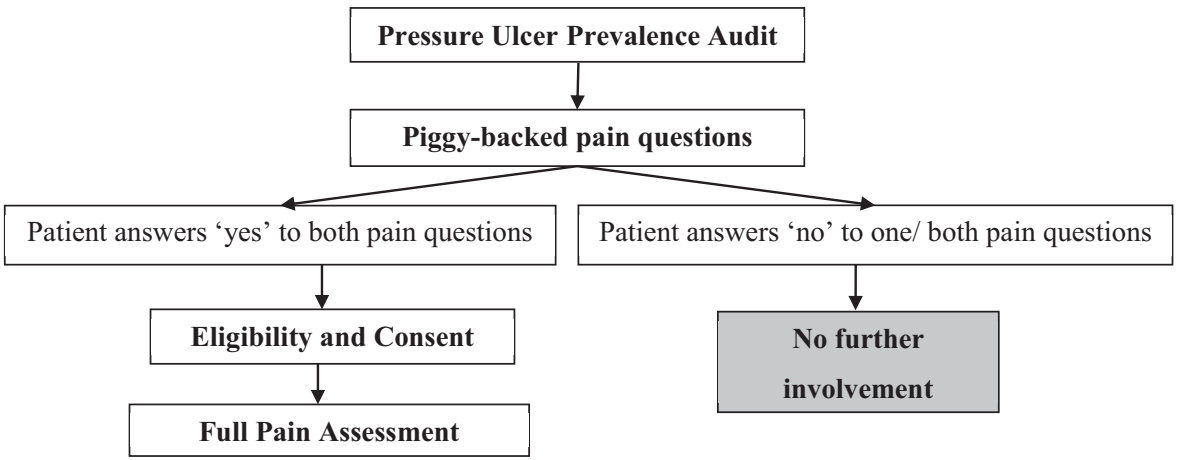
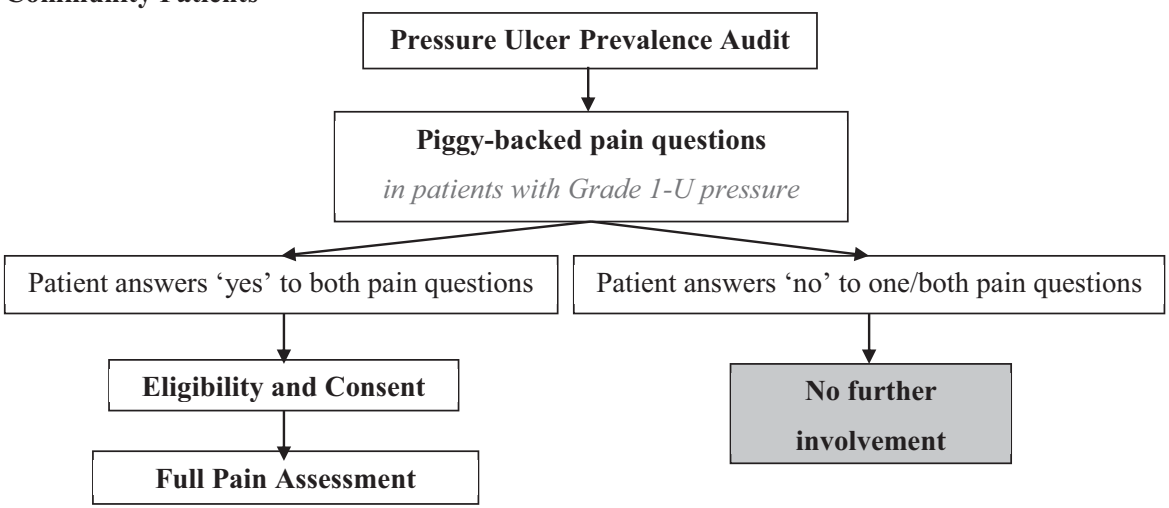
NB: This study protocol (version 3, dated 18 Jan 2010) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to serious adverse events, data monitoring, quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, and publication policy are available upon request

3 Flow diagram

Hospital Patients



Community Patients



5 Objectives

The objectives of this study are to:

1. determine the prevalence of localised PU pain in 'pressure areas'.
2. assess the type and severity of localised PU pain in 'pressure areas' in patients with clinically assessed normal skin and Grade 1-U PUs (see Table 1)
3. explore the association between pain and skin classification.

Table 1. EPUAP Pressure Ulcer Classification System[4]. For the purpose of the research the classification has been adapted to enable grading of normal skin and unstageable pressure ulcers.

Grade	Description
Grade 0	Normal skin
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.
Grade U	Unstageable. Full thickness skin loss in which *actual* depth of the ulcer is *completely* obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

6 Methods

6.1 Design

We plan to undertake pain prevalence surveys in acute and community NHS Trusts. We will piggy-back questions on pain onto the routine annual PU prevalence audits in NHS Trusts. Anonymised individual patient data is recorded by a ward/community nurse. In addition to the standard PU data, patients will be asked two questions relating to localised skin pain to establish PU pain prevalence. Where pain is indicated, consenting patients will undergo a detailed pain assessment using the adapted Leeds Assessment of Neuropathic Symptoms and

Signs (LANSS) Pain Scale (Appendix 2)[8,9] and a numerical rating scale for pain severity[10,11]. Skin classification will also be verified. This will establish the type and severity of localised PU pain and skin classification.

