

**The Development of a Pressure Ulcer Risk
Assessment Framework and Minimum Data Set**

Susanne Coleman

Submitted in accordance with the requirements for the degree of
Doctor of Philosophy

University of Leeds
School of Healthcare

July 2014

Intellectual Property and Publication Statements

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

The research included in this thesis was supported by a project team which included Professors Jane Nixon (JN), Andrea Nelson (EAN), Justin Keen (JK) and Carol Dealey (CD), Dr Elizabeth McGinnis (EMc) and Mrs Nikki Stubbs (NS), Lyn Wilson (LW) and Miss Delia Muir (DM). My own contribution and that of members of the project team, as well as other contributors to specific publications/chapters are clearly articulated below.

Chapter 3 – Published: Coleman, S., Gorecki, C., Nelson, E., A., Close, S.J., Defloor, T., Halfens, R., Farrin, A., Brown, J., Schoonhoven, L. & Nixon, J. (2013) Patient risk factors for pressure ulcer development: systematic review. *International Journal of Nursing Studies*, 50, 974–1003.

Contributions: Susanne Coleman (SC): lead role in developing the quality appraisal and data synthesis and analysis methodology. Contribution to eligibility assessment and data extraction. Lead role in quality appraisal, evidence tables, analysis, interpretation of results and drafting and revising the manuscript.

Jane Nixon: grant lead applicant, conception, lead role in protocol development. Contribution to eligibility assessment, data extraction, quality appraisal, analysis, interpretation of results and revising the manuscript.

Claudia Gorecki (CG): lead role in protocol development. Contribution to eligibility assessment, data extraction, interpretation of results and revising the manuscript.

E Andrea Nelson (EAN): grant co-applicant, contribution to protocol development, interpretation of results and revising the manuscript.

Amanda Farrin (AF): contribution to quality appraisal methodology, interpretation of results and revising the manuscript.

Julia Brown (JB): grant co-applicant, contribution to protocol development, statistical review (eligibility, data extraction), interpretation of results and revising the manuscript.

Tom Defloor (TD), Ruud Halfens (RH), Lisette Schoonhoven (LS) and Jose Closs (SJC): contribution to protocol development, interpretation of results and revising the manuscript.

Chapter 4 – Published: Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J. M. G. A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D. L., Gefen, A., Oomens, C. W. J., Schoonhoven, L. and Nixon, J. (In Pres) 'Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework.', *Journal of Advanced Nursing*.

Contributions: Susanne Coleman (SC): led the conception and design of the study, co-ordination of the study, facilitation of the expert group and Pressure Ulcer Research Service Use Network (PURSUN) meetings, development of questionnaires. Led the working group, analysis and interpretation of the results, drafted and revised the manuscript, final approval of the version to be submitted. E. Andrea Nelson (EAN) and Jane Nixon (JN): contributed to the conception and design of the study, participation in the expert group meeting(s) and questionnaire completion, participation in the working group and contributed to interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Amanda Farrin (AF): contributed to the conception and design of the study, interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Justin Keen (JK), Lyn Wilson (LW), Elizabeth McGinnis (EMc), Carol Dealey (CD), and Nikki Stubbs (NS): contributed to the conception and design of the study, participation in the expert group meeting(s) and questionnaire completion, participation in the working group, contributed to interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Delia Muir (DM): contributed to the conception and design of the study, facilitation of the Pressure Ulcer Research Service Use Network (PURSUN) meetings and feedback at expert group meetings, participation in the working group, contributed to interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Dawn Dowding (DD), Jos .M. G .A .Schols (JMGAS), Janet Cuddigan (JC), Dan Berlowitz (DB), Edward Jude (EJ), Peter Vowden (PV), Dan. L. Bader (DLB), Amit Gefen (AG), Cees.W.J.Oomens (CWJO) and Lisette Schoonhoven (LS): participation in the expert group meeting(s) and questionnaire completion,

contributed to interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Chapter 5 – Published: Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Farrin, A., Dowding, D., Schols, J. M. G. A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Schoonhoven, L., Bader, D. L., Gefen, A., C.W.J., O. and Nelson, E. A. (2014) 'A New Pressure Ulcer Conceptual Framework', Journal of Advanced Nursing, DOI:10.1111/jan.12405

Contributions: Susanne Coleman (SC): led the conception and design and of the study, facilitation of the conceptual framework meeting. Led the analysis and interpretation of results, developed the pressure ulcer conceptual framework and theoretical causal pathway and drafted and revised the manuscript and final approval of the version to be submitted.

E. Andrea Nelson (EAN) and Jane Nixon (JN): contributed to the conception and design of the study, participation in the conceptual framework meeting, contributed to interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Amanda Farrin (AF): contributed to the conception and design of the study, interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Justin Keen (JK), Lyn Wilson (LW), Elizabeth McGinnis (EMc), Carol Dealey (CD), and Nikki Stubbs (NS): contributed to the conception and design of the study, participation in the conceptual framework meeting, contributed to interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Dawn Dowding (DD), Jos .M. G .A .Schols (JMGAS), Janet Cuddigan (JC), Dan Berlowitz (DB), Edward Jude (EJ), Peter Vowden (PV), Dan. L. Bader (DLB), Amit Gefen (AG), Cees.W.J.Oomens (CWJO) and Lisette Schoonhoven (LS): participation in the conceptual framework meeting, contributed to interpretation of the results, revising the manuscript and final approval of the version to be submitted.

Chapter 6

Contributions: Susanne Coleman (SC): led the design of the Risk Assessment Framework and led the conception and design of the pre-test study. Led the development of the study protocol and documents including study information sheets and consent forms, topic guides, questionnaires and case studies, led the

pre-test sessions, facilitated the focus groups, conducted the analysis and led the interpretation of results.

E. Andrea Nelson (EAN) and Jane Nixon (JN), Amanda Farrin (AF), Justin Keen (JK), Carol Dealey (CD), and Nikki Stubbs (NS): contributed to the design of the Risk Assessment Framework, contributed to the conception and design of the pre-test study and the development of the study protocol and documents (information sheets and consent forms, topic guides, questionnaires, case studies).

Elizabeth McGinnis (EMc) and Delia Muir (DM): contributed to the design of the Risk Assessment Framework, contributed to the conception and design of the pre-test study and the development of the study protocol and documents (information sheets and consent forms, topic guides, questionnaires, case studies) and conducted think out loud interviews.

Lyn Wilson (LW) contributed to the design of the Risk Assessment Framework, contributed to the conception and design of the pre-test study, the development of the study protocol and documents (information sheets and consent forms, topic guides, questionnaires, case studies) and co-facilitated the focus group meetings.

Presentations

International Conference (oral)

Susanne Coleman on behalf of the PURE Collaborative Group. Challenges in identifying risk factors for pressure ulceration: systematic review of risk factors and problems addressed. RCN International Nursing Research Conference, Harrogate, May 2011.

Local Conference (oral)

S Coleman. A Systematic Review of Pressure Ulcer (PU) Risk Factors. Post grad research conference, University of Leeds, June 2011.

International Conference (oral)

Suanne Coleman on behalf of the PURE Collaborative Group. A Systematic Review of PU Risk Factors. 14th Annual European Pressure Ulcer Meeting, Oporto, Portugal, Sept 2011.

Local Conference (invited speaker)

S. Coleman and L Wilson on behalf of the project team. Pressure Ulcer Risk Assessment. Building Blocks of wound care conference NTVNA, Leeds, Sept 2011.

Local Conference (invited speaker)

S Coleman. The Development of Pressure Ulcer Minimum Data Set (PU-MDS) Using Consensus Methods. Post Grad research conference, Leeds Oct 2012.

International Conference (poster)

S Coleman, J Nixon, C Gorecki, E A Nelson on behalf of the on behalf of the PURE Collaborative Group. Systematic Review of Pressure Ulcer Risk Factors, NPUAP 2013 Biennial Conference, Houston Texas, Feb 2013.

National Conference (oral)

Invited: S Coleman. From systematic review to clinical practice – risk factor domains to be considered in pressure ulcer risk assessment. Tissue Viability Society, the 2013 Conference. Kettering, April 2013.

International Conference (oral)

S Coleman, J Nixon, Nelson A and Farrin A on behalf of the RAF study group (local project team and expert group). From systematic review to clinical practice: Using consensus methods to develop a Pressure Ulcer Risk Assessment Framework. 16th EPUAP Meeting Vienna, Sept 2013.

International Conference (oral)

S Coleman, J Nixon, Nelson A and Farrin A on behalf of the RAF study group (local project team and expert group) The Design and Pre-testing of a Pressure Ulcer Risk Assessment Framework 16th EPUAP Meeting Vienna, Sept 2013.

National Conference (invited speaker)

Susanne Coleman, Nikki Stubbs, Elizabeth McGinnis and Jane Nixon on behalf of the PUPPs and PURPOSE T Implementation Team. Pressure Ulcer Prevention Pathways (PUPPs) and Pressure Ulcer Risk Primary Or Secondary Evaluation Tool (PURPOSE T) Workshop. Tissue Viability Society, the 2014 Conference, York. April 2014.

International Conference (invited speaker)

Susanne Coleman and Jane Nixon. Translational Gap: Measuring Risk Factors in Clinical Practice. “2nd EPUAP Focus Meeting on Skin Health and Microclimate, University of Southampton. April 2014.

Local Conference (invited speaker)

Susanne Coleman and Jane Nixon. Pressure Ulcer Recognition and Prevention: The Value of Risk Assessment. Stop the Pressure Ulcer Student Conference, School of Healthcare, University of Leeds. June 2014.

Planned Future Presentations*International Conference (invited speaker)*

Susanne Coleman and Jane Nixon. Risk factors in context; from conceptual framework to risk assessment in practice. 17th EPUAP Meeting Stockholm, Aug 2014.

International Conference (invited speaker)

Susanne Coleman, Jane Nixon and Nikki Stubbs on behalf of the PUPPs and PURPOSE T Implementation Team. Pressure Ulcer Prevention Pathways (PUPPS: Active Monitoring Model of Care Incorporating PURPOSE T. 17th EPUAP Meeting Stockholm, Aug 2014.

This copy has been supplied on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

© 2014 The University of Leeds and Susanne Coleman.

The right of Susanne Coleman to be identified as Author of this work has been asserted by her in accordance with the Copyright, Designs and Patents Act 1988.

Acknowledgements

The work of this PhD was made possible as part of funding obtained from the National Institute of Health Research (NIHR) under the Programme Grants for Applied Research programme (Pressure Ulcer Programme Of Research: PURPOSERP -PG-0407-10056). Additional funding was also obtained from the Smith and Nephew Foundation for the systematic review and the World University Network (WUN) facilitating international collaboration in the consensus study of the PhD. I am grateful for this financial support.

This research was led by Susanne Coleman and supported by a project team comprising Jane Nixon, E Andrea Nelson, Justin Keen, Lyn Wilson, Elizabeth McGinnis, Carol Dealey, and Nikki Stubbs and Delia Muir. My own contributions, fully and explicitly indicated in the thesis, have been noted for chapters 3-5 in the intellectual property and publication part of this thesis. In addition I confirm that the development and writing of chapters 1, 2, 6 and 7 was undertaken solely by myself.

The contributions of other members of the local team, comprising Jane Nixon, E Andrea Nelson, Justin Keen, Lyn Wilson, Elizabeth McGinnis, Carol Dealey, Nikki Stubbs and Delia Muir throughout the work of this PhD have been noted in part, in the intellectual property and publication part of this thesis. In addition, the team supported the development of the consensus and pre-test study protocols and documents including study information sheets and consent forms, topic guides, questionnaires, case studies, expert group reports and meeting documentation, pre-test reports and the Risk Assessment Framework. Specific members (Elizabeth McGinnis and Delia Muir) also conducted think out loud interviews or co-facilitated the focus group meetings (Lyn Wilson) at pre-test sessions. I am grateful to each and every member of the team for their unwavering support.

The systematic review was conducted as part of a wider collaboration called the Pressure Ulcer Risk Evaluation (PURE) team comprising Susanne Coleman, Jane Nixon, Claudia Gorecki, E Andrea Nelson, S. Jose Close (SJC), Tom Defloor, Ruud Halfens, Amanda Farrin, Julia Brown and Lisette Schoonhoven. Their role in this work is clearly articulated in the intellectual property and publication part of this thesis. In addition, Gillian Worthy gave statistical advice at the protocol development stage of the systematic review. I would like to thank all who were involved in this work.

The Pressure Ulcer Research Service User Network (PURSUN) participated in meetings to discuss the acceptability of proposed assessment elements in the consensus study and in the review of the Risk Assessment Framework. PURSUN

also contributed to the development of pressure ulcer case studies used at the pre-test session. I would like to thank them for attending meetings and sharing their personal experiences and insights into pressure ulcer risk assessment and for influencing the development of the Risk Assessment Framework.

The consensus study was supported by an expert group which comprised the local team already noted above and Dawn Dowding, Jos .M. G .A .Schols, Janet Cuddigan, Dan Berlowitz, Edward Jude, Peter Vowden, Dan. L. Bader, Amit Gefen, Cees.W.J.Oomens and Lisette Schoonhoven. Their contributions are noted in the intellectual property and publication part of this thesis. In addition the expert group also reviewed the Risk Assessment Framework following pre-testing. I would like to express my gratitude to them for taking time out from their busy schedules and sharing their expertise and enthusiasm when participating in the consensus study and subsequent publications.

I would like to thank Brian Parkinson who assisted in the graphic design of the Risk Assessment Framework. I would also like to thank the Community and Acute Registered Nurses who took the time to participate in the pre-test study to improve the usability of the Framework. I hope the final version of the tool will eventually assist them in their everyday clinical practice.

I would particularly like to express my gratitude to Andrea Nelson and Jane Nixon who guided me through the ups and downs of undertaking the research and in writing this PhD thesis. I am grateful to them for their encouragement, commitment and patience and for nurturing my confidence as a researcher. I am also indebted to them for their subject specific and methodological expertise. Additionally I would like to thank Claudia Gorecki and Maria Bryant for their methodological advise and Lyn Wilson for her emotional support.

On a personal note I will be eternally grateful to Ian who has been by my side throughout this PhD and without whose support it would not have been possible. Thank you to Grace and Seany for their help, patience and understanding. Finally I would like to thank my wider family, Mum, Trevor, Dad, Anne, Barbara, Sean, Becky, Jack, Will, Rosie, Pam, Robert, Julia and Janey for their unfaltering love and support in the pursuit of my personal goals and in completing this PhD.

Abstract

Background

Pressure ulcers are associated with ill health and poor mobility and are a considerable healthcare problem worldwide. Risk assessment is considered the cornerstone to pressure ulcer prevention.

Aim

To develop a Risk Assessment Framework for use with adult populations in clinical practice, underpinned by a risk factor Minimum Data Set.

Methods

The methodological approach comprised 4 phases:

- 1) Systematic review of pressure ulcer risk factors.
- 2) Consensus study involving 17 international experts with service user involvement.
- 3) Conceptual framework and theoretical causal pathway development.
- 4) Design and pre-testing of the draft Risk Assessment Framework using cognitive pre-testing methods, incorporating 3 sessions and 34 nurses.

Results

- 1) The review of 54 studies identified 3 primary risk factor domains, mobility/activity, skin/pressure ulcer status and perfusion (including diabetes), but suggests no single factor can explain pressure ulcer development.
- 2) The consensus study facilitated the agreement of risk factors and assessment items of 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.
- 3) The new conceptual framework incorporates key physiological and biomechanical components and their impact on internal strains, stresses and damage thresholds. Direct and key indirect causal factors suggested in the theoretical causal pathway are mapped to the physiological and biomechanical components of the framework.
- (4) The design and pre-testing of the Risk Assessment Framework confirmed content validity and led to improved usability over the course of the pre-test. The preliminary Risk Assessment Framework incorporates the Minimum Data Set, a 2 stage assessment process (screening and full assessment), support for decision making and primary prevention and secondary prevention/treatment pathways.

Conclusion

The resulting Risk Assessment Framework makes an important contribution to the pressure ulcer field and now requires further clinical validation and evaluation.

