NB: This study protocol (version 3, dated 4 Feb 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 confidentiality, archiving, statement of indemnity, study organisational structure, publication policy, and dissemination are available upon request.

4 AIMS

The aim of the research study is to identify the unexplained reasons which may contribute to the development of severe pressure ulcers, using innovative methods of investigation (Vaughan, 1996; Perrow, 1984; Waring et al., 2006; Pawson, 2006; 2008).

5 STUDY DESIGN

5.1 Brief Overview

Following a similar approach to a public Inquiry (e.g. the tragic case of Victoria Climbié or the Bristol heart babies inquiry) the study will use a retrospective case study approach (Ragin, 2000). This involves examining patients with severe (Category 3 and 4) pressure ulcers, starting at the point where they have already developed. This study will seek to explain which *non-clinical* influences could lead to a patient developing a Category 3 and 4 pressure ulcer.

5.2.1 Stage 1

This first stage will involve identifying one person who presents unexpectedly with a Category 3 or 4 pressure ulcer according to the TVT (see Nixon et al, 2007). It may be that the person has few known clinical risk factors for developing a severe pressure ulcer, yet develops one. The reason for choosing such a patient is that multiple clinical risks of developing a severe pressure ulcer may mask any underlying non-clinical influences. Therefore the aim is to keep clinical risk factors to a minimum at this stage.

The overall purpose is to create a coherent account of what happens during the development of a severe (Category 3 or 4) pressure ulcer. By ‘coherent account’ we mean one which makes the best sense of available, yet relevant evidence, similar in nature to the process

police use when they build evidence against a suspect. We will sift through the accumulated evidence (environmental, individual and so forth), and look for other 'clues' about what may have a bearing on the person's developing a Category 3 and 4 pressure ulcer. This will involve retrospective searching of a person's care 'pathway', firstly talking to a patient about his or her experience of care from the start of the pressure ulcer, and searching all relevant healthcare documentation, to start to produce a coherent account.

We will also talk to other people involved in a patient's care pathway, such as informal and professional carers, nurses, and other relevant people, gaining their personal experience of the development of the severe pressure ulcer. This further information will help consolidate the coherence account as more evidence is uncovered. A timeline of events and a narrative chronology will be used to help with searching, and provide a basis to compare further patient experiences. This stage will conclude with *tentative hypotheses* about non-clinical explanations, such as we might find that a patient moving around different services seems to have an impact on their developing a Category 3 or 4 pressure ulcer, and this would then be a tentative hypothesis. We will provide feedback, and work closely with the Tissue Viability Team, to make sure the tentative hypotheses remain relevant to practice.

5.2.2 Stage 2

In our first protocol (v1.0) we proposed that we would develop the method as we carried out the research (see Section 8.1 Developing the method). While carrying out Stage 1, we found there were areas of potential bias which need addressing, and this has meant slight changes to the design of the study, collecting the data in a slightly different manner, and analysing the data differently.

We have identified a need for:

a) Closer professional involvement to help guide data collection
b) An expert panel to provide feedback on evidence.
c) A 'good usual care' account to balance the data

Methodology

After initial case note review, interview data collection and documentary analysis, the researcher will feed back findings at length to an on-site Principal Investigator (PI), who will conduct a parallel case note review and look over the initial patient interview. This will help

to interpret the data with expert advice. The researcher will then collect further data, which will be discussed again with the PI. This process will help the researcher construct a fully 'coherent account' of how the pressure ulcer developed, which will remain grounded in practice and informed by professional judgement.

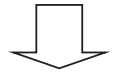
Stages of expert involvement in the research process:

Stage A (which is iterative, and stages can be repeated)

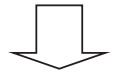
Data collection Patient interview/patient notes (researcher)

Parallel case note review by researcher and site principal investigator (PI)

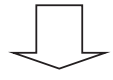
Researcher discusses data collection with Site Principal Investigator



Researcher gathers more data, anonymises and builds coherent account in collaboration with PI



Coherent account overseen by subgroup (n=3) consisting of two TVNs (not onsite PI: one hospital TVN; one community TVN) and one non-clinical academic



Sub group comments incorporated into account

Coherent account overseen by Chief Investigators of project team (n=2). Comments incorporated into account.

The account will then be overseen by the Chief Investigators, who will help to create a final version of a coherent account of the second, and further cases, and limit any researcher bias as far as possible.