6.2 Eligibility

6.2.1 Routine PU Prevalence Audit

As per standard PU prevalence audit methodology all inpatients/community nursing case-load patients on the date or period of the participating Trust's PU prevalence audit that are 18 years of age or older are included. Patients in paediatric, obstetric, and psychiatric care settings will be excluded.

6.2.2 PU Pain Prevalence Audit – Hospital

Patients will be eligible for the two pain questions where they are considered well and able to report the presence or absence of localised skin pain, by the clinical team. Patients will be excluded from the two pain questions where it is considered ethically or clinically inappropriate by the clinical team, for example, very sick patients or those where death is imminent.

6.2.3 PU Pain Prevalence Audit – Community

Patients will be eligible for the two pain questions where they have a skin area assessed as a Grade 1-U pressure ulcer and are considered well and able to report the presence or absence of localised skin pain, by the clinical team. Patients will be excluded from the two pain questions where it is considered ethically or clinically inappropriate by the clinical team, for example, very sick patients or those where death is imminent.

6.2.4 Full Pain and Skin Assessment

Patients who reply 'yes' to both pain prevalence questions will be eligible for the full pain and skin assessment. Patients will be excluded where it is considered ethically or clinically inappropriate by the clinical team, for example, very sick patients or those where death is imminent. Patients will also be excluded if they are unable to provide consent.

6.3 Assessments and Data Collection

6.3.1 Routine PU Prevalence Audit

Standard practice for the PU prevalence audit will be used to assess and record data. Anonymised individual patient data will be recorded by a ward/community nurse who is trained in the use of the data collection form and skin assessment as part of the PU prevalence audit preparation and planning. In the hospital setting all patients are assessed on one designated day. In the community setting all patients are assessed over a one-two week period.

Data recorded will include:

- Name of Trust
- Ward Speciality/Community Setting
- Date of birth
- Gender
- Ethnicity
- Height
- Weight
- Mobility
- Risk Assessment Scale (as per local policy)
- Skin classification by skin site
- Hospital or community acquired
- Present on this hospital admission/community referral
- Prevention/treatment interventions

6.3.2 PU Pain Prevalence Audit

In addition, the ward/community nurse will consider whether each patient is well and able to report the presence or absence of localised skin pain. Where patients are assessed as not able to report pain this will be noted. Patients assessed as able will be asked the following two questions:

1. At any time, do you get pain, soreness, or discomfort on a pressure area? (*Prompt*: back, bottoms, hips, elbows, heels, or other as applicable to patient.)?
2. Do you think this is related to either: your pressure sore OR laying in bed for a long time OR sitting for a long time?

6.3.3 Full Pain and Skin Assessment

Patients who reply ‘yes’ to both of the pain prevalence questions will be flagged to a member of the Trust Tissue Viability Team (TVT; Tissue Viability Nurse

Consultant/Specialist/Research Nurse), and, subject to their consent, will have a full pain assessment and verification of skin assessment.

Patients will be asked about pain for all pressure area sites using a numerical rating scale[8,9] for pain intensity (for most severe pain over the past week).

Up to two skin areas will be assessed using the Leeds Assessment Neuropathic Symptoms and Signs (LANSS) Pain Scale[10,11] (Appendix 2). The LANSS Scale[10] (Appendix 2) consists of a brief clinical assessment and is easy to score in the clinical setting. The questionnaire contains 5 symptom items and 2 clinical sensory testing items associated with neuropathic pain. The LANSS is a clinically validated tool which allows assessment of neuropathic and inflammatory pain, and has been used in a wide variety of clinical settings[11]. The two sites assessed using the LANSS will include the most painful skin site located on the torso (i.e. sacrum, buttocks, ischial tuberosities, hips) and the most painful site located on a limb (i.e. heels, elbows).

In addition patients will be asked if they have been offered any treatment for pain. Skin assessments undertaken by the ward/community nurse for the PU prevalence audit will be verified through nursing records or clinical assessment by the Trust TVT member.

6.4 Consent

6.4.1 Routine PU and PU Pain Prevalence Audit

Anonymised data from all patients will be collected as part of the PU and PU pain prevalence audit, and consent will not be obtained.

6.4.2 Full Pain and Skin Assessment

Patients responding 'yes' to the two pain prevalence questions (section 6.3.2) will be provided with verbal and written details about the more detailed pain assessment and will be asked to provide consent for this study. The verbal explanation of the study and Patient Information Sheet and Consent Form will be provided by the attending clinical staff or a member of the Trust TVT for the patient to consider. This will include detailed information about the rationale, design, and personal implications of the study. Following information provision, patients will have as long as they need to consider participation and will be given the opportunity to discuss the study with their family and other healthcare professionals before they are asked whether they would be willing to take part in the study.

Patients will then be invited to provide informed, written consent. A record of the consent process detailing the date of consent will be kept in the patient healthcare records. Assessment of eligibility and informed consent will usually be undertaken by a member of the Trust TVT. 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 without giving reasons and without prejudicing any further treatment.