Contents

Intellectual Property and Publication Statements	ii
Acknowledgements	viii
Abstract	x
Contents	xii
List of Tables	xviii
List of Figures	xx
Abbreviation	xxi
Chapter 1 Background	1
1.1 Introduction	1
1.2 Thesis Overview.....	1
1.3 Origins of the PhD.....	2
1.4 Pressure Ulcer Definition.....	2
1.5 The Extent of the Problem.....	5
1.6 Quality of Life	6
1.7 Financial Burden	7
1.8 Pressure Ulcer Conceptual Frameworks.....	7
1.9 Pressure Ulcer Aetiology.....	11
1.10 Introduction Pressure Ulcer Risk Factors.....	13
1.11 Pressure Ulcer Prevention	14
1.11.1 Skin Assessment/Care.....	15
1.11.2 Support Surfaces	16
1.11.3 Repositioning	18
1.11.4 Nutrition.....	21
1.11.5 Pressure Ulcer Prevention Initiative	22
1.12 Summary and Subsequent Thesis Chapters.....	23
Chapter 2 Risk Assessment	25
2.1 Introduction	25
2.2 Pressure Ulcer Risk Assessment.....	25
2.3 Risk Assessment Instruments within the wider Health Measurement Context.....	26
2.4 The Development and Validation of Existing Pressure Ulcer Risk Assessment Instruments.....	29
2.4.1 Risk Assessment Instrument Development.....	30

2.4.1.1	Content Validity.....	32
2.4.2	Instrument Validation	42
2.4.3	Reliability.....	42
2.4.4	Construct Validity	43
2.4.4.1	Convergent Validity.....	43
2.4.4.2	Known Groups	44
2.4.4.3	Discriminant Validity.....	45
2.4.5	Responsiveness.....	45
2.4.6	Criterion Validity	45
2.4.6.1	Concurrent Validity.....	45
2.4.7	Predictive Validity.....	46
2.4.7.1	Sensitivity and Specificity.....	46
2.4.7.2	Predictive validity of existing instruments.....	48
2.4.8	Effectiveness.....	50
2.4.9	Summary of Existing Risk Assessment Scale development and validation	51
2.5	The Need for a New Approach to Pressure Ulcer Risk Assessment.....	52
2.6	Aim of PhD.....	54
2.7	Methodological Overview	54
2.7.1	Important Psychometric Properties in the Development and Validation of a New Risk Assessment Framework	54
2.7.2	Methodological Considerations	56
2.7.3	Methodological Approach of PhD.....	58
2.8	Summary.....	58
Chapter 3	Systematic Review of Pressure Ulcer Risk Factors.....	61
3.1	Introduction	61
3.2	Systematic reviews	61
3.3	The need for a systematic review in this PhD	62
3.4	Aim	62
3.5	Methodological Considerations	63
3.5.1	Study Design Considerations.....	63
3.5.2	Quality Appraisal Considerations	66
3.6	Methods	67
3.6.1	Study Eligibility.....	67
3.6.1.1	Inclusion criteria.....	68

3.6.1.2	Exclusion criteria.....	69
3.6.2	Search and Data Sources	69
3.6.3	Data extraction	69
3.6.4	Quality Assessment	70
3.6.5	Study Classification.....	72
3.6.6	Data Synthesis	72
3.7	Results	75
3.7.1	General Study Characteristics.....	75
3.7.2	Study Quality.....	96
3.7.3	Risk Factor Domains and Sub-domains.....	96
3.7.3.1	Mobility/Activity	117
3.7.3.2	Skin/Pressure Ulcer Status	117
3.7.3.3	Perfusion.....	118
3.7.3.4	Haematological Measures.....	119
3.7.3.5	Moisture	120
3.7.3.6	Body Temperature	120
3.7.3.7	Nutrition.....	121
3.7.3.8	Increasing Age	122
3.7.3.9	Sensory Perception.....	123
3.7.3.10	Mental Status.....	123
3.7.3.11	Race	123
3.7.3.12	Gender.....	123
3.7.3.13	General Health Status.....	124
3.7.3.14	Medication.....	124
3.7.3.15	Risk Assessment Instruments.....	124
3.8	Discussion.....	125
3.9	Conclusions.....	131
Chapter 4	Using Consensus Methods to Develop a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework.....	133
4.1	Introduction	133
4.2	Consensus Methods	133
4.3	Delphi Method.....	135
4.4	Nominal Group Technique	136
4.5	RAND/UCLA Appropriateness Method	137
4.6	Consensus Development Conference.....	138

4.7	Methodological Issues Concerning Consensus Methods.....	138
4.7.1	Validity	138
4.7.2	Reliability.....	139
4.7.3	Expert Groups	139
4.7.4	Use of Evidence.....	141
4.7.5	Patient Involvement.....	142
4.7.6	Defining Consensus	143
4.8	Comparisons of Consensus Methods	144
4.9	The rationale for the Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework Consensus Study.....	145
4.10	Consensus study.....	146
4.11	Aim	146
4.12	Design.....	146
4.13	Sample/Participants	147
4.14	Data Collection.....	148
4.15	Ethical Considerations	151
4.16	Data Analysis	151
4.17	Validity and Reliability	152
4.18	Results	153
4.19	Cycle 1 Risk Factors	153
4.20	Cycle 2: Assessment Items for Risk Factors.....	159
4.21	Draft Risk Assessment Framework.....	159
4.22	Discussion.....	162
4.23	Conclusion	166
Chapter 5	Development of a New Pressure Ulcer Conceptual Framework.....	167
5.1	Introduction	167
5.2	Aim	167
5.3	Design.....	167
5.4	Data Collection.....	167
5.5	Data Analysis	168
5.6	Validity and Reliability	168
5.7	Results	169
5.7.1	Direct Causal Factors.....	174
5.7.2	Key Indirect Causal Factors	175

5.7.3	Other Potential Causal Factors	175
5.7.4	New Conceptual Framework	175
5.8	Discussion	176
5.9	Conclusion	179
Chapter 6	Design and Pre-testing of the Risk Assessment Framework (incorporating risk factor Minimum Data Set)	180
6.1	Introduction	180
6.2	Design of Risk Assessment Framework.....	180
6.3	Pre-test Study Aims	183
6.4	Methods	183
6.4.1	Focus Groups.....	183
6.4.2	Think Out Loud interviews.....	184
6.4.3	Participants	184
6.5	Ethics	184
6.6	Data collection.....	185
6.7	Analysis.....	186
6.8	Results	187
6.9	Review by PURSUN and Expert Group	198
6.10	Preliminary Risk Assessment Framework.....	198
6.11	Discussion.....	201
6.12	Conclusion	203
Chapter 7	General Discussion.....	204
7.1	Introduction	204
7.2	Summary of Findings	204
7.2.1	Phase 1, Pressure Ulcer Risk Factor Systematic Review	204
7.2.2	Phase 2, Consensus Study	205
7.2.3	Phase 3, Conceptual Framework	206
7.2.4	Phase 4, Design and Pre-testing of the Risk Assessment Framework.....	207
7.3	The Preliminary Risk Assessment Framework.....	207
7.3.1	Main Differences Between the Preliminary Risk Assessment Framework and Other Widely Used Pressure Ulcer Risk Assessment Instruments	210
7.4	Methodological development.....	212
7.5	Methodological Limitations	215
7.6	Future Validation of the Risk Assessment Framework.....	218

7.7 Implications of the PhD for Clinical Practice.....	219
7.8 Implications of the PhD for Research.....	221
7.9 Conclusion	223
References.....	225
Appendices.....	247
Appendix 1 Norton Scale.....	247
Appendix 2 Waterlow Score	248
Appendix 3 Braden Scale.....	249
Appendix 4 Pressure Ulcer Risk Assessment Scale Validity Search.....	250
Appendix 5 PRISMA Checklist	251
Appendix 6 Systematic Review Search Strategy	254
Appendix 7 Skin Conditions Evidence Tables	257
Appendix 8 SHREC approval for consensus study	261
Appendix 9 Nominal Group Information Sheet for Consensus Study.....	262
Appendix 10 Nominal Group Participant Consent Form for Consensus Study	265
Appendix 11 SHREC Approval for Pre-test Study.....	266
Appendix 12 Participant Information Sheet for Pre-test Study	267
Appendix 13 Consent Form for Pre-test Study.....	270
Appendix 14 Agenda for Pre-test session	271
Appendix 15 Vignette Case Studies for Pre-test Study	272
Appendix 16 Pre-Test Focus Group Topic Guide.....	277
Appendix 17 Pre-Test Think out loud Topic Guide.....	278
Appendix 18 Risk Assessment Framework User Guide.....	280

List of Tables

Table 1.1 NPUAP/EPUAP Pressure Ulcer Classification System (2009)	4
Table 1.2 Pressure ulcer Prevalence and Incidence Ranges reported in Kaltenhaler et al 2001	6
Table 1.3 Glossary of Biomechanical Terms based on NPUAP/EPUAP (2009) Clinical Practice Guidelines and Oomens, Loerakker and Bader (2010 (Oomens, Loerakker and Bader 2010)).	10
Table 1.4 Repositioning effects on skin colour reported by Knox et al (1994).....	19
Table 2.1 Key Health Measurement Terminology	28
Table 2.2 Psychometric Properties of an Instrument.....	31
Table 2.3 Summary of the Risk Assessment Instruments Included in the NICE Systematic Review (NICE 2014) and their Development.....	33
Table 2.4 Risk factors included in Risk assessment Instruments included in the NICE systematic Review	39
Table 2.5 The relationship between a Risk Assessment Instrument result and pressure ulcer development	47
Table 2.6 Overview of NICE (2013) Review Evidence of AUC for 3 Commonly used and Researched Instruments	49
Table 2.7 Overview of NICE (2014) Review Evidence of Sensitivity and Specificity for 3 Commonly used and Researched Instruments	50
Table 3.1 Relationship between the Quality Criteria and Domains	73
Table 3.2 Relationship between Key Quality Domains.....	74
Table 3.3 Summary of included studies	76
Table 3.4 Quality Assessment of Included Studies	97
Table 3.5 Summary of evidence for risk factor domains/sub-domains	106
Table 4.1 Summary of characteristics of informal and formal consensus methods	134
Table 4.2 Risk Factors for <i>Screening Stage</i> of Minimum Data Set and Risk Assessment Framework.....	154
Table 4.3 Risk Factors for <i>the Full Assessment Stage</i> of Minimum Data Set and Risk Assessment Framework	156
Table 4.4 Uncertain risk factors.....	157
Table 4.5 Minimum Data Set (to be incorporated in Risk Assessment Framework).....	160
Table 5.1 Mapping of Direct Causal and Key Indirect Causal Factors to the Conceptual Framework	172

Table 6.1 Colour coding of risk factors	182
Table 6.2 Summary of Quantitative Analysis.....	186
Table 6.3 Item level completion for assessments that concluded at step 1 (screening)	188
Table 6.4 Item level completion for assessments that included step 1(screening) and 2(full assessment)	189
Table 6.5 Overall total Item completion for assessments	190
Table 6.6 Overall total Item completion for assessments with decision pathway allocated	190
Table 6.7 Appropriate decision pathway allocation	192
Table 6.8 Step 3 Assessment decision instructions	199

List of Figures

Figure 1.1 NPUAP/EPUAP (2009) Factors that Influence Susceptibility	9
Figure 1.2 New proposal for pressure/time curve (NPUAP/EPUAP 2009).....	13
Figure 2.1 Research Overview of Development and Measurement Properties.....	60
Figure 3.1 PRISMA Flow Chart of Studies	75
Figure 4.1 Overview Consensus Cycle	149
Figure 4.2 Example questionnaire items from the cycle 1 questionnaire...	150
Figure 4.3 Risk Factor Progression.....	158
Figure 4.4 Draft Risk Assessment Framework with Underpinning Minimum Data Set.....	161
Figure 5.1 NPUAP/EPUAP (2009) Original Conceptual Framework - Factors that Influence Susceptibility.....	170
Figure 5.2 Amendment of NPUAP/EPUAP (2009) Conceptual Framework -Factors that Influence Susceptibility for Pressure Ulcer Development.....	171
Figure 5.3 Theoretical Schema of Proposed Causal Pathway for Pressure Ulcer Development	173
Figure 5.4 Theoretical Schema of Proposed Causal Pathway for Pressure Ulcer Development	177
Figure 6.1 Percentage of missing data at each pre-test session.....	191
Figure 6.2 Percentage decision pathway allocated at each pre-test session.....	191
Figure 6.3 Changes to Risk Assessment Framework following each pre-test sessions.....	194
Figure 6.4 Pre-Test 1 Risk Assessment Framework (Draft)	195
Figure 6.5 Pre-Test 2 Risk Assessment Framework (Draft)	196
Figure 6.6 Pre-Test 3 Risk Assessment Framework (Draft)	197
Figure 6.7 Preliminary Risk Assessment Framework for Clinical Evaluation	200

Abbreviation

ADL	Activities of Daily Living
APACHE	Acute Physiology & Chronic Health Evaluation
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AUC	Area Under Curve
AP	Alternating Pressure
BP	Blood Pressure
CI	Confidence Interval
CQUIN	Commissioning for Quality and Innovation
CRD	Centre for Reviews and Dissemination
CTRU	Clinical Trials Research Unit
DES	Department for Education and Skills
DH	Department of Health
FDA DHHS	Food and Drug Administration, Department of Health and Human Services (US)
EPUAP	European Pressure Ulcer Advisory panel
FDA	Food & Drug Administration
HQS	High Quality Study
HSCIC	Health and Social Care Information Centre
HTA	Health Technology Assessment
IAD	Incontinence Associated Dermatitis
ICC	Interclass correlation
ICU	Intensive Care Unit
IPR	Interpercentile range
IPRAS	Interpercentile range adjusted for symmetry (
LOS	Length Of Stay
LQS	Low Quality Study
MADM	Mean Absolute Deviation from the Median
MDS	Minimum Data Set
MQS	Moderate Quality Study
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NGT	Nominal Group Technique
NPUAP	National Pressure Ulcer Advisory Panel
NH	Nursing home

OR	Odds Ratio
PPI	Patient and Public Involvement
PRO	Patient-Reported Outcome
PU	Pressure Ulcer
PURSUN UK	Pressure Ulcer Research Service User Network UK
PRESSURE 2	<u>P</u> ressure <u>R</u> elieving <u>S</u> upport <u>S</u> urfaces: a <u>R</u> andomised <u>E</u> valuation 2
PURPOSE	Pressure Ulcer Programme of Research
RAF	Risk Assessment Framework
RAND/UCLA	Research and Development / University of California at Los Angeles
SAC	Scientific Advisory Committee.
QoL	Quality of Life
RCT	Randomised Controlled Trial
RN	Research Nurse
ROC	Receiver Operator Characteristic
RR	Relative Risk
SCI	Spinal Cord Injury
TVN	Tissue Viability Nurse
VAS	Visual Analogue Scale
VLQS	Very Low Quality Study
SEM	Sub-epidermal Moisture

Chapter 1 Background

1.1 Introduction

This chapter provides an overview of the PhD Thesis and the origins of its development within the context of a National Institute of Health Research (NIHR) funded Pressure Ulcer Programme Of Research (PURPOSE). It goes on to provide a general overview of pressure ulcers, explaining what they are, their classification (in terms of severity), the extent of the pressure ulcer problem, their effect on patients' quality of life as well as their financial impact. Pressure ulcer conceptual frameworks and aetiology are then considered and risk factors are introduced. Finally commonly encountered preventative interventions for adult populations (skin assessment, repositioning, support surfaces, nutrition) are discussed.

1.2 Thesis Overview

This PhD Thesis provides a detailed account of research undertaken to develop a decision tool, the Pressure Ulcer Risk Assessment Framework (with underpinning Minimum Data Set), to be used for the prevention and management of generic mobility related pressure ulcers, for adult populations, in clinical practice. It explores the need for the new Risk Assessment Framework and its required properties to support clinical decision making in the assessment of pressure ulcer risk and subsequent care planning/delivery. The Thesis critically examines the adopted research pathway which incorporates 4 distinct phases:

- 1) Systematic review of pressure ulcer risk factors.
- 2) Consensus study involving 17 international experts with service user involvement.
- 3) Conceptual framework and theoretical causal pathway development.
- 4) Design and pre-testing of the draft Risk Assessment Framework using cognitive pre-testing methods

Work undertaken for this PhD Thesis links to a wider programme of research described below.

1.3 Origins of the PhD

The origins of this PhD are nestled in the NIHR PURPOSE Programme of Research which comprised two research themes:

- Theme 1: To reduce the impact of pressure ulcers on patients through early identification of patients at risk of developing pressure ulceration.
- Theme 2: To reduce the impact of pressure ulcers on patients through the development of methods to capture patient-reported HRQL and health utilities for routine clinical use and future research.

Theme 1 was particularly pertinent to this PhD as it focussed on improving our understanding of individuals' and organisational risk factors and on improving the quality of risk assessments. Theme 1 comprised three work packages:

- The pain package aimed to determine the extent of pressure area and pressure ulcer pain and explore the role of pain as a predictor of Category ≥ 2 pressure ulcers in acute hospital and community populations and incorporated a pain prevalence study and a pain cohort study.
- The severe pressure ulcer package aimed to describe and explain the ways in which the organisation of treatment/care influences the development of severe pressure ulcers and identify ways to improve cause analyses.
- The Risk Assessment Framework package aimed to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of an evidence-based Risk Assessment Framework to guide decision making about the risk of developing and progression of pressure ulceration.

The Risk Assessment Work package of the NIHR PURPOSE Programme was led by the researcher (SC) and the first 4 phases of this work underpin this PhD Thesis.

1.4 Pressure Ulcer Definition

Pressure ulcers are defined as 'localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear' (NPUAP/EPUAP 2009). Classification systems have been developed which incorporate numerical categories, sometimes referred to as grades or stages (terms which are used interchangeably or as reported in primary studies throughout this thesis) to describe the severity of the ulcer and the tissue layers involved (Shea 1975; Torrance 1983; AHCPR 1992; EPUAP 1999; NPUAP/EPUAP 2009). The most widely used pressure ulcer classification system was developed by the NPUAP and EPUAP (2009) and incorporates 4 numerical categories and 2

additional categories described in Table 1.1. Category/grade 1 pressure ulcers are areas of skin redness which do not blanch under light pressure and, whilst included in pressure ulcer classification, are more usually regarded as a precursor to pressure ulcer development (Nixon and McGough 2001). Previous classification systems have considered blanching redness as stage I (Torrance 1983) but this is considered to be a transient state (Nixon, Cranny and Bond 2007). Category/grade 2 pressure ulcers, involve skin damage and are reportable as clinical incidents across the NHS. Category/grade 3 or 4 pressure ulcers involve loss of fat, muscle and bone and represent serious clinical events and are increasingly subject to complaints and medical malpractice investigations. Indeed, changes in legislation and guidance relating to mental capacity and safeguarding (Department of Health (DH) 2000; The Mental Capacity Act 2005; Department for Education and Skills 2006; DH 2010) has prompted pressure ulcers to be investigated as part of the safeguarding vulnerable adult's agenda.

