NB: This study protocol (version 3, dated 25 Jun 2008) is in a reduced format including only the study aims and methods. Sections pertaining to study background have been removed as they are included as a chapter section.

2. Study objectives

Ethics approval is sought to undertake Phase 1 development. The aim of this study is to undertake in-depth qualitative interviews with a sample of patients with PUs. The information obtained will be used to develop a conceptual framework of HRQL in PUs. This will complete the first phase of the PU-QOL measure development process.

The study objectives are:

1. To identify outcomes and HRQL issues which are relevant and important to patients with grade 1, superficial and severe PUs
2. To identify whether PROs and HRQL issues for patients with grade 1, superficial, and severe PUs are the same in relation to the impact of interventions.
3. To gain insight into the relative PU burden and what it is like to live with a PU

2.1. Study design

Development of a conceptual framework

In phase 1 of the health-outcome measure development process, the conceptual framework will be developed by utilising three sources; literature, patients, and experts in the field. A systematic review of qualitative and quantitative literature has been undertaken and from this, patient-reported themes associated with PU interventions and general issues associated with having a PU will be summarised and grouped into relevant HRQL domains. This will produce an exhaustive list (working framework) of relevant PROs that cover all HRQL domain(s) associated with PU occurrence, symptoms, and interventions. The working framework will be used for the development of an interview schedule for the qualitative interviews. Expert group review will be sought through all stages of the conceptual framework, interview schedule development, and data analysis stages.

Qualitative interviews

Each participant will be interviewed using an in-depth qualitative interview method following an interview schedule, in order to assess the impact of PUs and PU interventions on HRQL.

Up to 24 patients will be recruited from various hospitals around the UK. Each patient will be interviewed once and interviews will last approximately 1 hour. The interview will be discontinued at any time upon the patient's wishes. Interviews will consist of various probing questions to get the patient to reflect and to speak openly about their experience of having a PU. The patients will also be asked to comment and assess the importance of the HRQOL domains identified from the literature review. All interviews will be recorded.

The interviews will be conducted, recorded, and analysed by the primary researcher. The data will then be reviewed by the multidisciplinary expert group and discussed until a consensus view is achieved. This final process will produce a conceptual framework.

2.2. Inclusion/exclusion criteria

Patients with grade 1 (at-risk), superficial, and severe ulcers, from vascular, orthopaedic, medical, or care of the elderly wards, as well as patients in the community under the care of tissue viability nurse (TVN) specialists and consultants, and TVN teams, will be eligible to take part in the study.

Eligible patients will be included in the study if they fulfil the following criteria:

- understand and speak fluent English AND
- aged more than 18 years of age AND
- with current PU of any grade (1-4) (Table 1) OR
- had a PU grade 2-4 healed within the last 3 months AND
- able to share their experience in a thoughtful and reflective way AND
- able to give their written informed consent to take part

2.3. Recruitment & consent procedures

Patients will be purposively sampled (15-24 patients) ensuring balanced representation of patients in grade 1, superficial ulcer (grade 2) and severe ulcer (grade 3/4) categories. Consecutive patients will be identified from each PU category and approached to participate.

Recruitment will continue on a rolling basis until a minimum of five and maximum of eight patients from each PU group are recruited from the participating sites, and interviews undertaken. A sample size of up to 24 patients will allow for any initial changes to the interview schedule should they be required following the first few interviews.

Table 1 EPUAP pressure ulcer classification (EPUAP, Pressure ulcer treatment guidelines, 1999)

Grade 1	Non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.
Grade 2	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.
Grade 3	Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to but not through underlying fascia.
Grade 4	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.

TVNs at participating hospital and community services will identify potential patients. Those who meet the eligibility criteria will be approached, informed about the study, and provided with; 1) a project information sheet that includes details about the rationale, design, and personal implications of the study, and 2) an 'agree to be contacted by the researcher' form either to be contacted by telephone (PCT version) or visited at the ward (in-patient version).