At this point the data will be anonymised according to Leeds University Clinical Trials Research Unit guidelines on data confidentiality. The data will then be encrypted for further security, and to allow access by the rest of the research team. The anonymised and encrypted

coherent account of the first case will then be presented to a further panel of experts (which consists of two tissue viability nurse specialists and a non-clinical academic), who do not have direct clinical involvement with the patient. They will check the account for validity using evidence from the documentation, and their comments will be incorporated. This will help avoid individual researcher bias and provide a transparent trail of evidence (Yin, 1994).

'Good usual care' account

For all cases after Patient 1, we have chosen to combat some of the sources of bias, by constructing an account of 'good usual care'. This normative account will provide a benchmark against which the care of the patients in the study can be judged. The 'good usual care' account will also provide a way of minimising effects of bias i.e.:

i) Clinicians' beliefs
ii) PURPOSE team beliefs
iii) Weighting of different perspectives in patient accounts
iv) Hindsight bias

The account will:

1. Draw on national guidance such as the NICE guidelines key recommendations (RCN, 2001; 2005).
2. Include a summary of local site protocol recommendations as set out by the site Tissue Viability Nurse.
3. Include information not available from points 1 and 2, which incorporates information from Tissue Viability Nurse specialists as expert witnesses, and further information from interviews with various stakeholders.
4. Be mapped against the actual chronological events within a case to look for points of commonality and for events which do not meet the 'good usual care' criteria.

Please see below for a summarised example account strategy, as it would be mapped against actual chronological events. The account will be more detailed, and consists of two tables, one which incorporates key events by data source, and these are then cross referenced to our external judgement criteria table:

Source of data (below)	**Time 1**	**Time 2**	**Time 3**

	30 March 2009 (patient notes)	2 April 7pm	2 April 9pm
Patient/nursing notes	Significant event 1 Patient admitted for surgery with SPU.	Event 2 Patient prepared for surgery.	Event 3 Patient returned from surgery.
Patient's version of events	Waiting since January for surgery.		
Consultant's version of events			Consultant instructed patient to be turned L and R side every 3 hours.
Ward Manager's version of events			Patient was being difficult about turns.
Significant others' version of events, e.g. TVN, HCA, Informal carer			Nurses note turns
Organisational information/details	Patient admitted to a surgical ward.		Ward really busy. Understaffed (staff off duty)

The above data sources will be cross tabbed against external criteria as follows:

	Event 1	Event 2	Event 3
	Patient not risk assessed (no record in notes)	Patient admitted onto ward and not turned	
Local protocol guidelines	Patient should be Risk assessed using Waterlow scale, Care plan written up…	Turning regime should be followed as per patient care plan.	Ward requires one qualified staff per patient at all times
NICE guidelines	Patients should receive		All patients should be

	initial and ongoing PU assessment. Ulcer assessment should include: cause of ulcer…etc.		monitored post op etc.
Specific clinical/co morbid risks for patient	Older age, diabetes		There is a risk post op of low blood pressure.
Expert witness account of usual care	Normally patients will receive a care plan assessment, and will always undergo a Risk assessment.		
Weighted evidence. Does the event meet expected criteria?			

The first case, from Stage 1 will be compared with 4 or 5 further cases. These will be selected to present with the widest possible range of personal and service characteristics (see Inclusion Criteria). We will use evidence from this stage to refine the initial coherence account. It may be that there are no plausible explanations at this point, in which case another patient will be chosen with an unexpected pressure ulcer or few known clinical risk factors once again. Again, the aim will be refining the coherence account of the patient's experience, using the same methods of gathering evidence as in Stage 1.

Using a 'building block' approach to sampling (Blaikie, 2000; Pawson, 2006) more cases will be selected which are best able to help develop explanations. The coherence account will become more refined as up to 6 more cases are compared (a maximum of 12 cases). Hypotheses around plausible explanations why a patient should develop a severe pressure ulcer, will be confirmed or refuted as more evidence is gathered (see Ragin, 2000). This may be apparent by just a few patients, or may need all 12 patients before we are able to start to

make generalisations. This might also involve retracing steps and looking for further evidence to elaborate the existing coherence account, as further evidence is uncovered.
In this stage, and through all stages of the research, we will work closely with the Tissue Viability Team (TVT) and provide regular feedback to staff verbally, and with summary reports, so that the explanations we offer remain constantly relevant to practice. For example; if a patient's movement through services appears, once again, to have a possible impact on severe pressure ulcer development, we would look to confirm this hypothesis with further cases. Stage 2 will conclude with a refined version of the coherence account, which will be used to produce an explanatory model to explain why patients develop Category 3 and 4 pressure ulcers.