Should the patient be capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent should be obtained using the Witnessed Consent Form. An appropriate witness would be a family member or friend of the patient, or another member of the patient's healthcare team who is not directly involved in the research study.

The original consent form will be retained in the Investigator Site File, a copy of the consent will be given to the patient and a second copy filed in the patient healthcare notes.

6.4.3 Non-participation

An anonymised log of all patients who are considered for full pain assessment but who do not participate will be collected, including reason for non-participation.

7 Statistical Considerations

7.1 Sample size

Our aim in this study is to assess the prevalence of PU pain in hospital and community patient populations. We will piggy-back this work onto routine PU prevalence surveys in a minimum of 2 acute and 2 community NHS Trusts (2,000 hospital and 6,000 community patients) therefore an approximate number of 8,000 patients is planned for the PU prevalence audit.

It is estimated that the prevalence of PUs in hospital patients is 10% and in community patients 5%; 30% of these are patients with Grade 2-U PUs and we estimate that 25-50% of these patients will report localised PU pain; the remaining 70% of patients have a Grade 1 PU, and we estimate that between 5-20% of these patients will report PU pain[3,5]. Of the remaining 90% hospital and 95% community patients without PUs, we estimate that localised skin pain may be reported in 2.5-5% of patients. Based on these assumptions, we estimate that between 259 and 555 patients will report localised PU-related pain (see Table 2, over page), i.e. that 3-7% of patients will report localised skin pain on a pressure area.

A sample of 8,000 patients will enable us to estimate a pain prevalence of 3% to within ± 0.38% (n = 7,742) and a pain prevalence of 7% to within ± 0.56% (n = 7,975).

8 Statistical Analysis

8.1 General Considerations

Statistical analysis is the responsibility of the CTRU Statistician. 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 (SOPs) and will be finalised and agreed by the following people: Trial Statistician, Supervising Statistician, Chief Investigator, Senior Trial Manager, and Programme Manager. Any changes to the final analysis plan and reasons for change will be documented.

Table 2: Estimated number of patients with PU pain

Setting	Pressure ulcer (PU) status		Pain	
			n	%
Hospital (n = 2,000)	No PU (90%; n = 1,800)		45-90	2.5-5%
	PU (10%; n = 200)	Grade 1 (70%; n = 140)	14-42	10-30%
		Grade 2-4 (30%; n = 60)	15-30	25-50%
Community (n = 6,000)	No PU (95%; n = 5,700)		142-285	2.5-5%
	PU (5%; n = 300)	Grade 1 (70%; n = 210)	21-63	10-30%
		Grade 2-4 (30%; n = 90)	22-45	25-50%

8.2 Routine PU Prevalence Audit

Standard PU prevalence results and analysis as per usual practice will be provided to each participating centre and will include the overall prevalence of PU by grade, risk profile, age, department and gender.

8.3 PU Pain Prevalence Audit

The proportion of patients reporting localised skin pain will be summarised for the overall population and for each acute/community Trust.

8.4 Full Pain and Skin Assessment

For those patients reporting pain and undergoing further assessment, the intensity and type of pain (whether neuropathic or nociceptive) will be summarised using means and standard deviations, or percentages and 95% confidence intervals, by skin site (e.g. sacrum, buttocks, heels) and skin classification at that site.

11.2 Ethical Considerations

This project will assess all hospital and community nursing patients including those with PUs and therefore will include elderly and highly dependent patients considered as vulnerable. Ethical issues are largely related to the involvement of vulnerable adults/elderly patients with high levels of co-morbidity including acute and chronic illness. The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and include piggy-backing the pain prevalence onto routine PU prevalence surveys and the use of local staff including experienced nurses and members of the Trust TVT to assess patients. The study will be submitted to and be 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 leaflets, consent forms, and all other relevant study documentation.

16 References

(4) European Pressure Ulcer Advisory Panel (EPUAP) Pressure Ulcer Treatment Guidelines (1998). http://www.epuap.org/gltreatment.html (accessed 23/01/2008).

(8) Royal College of Physicians, British Geriatrics Society and British Pain Society. The assessment of pain in older people: national guidelines. Concise guidance to good practice series, No 8. London: RCP, 2007.

(9) Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations. The Journal of Pain 2008; 9(2): 105-121.

(10) Bennett M. The LANSS Pain Scale: The Leeds assessment of neuropathic symptoms and signs. Pain 2001; 92(1-2): 147-157.

(11) Briggs M, Bennett MI, Closs SJ, Cocks K. Painful leg ulceration: a prospective, longitudinal cohort study. Wound Repair and Regereration 2007; 15(2): 186-191.

Appendix 2: The LANSS Pain Scale

Leeds Assessment of Neuropathic Symptoms and Signs[10] (with adaptations)[11]

[NB: The LANSS scale was collected however the scale is omitted due to copyright. The LANSS scale can be obtained from: Bennett M. The LANSS Pain Scale: The Leeds assessment of neuropathic symptoms and signs. Pain 2001; 92(1-2): 147-157].