Additional categories of unstageable (full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough and/or eschar) and suspected deep tissue injury are also incorporated in the classification system for implementation in the US (NPUAP/EPUAP 2009). The suspected deep tissue injury category relates to an alternative pathway for pressure ulcer development first identified in an early pathological study whereby necrosis of muscle and fat occurs before destruction of the superficial layers and the appearance of a deep ulcer (as opposed to the ulcer presenting as superficial loss of the epidermis that progresses to deeper tissues if the pressure remains unrelieved) (Barton and Barton 1981).

Table 1.1 NPUAP/EPUAP Pressure Ulcer Classification System (2009)

Category/Grade	Description
Cat/grade I Non-blanchable erythema	Intact skin with non-blanchable redness of a localised area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/stage I may be difficult to detect in individuals with dark skin tones. May indicate 'at risk' persons (a heralding sign of risk)
Cat/grade II Partial thickness skin loss	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-filled filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising*. This category/stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation. * Bruising indicates suspected deep tissue injury
Cat/grade III Full thickness skin loss	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. The depth of a category/stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear occiput and malleolus do not have subcutaneous tissue and category/stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep category/stage III pressure ulcers. Bone/tendon is not visible ore directly palpable.
Cat/grade IV Full thickness tissue loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling. The depth of a category/stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Category/stage IV ulcers can extend into muscle and/or supporting structures (e.g. fascia, tendon, or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.
Cat/grade U (Unstageable/ Unclassified) Full thickness skin or tissue loss – depth unknown	Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, grey, green, or brown) and/or eschar (tan, brown, or black) in the wound bed. Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore category/stage, cannot be determined. Stable (dry adherent, intact without erythema or fluctuance) eschar on heels serves as 'the body's natural (biological) cover' and should not be removed
Suspected Deep Tissue Injury (DTI) – Depth Unknown	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

1.5 The Extent of the Problem

In the literature the extent of the pressure ulcer problem is explained most commonly via prevalence and incidence rates. Prevalence is defined as 'a cross-sectional count of the number of cases at a specific point in time' (Kaltenthaler *et al.* 2001) and includes old and new pressure ulcers. It provides an indication of the extent of chronic disease particularly relating to severe pressure ulcers and the burden these pose to services (Bridel 1993). Incidence relates to new cases of disease occurring in a population that were initially disease free (Fletcher, Fletcher and Fletcher 2005). Cumulative incidence refers to the proportion of the population studied that develops a new pressure ulcer over a specified time period (Baharestani *et al.* 2009). Incidence is a useful measure of an acute and quickly recoverable event such as a superficial pressure ulcer (Bridel 1993). Care should be taken when interpreting prevalence and incidence studies due to confusion over definitions of the terms incidence and prevalence, difficulties associated with conducting the studies (i.e. collecting and recording data, defining the study populations, identifying and classifying pressure ulcers), and lack of awareness of the pitfalls of comparing prevalence and incidence studies (Baharestani *et al.* 2009).

Pressure ulcers are a significant healthcare problem worldwide. A review of pressure ulcer prevalence and incidence data for the UK, US and Canada, incorporating sixty primary studies, reported great variation in both prevalence and incidence (Table 1.2) data (Kaltenthaler *et al.* 2001). This was attributed to the substitution of incidence for prevalence in analysis, use of different classification systems, under-reporting of pressure ulcers on transfer from different care facilitates and when pressure ulcers were used as a quality marker, inappropriate comparison of prevalence data by not taking case-mix into account and use of different study designs and methods of data collection (Kaltenthaler *et al.* 2001). It should be acknowledged that the variability of methods used meant that the results were not always comparable (Kaltenthaler *et al.* 2001).

Table 1.2 Pressure ulcer Prevalence and Incidence Ranges reported in Kaltenhaler et al 2001

	UK	USA and Canada
Hospital Prevalence	5.1 to 32.1%	4.7% to 29.7%
Community Prevalence	4.4 to 6.8%	19.2% to 29%
Nursing Home Prevalence	4.6 to 7.5%	15.3% to 20.7%
Hospital Incidence	2.2% per annum to 29% over a maximum period of 6 weeks	8.5% over a one to four week period to 13.4% for a maximum of two weeks
Community Incidence	20% over a maximum period of 6 weeks	0% over a six month period to 16.5% (time period not stated)
Nursing Home Incidence	None reported	6.2% over 6 months to 13.2% over one year

Another review of pressure ulcer incidence and prevalence was undertaken and included studies that were conducted over an 11 year period, from January 2000- November 2011 (Pieper 2012). The review included 43 studies (18 conducted in US hospitals and 24 in international hospitals) and reported varying pressure ulcer rates in different clinical settings. For general acute settings prevalence ranged from 11.9 to 15.8% and incidence ranged from 2.8-9.0%, confirming that pressure ulcers remain an important healthcare problem.

More locally a prevalence study conducted in 9 UK acute hospitals including 3,397 patients found 502 (14.8%) patients to have 1066 pressure ulcers (mean 2.1 per patient, SD 1.63, range 1-13) (Briggs *et al.* 2013). The majority of the ulcers were Grade 1 (70.5%; 752/1066), with grade 2 (22.2%; 237/1066) and severe pressure ulcers (7.2%; 77/1066) being reported less frequently (Briggs *et al.* 2013). Pressure ulcers most frequently occur on the sacrum followed by the heels, with other sites including the buttocks, trochanter, hips, elbows and ankles (Dealey 1991; Schoonhoven, Bousema and Buskens 2007; Vowden and Vowden 2009).

1.6 Quality of Life

Several qualitative studies have highlighted the negative impact pressure ulcers have on patients' quality of life. Key emerging themes include pain, exudate levels, loss of independence, emotional factors, worry about healing, relationships, body image and social isolation (Fox 2002) and pain, restricted life and coping with

pressure ulcers (Hopkins *et al.* 2006). Furthermore, a systematic review of quality of life incorporating 31 primary studies of both qualitative and quantitative research designs found that pressure ulcers and related interventions had a detrimental effect on the patients' quality of life (Gorecki *et al.* 2009). The review which involved a meta-synthesis of studies involving direct patient reports highlighted that concerns related to severe pain, treatments increasing discomfort and pain, health care professionals ignoring patient views and concerns, lack of action to warning signs (e.g. pain) and physical, social and psychological aspects of care not being met. Pressure ulcers are also associated with longer hospitalisation (Dealey, Posnett and Walker 2012).

1.7 Financial Burden

It is estimated that pressure ulcer management accounts for 4% of the total UK NHS expenditure (Bennett, Dealey and Posnett 2004) and recent work indicates the mean cost of treating a pressure ulcer in the UK varies from £1,214 (category I) to £14,108 (category IV) (Dealey, Posnett and Walker 2012). In the Netherlands Severens *et al.* estimated the cost to amount to 1% of the total healthcare budget (Severens *et al.* 2002), with more recent estimates suggesting this is between 1.21 -1.41% for hospitals alone (Schuurman *et al.* 2009). Annual pressure ulcer preventative costs in Dutch hospitals are estimated to be €27.5 - 63.6 million, while treatment costs are estimated to be considerably more, amounting to €174.5-178.8 million (Schuurman *et al.* 2009). In the US the Agency for Healthcare Research and Quality (AHRQ) reported that pressure ulcer costs were \$9.1-11.6 billion annually, and approximately 60,000 patient deaths per year were directly related to pressure ulcers (Berlowitz *et al.* 2011).

1.8 Pressure Ulcer Conceptual Frameworks

A pressure ulcer conceptual framework provides a theoretical model of the critical determinants of pressure ulcer development. This is important for both research and clinical practice. From a research perspective, pressure ulcer studies should be underpinned by a conceptual framework that is informed by evidence from all relevant fields of enquiry. This will guide study aims and objectives and allow theory to be tested, to further develop the evidence base and conceptual framework. From a clinical perspective conceptual frameworks are used to underpin pressure ulcer prevention strategies. It is therefore critically important that they are updated as new evidence emerges to facilitate translation of evidence into practice. Several

pressure ulcer conceptual frameworks have been proposed over the last three decades (Braden and Bergstrom 1987; Defloor 1999; NPUAP/EPUAP 2009; Benoit and Mion 2012).

Braden and Bergstrom, in their conceptual model implicated intensity and duration of pressure and tissue tolerance. The latter related to the ability of the skin and its underlying structures to tolerate pressure without damage (Braden and Bergstrom 1987). It was proposed that tissue tolerance would be influenced by extrinsic and intrinsic factors incorporating pressure ulcer risk factors. Defloor (1999) developed his conceptual scheme highlighting the importance of pressure (in the form of compressive and shearing forces), while recognising that tissue tolerance is an important consideration (Defloor 1999). However, he viewed the latter as an 'intermediate variable and not a causal factor'. Benoit and Mion (2012) developed their conceptual model for critically ill patients and also incorporate pressure and tissue tolerance with the latter highlighting extrinsic factors (Braden moisture and friction and shear) and intrinsic factors (metabolic supply and demand, pressure distribution capacity and threats to skin integrity).

Another conceptual framework was proposed by NPUAP/EPUAP (2009) and underpins international guidance on the prevention and treatment of pressure ulcers. It is based on factors that influence mechanical boundary conditions and the susceptibility of the individual (Figure 1.1). The framework provides a theoretical model of the important biomechanical and physiological conditions (of both the local area and systemically) which influence the development of pressure ulcers. A summary of the aetiological factors that lead to pressure ulcer development and a glossary of terms is presented in Table 1.3.

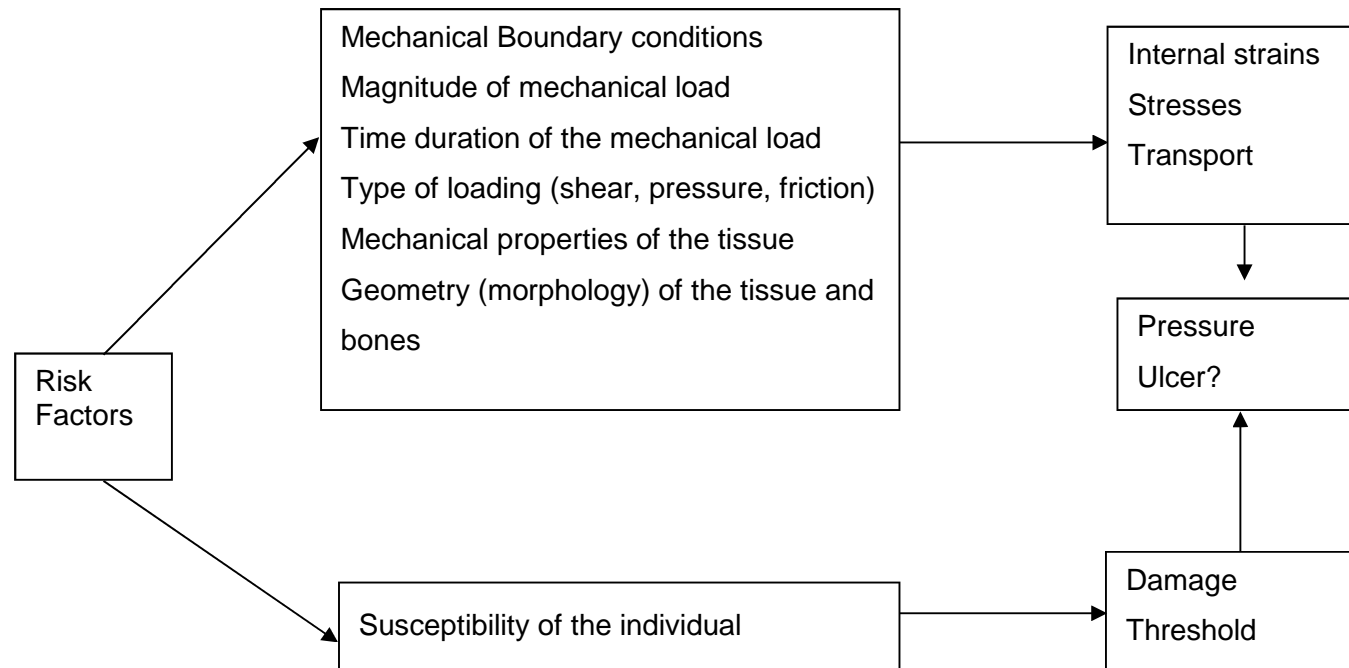


Figure 1.1 NPUAP/EPUAP (2009) Factors that Influence Susceptibility

Used with permission from the National Pressure Ulcer Advisory Panel, 8th May 2014

Table 1.3 Glossary of Biomechanical Terms based on NPUAP/EPUAP (2009) Clinical Practice Guidelines and Oomens, Loerakker and Bader (2010 (Oomens, Loerakker and Bader 2010)).

External Mechanical Load: comprises of all modes of external loading applied to a person's skin as a result of contact between the skin and a support surface (including air-filled or water filled devices which provide support) or contact between the skin of two body surfaces. The loading can be resolved into:

Normal force: perpendicular to the skin surface; or

Shear force: parallel to the skin surface

Pressure: normal force per unit surface area

In a clinical situation, shear forces require actual contact between the skin and the support surface, associated with normal forces, so that the skin will be exposed to a combination of both normal and shear forces.

Normal forces are distributed over the contact area which necessitates use of the term pressure, namely normal force divided by the contact area. Shear forces are also distributed over the contact area and create external shear stresses.

Friction: technically this describes all phenomena that relate to interface properties and sliding of surfaces with respect to each other (e.g. a person's skin over clothing or bed sheets). In pressure ulcer literature the term 'friction' has often been defined as the contact force parallel to the skin surface in case of 'sliding' (i.e. sliding of surfaces along each other).

Mechanical Boundary Condition: the mechanical load that is applied to the skin at the interface with the supporting surface represents a boundary condition.

Non-uniform Force: localised to a specific area of the skin surface for which the magnitude of force may be variable.

Deformation: change of dimension (shape) as a result of applied loading.

Strain: a measure of the relative deformation.

Stress: force transferred per unit area. Pressure represents a special type of stress where the forces are all normal to the area over which they act.

Morphology: size and shape of the different tissue layers.

Mechanical Properties of the Tissue: refers to the stiffness and strength of the tissue material.

Transport Properties: refers to the rate of transport of biomolecules into/out of tissues which may be either passive or active in nature. Active transport, which is sometimes called convection, involves metabolite transport by flow in blood and/or lymph vessels.

1.9 Pressure Ulcer Aetiology

The primary cause of pressure ulcers is mechanical load in the form of pressure or pressure and shear, applied to soft tissues, generally over a bony prominence (NPUAP/EPUAP 2009). Load that is distributed in a non-uniform or localised manner, as opposed to a uniform distribution, is potentially far more damaging to the tissues and shear forces are thought to increase tissue damage caused by pressure (Dinsdale 1974; Defloor 1999; Linder-Ganz and Gefen 2007). Shear forces are increased by friction which keeps the skin in position against the support surface while the patients body moves (i.e. as occurs when a patient in the semi-recumbant position slips down the bed) (Reger *et al.* 2010). While it is universally recognised that both intensity and duration of pressure are of prime relevance in the development of pressure ulcers, it is difficult to determine the relative contribution of these two parameters.

Laboratory and animal studies propose several aetiological mechanisms by which stress and internal strain interact with damage thresholds to result in pressure ulcer development including localised ischemia, reperfusion injury, impaired lymphatic drainage and sustained cell deformation (Bouten *et al.* 2003):

- Localised ischemia: conventionally, ischemia was thought to be the dominant aetiological factor associated with pressure ulcer development. Obstruction or occlusion of the blood vessels in soft tissues caused by external loading results in ischemia, reduced supply of nutrients to cells and elimination of metabolites (and associated change of pH) from localised areas eventually leading to tissue damage (Kosiak 1961; Bader, Barnhill and Ryan 1986; Dinsdale 1974; Gawlitta *et al.* 2007).
- Reperfusion injury: during the unloading reperfusion phase, damage caused by ischemia may be exacerbated as a direct result of the release of harmful oxygen free radicals (Peirce, Skalak and Rodeheaver 2000; Unal *et al.* 2001; Tsuji *et al.* 2005)
- Impaired lymphatic drainage: Occlusion of lymph vessels in soft tissues caused by external loading is associated with an accumulation of waste products and an increase in interstitial fluid contributing to pressure ulcer development (Miller and Seale 1981; Reddy, Cochran and Krouskop 1981).

- Deformation: recent studies involving, animal, engineered muscle tissue and finite element modelling have focused on the role of deformation in pressure ulcer development. These studies revealed that strains of sufficient magnitude have the potential to cause cell death over very short periods of time (Gefen *et al.* 2008). Gawlitta *et al.* considered the differences in influence of deformation and ischemia, using tissue engineered muscle, and found that deformation per se had an immediate effect whereas hypoxia reduced cell viability over prolonged loading periods (Gawlitta *et al.* 2007) . Furthermore, animal experiments involving 2 hours of muscle compression showed that while a complete area of muscle was ischemic, damage occurred in specific regions where high shear strain values were observed (Stekelenburg *et al.* 2007). Subsequent work using finite element simulations revealed that the areas of tissue damage coincided with those in which the predicted strains exceeded a critical threshold (Ceelen *et al.* 2008).
- Once the critical threshold has been exceeded the length of the exposure determined the extent of tissue damage, (Loerakker *et al.* 2010). Loerakker further examined the additional effects of reperfusion(Loerakker 2011). The results indicated that over short periods of loading exposure the level of deformation was the most important factor in the damage process for muscle tissue, while ischemia and reperfusion gradually become dominant over prolonged exposure periods. These bioengineering studies have provided important new insights into the damage thresholds for muscle tissue, but skin and fat are also implicated in pressure ulcer development.