The model(s) will be implemented into a critical incident/adult neglect review protocol as part of future joint work with Study 3 (NIHR Pressure Ulcer Programme). This will also inform a severe pressure ulcer risk assessment framework. See flowchart 5.3 below.

Sections 6, 7, 8 METHOD (INCLUDING ANALYSIS)

6 ELIGIBILITY

6.1 Inclusion Criteria

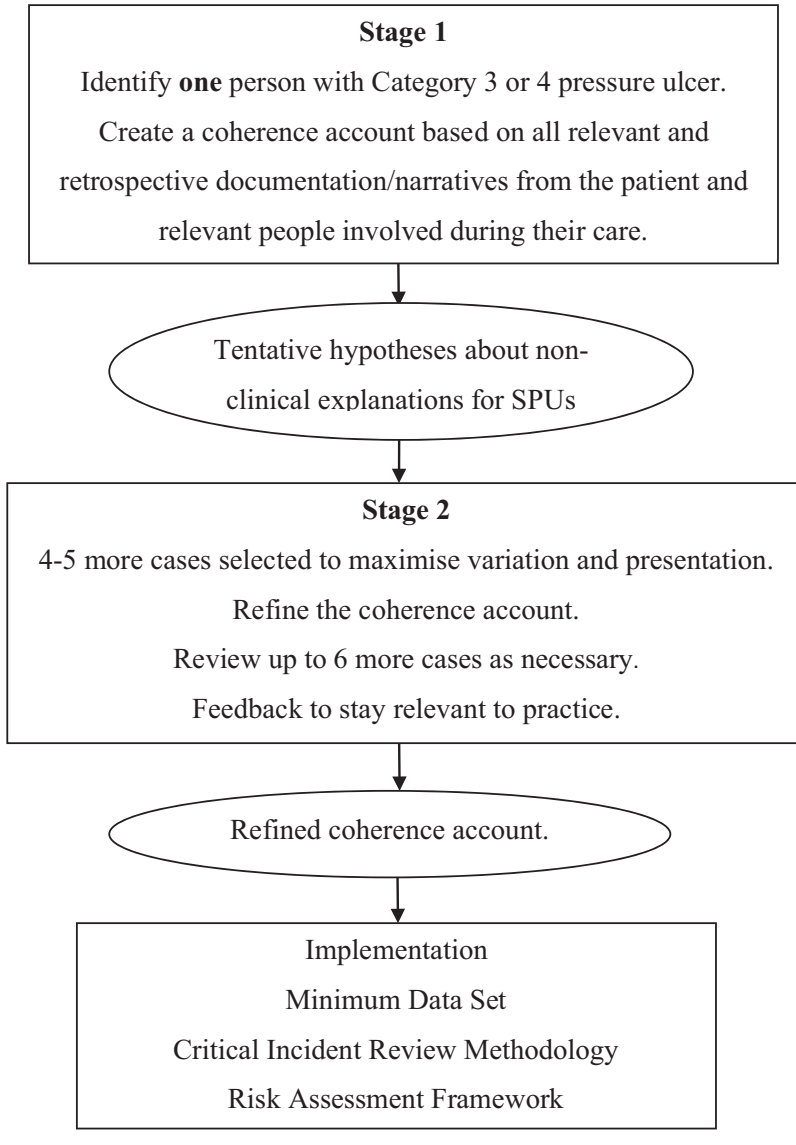
(Stage 1) will include one participant who has few clinical risk factors, e.g. an elective orthopaedic patient (Nixon, 2007) who presents with a Category 3 or 4 Pressure Ulcer.

