Education and Skills *(2006) Safeguarding Vulnerable Groups Bill,* London, The Stationery Office.

Department of Health (2000) *No Secrets: Guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse* [online] London. Department of Health. Available from: www.doh.gov.uk/scg/nosecrets.html

Department of Health. (2001a) *National Service Framework for Older People*. London, The Stationery Office.

Department of Health (2001b*) Essence of Care: Patient Focused Benchmarking for Health Care Professionals*. London, The Stationery Office.

Department of Health (2008) Using the Commissioning for quality and Innovation (CQUIN) Payment Framework for the NHS England. London.

Department of Health (2009) NHS 2010-2015, Good to Great, Preventative People Centred, Productive. The stationary Office, London.

Department of Health (2010) Clinical Governance and Adult Safeguarding. London.

European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel. Prevention and treatment of pressure ulcers: quick reference guide. Washington DC: National Pressure Ulcer Advisory Panel. 2009. Available from http://www.epuap.org/guidelines/Final_Quick_Prevention.pdf

Hutchings A, Raine R, Sanderson C and Black N. 2006. A Comparison of formal Consensus Methods Used for Developing Clinical Guidelines. Journal of Health Services Research Policy Vol 11, No 4.

Institute for Innovation and Improvement (2009) High Impact Actions for Nursing and Midwifery. London

Jackson A, Hettinga DM, Mead J, Mercer C. 2009. Using Consensus Methods in Developing Clinical Guidelines for Exercise in Managing Persistent Low Back Pain. Physiotherapy 94:302-313

Kadam U. Jordan K, Croft R. 2006. A comparison of Two Consensus Methods for Classifying Morbidities in a Group Showed the Same Outcomes. Journal of clinical Epidemiology 59:1169-1173

Kaltenthaler E, Whitfield MD, Walters SJ, Akehurst RL, Paisley S. 2001. UK, USA and Canada: how do their pressure ulcer prevalence and incidence data compare? *Journal of Wound Car.* 10(1), pp530-535.

National Institute for Health and Clinical Excellence (NICE). 2005. *Pressure ulcer management: The Management of pressure ulcers in primary and secondary care: A clinical Practice Guideline.* RCN.

McColl E, Jacoby A, /Thomas L, Soutter J, Bamford C, Steen N, et al. 2001. Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients. Health Technology Assessment. 5 (31)

Nixon J, Gorecki C, Nelson EA, Closs J, Defloor T, Halfens R, Worthy G, Schoonhoven L, Brown JM. Pressure Ulcer risk factors: a systematic review. *Wound Repair and Regeneration*. Submitted

Nixon J, McGough A. 2001. Principles of Patient Assessment: Screening for Pressure Ulcers and Potential Risk. In Morison M, ed. The Prevention and Treatment of Pressure Ulcers. Edinburgh: Mosby, pp55-74.

Raine R, Sanderson C, Black N. 2005. Developing clinical guidelines: a challenge to current methods. BMJ 331:631-633

Rycroft Malone J. 2001. Formal Consensus: the Development of a National Clinical Guideline

Safeguarding Vulnerable Groups Bill (2006), HL Bill 79.

Scott EA and Black. 1991. Appropriateness of Cholcystectomy in the UK – A Consensus Panel Approach. Gut 32:1066-1070

Sopher R, Nixon J, Gorecki C, Gefen A. (2010) Exposure to Internal Muscle Tissue Loads under the Ischial Tuberosities during Sitting is Elevated at Abnormally High or Low Body Mass Indices. Journal of Biomechanics 43(2):280-286.

The Mental Capacity Act (2005). MC Act, London, HMSO.