Bouten *et al.* suggest that the type of ulcer that develops (i.e. those presenting as superficial loss of the epidermis that progresses to deeper tissues if the pressure remains unrelieved or deep tissue injury with necrosis of muscle and fat before destruction of the superficial layers and the appearance of a deep ulcer) depends on the nature of the surface loading: superficial pressure ulcers are mainly caused by shear stresses within the skin layers while deep ulcers are mainly caused by sustained compression of the tissues (Bouten *et al.* 2003).

At the present time, there is insufficient evidence to provide definitive numerical values for the duration of pressure or damage thresholds for pressure ulcer development in a human population. The original Reswick and Rogers (Reswick

and Rogers 1976) curve has been revised (Figure 1.2), as illustrated in the NPUAP/EPUAP clinical practice guideline (2009), to more accurately reflect the risk of tissue damage at the extremes of the loading periods (i.e. at very short and very long loading times): this indicates that the magnitude of pressure to induce tissue damage in the short-term is less than originally predicted by Reswick and Rogers and a new pressure/time curve was proposed (Linder-Ganz *et al.* 2006; Stekelenburg *et al.* 2007).

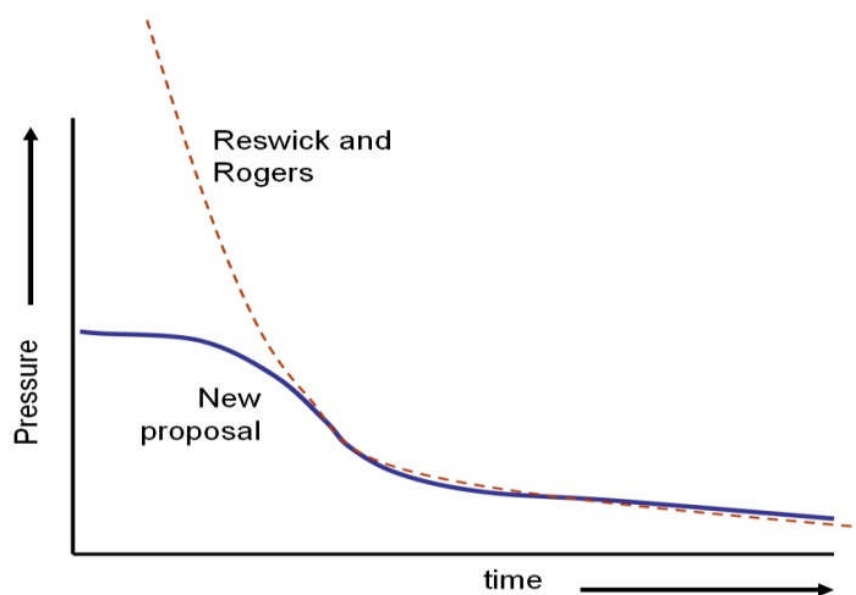


Figure 1.2 New proposal for pressure/time curve (NPUAP/EPUAP 2009)

Used with permission from the National Pressure Ulcer Advisory Panel, 8th May 2014

Furthermore, there is inherent variability in both individual susceptibility and local tolerance to loading parameters associated with factors including morphology and the mechanical properties of the intervening tissues. These, in turn, are affected by the patients' characteristics, health status and exposure to specific risk factors. This suggests that epidemiological evidence should also be considered in the development of a pressure ulcer conceptual framework, to facilitate translation of biomechanical/physiological concepts to characteristics which nurses can observe in their patients.

1.10 Introduction Pressure Ulcer Risk Factors

Populations who have been found to be at high risk of pressure ulcer development include patients who are elderly, have experienced trauma, have spinal cord injury,

are acutely ill and those in intensive care, long-term homes or community care environments (NPUAP/EPUAP 2009). These populations are more likely to be characterised by pressure ulcer risk factors. Risk factors are characteristics associated with an increased risk of becoming diseased (Fletcher, Fletcher and Fletcher 2005).

Within the pressure ulcer field epidemiological studies of different research designs and varying quality have considered the risk factors for pressure ulcer development. These consider whether risk factors are independently associated with pressure ulcer development, that is, “a risk factor that retains its statistical association with the outcome when other established risk factors for the outcome are included in the statistical model” (Brotman *et al.* 2005). However, it should be noted that being ‘independent’ is a statistical concept, depends on the risk factor variables included in the model and does not imply causality (Brotman *et al.* 2005). Careful consideration should therefore be given to the whether the statistical associations have clinical relevance.

Early epidemiological studies identified reduced activity and mobility as the key risk factor for pressure ulcer development (Allman *et al.* 1995; Berlowitz and Wilking 1989). Other risk factor themes which have been considered include skin condition, perfusion, moisture and nutrition, but the relative contribution these make to pressure ulcer development cannot be reliably determined from individual studies. An improved understanding of the relative contribution risk factors make to the development of pressure ulcers could improve our ability to identify patients at high risk of pressure ulcer development and target resources appropriately. Pressure ulcer risk factors will be discussed in more detail in chapters 2 and 3.

1.11 Pressure Ulcer Prevention

Pressure ulcers have been identified in successive Department of Health policies as a key quality indicator (DH 2001a; DH 2001b). The NHS 2010-2015 From Good to Great document, sets out the ambitious aim of eliminating all avoidable pressure ulcers in NHS provided care (DH 2009a) and a Commissioning for Quality and Innovation (CQUIN) payment framework has been developed to facilitate this (DH 2008). Pressure ulcers have subsequently been identified as high impact actions for Nursing and Midwifery (DH 2009b) and are incorporated into the new NHS monitoring tool, the Safety Thermometer (HSCIC 2013).

Pressure ulcer prevention strategies highlight the importance of five key elements incorporating risk assessment, skin assessment/care, nutrition, support surface/

pressure relieving devices, repositioning and nutrition (NICE 2005; NPUAP/EPUAP 2009; NICE 2014). Risk assessment is widely accepted as the cornerstone to prevention, as identifying those at increased risk of pressure ulcer development can facilitate the development and instigation of appropriate preventative interventions in clinical practice. Risk assessment will be discussed in more detail in Chapter 2.

1.11.1 Skin Assessment/Care

Clinical guidelines emphasise the importance of incorporating skin assessment into pressure ulcer risk assessment policies and educating professional how to undertake skin assessment (NPUAP/EPUAP 2009; NICE 2014). Skin assessment allows the identification of early pressure damage (Dealey 2005) and also gives an indication of the effectiveness of preventative interventions. Skin assessment in clinical practice is reliant on the nurse directly observing the pressure area/ulcer. While the NPUAP/EPUAP (2009) pressure ulcer classification system offers a structured tool for the assessment of pressure ulcers, no such tool is available for assessment of skin vulnerability (i.e. the pre-cursor to pressure ulcer development). At present this relies on the nurse's skill and experience at undertaking this. Blanching erythema of the skin indicates that the body has not recovered from previous loading and the need for an informed clinical decision regarding the risk of pressure ulcer development (Nixon and McGough 2001), which may prompt more frequent repositioning or different support surface allocation. Recent guidance advocates the use of finger palpation or discopy to identify whether discolouration is non-blanching erythema and consideration of any pain or discomfort reported by the patient (NICE 2014).

Other aspects of skin vulnerability that have been noted in the literature include dryness which reduces tensile strength and flexibility (Clark *et al.* 2010) and moisture (e.g. from incontinence and perspiration) which can cause skin maceration, increasing the likelihood of friction and shear (Defloor 1999; Reger *et al.* 2010). The management of controlling the cause of extreme temperature and skin moisture has been emphasised (Clark *et al.* 2010). Where skin moisture is a problem consideration should be given to the aetiology of any lesion noted and whether pressure is present, as historically trunk wounds have been labelled as pressure ulcers but there is confusion between Incontinence Associated Dermatitis (IAD) (which can occur without the presence of pressure) and superficial pressure ulcers (Beeckman *et al.* 2011; Doughty 2012). Guidance advocates effective skin care to ensure skin is well hydrated (i.e. by use of emollients for dry skin) or protected from excessive moisture exposure (i.e. with barrier products) and that

pressure areas are not massaged or vigorously rubbed (NPUAP/EPUAP 2009; NICE 2014).

1.11.2 Support Surfaces

As pressure (and shear) is the primary cause of pressure ulcer development (NPUAP/EPUAP 2009) much effort is made to reduce this for immobile patients in clinical practice. This is achieved by the provision of specialist support surfaces (mattresses and cushions) and repositioning the patient. Support surfaces are used to reduce pressure to vulnerable skin sites. These either mould to the patients' body, dispersing their weight over a large area providing 'constant low pressure' (McInnes *et al.* 2011) or they mechanically vary the pressure beneath the patient, so reducing the duration of the applied pressure (alternating pressure mattresses). Constant low pressure mattresses include those made of foam, foam and air, foam and gel, profiled foam, hammocks, air suspension, water suspension and air-particulate suspension/air fluidised (McInnes *et al.* 2011). The most commonly encountered constant low pressure mattresses in clinical practice are made from foam and are classified as 'low tech' devices (i.e. of a lower technical specification). Alternating pressure devices involve the inflation and deflation of air filled cells and are available as cushions, mattress overlays, single or multi-layer mattress replacements and are classified as 'high tech' devices (i.e. of a high specification) (McInnes *et al.* 2011). Some support surfaces also assist with the management of heat and moisture (Clark *et al.* 2010).

The use of pressure relieving equipment has implications for patients quality of life. A qualitative study of patients who live with pressure ulcers reported the impact of alternating pressure mattresses on patient's pain was considerable (Hopkins *et al.* 2006). Another study comparing alternating pressure overlay mattresses with alternating pressure replacement mattresses found that some patients found the mattresses uncomfortable, noisy and reported difficulties in moving in bed (Nixon *et al.* 2006a). It is therefore important to consider the patients personal circumstance and preferences and involve them in the decision making process when making equipment choices.

A Cochrane review of the effectiveness of support services on the prevention of pressure ulcers was undertaken which included 53 studies evaluating the effectiveness of various mattress types (McInnes *et al.* 2011). The review identified limitations in the literature including poor study quality and the lack of definition of standard hospital mattresses in many of the primary studies making interpretation

difficult. However, for the five studies that compared foam alternatives with the standard hospital foam mattresses the results were pooled (RR 0.40 95% CI 0.21 to 0.74) and a separate UK study analysis (RR 0.41; 95% CI 0.19 to 0.87) was undertaken (where variation in the term 'standard hospital mattress' was less likely) where the significant benefit of alternative foam over standard foam was maintained. Due to continued heterogeneity a further analysis was undertaken (excluding one study which included grade 1 pressure ulcers) which still favoured the alternative foam support (RR 0.29 95% CI 0.16 to 0.52) but there was inadequate evidence of which specific alternative foam mattress was superior (McInnes *et al.* 2011).

The review also considered comparisons between alternating pressure mattress's and standard hospital mattresses and constant low pressure and alternating pressure mattresses (McInnes *et al.* 2011). The alternating pressure and standard hospital mattress comparison, involved two studies which indicated a statistically significant reduction in pressure ulcer development in the alternating pressure mattress group (RR 0.31; 95% CI 0.17 to 0.58). However this should be interpreted cautiously as the studies were at high risk of bias. The constant low pressure and alternating pressure mattress comparison was considered in 10 studies but the advantages of one over the other remains unclear (McInnes *et al.* 2011). This has important clinical implications as both constant low pressure and alternating pressure devices are routinely used in clinical practice yet evidence about the benefits of one over the other is lacking. The financial implications and potential savings related to equipment choices are substantial, with the unit cost for constant low pressure high specific foam mattress being £18-£600, while the unit cost for an alternating pressure replacement mattress is £1000-£5000.

The Cochrane review (McInnes *et al.* 2011) was recently adapted and updated by NICE (2014) to consider the most clinical and cost-effective pressure re-distributing device for pressure ulcer prevention, to inform their clinical guideline. NICE acknowledged the limited evidence of effectiveness for redistributing devices and recommended this as a key research priority (NICE 2014). This work is being taken forward by the PRESSURE 2 (ISRCTN01151335) study which is currently in progress and is comparing high specification foam with alternating pressure mattresses.

In light of equipment related findings the recent NICE guidance makes the following recommendations for pressure ulcer prevention ((NICE 2014), Section 5.3)):

- ‘the use a high-specification foam mattress for adults who are admitted to secondary care
- the use a high-specification foam mattress for adults who are assessed as being at high risk of developing a pressure ulcer in primary and community care settings
- Consider a high-specification foam theatre mattress or an equivalent pressure redistributing surface for all adults who are undergoing surgery.
- Consider the seating needs of people at risk of developing a pressure ulcer who are sitting for prolonged periods.
- Consider a high-specification foam or equivalent pressure redistributing cushion for adults who use a wheelchair or who sit for prolonged periods’.

There is further guidance for adults with an existing pressure ulcer including that the ‘use of a dynamic support surfaces should be considered for adults with a pressure ulcer, where the use of high-specification foam mattresses is not sufficient to redistribute pressure’ (NICE 2014).

In addition to mattresses and cushions there are also some pressure relieving devices which have been developed to reduce pressure to heels. Guidance indicates that heel devices should ‘elevate the heel completely in such a way as to distribute the weight of the leg along the calf without putting pressure on the Achilles tendon. The knee should be in slight flexion’ (hyperextension of the knee may cause obstruction to the popliteal vein predisposing a deep vein thrombosis). (NPUAP/EPUAP 2009).

NICE (2014) recently undertook a systematic review in relation to heel devices for pressure ulcer prevention. The review involved 16 studies which compared the effectiveness of different devices on heel pressure ulcer development. Due to the limited evidence of effectiveness of any one device, NICE recommends that for adults at high risk of developing a heel pressure ulcer strategies to offload heel pressure should be discussed with the patient and where appropriate their family or carers, as part of an individualised care plan (NICE 2014).

1.11.3 Repositioning

Repositioning the patient is undertaken to relieve pressure from areas vulnerable to pressure damage e.g. turning a patient onto their side to relieve pressure on the

buttocks sacrum and heels. Repositioning practice stems from early small studies of inadequate design that noted a link between increased patient movement (Exton-Smith and Sherwin 1961) and regular turning (as often as 12 times in a 24 hour period) (Norton, McClaren and Exton-Smith 1962) and lower pressure ulcer incidence. Another quasi-experimental study was undertaken to determine the effects of 1 hourly, 1.5 hourly and 2 hourly turning on the skin over the sacrum and trochanter of 16 healthy, older adults (Knox, Anderson and Anderson 1994). The results indicated that while skin temperature increased significantly with increasing time of immobility, particularly over the trochanters, measures of interface pressures did not show any significant changes. The effects on skin colour were also noted and are detailed below in Table 1.4.

Table 1.4 Repositioning effects on skin colour reported by Knox et al (1994)

	No redness	Moderate redness	Severe Redness
1 hourly	6 (38%)	7 (44%)	3 (19%)
1.5 hourly	7 (44%)	4 (25%)	5 (31%)
2 hourly	8 (50%)	3 (19%)	5 (31%)

The limitations of this study relate to the inappropriate study design (i.e. is not an RCT) and small sample (n=16) not being representative of the pressure ulcer population (i.e. people with pressure ulcers are not healthy and usually have co-morbidities). Nevertheless, the study recommended that 1 and 1 1/2 hourly time period be considered a viable alternative to the 2 hourly turning interval (Knox, Anderson and Anderson 1994).

Several more recent studies using cluster randomisation design have considered the effects of repositioning on pressure ulcer incidence in elderly populations (Defloor, Bacquer and Grypdonck 2005; Vanderwee *et al.* 2007; Moore 2009). The first considered the effect of various combinations of turning regimes and pressure reducing devices (2 hourly turning on a standard hospital mattress, 3 hourly turning on a standard hospital mattress, 4 hourly turning on a viscoelastic foam mattress and turning every 6 hours on a viscoelastic foam mattress) compared with standard care (based on nurses clinical judgement including the use of water, alternating pressure mattresses, sheep skins and gel cushions) on the incidence of non-blanchable erythema (grade 1) and pressure ulcers (grade 2 \geq) involving 838 nursing home patients (Defloor, Bacquer and Grypdonck 2005). The results for the group

allocated to 4 hourly turning on a viscoelastic foam mattress had a significantly lower ($p = 0.003$, OR 0.12, 95% CI 0.03-0.48) incidence of pressure ulcers (3%, $n = 2/66$) compared with the other groups where the incidence ranged between 14.3% ($n = 9/63$) and 24.1% ($n = 14/58$).

Another nursing home study involving 235 patients that were all nursed on viscoelastic foam overlays, compared the pressure ulcer incidence (grade 2-4) of an experimental group (repositioned alternately 2 hours in a lateral position and 4 hours in a supine/semi-fowler position) with a control group (nursed in the same positions as the experimental group but being re-positioned every 4 hours for all positions) (Vanderwee *et al.* 2007). While the results indicated a lower pressure ulcer incidence in the experimental group (16.4%; $n = 20/122$, compared with 21.2%; $n = 24/113$ in the control group) this was not statistically significant. Given that the interventions for each group were similar the results are not surprising.