Following information provision, patients will have as much time as they need to complete the "agree to researcher contact" form, which will be either faxed or posted back to the CTRU. The TVN, the researcher, and the research supervisor will be available to answer any questions that patients might have about the study. After receiving a signed agreement to be contacted form from the patient, the researcher will telephone the patient to arrange a time for the interview. The researcher will provide information about the study and interview process and will answer any questions before gaining verbal consent and arranging an interview at a mutually convenient time. For in-patients who cannot be contacted by telephone and who are expected to be in the hospital during the interview, with the patient's permission, the TVN will liaise with the researcher and patient to arrange a mutually convenient time for the researcher to see the patient on the ward to discuss the study further.

The researcher will interview patients in their own home, in the out-patient clinic, or in-patient ward, as determined by the patient's circumstances and preferences at the time of the interview. It is anticipated that a similar number of community and hospitalised patients will be interviewed. Before the interview, each participant will be given a further verbal explanation of the study by the researcher, informed that the interview will be recorded but that all identifiable information will remain anonymous, reminded that they can withdraw from the study at any time without it affecting their care, and then invited formally to participate. They will be given an opportunity to ask any questions and then if they agree to take part, the participant will be asked to sign the consent form. For any patients who may have difficulty in writing but who fully comprehend, a tape recording will be taken of the verbal agreement. All participants will be sent a thank you letter after the interview. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time, again, without giving reasons and without prejudicing any further treatment.

2.4. Data collection

Patients will be interviewed by the researcher using the patient interview schedule and guide. Details regarding the PU (i.e. PU grade, location, duration) and treatment will be requested verbally from the treating nurse. These in-depth qualitative interviews will be undertaken to establish the relative importance of HRQL domains and identify any omitted HRQL themes that are important to patients. Therefore, patients will be asked questions to get them to think about important HRQL issues and themes, comment on their subjective importance, and asked to reflect on their experience of the interventions they have received and what it is like or has been like to live with a PU.

2.5. Data analysis

Interviews will be recorded and transcribed verbatim as soon as possible following the interview. Preliminary analysis will be carried out after the first three patients have been interviewed to assess whether the interview schedules' HRQL domains compare with the emerging themes, and to identify any gaps in information. The expert group will be consulted and if deemed necessary the HRQL domains will be developed and changed as data collection progresses. Theoretical thematic analysis will be used to analyse and report

themes from the data by the researcher. Upon completion of the data analysis, a provisional report will be sent to the expert group to provide clarification and to ensure the research remains participative.

The working framework and information gathered from the qualitative interviews will formulate a conceptual framework which will be used to generate items for the PUQ-OL instrument. The following information will be sought from the interview:

- how does having a PU impact on life from the perspective of the sufferer
- what are all the HRQL issues important to PU patients and do patients find some HRQL issues more important than others
- how do PU interventions impact on patient HRQL
- what do patients feel are important intervention outcomes
- gain an understanding of the way patients define small, medium and large differences
- how important is it to patients to have HRQL issues addressed as part of their healthcare; do they think that this should be incorporated into PU management

3. Confidentiality

Any information which would allow individual participants, healthcare professionals, or wards to be identified will not be released. All the participating hospitals, community services, and the CTRU at the University of Leeds will comply with all aspects of the Data Protection Act 1998. All participants will be assigned a project number on recruitment, and confidentiality and anonymity will be maintained throughout the duration of the project and in the dissemination of results.

4. Ethical considerations

This study will recruit patients with PUs and therefore will include elderly and highly dependent patients considered as vulnerable. Clinically, older patients are treated in the same way as younger patients and it is therefore important to ensure that the study is representative of the clinical population. The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and include a thought out consent process, the use of one-to-one semi-structured interviews, and the use of experienced researchers able to provide a flexible and supportive interview environment.

This project will be conducted in accordance with the Declaration of Helsinki in its latest form. The study will be submitted to and approved by a Research Ethics Committee (REC) prior to identifying eligible patients. The CTRU will provide the REC with a copy of the final protocol, patient information sheets, consent forms, and interview schedule and guide.