Table 1. EPUAP Pressure Ulcer Classification System[4]

Category	Description
Category 0	Normal
Category 1 Non-blanchable erythema of intact skin	Intact skin with non-blanchable erythema of a localised area usually over a bony prominence. Discolouration of the skin, warmth, oedema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching.
Category 2 Partial thickness skin loss or blister	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum or sero-sanginous-filled blister.
Category 3	Full thickness tissue loss. Subcutaneous fat may be visible

Full thickness skin loss	but bone, tendon or muscle are *not* exposed. Some slough may be present. *May* include undermining and tunnelling.
Category 4 Full thickness tissue loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. *Often* includes undermining or tunnelling.
Category U	Unstageable

5.3 Flowchart of research design:



For Stage 2, four or five patients from participating acute and community trusts will be chosen if they have had or have currently a Category 3 or 4 pressure ulcer (EPUAP 2008). These may include hospital in-patients, hospital out-patients, intermediate care or community patients under the care of community nursing services. This stage will aim to maximise variation and presentation of severe (Category 3 and 4) pressure ulcers. The sample will also be monitored for anatomical site of the pressure ulcer (e.g. heel, sacrum, buttocks) to allow for variation amongst patients. Further participants will be chosen following the procedures set out in the research design.

6.2 Exclusion Criteria

Patients who it would be ethically inappropriate to approach, for example, those where death is imminent, will not be approached.

Additionally, patients who are unable to tell their story (narrative) of their experience will be excluded, as this forms part of the main design of the study.

7 RECRUITMENT AND CONSENT PROCEDURE

7.1 Patients (ward based)

Members of the tissue viability team (TVT) which includes the local principal investigator and other members of their local team (i.e. tissue viability nurse specialists and clinical research nurses) at participating trusts will screen potentially eligible patients through critical incident reporting systems, healthcare records and referrals. The patients will be approached by a member of the TVT, informed about the study, and provided with a project information leaflet which includes details about the rationale, design, and personal implications of the study and an ‘agree to be contacted by the researcher’ form. Members of the TVTs at participating trusts will provide an anonymous record of patients identified as potentially eligible, approached to participate, refusals, and those agreeing to be contacted.

Following information provision, patients will have as much time as they need to discuss the study with their family, advocate, carers, and healthcare provider. They will be asked to complete the ‘agree to researcher contact’ form, which will be posted back to the Centre for Health and Social Care. The TVT and the researcher will be available to answer any questions that patients might have about the study. After receiving the signed ‘agreement to

be contacted' form from the patient, the researcher will contact the patient, carer, healthcare professional etc. to arrange a convenient time for possible interview and written consent. 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, the TVT member 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, and seek written consent or conduct an interview.

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. 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. A copy of the consent form will be given to the patient to keep, one copy will be filed in their healthcare records, and the original will be kept by the researcher and filed securely in the Study Master File at the Centre for Health and Social Care.

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.

7.2 Patients based in the community

A similar approach to the above ward-based procedure will be followed; however this will involve a third stage:

Members of the tissue viability team (TVT) will screen potentially eligible patients through critical incident reporting systems, healthcare records and referrals. The patients will be approached by a member of the TVT, informed about the study, and provided with a project information leaflet, which includes details about the rationale, design, and personal implications of the study, and an 'agree to be contacted by the researcher' form. Members of

the TVTs at participating trusts will provide a record of those identified as potentially eligible, approached to participate, refusals, and those agreeing to be contacted.

Following information provision, patients will have as much time as they need to discuss the study with their family, advocate, carers, and healthcare provider. They will be asked to complete the 'agree to researcher contact' form, which will be posted back to the Centre for Health and Social Care). The TVT and the researcher will be available to answer any questions that patients might have about the study.

After receiving the signed 'agreement to be contacted' form from the patient, the researcher will accompany a TVT member and personally introduce the researcher to the patient in their home. The researcher will provide information about the study and interview process and will answer any questions before gaining possible verbal consent, and then arranging an interview at a mutually convenient time, where written consent will be sought. This will allow for the patient to feel more comfortable with the researcher at a second meeting, as part of the study is to get a narrative account from the patient's perspective. In this way, the patient will feel also less vulnerable being alone with the researcher.

7.3 Stakeholders involved in the patient's care 'pathway', for example their informal carer, advocate, nursing staff, paid carer, other healthcare provider.

After the patient has been approached, given his or her consent, and interviewed, carers and healthcare professionals involved throughout their care pathway will be sought out through the patient interviews and examination of the patient's healthcare records, and any other documentation concerned with their care, and using an approach similar to that of patient recruitment, except that carers and staff will be approached directly (face to face or by phone) and asked if they would be interested in participating. Information will be provided about the study and a 'cooling off' time will be allowed before their consent is sought to take part. The guidelines will follow those of the patient consent procedure apart from this initial difference in approaching participants. A snowballing technique will be used to enlarge the sample until data saturation is reached.