Another study of 213 patients undertaken in a long-term care hospital compared the pressure ulcer incidence (grade 1-4) of an experimental group being turned 3 hourly at night (using the 30 degree tilt method) and the control group receiving standard care (on average being turned 6 hourly, 90 degree lateral rotation) (Moore 2009). The results indicated statistically significant differences ($p = .035$, 95% CI .031-.038) in incidence rates with the experimental group having 3% ($n = 3/99$) incidence compared with 11% ($n = 13/114$) incidence of the control group.

A very recent multi-site randomised trial was undertaken in US and Canadian Nursing Homes and included 967 patients. In this study patients were randomly allocated using risk stratification (moderate and high according to Braden Scale) to a repositioning schedule (2, 3 or 4 hourly) while being nursed on high density foam mattresses (Bergstrom *et al.* 2013). Overall the incidence of pressure ulcers (stage 1-U) in the study was low (2%), with only 19 participants developing a total of 21 pressure ulcers (stage 2: $n = 19$; stage 1: $n = 2$). This low incidence presented a problem for detecting differences between the interventions and the results indicated there was no significant difference in pressure ulcer incidence ($p = .68$) between the three different repositioning schedule groups (Bergstrom *et al.* 2013). It is likely that the highly protocolised care, compliance monitoring and use of preventative equipment prompted reduced pressure ulcer incidence. This is an important consideration for future research in the area. Interpreting the results of repositioning studies and their implications for practice is generally hampered by the varying comparisons made and different support surfaces used.

The recent NICE guidance incorporates a systematic review of repositioning effectiveness. The search for this review included studies identified up to August 2013 and so did not include Bergstrom *et al.*'s (2013) most recent study reported above. However, it did identify 3 additional parallel RCTs (Smith and Malone 1990; Young 2004; van Nieuwenhoven *et al.* 2006) which considered the effectiveness of various repositioning schedules on pressure ulcer incidence. Two of the studies were very small (Smith and Malone 1990; Young 2004) and none found any significant differences between the interventions considered.

Despite the limited evidence of effectiveness, repositioning provides a common sense and widely accepted approach to prevention (NICE 2005; NPUAP/EPUAP 2009; NICE 2014). Recent guidance advocates that adults who are assessed as being 'at risk' or at 'high risk' of pressure ulcer development should change their own position or have assistance to change their position (using appropriate equipment) at least every 6 hours or 4 hours respectively (NICE 2014) .

1.11.4 Nutrition

While there is face validity among clinicians for poor nutrition being a risk factor for pressure ulcer development (and for delayed healing) the exact causal relationship between poor nutrition and pressure ulcer development remains unclear (NPUAP/EPUAP 2009). Studies have explored the effectiveness of various types of nutritional support on pressure ulcer prevention. A Cochrane systematic review was undertaken which included 8 trials (mostly small and of poor methodological quality) with regard to the effectiveness of enteral (absorbed by digestive system i.e. supplements via mouth or nasal passages) and parenteral (outside the digestive system i.e. IV infusion or intramuscular injection) nutrition on the prevention and treatment of pressure ulcers (Langer *et al.* 2003). Because of heterogeneity of patients groups, interventions and outcomes meta-analysis was deemed inappropriate. From a pressure ulcer prevention perspective the comparison of mixed nutritional supplements with a standard hospital diet was made in four studies. While all reported a reduced pressure ulcer incidence, 3 of the 4 studies lacked power while the fourth demonstrated a reduction in pressure ulcer incidence with an RR 0.83, 95% CI 0.70-0.99 (Langer *et al.* 2003).

Four studies considered in the Cochrane Review (Langer *et al.* 2003) were included in a recent systematic review to identify the most clinically and cost effective nutritional interventions for the prevention of pressure ulcers (NICE 2014). After separating the differences in the studies in terms of populations, interventions and

outcomes this review undertook meta-analyse. The review identified 4 additional studies so a total of 8 studies were included in different aspects of the review. Five RCTs of older hospital patients in multiple settings considered the effect of a standard hospital diet compared with a standard hospital diet and nutritional supplements of various composition and these were subject to meta-analyse (Delmi *et al.* 1990; Hartgrink *et al.* 1998; Bourdel-Marchasson *et al.* 2000; Houwing *et al.* 2003; Dennis, Lewis and Warlow 2005). The results indicated the studies were at very serious risk of bias and found the incidence of pressure ulcers for those receiving a standard hospital diet was 10.7% (n=269/2516) compared with 7.6% (n=185/2435) for those receiving standard hospital diet and nutritional supplements (NICE 2014). The review authors acknowledged that this evidence mainly related to those with inadequate nutritional status and recommended that nutritional supplements and subcutaneous or intravenous fluids, need not be offered to adults who have adequate nutritional intake and hydration specifically for pressure ulcer prevention (NICE 2014).

However, as poor nutrition is considered a reversible pressure ulcer risk factor, prevention and treatment guidelines promote the early identification and management of poor nutrition and support the use of nutritional screening (using a valid and reliable tool) to prompt appropriate dietetic referral and nutritional plans of care and interventions (NICE 2005; NPUAP/EPUAP 2009; NICE 2014).

1.11.5 Pressure Ulcer Prevention Initiative

In the literature there is evidence of quality/prevention/bundle initiatives whereby various combinations of the above preventative measures (i.e. risk assessment, skin assessment/care, repositioning, support surface allocation, nutritional assessment/care) are implemented in health care organisations and incidence or prevalence monitoring is undertaken before and after implementation to detect changes in pressure ulcer rates (Courtney, Ruppman and Cooper 2006; Gibbons *et al.* 2006; Hiser *et al.* 2006; Tippet 2009; Baldelli and Paciella 2008; Elliott, McKinley and Fox 2008; McInerney 2008; Lyman 2009; Orsted, Rosenthal and Woodbury 2009; Gray-Siracusa and Schrier 2011). These initiatives also incorporate leadership/management and staff resource components, staff education and feedback mechanisms. They all claim to have made improvements in their pressure ulcer rates e.g. in acute care hospitals Hiser *et al.* reported a reduced overall prevalence from 9.2% before the initiative to 6.6% following implementation (Hiser *et al.* 2006); Baldelli and Paciella reported pre initiative prevalence of 22% and incidence of 12% before implementation and 15% prevalence and 7% incidence

after implementation (Baldelli and Paciella 2008); and McInerney reported a pre-initiative hospital acquired prevalence of 12.8% and a 5.1% prevalence post-implementation (McInerney 2008). Gibbons et al (2006) reported pressure ulcer incidence was reduced from an estimated annualized incidence of 365 in 2004, to 256 in 2005 following implementation of the SKIN bundle initiative.

The SKIN bundle is perhaps the most widely acknowledged prevention initiative in the UK and while it has been implemented in Wales (Whitlock 2011) and Scotland it was originally developed in Florida US in a large adult in-patient facility (Gibbons *et al.* 2006). The development process for the SKIN bundle involved establishing a local leadership team, undertaking a literature review of best practice, reviewing current processes and undertaking and 'expert meeting' involving representative from the Institute of Healthcare Improvement and Ascension health as well as Wound Ostomy and Continence Nurses from across the US. This led to the development of the SKIN bundle to be used for patients who were considered to be at risk of pressure ulcer development as determined by the Risk Assessment Instrument. SKIN refers to (Gibbons *et al.* 2006):

- **S**urfaces – mattress/ cushion on which the patients' lay or sit
- **K**eeP the patient turning or moving
- **I**ncontinence – manage incontinence
- **N**utrition and hydration

The SKIN initiative was supported by staff training, a tool kit for implementation, a simple reminder chart of SKIN guidance and the pressure ulcer monitoring tool to ensure compliance in the documentation of the SKIN Bundle.

The prevention initiative area of literature is limited by the use of before and after study designs, use of prevalence data and high likelihood of publication bias (i.e. institutions who do not demonstrate improved rates are unlikely to publish). The effectiveness of such strategies can only be established through an adequately powered RCT. This would be no simple undertaking as such a trial would have both methodological and ethical challenges, owing to the wide use of preventative interventions finding control groups could be problematic.

1.12 Summary and Subsequent Thesis Chapters

Pressure ulcers remain a significant problem worldwide. They have a detrimental effect on patients' quality of life and present a financial burden to healthcare organisations. Pressure ulcer prevention guidance advocates the use of risk

assessment, skin assessment/care, repositioning, support surface provision and nutritional assessment and interventions. Risk Assessment is viewed as the foundation for prompting preventative interventions and the subsequent chapters of this Thesis considers the key phases of work undertaken to develop a new pressure ulcer Risk Assessment Framework for use in clinical practice, incorporating:

- Chapter 2, Risk Assessment: to provide an overview of pressure ulcer risk assessment and existing Risk Assessment Instruments within the context of wider health measurement. It will consider important psychometric properties in the development and validation of an instrument, highlight the need for a new approach to pressure ulcer risk assessment in practice and propose a methodological approach to achieve this.
- Chapter 3, Systematic Review of Pressure Ulcer Risk Factors: to provide a clearer understanding of the risk factors most predictive of pressure ulcer development, using the best quality evidence.
- Chapter 4 Using Consensus Methods to Develop a Risk Assessment Framework: in the absence of absolute evidence relating to pressure ulcer risk factors consensus methods were used to identify the risk factors most important for summarising pressure ulcer risk.
- Chapter 5, The Development of a new Pressure Ulcer Conceptual Framework: explores the critical determinants of pressure ulcer development. Using the results of the consensus study and risk factor terminology physiological and biomechanical elements were translated to characteristics which nurses can observe in their patients.
- Chapter 6, Design and Pre-Testing of the Risk Assessment Framework: considers the design of the Risk Assessment Framework incorporating the weighting and colour coding of risk factor items and support for clinical decision making.

Each chapter explores methodological considerations associated with the work, critically reviews its strengths and weaknesses and presents and discusses the results. The final General Discussion Chapter (7) summarises the key findings of this PhD and discusses the overall methodological approach, its limitations and highlights areas of methodological development and innovation. It goes on to discuss the implications of this PhD for clinical practice and research and to discuss plans for the ongoing validation of the Risk Assessment Framework.

Chapter 2 Risk Assessment

2.1 Introduction

This chapter provides a general overview of pressure ulcer risk assessment and Risk Assessment Instruments in the context of health measurement. It details the characteristics of the most commonly used Risk Assessment Instruments that were considered in a recent NICE systematic review (NICE 2014), as well as the basis of their development. It will discuss important psychometric properties incorporating validity, reliability and usability in instrument development and how they have been evaluated. It will also highlight key methodological limitations associated with this area of literature. It will go on to highlight the need for the development of a new Risk Assessment Framework for adult populations in clinical practice, describe the aims of this PhD and provide an overview of the adopted methodological approach.

2.2 Pressure Ulcer Risk Assessment

It is not appropriate to prevent pressure ulcers by subjecting all patients to resource intensive interventions (such as repositioning by nurses, expensive mattresses) which may impact on their quality of life (by disturbing sleep, for example) and divert nursing time from other essential areas, hence we must target care appropriately. Targetting patients for whom pressure ulcer prevention interventions are appropriate is achieved by considering the patients characteristics, a process known as risk assessment.

Regardless of context, risk assessment is widely accepted as being essential to pressure ulcer prevention (AHCPR 1992; NICE 2003; NPUAP/EPUAP 2009; NICE 2014) 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. To support clinical practice, Risk Assessment Instruments often referred to as 'scales' and sometimes referred to as 'tools' or 'measures' have been developed. These are commonly used to systematically identify patients at risk in preference to clinical 'judgement' of risk alone (AHCPR 1992; NICE 2003; NPUAP/EPUAP 2009; NICE 2014). They are thought to convey some advantages in that they set minimum standards of assessment and give some structure to the assessment process and decision making regarding the need to use (or not) preventative interventions

(NPUAP/EPUAP 2009; Moore and Cowman 2014). Pressure ulcer Risk Assessment Instruments enable the measurement of characteristics or risk factors which are considered important in pressure ulcer development. The pressure ulcer Risk Assessment Instruments that have undergone the most scrutiny in the literature, reflecting their widespread use in clinical practice include the Norton, Waterlow and Braden scales (Appendix 1-3) (Gould *et al.* 2002; Pancorbo-Hidalgo *et al.* 2006; Papanikolaou, Lyne and Anthony 2007; NICE 2014).

2.3 Risk Assessment Instruments within the wider Health Measurement Context

At this point it is important to consider Risk Assessment Instruments within the wider context of health measurement. Health Measurement is a very broad concept which comprises both patient and population level assessment, monitoring and evaluation of health (Ware Jr *et al.* 1981; SAC 2002; McDowell 2006). It is undertaken for a variety of different reasons including measuring the effectiveness of medical interventions, assessing quality of care, estimating needs of a population, improving clinical decisions and understanding the causes and consequences of differences in health (Ware Jr *et al.* 1981). The theoretical basis of Health Measurement has grown over the last 30 years leading to the development and validation of a wide range of instruments designed to measure health status and quality of life (SAC 2002). While for some disciplines the word 'instrument' is precisely defined (as for PRO instrument see Table 2.1), in the wider literature it is considered an overarching term to describe a range of measures which assess or diagnose aspects of health and disease via patient self-report or clinician assessment (Liang *et al.* 1985; McDowell 2006; Streiner and Norman 2008; Cano and Hobart 2011). The diverse range of instruments is demonstrated in the Health and Psychosocial Instruments (HaPI) database which incorporates measurement instruments such as questionnaires, interview schedules, vignettes/scenarios, coding schemes, rating and other scales, checklists, indexes, tests and projective techniques (HaPI Accessed Oct 2014).

Other related terminology that is commonly encountered in the literature includes 'scales' and 'tools' (Liang *et al.* 1985; McDowell 2006; Streiner and Norman 2008). While precise definitions for scales are apparent (Table 2.1) this is not the case for the tools. In the context of the pressure ulcer risk assessment literature the terms 'scales', 'tools' and 'measures' fulfil the definition of an instrument since they incorporate measurement scales with scoring, interpretation and application

guidance (Deeks 1996; Moore and Cowman 2014; NICE 2014). Throughout this thesis the term 'Risk Assessment Instrument' will be used other than when the 'term 'scale' appears in the title of specific instruments.

Further definitions have been developed for different types of scales, influenced by how numerals are assigned (Stevens 1946). Stevens (1946) identified 4 types of measurement scales comprising the Nominal, Ordinal, Interval and Ratio Scales (descriptions for each were updated (McDowell 2006) and are highlighted in Table 2.1. Pressure ulcer Risk Assessment Instruments tend to incorporate ordinal scoring systems in which scores for each risk factor are added together to give the patients overall score (McGough 1999; Nixon and McGough 2001). This overall score is then compared to a standard reference value to allocate the patient to a level of risk (e.g. high risk, moderate risk, at risk). The score is a key consideration in clinical decision making when planning preventative interventions in clinical practice (Gould *et al.* 2002; Papanikolaou, Lyne and Anthony 2007; Kottner and Balzer 2010).

The clinical decision making aspects of Risk Assessment Instrument's link to another related body of literature, 'decision aids' and 'decision tools'. Decision aids appear to be more focussed on patient decision making (Bekker, Hewison and Thornton 2003; Neuman, Charlson and Temple 2007; Stiggelbout and Timmermans 2010; McDonald, Charles and Gafni 2011), i.e. aids for patients facing health treatment or screening decisions and 'are designed to prepare patients to make informed decisions that are congruent to their own values' (Nelson *et al.* 2007). Whereas decision tools (Table 2.1) have broader application incorporating both health professional and patient decision making (Liu, Wyatt and Altman 2006).

Decision tools have 4 key characteristics (Liu, Wyatt and Altman 2006):

- To aid a clinical decision by a health professional and/or patient.
- Decisions concern an individual patient.
- Uses patient data and knowledge to generate an interpretation that aids clinical decision making
- Is used before the health professional or patient takes the relevant decision.

Table 2.1 Key Health Measurement Terminology

Measurement: the assignment of numerals to objects or events according to rules' (Stevens 1946).

Instrument: the constellation of items contained in questionnaires and interview schedules along with their instructions to respondents, procedures for administration, scoring, interpretation of results, and other instructions found in a user manual (SAC 2002).

Scale: 'the system of numbers or verbal anchors by which a value or score is derived for an item' (FDA DHHS 2009).

Nominal scales: Numbers are assigned arbitrarily with no implication of an inherent order to their categories, as in telephone numbers. Such scales may only be used as classifications; no statistical analyses may be carried out that use the numerical characteristics of the scale' (McDowell 2006, p715).

Ordinal scales: Classification into a scale that implies a distinct order among the categories (e.g., building numbers on a street), but where there is no assumption concerning the relative distance between adjacent values. Statistical methods such as rank order correlations may be used, but addition and subtraction, or calculation of averages, may not be appropriate' (McDowell 2006, p715).

Interval scales: 'Interval scales are so named because the distance between adjacent numbers in one region of the scale is assumed to be equal to the distance between adjacent numbers at another region of the scale (as in Fahrenheit or Celsius scales). Addition and subtraction are permissible, but not multiplication or division of such scales; statistical analyses such as the Pearson correlation, factor analysis, or discriminant analysis may be used with interval scales' (McDowell 2006, p715)

Ratio scales. 'A ratio scale is an interval scale with a true zero point, so ratios between values are meaningfully defined. Examples include weight, height, and income, because in each case it is meaningful to speak of one value being so many times greater or less than another value. All arithmetical operations, including multiplication and division, may be applied, and all types of statistical analysis may be used' (McDowell 2006 p715).

Decision tool: 'an active knowledge resource that uses patient data to generate case-specific advice which supports decision making about individual patients by health professional, the patients themselves or others concerned about them' (Liu, Wyatt and Altman 2006).

The decision tool field has been driven by the need to support health professionals decision making in areas of clinical uncertainty, to improve their efficiency and cost effectiveness (Stiell and Wells 1999). Many decision tools incorporate measurement and fulfil the definition of an instrument. They take many different forms including algorithm/flowcharts, care pathways, profile checklists, diagnostic/prognostic models and may be computer (computerised decision support systems: DSS) or paper based (Liu, Wyatt and Altman 2006). Examples of decision

tools in the literature include anticoagulant management, glucose regulation, a predictive instrument to estimate the risk of mortality following cardiovascular surgery and other clinical prediction models (Randell *et al.* 2007; Boulton *et al.* 2011; Steyerberg 2010). Existing pressure ulcer Risk Assessment Instruments have some features of decision tools and meet all of the criteria highlighted above (Liu, Wyatt and Altman 2006), i.e. patient data is used to provide an overall score which is used to guide decision making about preventative interventions. However the decision making aspect of the instrument comes at the end of the assessment by use of the overall score and is not integrated throughout the assessment process. This is important as using the overall score to aid decision making could result in inappropriate allocation of preventative or management interventions i.e. patients with the same scores may need completely different preventative or management interventions to address their needs.

2.4 The Development and Validation of Existing Pressure Ulcer Risk Assessment Instruments

It has previously been proposed that there are three applications of health instruments, comprising discrimination, prediction and evaluation (Kirshner and Guyatt 1985). The purpose of intended use influences the measurement properties of the instrument and its design (Kirshner and Guyatt 1985; Greenhalgh *et al.* 1998). In the context of pressure ulcer Risk Assessment Instruments all three characteristics are relevant as an ideal instrument would allow prediction of those most likely to develop a pressure ulcer (prediction), would allow 'not at risk', and 'at risk' individuals to be distinguishable (discrimination). It would also be responsive allowing changes in the patient's condition (evaluation) to be identified over time. In addition Risk Assessment Instruments need to be acceptable and relevant to clinical nurses who will use them (Greenhalgh *et al.* 1998).

Key considerations in the development and evaluation of instruments relate to establishing their psychometric properties, that is their validity and reliability (Nunnally 1970). The overall concept of validity relates to 'the degree to which the instrument measures what it purports to measure' (SAC 2002). Various types of validity are of importance (see Table 2.2.) including content-related, construct-related and criterion-related validity (SAC 2002). Another important property relates to reliability or 'the extent to which the measure is consistent and minimises random error' (Bowling 2009, p468). Attention should also be given to the usability and acceptability of the instrument to clinical nurses. This is important as poor usability and acceptability could impact upon the reliability and validity of the instrument.

Table 2.2 provides an overview of potentially important characteristics and the following sections consider existing Risk Assessment Instruments and whether these characteristics have been considered in their development and evaluation.

2.4.1 Risk Assessment Instrument Development

The basis of existing pressure ulcer Risk Assessment Instrument development has been largely overlooked in the literature but is of fundamental importance to the validity and reliability of an instrument. An early systematic review identified more than 40 pressure ulcer Risk Assessment Instruments but only seven were 'original' instruments (McGough 1999). Indeed, from the 13 Risk Assessment Instruments included in the more recent systematic review (NICE 2014) of predictive validity and detailed in Table 2.3 we can see that the majority have been developed on the basis of a combination of existing instruments, clinical opinion and literature reviews with only two original instruments (Bergstrom *et al.* 1987; Suriadi *et al.* 2008) reporting a conceptual framework. Where development was informed by a literature review it should be noted that these were in the main undertaken in the 1980s, when the epidemiological evidence was limited in quality and quantity with few studies exploring the contribution of individual risk factors to pressure ulcer development (Table 2.3.3).

It has been argued that pressure ulcer Risk Assessment Instruments need to be developed on the basis of multivariable analyses to identify factors that are independently associated with pressure ulcer development (Bridel 1994; Cullum *et al.* 1995; Nixon and McGough 2001). This would advance our understanding of the relative contribution different risk factors make to pressure ulcer development. This type of instrument development has in the main been undertaken only in single centre populations, with methodological limitations including inadequate sample sizes and/or use of the same data set for development and validation (Perneger *et al.* 2002; Suriadi *et al.* 2008; Page, Barker and Kamar 2011) (Table 2.3).

Table 2.2 Psychometric Properties of an Instrument

Property	Definition
Data Quality data completeness and acceptability	The extent to which scale items are completed and used to allocate a risk category; quality of data is assessed by data completeness for each element of the scale and score distributions (McHorney <i>et al.</i> 1994). Acceptability of instrument use with clinical nurses.
Usability	Compliance with the recommended completion guidelines i.e. is completed as intended. Easy to interpret and use.
Content Validity	The extent to which items of an instrument adequately represent the domain they are supposed to measure (Kaplan, Bush and Berry 1976)
Construct Validity	Evidence that relationships among items, domains and concepts conform to a priori hypotheses concerning logical relationships that should exist with measures of related concepts or scores produced in similar or diverse patient groups.(FDA DHHS 2009)
Convergent Validity	Evidence that constructs are correlated with other measures of the same or similar constructs; assessed by correlations between the measure and other similar measures (Kaplan, Bush and Berry 1976)
Discriminant validity	Evidence that the scale is not correlated with measures of different constructs; assessed on the basis of correlations with measures of different constructs (Gorecki 2011)
Known group differences	The ability of the measure/scale to differentiate known groups; assessed by comparing risk categories for subgroups who are expected to differ on the construct being measured (significant differences between known group or difference of expected magnitude) (Gorecki 2011).
Reliability	The extent to which the measure is consistent and free from random error (Bowling 2009).
Inter-rater reliability	Inter-rater reliability assesses the extent to which the results obtained by two or more raters agree for the same population. (Bowling 2009).
Test Re-Test Reliability	Test re-test reliability assesses the stability of the scale/tool over a period of time in which the patient's condition is not expected to change(Bowling 2009).
Criterion Validity	The correlation of a scale with some other measure of the trait or disorder under study, ideally, a 'gold standard' which has been used and accepted in the field (Streiner and Norman 2008).
Concurrent Validity	Independent corroboration that the instrument is measuring what it intend to measure e.g. the corroboration of a physical functioning scale with observable criteria (Bowling 2009).
Predictive Validity	The accuracy in separating patients who are at risk from patients who are not at risk (Nixon and McGough 2001) .
Responsiveness	An instruments ability to detect change (SAC 2002).

Adapted from Gorecki (Gorecki 2011) and PURPOSE Monograph (Nixon *et al.* Submitted).

It is also noteworthy that only a few papers (Abruzzese 1985; Waterlow 1985; Pritchard 1986; Cubbin and Jackson 1991) describing the development of Risk Assessment Instruments included in the NICE (2014) review, reported limited information of usability testing with clinical nurses (Table 2.3) and this could impact the reliability of the instrument. The reporting of patient involvement in the development of the Risk Assessment Instruments is also lacking and this is important, particularly when considering the acceptability of assessment methods (Table 2.3).

2.4.1.1 Content Validity

Content validity i.e. ensuring all relevant risk factors are included in Risk Assessment Instruments is fundamental to measuring pressure ulcer risk. However, due to the limitations of instrument development methods detailed above, there is inconsistent inclusion of risk factors in existing Risk Assessment Instruments as detailed in Table 2.4. Those most frequently incorporated are mobility, nutrition and continence/moisture (Table 2.4). The variability of included risk factors in existing Risk Assessment Instruments raises concern about their content validity and therefore their ability to adequately identify risk (Nixon and McGough 2001; Gould *et al.* 2002; Kottner and Balzer 2010).

It should also be noted that only a few instruments incorporate weighted risk factors (and it is often not clear on what this is based), with most employing an equally weighted scoring systems (Table 2.3). This assumes that each risk factor has an equal role in pressure ulcer development, but their precise contribution is as yet unknown and is likely to vary (Nixon and McGough 2001; Gould *et al.* 2002; Kottner and Balzer 2010; Papanikolaou, Lyne and Anthony 2007). This will affect the accuracy of the instrument in predicting those at risk.

Table 2.3 Summary of the Risk Assessment Instruments Included in the NICE Systematic Review (NICE 2014) and their Development

Instrument	Country	Brief Description of Instrument	Instrument development					How included risk factors determined
			Evidence of Conceptual framework	Population developed in clearly stated	Population of intended use clearly stated	Service users involved in development	Evidence of Acceptability/ Usability evaluation with clinical nurses	
Andersen (Andersen <i>et al.</i> 1982)	Denmark	Ordinal score system incorporating 8 risk factors : age, restricted mobility, incontinence, pronounced emaciation, redness over bony prominence, unconsciousness, dehydration, and paralysis A score of 2 or more indicated risk. Unconsciousness, paralysis and dehydration were given a score of 2 while the remainder had a score of 1. Not clear on what this weighting was based.	N	Y patients admitted to hospital with acute conditions	Y As previous	N	N	Clinical/ expert opinion
Braden (Bergstrom <i>et al.</i> 1987)	US	Ordinal score system incorporating 6 risk factors: nutrition, mobility, activity, sensory perception, moisture, friction and shear. Scores for each are of equal weighting with the exception of friction and shear. Overall scores can range from 6-23 with lower score indicating an increased risk of pressure ulcer development. Originally a score of 16 or less indicated the patient was 'at risk'.	Y	Y rehabilitation and nursing home population	P clinical use, sensitivity and specificity testing needed for each setting	N	N	Conceptual framework based on overview of literature
Modified Braden (Kwong <i>et al.</i>	China	Ordinal scoring system incorporating the 5/6 original risk factors detailed in Braden (excluding nutrition) plus 2 more: skin type and body build for	P *	Y Acute care hospital in	Y As previous	N	P	Adapted from Braden: Informed by finding of previous study

				Instrument development				
Instrument	Country	Brief Description of Instrument	Evidence of Conceptual framework	Population developed in clearly stated	Population of intended use clearly stated	Service users involved in development	Evidence of Acceptability/ Usability evaluation with clinical nurses	How included risk factors determined
2005)		height. Scores for each are of equal weighting with the exception of friction and shear. Scores can range from 8-31 with lower scores indicating greater risk. A score of 16 or less indicated the patient is 'at risk'.		China				(Pang and Wong 1998)
Cubbin-Jackon (Cubbin and Jackson 1991)	UK	Ordinal score system incorporating 10 risk factors: age, weight, general skin condition, mental condition, mobility, incontinence and hygiene, haemodynamic status, respiration, nutrition. Scores for each are of equal weighting. Score ranges from 10-40, those with a score of 24 or more were considered 'at risk'.	N	Y Intensive care patients.	Y As previous	N	Y very small pilot	Adapted from Norton and ITU clinical opinion
Douglas (Pritchard 1986)	UK	Ordinal score system adapted from Norton score including activity, incontinence, mental state, nutritional state and low haemoglobin, pain and skin condition. Scores were of equal weighting. Special risk factors including steroids, diabetes, cytotoxic therapy and dyspnoea could lead to further deductions in the score (2 for each- not clear on what this was based). It was envisaged that further speciality specific risk factors could be added. Lower scores indicated increased risk. Scores of 18 or less indicated 'at risk)	N	Y medical ward patients	Y As previous and possibility for adapting to other areas	N	Y	Adapted from Norton informed by clinical opinion

Instrument	Country	Brief Description of Instrument	Instrument development					How included risk factors determined
			Evidence of Conceptual framework	Population developed in clearly stated	Population of intended use clearly stated	Service users involved in development	Evidence of Acceptability/ Usability evaluation with clinical nurses	
Fragment (Perneger <i>et al.</i> 2002)	Switzerland	Ordinal scoring system incorporating the following risk factors: friction and shear, mobility, mental status, age. Weighting based on regression coefficients: age 0-4, mobility 0-2, mental status 0-2, friction/shear 0-2 Low risk represented by a low score. 0-3 low risk, 4-6 require standard prevention, 7-10 more intensive preventative interventions.	N	Y Acute care hospital	Y As previous	N	N	Based on multivariable modelling of Braden and Norton risk factors.
Gosnell (Gosnell 1973; Gosnell 1989)	US	Ordinal scoring system incorporating 5 risk factors: mental status, continence, mobility, activity, and nutrition. Scores for each range from 1-4 for each with the exception of mental status (1-5) and nutrition (1-3) In addition information regarding colour, skin appearance, vital signs, fluid balance, diet, interventions and medication is evident though not included in the scoring system. Scores can range from 5- 20 with lower score indicating higher risk.	N	Y Over 65 extended care facility.	P Could be used in numerous settings	N	N	Adapted from Norton
Knoll (Abruzzese 1985)	US	Ordinal scoring system incorporating the following risk factors: general health, mental status, activity, mobility, incontinence, oral nutrition, oral fluid intake and predisposing diseases. The highest 2 scores for mobility, activity and incontinence were given double weighting as thought to be critical variables. Higher score	N	Y- Large metropolitan Hospital	U	N	Y	Factors identified from 1 year audit and literature review

				Instrument development				
Instrument	Country	Brief Description of Instrument	Evidence of Conceptual framework	Population developed in clearly stated	Population of intended use clearly stated	Service users involved in development	Evidence of Acceptability/ Usability evaluation with clinical nurses	How included risk factors determined
		indicated higher risk. Score of 12 should be considered 'at risk'. Score can range from 0-33.						
Norton (Norton, McClaren and Extton-Smith 1962)	UK	Ordinal scoring system incorporating the following risk factors: general physical condition, mental status, mobility, activity, and incontinence all with equal weighting. Scores can range from 5-20 with lower score indicating increased risk. Scores of 14 or less indicated liability to ulcers; scores of <12 indicated very high risk.	N	Y Elderly hospital patients	n/a	N	N	Originally developed as a pressure ulcer research tool and found to be correlated with PU incidence. Subsequently used as a clinical risk assessment instrument
Northern Hospital Pressure Ulcer Plan (Page, Barker and Kamar 2011)	Australia	Ordinal scale incorporating the following risk factors: age (≥ 65), admission to ICU during current admission, reduced sensation, cognitive impairment and requires assistance to move in bed. The weighting of scores was derived using risk factor coefficients. Each risk factor has a score of 1 point except require assistance to move in bed which was given a score of 2. The cut point of 3 or more indicated high risk	N	Y Acute hospitals	Y As previous	N	N	Literature review, chart audit , from 2 pressure ulcer prevalence surveys and multivariable analysis

				Instrument development				
Instrument	Country	Brief Description of Instrument	Evidence of Conceptual framework	Population developed in clearly stated	Population of intended use clearly stated	Service users involved in development	Evidence of Acceptability/ Usability evaluation with clinical nurses	How included risk factors determined
Risk Assessment Pressure sore Scale (RAPS) (Lindgren <i>et al.</i> 2002)	Sweden	Ordinal scale incorporating the following risk factors: general physical condition, activity, mobility, food intake, fluid intake, moisture, sensory perception, friction and shear, body temperature and serum albumin. Body constitution and skin type were also in the original scale though were subsequently excluded as were found to be weakly correlated with the scale as a whole and other items. Scores for each are of equal weighting with the exception of friction and shear. Score can range from 12-39 with lower scores indicating greater risk	P	Y Acute hospital with mixed populations	Y Medical patients	N	N	Based on the Norton, modified Norton and Braden.
Song and Choi (Song and Choi 1991) Information regarding scale obtained from Song and Choi abstract and Kim <i>et al</i> as original main	Korea	. Ordinal scale incorporating Braden scale risk factors and body temp temperature and medication. Scores for each are of equal weighting with the exception of friction and shear. Score range from 8-31 with lower scores indicating higher risk.	Y	Y Developed for patients with neurological problems	U	U	U	Modified from the Braden scale.

				Instrument development				
Instrument	Country	Brief Description of Instrument	Evidence of Conceptual framework	Population developed in clearly stated	Population of intended use clearly stated	Service users involved in development	Evidence of Acceptability/ Usability evaluation with clinical nurses	How included risk factors determined
paper in Korean (Kim <i>et al.</i> 2005)								
Suriadi and Sanada (Suriadi <i>et al.</i> 2008)	Indonesia	Ordinal scale incorporating interface pressure, body temperature and cigarette smoking. Scores were weighted using regression coefficient values. Scores range from 0-9 with higher scores indicating higher risk. The recommended cut-off is ≥ 4 .	Y	Y Intensive care patients	Y	N	N	Based on the statistical analysis of a previous prospective ICU cohort study
Waterlow (Waterlow 1985)	UK	Ordinal scoring system incorporating 10 risk factors: nutrition/appetite, mobility, build/weight, continence/ sex/age, skin type, tissue malnutrition, neurological deficit, major surgery/trauma, medication. The scoring system allowed multiple scores for each category. Scores can range from 2-20+. In the original presentation of the Waterlow card a score of 10 indicated the patient was 'at risk'; a score of 15 indicated the patient was at 'high risk' and; a score of 20 indicated the patient was at very high risk.	N	Y Acute hospital	U	N	Y	Literature review, clinical opinion and survey

Table components (horizontal headers) adapted from (Bryant *et al.* In pres). Y=yes; N=no; P-partial P*-based on Braden, U-unclear

Risk Factor Domains	Anderson	Braden	Modified Braden	Cubbin Jackon	Fraggment	Douglas	Gosnell	Knoll	Norton	NHP-PUP	RAPS	Song and Choi	Suriadi	Waterlow	Total
Age	√			√	√					√				√	5
Sensory Perception (including pain, poor sensation or cognitive impairment)		√	√			√				√ x2	√	√		√	7
Skin condition	√		√	√		√								√	5
Orthopaedic surgery/ fracture below waist														√	1
Medication						√x2						√		√	3
Unconsciousness	√														1
Paralysis	√														1
Respiration				√		√									2
Admission to ICU during current admission										√					1
Predisposing diseases								√							1
Body Temp											√	√	√		3
Interface pressure													√		1

Risk Factor Domains	Anderson	Braden	Modified Braden	Cubbin Jackon	Fraggment	Douglas	Gosnell	Knoll	Norton	NHP-PUP	RAPS	Song and Choi	Suriadi	Waterlow	Total
Serum albumin											√				1
Hygiene				√											1

*assistance to move in bed

2.4.2 Instrument Validation

It is recognised that an appropriate validation process is dependent on the nature of the instrument under development, always requires empirical investigations and 'is a matter of degree rather than an all or none property' ((Nunnally 1967) pp75). The literature relating to the validation of pressure ulcer Risk Assessment Instruments has primarily focussed on predictive validity and reliability but other types of validity and the responsiveness of the instrument to detect clinically relevant changes are also relevant. A literature search of pressure ulcer risk assessment validation terms was undertaken to reveal relevant literature (Appendix 4).