8 PROCEDURES/DATA COLLECTION/ANALYSIS

In principal patient interviews will be undertaken prior to documentary analysis to ensure the researcher does not absorb any preconceived ideas from patient documentation about the causes of severe pressure ulcers. A step by step approach will be used:

8.1 Stage 1 (Case 1)

Developing the method (see Perrow, 1984; Vaughan, 1996)

1. An in-depth interview with the patient (and carers if appropriate) to gain his or her personal story of how their pressure ulcer developed. Interviews will be recorded
2. The researcher will then access patient case notes/healthcare records and patient held records. Nurses, GPs and other healthcare professionals who have a responsibility regarding their patient's records will be kept fully informed of the study, and a mutually convenient time will be arranged to access the records. We will examine the notes using a range of practical tools:
    a. Timelines to record the main sequence of event s (e.g. movements between wards)
    b. Records of where key players were and other relevant people,
    c. Chronological accounts of key events, sometimes referred to as clinical incident sheets

We may use other methods, which will be identified while collecting data, to help further with our systematic searching. All the documentary analysis will be done on site, e.g. NHS ward, patient's home, care home, which will avoid issues with confidentiality.

We will use the data to create a coherence account, as described in Section 5. The analysis will run in parallel with data collection, and begin after the first interview. The academic process involves developing a clear account using and refining our evidence, and 'this interaction of ideas and evidence leads to theories based on what we have analysed' (Ragin, 1994). Software (NVivo 8; QSR) will be used as an aid to organise and categorise the data.

Other people will be sought out who are relevant to the patient's story of how their pressure ulcer started. These participants will also be chosen according to what evidence is found from relevant documentation. We will conduct in-depth interviews with the chosen participants (see Topic guide). The people chosen in Step 3 are likely to include informal and professional carers, nurses and other professionals involved in the care of the patient, but they could be

anyone who has been identified as having an influence in the development of the pressure ulcer, by the patient or by documentary evidence.

8.2 Stage 2 (cases 2, 3, 4, 5, 6 up to 12)

We will use the same methods of data collection as Stage 1 for the next four or five more cases. In-depth interviews and documentary evidence will be used to help refine our coherence account. We will then continue to collect data for more cases (up to 12) to refine the coherence account.

If we have to review the first case, or previous cases, to look for more evidence which supports newly uncovered insights (see study design) and refine our coherence account we will do this looking for newly relevant data. As the data set builds, the process of analysis will be refined and more causal explanations will be generated until saturation point is reached. Verbal feedback and summary reports will be sent to Tissue Viability team.

The findings and conclusions drawn will provide a structured, theory informed basis from which to develop an adult incident critical incident methodology and risk assessment protocol. The findings will be used in practice at pilot sites, if the models are found to be explanatory.

8.3 Flow chart of data collection /consent seeking process:

Possible patients identified using critical incident reporting and caseload review by TVTs, and according to minimum clinical risk factors

TVTs contacts researcher and researcher identifies first case

TVT approaches patient to seek ‘researcher contact’

Researcher contacts the patient to seek verbal consent and arrange interview

Researcher conducts in-depth interview with patient

Researcher searches documents and healthcare records related to patient pathway.

Researcher seeks consent for interview from other relevant stakeholders in patient pathway (identified in patient documents/interviews).

Tentative hypotheses developed arising from case 1

4 -5 further cases identified using hypotheses/potential explanations from Case 1

Process repeats until no more potential explanations can be found.

9 DATA ANALYSIS

The analysis of the interview and documentary data will be conducted in parallel with the data collection (see Section 6). This will include ongoing analysis following the procedures set out in the study design (Section 5), i.e. sifting through and refining the data over and over again until causal explanations are produced. NVivo 8 (QSR) software will be used to organise the data.

12 ETHICAL CONSIDERATIONS

This project will recruit patients with Category 3 and 4 PUs and will therefore include elderly and highly dependent patients considered as vulnerable. Ethical issues relate to the involvement of vulnerable adults/elderly patients with high levels of co-morbidity including acute and chronic illness. The study also raises ethical issues in relation to recruiting patients who may have fluctuating lack of capacity; however this will be assessed at the time of consent seeking. The ethical issues surrounding these potentially vulnerable patients have

been addressed through the study design and include a thought out consent process, which also follows current Mental Capacity Act guidelines.