2.4.3 Reliability

Reliability relates to the degree to which measurement error is non-existent in the obtained scores (Bowling 2009). Reliability is a vital requirement for any instrument and underpins validity i.e. a large amount of measurement error would prevent reflection of the criterion of interest (Kottner and Dassen 2008a). The literature search (Appendix 4) identified pressure ulcer studies reporting the assessment of the inter-rater reliability, that is the extent to which the results obtained by two or more raters agree for the same population (Bowling 2009).

A systematic review considered the predictive validity and reliability of existing pressure ulcer Risk Assessment Instruments and included 33 cohort studies or controlled clinical trials (Pancorbo-Hidalgo *et al.* 2006). This review reported the inter-rater reliability of the included Risk Assessment Instruments if reported in the primary studies of the review and comprised 13 studies considering the Braden Scale, 2 studies considering the Norton Scale and 2 studies considering the Waterlow Scale. It is presumed that the reliability rates reported in the review are for Scale total scores (as is usually the case) rather than the individual items, though this is not reported in the review (Pancorbo-Hidalgo *et al.* 2006). The review reported high inter-rater reliability for the Braden (Pearson correlation coefficient: $r = 0.83-0.99$), Norton ($r = 0.99$ and 100% agreement), and Waterlow Scales ($r = 0.99$ and 92.5% agreement). However it should be noted that only 2 studies considered the reliability of the Waterlow Scale and the Norton Scale. Overall the Braden Scale has been subjected to the most testing and suggests high levels of inter-rater reliability for the total score.

Several more recent studies considered the inter-rater reliability of the Braden Scale and the Waterlow Scale. The Braden Scale was considered in nursing home, home care and intensive care settings (Kottner and Dassen 2008b; Kottner, Halfens and Dassen 2009; Kottner and Dassen 2010) and the Waterlow Scale was also

considered in the Intensive care study (Kottner and Dassen 2010) and in acute care settings (Webster *et al.* 2010). Overall the results concur with those found previously (Pancorbo Hidalgo), though inter-rater reliability was reduced for the Waterlow total score in an intensive care environment where the total score intraclass correlation coefficients (ICC) were 0.36 (95% CI 0.09-0.63) and 0.51 (95% CI 0.27-0.72) (Kottner and Dassen 2010).

Three studies also considered the inter-rater reliability for individual instrument items which overall were lower than for total scores (Kottner and Dassen 2008b; Kottner, Halfens and Dassen 2009; Kottner and Dassen 2010). This could be important in considering the usability of the instrument and in identifying items which may be more difficult to complete (Kottner and Dassen 2008b). The use of test re-test reliability could also be usefully considered in order to assess the stability of the Instrument over a period of time in which the patient's condition is not expected to change, but no evidence of this was found in the literature search (Appendix 4).

2.4.4 Construct Validity

Evidence supporting construct validity comes from testing theoretical hypotheses, often gained by consideration of known groups, convergent and discriminant validity (Kaplan, Bush and Berry 1976; Kottner and Balzer 2010) as highlighted in Table 2.2. The search (Appendix 4) revealed evidence of these properties in the literature.

2.4.4.1 Convergent Validity

Several studies have considered the convergent validity of Risk Assessment Instruments to assess its correlation with other similar measures. An observational study of the Waterlow Score, Braden Scale and a Visual Analogue Scale (VAS) to measure pressure ulcer risk was undertaken in two intensive care units in Germany (Kottner and Dassen 2010). Correlation coefficients of the instrument sum scores indicated the lowest correlations were between the visual analogue scale and the Waterlow score ($r = 0.51$ and 0.52). The highest overall correlations were between the Waterlow and Braden score ($r = 0.71$ and 0.72). Overall the results indicate that the 3 instruments (visual analogue scale, Waterlow Score and Braden Scale) measured something similar (Kottner and Dassen 2010).

Others have considered the convergent validity of subscales of the Braden scale (Powers *et al.* 2004; Omolayo *et al.* 2013). A small observational study evaluated

the mobility subscale, involving 16 veteran home patients (4 for each of the 4 scores of the Braden mobility subscale) (Powers *et al.* 2004). The continuous movement of participants was recorded using a Motion logger Actigraph (for 72 hours). The results indicated there was a significant increase in recorded activity as the mobility sub-scale increased (Powers *et al.* 2004). The moisture subscale of the Braden scale was also examined in a secondary analysis of a multi-site RCT involving 343 patients (Omolayo *et al.* 2013). The results indicate a significant inverse relationship, where increasing subscale scores were associated with decreasing wet observations (Spearman rank correlation coefficient: $r_s = -0.233$; $p < .0001$) and soiled observations ($r_s = -0.133$, $p < 0.13$). A limitation of the study was the inclusion of only patients with a total Braden Score of 10-14.

The convergent validity of some Instruments has also been considered alongside care dependency measures. A cross sectional study incorporating 164 patients correlated the scores of the Braden Scale, Norton Score and the Bartel Index (Marrie, Ross and Rockwood 2003). The results indicated that the total scores for all three correlated highly with each other (>0.80). Another study showed similar findings in a large scale cross-sectional study (German national voluntary survey) incorporating more than 10,000 participants from nursing home and hospital settings (Mertens *et al.* 2008). This study found a high correlation between the Care Dependency Scale total scores and Braden Scale total scores (nursing home patients $r = 0.79$ ($p < 0.01$), hospital patients $r = 0.89$ ($p < 0.001$)). Other studies have also found high correlations between Risk Assessment Scales and Care Dependency measures (Balzer *et al.* 2007; Tannen *et al.* 2010).

2.4.4.2 Known Groups

Known-group comparisons are used to evaluate the clinical utility of instruments to assess the extent to which the overall assessment or items are able to discriminate between subgroups of patients known to differ in terms of clinical presentations (Table 2.2) (Kerlinger 1973). This has been confirmed in intensive care populations where higher prevalence and incidence rate are reflected by higher levels of pressure ulcer risk (Kottner *et al.* 2009). Known groups were also considered in a cross-sectional study that translated the risk assessment pressure sore (RAPs) scale to Norwegian (Fossum *et al.* 2012). The known groups assessed were nutrition/weight and pressure ulcer presence. It was anticipated that patients with high RAPS scores would have a higher BMI ($\geq 23 \text{ kg/m}^2$) and larger calf measurements ($\geq 31 \text{ cm}$) and those with lower RAPS scores would have a lower BMI (< 23) and smaller calf measurement ($< 31 \text{ cm}$). Those with pressure ulcers were

expected to have lower RAPS scores (indicating increased risk). The results supported these hypotheses indicating significant differences ($p < 0.001$) between the mean scores for these groups (Fossum *et al.* 2012).

2.4.4.3 Discriminant Validity

Discriminant validity relates to evidence that the scale is not correlated with measures of different constructs (Table 2.2). Only one study was found in the literature and this assessed discriminant validity by correlating 2 Risk Assessment Instruments (Braden and Norton) and the Bartel Index against age. It reported correlations of between 0.3 and 0.4 providing some evidence of discriminant validity (Marrie, Ross and Rockwood 2003).

2.4.5 Responsiveness

Responsiveness is the ability of the Instrument to detect clinically significant changes in the patient's condition which affect pressure ulcer risk status. Logically this should be an important feature in Risk Assessment Instruments as it could assist in the required escalation of preventative interventions where a patient's condition has deteriorated. Despite this no evidence was found in the literature search (Appendix 4).

2.4.6 Criterion Validity

The literature search (Appendix 4) identified a few studies considering concurrent validity as detailed below.

2.4.6.1 Concurrent Validity

Two studies used illustrated patient scenarios to examine the concurrent criterion validity of Risk Assessment Instruments (Gould *et al.* 2002; Gould *et al.* 2004). The first study considered 3 Risk Assessment Scales (Norton, Waterlow and Braden) and the nurses clinical judgement (Gould *et al.* 2002). The 'gold standard' used in this study was the consensus views of an expert tissue viability panel who rated the patients pressure ulcer risk from 1-10 on a visual analogue scale (VAS). The VAS score results were categorised as low risk: 1-3, medium risk: 3.5-5; high risk: 5.5-7.5: and very high risk: 8-10, though it is not clear how this was decided. The study compared risk estimations made by clinical nurses using the 3 Instruments (Norton, Waterlow and Braden) and their clinical judgement using the VAS, with the consensus views of an expert tissue viability panel. (Gould *et al.* 2002). The study included 236 clinical nurses (from acute and community sectors) and 941 assessments using four patient scenarios. The results indicated that the estimation of risk using the above Instruments only exactly matched the risk categories of the

expert panels' views in 20% of cases for the Waterlow Score, 8.5% of cases for the Braden Scale and 4.6% of cases for the Norton Score. The nurses clinical judgement measured on the VAS demonstrated exact risk category matches with that of the expert panels views on 69.1% of occasions (Gould *et al.* 2002). These results favour the use of clinical judgement, though study limitations associated with the use of patient scenarios, nurses 'clinical judgement' being contaminated by use of the Risk Assessment Instruments, and the lack of reporting of correlation coefficients should be acknowledged.

Furthermore, a follow-up study this time considering the Waterlow score and the VAS and including 115 clinical nurses, incorporating 230 assessments (Gould *et al.* 2004) did not support the findings of the previous study (Gould *et al.* 2002). This study used 2 patient scenarios and while the results related to the VAS (scenarios 1 differences mean -0.15, median 0; scenario 2 mean 0.97, median 1.0) were more similar to that of the expert panel assessments than the Waterlow Score (scenarios 1 differences mean 0.84, median 1.0; scenario 2 mean 1.56, median 2.0) neither agreed greatly with the expert panel. Indeed for one of the patient scenarios it was concluded that neither the VAS or the Waterlow score was considered effective in assessing that particular patients' pressure ulcer risk (Gould *et al.* 2004).

2.4.7 Predictive Validity

Most commonly studies evaluating the value of pressure ulcer Risk Assessment Instruments consider their predictive validity (Deeks 1996; NICE 2014). This is the accuracy in separating patients who are at risk from patients who are not at risk (Nixon and McGough 2001).

2.4.7.1 Sensitivity and Specificity

Evaluating predictive validity incorporates two important measures:

- Sensitivity – the extent to which a true characteristic is classified correctly (Defloor and Grypdonck 2004).
- Specificity – the extent to which the absence of a characteristic is correctly classified (Defloor and Grypdonck 2004).

The relationship between sensitivity and specificity is often illustrated in a receiver operator characteristic curve (ROC). This plots the true positive results (sensitivity) against the false-positive results (specificity) over a range of cut-off values (Table 2.5). Overall test accuracy is described as the area under the ROC curve, the larger the area the better the test (Fletcher, Fletcher and Fletcher 2014).

Table 2.5 The relationship between a Risk Assessment Instrument result and pressure ulcer development

		Pressure Ulcer development	
		Present	Absent
Risk assessment scale prediction	Positive (at risk)	True positive (correct)	False positive (incorrect)
	Negative (not at risk)	False negative (incorrect)	True negative (correct)

Based on Fletcher et al 2014 The relationship between a diagnostic test result and the occurrence of disease

Measures of sensitivity and specificity are also routinely used in the evaluation of diagnostic screening tests but there are important differences in the objectivity of the measures involved as well as the overall aims of these instruments. Diagnostic screening tests often incorporate information from objective laboratory measures e.g. amniocentesis testing to detect babies with chromosomal abnormalities in pre-natal care (Alfirevic, Mujezinovic and Sundberg 2009) and the Pap test to identify those with cervical cancer (Nanda *et al.* 2000). However, the measurement of pressure ulcer risk factors is more subjective because objective measures are not available in routine practice. Nurses' therefore use their clinical judgement regarding the presence and magnitude of risk factors e.g. a nurse assesses a patient's mobility by a combination of observation, history taking and sometimes liaison with other members of the Multi-Disciplinary Team rather than by an objective measure. Skin vulnerability is another example where no objective measure is routinely used, rather nurses' use clinical assessment skills which incorporates their subjective clinical judgement. These subjective measures are more prone to error which could affect the predictive validity of an instrument.

In addition while diagnostic screening tests aim to identify the actual presence of disease, Risk Assessment Instruments aim to identify the 'risk' of pressure ulcer development i.e. before it happens so that preventative measures can be put in place to avoid the development of a pressure ulcer (Defloor and Grypdonck 2004). This is a critical difference and presents a challenge to the sensitivity and specificity evaluation of pressure ulcer Risk Assessment Instruments. Firstly there is no reference standard for pressure ulcer 'risk' and despite the differences between pressure ulcer 'risk' and pressure ulcer 'presence', evaluation is commonly achieved by comparing the Risk Assessment Instrument risk categorisation (i.e. at risk or not at risk) with subsequent pressure ulcer outcome, i.e. pressure ulcer

development or not (Kottner and Balzer 2010). Secondly, the instigation of preventative interventions is a key element of standard clinical practice and this will impact the instrument performance in the study population i.e. it is possible that poor instrument performance is a result of effective preventative care (Deeks 1996; Defloor and Grypdonck 2004). Preventative care is a confounding variable that presents an irresolvable problem in predictive validity studies of Risk Assessment Instruments as it would be unethical to withhold care (Defloor and Grypdonck 2004; Gould *et al.* 2002). Risk Assessment Instruments are routinely used in clinical practice to guide decision making about the instigations of preventative interventions to reduce pressure ulcer development. Ideally then, their use would prompt action to prevent pressure ulcer development in those at risk, which would decrease sensitivity and specificity results, suggesting that predictive validity is not an appropriate property to evaluate Risk Assessment Instruments (Deeks 1996; Defloor and Grypdonck 2004). Furthermore, evaluation of predictive validity does not provide useful information to indicate whether use of the Risk Assessment Instrument leads to a reduction in pressure ulcer incidence (Deeks 1996)..

2.4.7.2 Predictive validity of existing instruments

Despite the limitations highlighted above there is a plethora of studies and several systematic reviews examining predictive validity of pressure ulcer Risk Assessment Instruments (Cullum *et al.* 1995; Pancorbo-Hidalgo *et al.* 2006; NICE 2014). The Pancorbo-Hidalgo (2006) review was used as a reference for a more recent systematic review conducted by NICE (2014). The NICE review identified 44 prospective cohort studies in which patients did not have pressure ulcers at baseline. Overwhelmingly reports of the predictive validity of adult Risk Assessment Instruments were about the Braden Scale (27) followed by the Norton Scale (11) and the Waterlow Scale (10). Clinical judgment was also considered in 2 studies. The results of the review should be interpreted cautiously as it was acknowledged that the sensitivity, specificity and AUC measures were likely to be inaccurate due to confounding of varying preventative treatments used in the included studies (NICE 2014). The review also identified that included studies were generally at high to very high risk of bias and had low pressure ulcer event rates (NICE 2014). Interpretation is further complicated by:

- the use of different cut-off thresholds for Risk Assessment Scales.
- the use of different time periods for assessment (longer time periods may result in increased pressure ulcer incidence and increased sensitivity).

- heterogeneity of study populations (relating to age, comorbidities and other risk factors) which would affect pressure ulcer incidence rates and sensitivity/specificity.
- differences in pressure ulcer outcome definitions i.e. category 1 and category 2 (which would affect incident rates and therefore predictive validity measures).

Whilst recognising the limitations of the review, Table 2.66 provides an overview of the AUC results for the three commonly used and researched Instruments (NICE 2014). It reports the summary statistic with its 95% confidence interval of the median study and the range across studies (NICE 2014).

Table 2.6 Overview of NICE (2013) Review Evidence of AUC for 3 Commonly used and Researched Instruments

Scale	No Studies	AUC (95% CI) R:range of point estimates
Braden	9	74% (70 to 78); R: 55-88%
Waterlow	4	59% (54 to 65); R:54-90
Norton	2	56% (51 to 61) & 74% (70 to 78)

The criteria for the AUC were – 50.0-59.0: fail to discriminate; 60.0-69.0: poor discrimination; 70.0-79.0: fair discrimination; 80.0-89.0: good discrimination; 90.0-100.0= perfect discrimination.

Table 2.77 provides an overview of the sensitivity and specificity results for particular cut- off thresholds (determined by instrument author recommendation) for the three commonly used and researched instruments (NICE 2014).