If any patient or other person involved in his or her care pathway were to disclose an instance of abuse or neglect, this subject will be discussed with the patient, and the researcher will inform the closest professional or carer depending on the circumstances. This will be explained to the participant before the interviews take place.

The study will be submitted to and approved by a flagged Research Ethics Committee (REC) prior to identifying eligible patients. The Centre for Health and Social Care will provide the REC with a copy of the final protocol, patient, staff and informal caregiver information leaflets, consent forms, and all other relevant study documentation.

17 REFERENCES

Action on Elder Abuse (2008) Consultation on key points relating to the review of No Secrets and In Safe Hands. London, Action on Elder Abuse

Bennett, G.,Dealey. C., Posnett, J. (2004) The Cost of Pressure Ulcers in the UK. Age and Ageing, vol. 33, no3, pp. 230-235

Blaikie, N. (2000) Designing Social Research. Cambridge , Polity Press,

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. (2001) National Service Framework for Older People. London, The Stationery Office.

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

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

EPUAP. Pressure Ulcer Treatment Guidelines. web . 1999. Oxford, European Pressure Ulcer Advisory Panel.

Fox C. (2002). Living with a pressure ulcer: a descriptive study of patients' experiences. British Journal of Community Nursing;7(6 Suppl):10, 12, 14, 16.Fox (2002)

George, A.L. and Bennett, A. (2005) Case Studies and Theory Development in the Social Sciences. Harvard University Press, Cambridge, MA.

Gorecki C, Nixon J, Brown J, (2007) On behalf of the EQUIP collaborative group. A systematic review of pressure ulcers and quality of life. 10th European Pressure Ulcer Advisory Panel Open Meeting.

Hammond, K.R. (1996) Human Judgment and Social Policy: Irreducible Uncertainty, Inevitable Error, Unavoidable Injustice. Oxford University Press US,

Institute of Medicine (2001) Crossing the quality chasm: A new health system for the 21st century. Washington DC: National Academy Press; 2001.

Laming, L (2003) The Victoria Climbie Inquiry. Report of an Inquiry. London, HMSO.

Langemo DK, Melland H, Hanson D, Olson B, Hunter S. The lived experience of having a pressure ulcer: a qualitative analysis. Advances in Skin & Wound Care 2000;13(5):225-35.

NICE (2001a) Pressure Ulcer Risk Assessment and Prevention. Inherited clinical guideline B. London, NICE

NICE (2001b) Guide for Patients and Their Carers on Working Together to Prevent Pressure Ulcers. NICE, London

NICE (2005) Nixon J, Gorecki C, Brown J, (2007) On behalf of the EQUIP collaborative group. Pressure ulcers risk evaluation (PURE) project. 10th European Pressure Ulcer Advisory Panel Open Meeting.

Nixon J, McGough A. (2001) Principles of Patient Assessment: Screening for Pressure Ulcers and Potential Risk. In: Morison M, editor. The Prevention and Treatment of Pressure Ulcers. 2 ed. Edinburgh: Mosby. p. 55-74.

Pawson, R. (2008) Don’t forget to think! Middle range theory as causal analysis. ESRC Research Methods Festival.

Pawson, R. (2006) Evidence-based Policy. A Realist Perspective. London, SAGE.

Pawson R, Tilley N. (1997) Realistic Evaluation. London, SAGE.

Perrow C. (1984) Normal accidents: Living with high-risk technologies. New York: Basic Books.

QSR NVivo Version 7- Doncaster, Australia: QSR International

Ragin C. Fuzzy-set social science. Chicago: University of Chicago Press; 2000.

Ragin C. (1994) Constructing Social Research. California, SAGE

RCN (2001) Pressure Ulcer Risk Assessment and Prevention. Clinical Practice Guideline. RCN, London

Reason, J. (1990) Human Error. Cambridge University Press, UK

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

Secretary of State for Health (2001). Learning from Bristol: Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary. London, The Stationery Office.

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

Vaughan D. (1996) The Challenger Launch Decision: Risky Technology, Culture and Deviance at NASA. Chicago: University of Chicago Press.

Waring J, McDonald R, Harrison S. (2006) Safety and Complexity: inter-departmental relationships as a threat to patient safety in the operating department. J Health Organ Manag 20(227):42.

Yin R. (2003) Case study research: Design and methods. 3rd ed. ed. CA: Sage.