Table 2.7 Overview of NICE (2014) Review Evidence of Sensitivity and Specificity for 3 Commonly used and Researched Instruments

Instrument	Follow-up period	Cut-off threshold	No Studies	Median sensitivity (95% CI) R: range	Corresponding specificity (95% CI) R: range
Braden	<1 week	≤ 18	4	75% (No CI) R: 60-88%	68% (No CI) R: 68-81%
	>1 week	≤ 18		80% (68 to 89) R: 46-100%	73% (66 to 79) R: 14-100%
Waterlow	> 1 week	≥ 10	3	87.5% (47 to 100) r: 82-90%	28% (22 to 35) R: 22-85%
Norton	> 1 week	≤ 14	4	16% (8 to 27) & 75% (35 to 97) R:0-89%	94% (91 to 97)& 67% (59 to 74) R61-94%

The AUC results show that only the Braden scale median response and one study of the Norton Scale has fair discrimination. In terms of sensitivity and specificity the Braden Scale has the highest AUC and best balance between sensitivity and specificity. The Waterlow Scale has the highest sensitivity at the cost of the lowest specificity, while this situation is reversed for the Norton Scale. Clinical judgement was also considered in a few studies of the review and found to have sensitivity of 50 % and 52% and specificity of 80% and 59% suggesting superiority of Risk Assessment.

2.4.8 Effectiveness

The effectiveness of pressure ulcer Risk Assessment Instruments has been subject to much discussion but few randomised controlled trials (RCTs) allowing comparisons of pressure ulcer incidence rates for patients who undergo risk assessment using an instrument, with those who undergo unstructured risk assessment based on clinical judgement (Cullum *et al.* 1995; Deeks 1996; Kottner and Balzer 2010; Pancorbo-Hidalgo *et al.* 2006; Beeckman *et al.* 2012). This was considered in a Cochrane review which was subsequently updated (Moore and Cowman 2010; Moore and Cowman 2014). The review identified only 2 eligible RCTs (Saleh, Anthony and Parboteeah 2009; Webster *et al.* 2011) which showed no statistically significant difference in pressure ulcer incidence rates between those who underwent risk assessment using a Risk Assessment Instrument and those

using the nurse's clinical judgement. While there were methodological weaknesses and high risk of bias with one study (Saleh, Anthony and Parboteeah 2009) due to small sample, potential selection bias, attrition bias and performance and detection bias, the second study (Webster *et al.* 2011) was considered to be at low risk of bias (Moore and Cowman 2014). The review noted the lack of published literature to assess the effectiveness of Risk Assessment Instruments on pressure ulcer outcomes. It was concluded that at present there is no reliable evidence to indicate that the use of structured Risk Assessment Instruments reduces the incidence of pressure ulcer development (Moore and Cowman 2014). Conversely, neither is there reliable evidence to support the use of clinical judgement over the use of Risk Assessment Instruments. In addition, the statistical power of the studies included in the Cochrane review has been questioned and it is proposed that there is a high risk (>70%) that clinically relevant differences between groups were not detected (Balzer *et al.* 2013). This needs to be considered when drawing conclusion from the review and further robust research is needed to fully establish clinical effectiveness. It is also important to note that the clinical effectiveness of a Risk Assessment Instrument is underpinned by its practical application and other properties relating to the development and validation of the instrument which are the focus of this PhD.

2.4.9 Summary of Existing Risk Assessment Scale development and validation

The limited literature available for existing instrument development demonstrates a lack of methodological rigour particularly with regard to ensuring content validity, as many instruments were developed on the basis of earlier instruments, clinical opinion and out of date literature reviews (Table 2.3) leading to the inconsistent inclusion of risk factors (Table 2.4). There is also limited evidence of usability testing during the development of existing instruments which is important when considering the reliability and potential for widespread implementation and use of the instrument. The involvement of patients to consider the acceptability of assessment components of existing Risk Assessment Instruments is lacking which could also impede implementation in clinical practice

The validation of existing Risk Assessment Instruments was most frequently undertaken following instrument development and implementation and involved consideration of reliability, aspects of validity and limited studies of effectiveness. While there is some evidence relating to construct validity involving measurement of convergent, known groups, and discriminant validity and criterion validity involving

concurrent validity, overwhelmingly the evidence relates to predictive validity of existing instruments (sections 2.4.2 - 2.4.7.2). However, the appropriateness of using predictive validity to evaluate Risk Assessment Instruments is questioned and a number of methodological issues highlighted.

2.5 The Need for a New Approach to Pressure Ulcer Risk Assessment

Some of the limitations and methodological difficulties associated with the development and validation of existing and widely used Risk Assessment Instruments have been highlighted above and increasing evidence makes it timely to re-consider conceptual and empirical base for instrument development. This has, in the main, been lacking in the development of previous risk assessment instruments (Table 2.3). In terms of the increasing epidemiological evidence, a review of papers identified in previous publications (Nixon and McGough 2001; Nixon *et al.* 2006b) identified the low quality of prospective cohort pressure ulcer studies and their data sets including the lack of comparable data fields. This suggested meta-analysis would not be feasible and highlighted the need to agree a pressure ulcer risk factor Minimum Data Set to encourage the use of consistent factors across studies. This would facilitate meta-analysis, case-mix adjustment and provide the fundamental components for pressure ulcer risk assessment in clinical practice.

In addition there are some practical problems associated with Risk Assessment Instrument use in practice. While many were designed for use on patients without pressure ulcers to identify those 'at risk', they are in practice often used for all patients, that is those with and without existing pressure ulcers and they do not differentiate between these two groups. This may be a key limitation, since it means that nurses might disregard the presence of an existing ulcer in their clinical assessment and decision making and hence fail to initiate appropriate secondary prevention and treatment interventions, which could lead to the progression of a more severe pressure ulcer. This resonates with findings from the Pressure Ulcer Programme of reSEarch (PURPOSE) severe pressure ulcer study, which was a small retrospective case study that identified that nurses failed to respond to signs that a patient had a pressure ulcer or was at risk of developing one (Pinkney *et al.* 2014). In addition, the PUPROSE pain cohort study indicated that the presence of a Category 1 pressure ulcer is a key predictor of subsequent Category ≥ 2 pressure ulcers increasing the odds by 2-3 fold (Nixon *et al.* Submitted). However,

assessment of skin condition is not universally incorporated into Risk Assessment Instruments (only included in 5 of the 14 instruments considered in the NICE systematic review –see Table 2.4) and is not included in some of the most widely used instruments (Norton and Braden), which increases the risk of this important factor being excluded from the nurses decision making process.

Another issue is that a full detailed risk assessment is undertaken on all patients even those who are clearly not at risk. This unnecessarily diverts nursing time away from other priorities. There is a need, therefore to streamline the assessment process to incorporate a screening stage that would allow those who are obviously 'not at risk' to be quickly identified, preventing the need for a more detailed full assessment. In addition, existing Risk Assessment Instrument incorporate scales and numerical scoring systems to identify levels of risk which are often used to provide the basis for care planning and the instigation of preventative interventions (Gould *et al.* 2002; Papanikolaou, Lyne and Anthony 2007; Kottner and Balzer 2010). However, it is noteworthy that patients with the same score could have different risk profiles and require different care interventions e.g. some patients may require management of skin moisture and some may require management of poor sensory perception. The use of an overall numerical score does not encourage nurses to consider the patients individual risk profile in care planning and this could lead to a lack of management of some risk factors.

While there remains some practical problems and empirical uncertainty regarding the benefits of using existing Risk Assessment Instruments there are coherent reasons for their continued use in clinical practice. Firstly, their use is advocated in current pressure ulcer prevention guidance (NPUAP/EPUAP 2009; NICE 2014) and is considered a key component of prevention initiatives such as the SKIN bundle (Gibbons *et al.* 2006; Whitlock 2011). Secondly they offer a standardised and transparent approach to the assessment process. This makes the use of Risk Assessment Instruments appealing to clinical experts and healthcare organisations who are concerned with delivering the UK NHS quality agenda including the Safety Thermometer (DH 2012), as well as providing evidence of assessment to facilitate legal defence in case of litigation (Kottner and Balzer 2010).

Taking into account the limitations of current Risk Assessment Instruments, a fresh approach is needed to incorporate a minimum risk factor data set (to enable future

multi-variable modelling and meta-analysis) and to enable a more thoughtful approach to the assessment process which should facilitate the following:

- Discrimination of patients 'at risk' and 'not at risk' of pressure ulcer development.
- Discrimination of patients with and without existing pressure ulcers
- Enhanced support for decision making with regard to:
 - i. the depth of the assessment required (i.e. screening and/or full more detailed assessment)
 - ii. the relative importance of specific risk factors when considering the patients risk status.
 - iii. Consideration of the patients individual risk profile (i.e. risk factors present) to provide a 'framework' for care (i.e. underpin appropriate care planning and the instigation of preventative/management interventions).

The term 'framework' refers to a basic structure underlying a system, concept, or text (Oxford and Dictionary Accessed October 2014) and in this context provides the foundation for subsequent care planning. For this reason the new instrument and decision tool will be referred to as the Pressure Ulcer Risk Assessment Framework.

2.6 Aim of PhD

The overall aim of this PhD was to develop a Risk Assessment Framework for use with adult populations in clinical practice, underpinned by a Pressure Ulcer Minimum Data Set. The Risk Assessment Framework is intended to be used for the prevention and management of generic mobility related pressure ulcers.

2.7 Methodological Overview

2.7.1 Important Psychometric Properties in the Development and Validation of a New Risk Assessment Framework

In order to identify an appropriate methodological approach the requirements of the new Risk Assessment Framework (section 2.5) were considered, allowing the key psychometric properties of importance to be identified. While the new Framework intends to move away from the traditional Risk Assessment Instrument approach of incorporating numerical scales which allow risk to be condensed into a single score,

the discriminatory and being able to identify pressure ulcer risk remain a key requirement for the new Framework. In addition, the new Framework will still need to incorporate some means of assigning a value for the presence of each risk factor, which can be taken into consideration in the overall assessment of the patients risk status and this is in keeping with scale characteristics (Table 2.1). Therefore some of the properties considered in the development and validation of traditional Risk Assessment Instruments are relevant and are discussed below.

The evaluative properties and the ability of the pressure ulcer Risk Assessment Framework to detect clinically meaningful changes in patients' condition over time is also a key consideration despite being overlooked in the literature. This is an important omission as in practice patients requiring an escalation of care interventions may be missed, increasing the risk of pressure ulcer development. Conversely, it could also result in those whose condition has improved, continuing to receive unnecessary interventions resulting in the inappropriate use of scarce resources.

At the development stage the underpinning and fundamental property that must be addressed to achieve Framework requirements is that of content validity (Table 2.2). Content validity is important to ensure that the instrument adequately represents the domain it is supposed to measure. It is important to establish content validity before other psychometric properties are evaluated as testing other measurement properties will not replace or rectify problems with content validity (FDA DHHS 2009). The acceptability and usability (format, design, clarity, comprehension, language) of the Risk Assessment Framework needs to be considered to facilitate the long-term implementation of the decision tool. This is particularly important due to the increased instructions and support for decision making which are integrated into the Framework and the need to ensure these can be interpreted as intended. This will also ensure its content is relevant to clinical nurses and would provide useful information to inform decision making (Greenhalgh *et al.* 1998). There is often a tension between maximising psychometric properties and the feasibility for use in routine practice (Greenhalgh *et al.* 1998) and this needs to be considered throughout development.

Moving forward the reliability (Table 2.2) of the Risk Assessment Framework will be assessed allowing the consistency and stability of the decision tool to be established (Streiner and Norman 2008). In addition, establishing the construct

validity of the Risk Assessment Framework will incorporate consideration of convergent, known groups and discriminant validity (Table 2.2). This is important as it will demonstrate evidence of logical relationships among items, domains and concepts that should exist with measures of related concepts or scores (FDA DHHS 2009). This is particularly relevant for the assessment of risk factor items that will be incorporated into the Framework e.g. one would expect there to be an association between the mobility items of the Risk Assessment Framework and mobility items of the Braden Scale which would provide some evidence of convergent validity. Evidence of known group differences could be considered by comparing the risk categories allocated for groups of patients where there would be expected differences e.g. elective and acute patients. It is recognised that construct validity is an ongoing process and further aspects of construct validity can be assessed as more is learnt about the instrument (Streiner and Norman 2008).

Once these fundamental aspects of validity are satisfied, the responsiveness of the Risk Assessment Framework to detect clinically significant changes can be assessed which is important as these changes would influence the instigation or withdrawal of preventative interventions. The limitations associated with evaluating the predictive validity of existing instruments are noted sections 2.4.7.1 and 2.4.9 and are relevant to the Risk Assessment Framework i.e. the instigation of preventative interventions prevents pressure ulcer development and affects the sensitivity and specificity of the instrument. The new decision tool does not aim to predict those who will develop a pressure ulcer, rather it aims to identify pressure ulcer risk and/or pressure ulcer presence to support clinical decision making and prompt the instigations of appropriate interventions, to address the patients specific risk profile. It is therefore not appropriate to evaluate the predictive properties of the decision tool. The longer-term evaluation should more usefully evaluate whether the use of the decision tool impacts the process of care, particularly whether its use prompts the instigation appropriate interventions in clinical practice. Furthermore, the impact of using the Risk Assessment Framework on patient outcomes should be assessed to establish its clinical effectiveness.

2.7.2 Methodological Considerations

As there is no universally recognised methodological approach specific to the development and validation of a pressure ulcer Risk Assessment Framework, instrument development methods used in other fields were considered. The theoretical basis of patient health status and patient reported outcome measures has accepted methods for instrument development and validation (SAC 2002).

Guidance for the review and evaluation of Patient Reported Outcome measures (FDA DHHS 2009) and review criteria for health status and quality of life instruments were developed (and subsequently updated) by the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust (SAC 2002). This guidance has influenced the development and validation of quality of life instruments (Gorecki *et al.* 2013) and the appraisal of health outcome measures (Bryant *et al.* In pres), providing examples of its application in different fields and was considered relevant to the development and validation of the Risk Assessment Framework. In addition evidence relating to the development and validation of decision tools such as clinical prediction models were considered (Steyerberg 2010).

The involvement of the population of intended use is generally considered important in the development of health status, outcome measures, quality of life patient reported outcome measures and decision tools (Greenhalgh *et al.* 1998; SAC 2002; FDA DHHS 2009; Bryant *et al.* In pres; Liu, Wyatt and Altman 2006). For the development of the Risk Assessment Framework the involvement of both nurses and patients was considered important. Nurses are the key users of Risk Assessment Instruments therefore their views should be sought with regard to the content, acceptability and usability of the new Framework during its development, though this is only reported for a few existing instruments (Table 2.3). While nurses may be the key users of Risk Assessment Framework they should be used in collaboration with the patient to facilitate shared decision making and it is proposed that the patients' views should be taken into account during Framework development. This may be particularly relevant to the acceptability of the assessment methods which could influence the usability and acceptability of the Framework.

When considering the content validity and predictive properties of the Risk Assessment Framework, methods for the development and validation of decision tools such as clinical prediction models are available. These include multivariable modelling (either from single studies or meta-analysis from a number of studies) to identify the content items for a risk instrument, with subsequent model testing on a 'new' prospective target population (Steyerberg 2010). This would also allow an evidence-based method of weighting risk factors rather than the process used for most available Risk Assessment Instruments where there is no weighting or arbitrary weighting. It is acknowledged that large datasets would be required to develop a data driven Risk Assessment Instrument (Papanikolaou, Lyne and Anthony 2007). This was a key consideration in the methodological approach of this

PhD particularly in relation to the need for a Minimum Data Set and the content of the Risk Assessment Framework.

2.7.3 Methodological Approach of PhD

Aspects of the methodology used in the development and validation of health status and quality of life instruments and clinical prediction models noted above (section 2.7.2) were considered relevant to the aim of the PhD and provided the basis for the development and validation of the pressure ulcer Risk Assessment Framework. The approach incorporates six distinct phases, the first four of which comprise this PhD and are concerned with developing the conceptual basis, content validity, and acceptability and usability of the Risk Assessment Framework (Figure 2.1):

- 1) developing the evidence base by undertaking a systematic review of the epidemiological literature relating to pressure ulcer risk factors to identify those most predictive of pressure ulcer development.
- 2) consensus study, incorporating an expert group, consideration of the evidence service user views to agree a list of patient characteristics and ensure content validity for Minimum Data Set and Risk Assessment Framework.
- 3) conceptual framework development to underpin the PhD and the Risk Assessment Framework.
- 4) design and pre-testing to confirm content validity with its intended end users and ensure the Risk Assessment Framework is easy to understand and use.

This leads to two post PhD phases for clinical evaluation (Figure 2.1):

- 5) reliability, data completeness, clinical usability & validity (convergent, discriminant & known groups).
- 6) responsiveness and the impact of using the Risk Assessment Framework on the care process and patient outcomes in clinical practice

A detailed account of the aims, methods and results of each of the PhD work phases will be undertaken in subsequent chapters of this Thesis and provides the foundation for the ongoing validation of the new Risk Assessment Framework.

2.8 Summary

While there are limitations associated with the development and validation of existing pressure ulcer Risk Assessment Instruments, they are routinely used in clinical practice in order to identify those at risk of pressure ulcer development to facilitate the instigations of preventative interventions. With more structured approaches to risk assessment being favoured and increasing epidemiological evidence being available, it is timely to consider the development and validation of

a new evidenced-based decision tool, the Risk Assessment Framework for use in adult populations in clinical practice. Its development will utilise a structure approach drawing on methods used in the development and validation of other types of health-related instruments. Each phase of development incorporating this PhD will be discussed in detail in subsequent Thesis chapters.

.

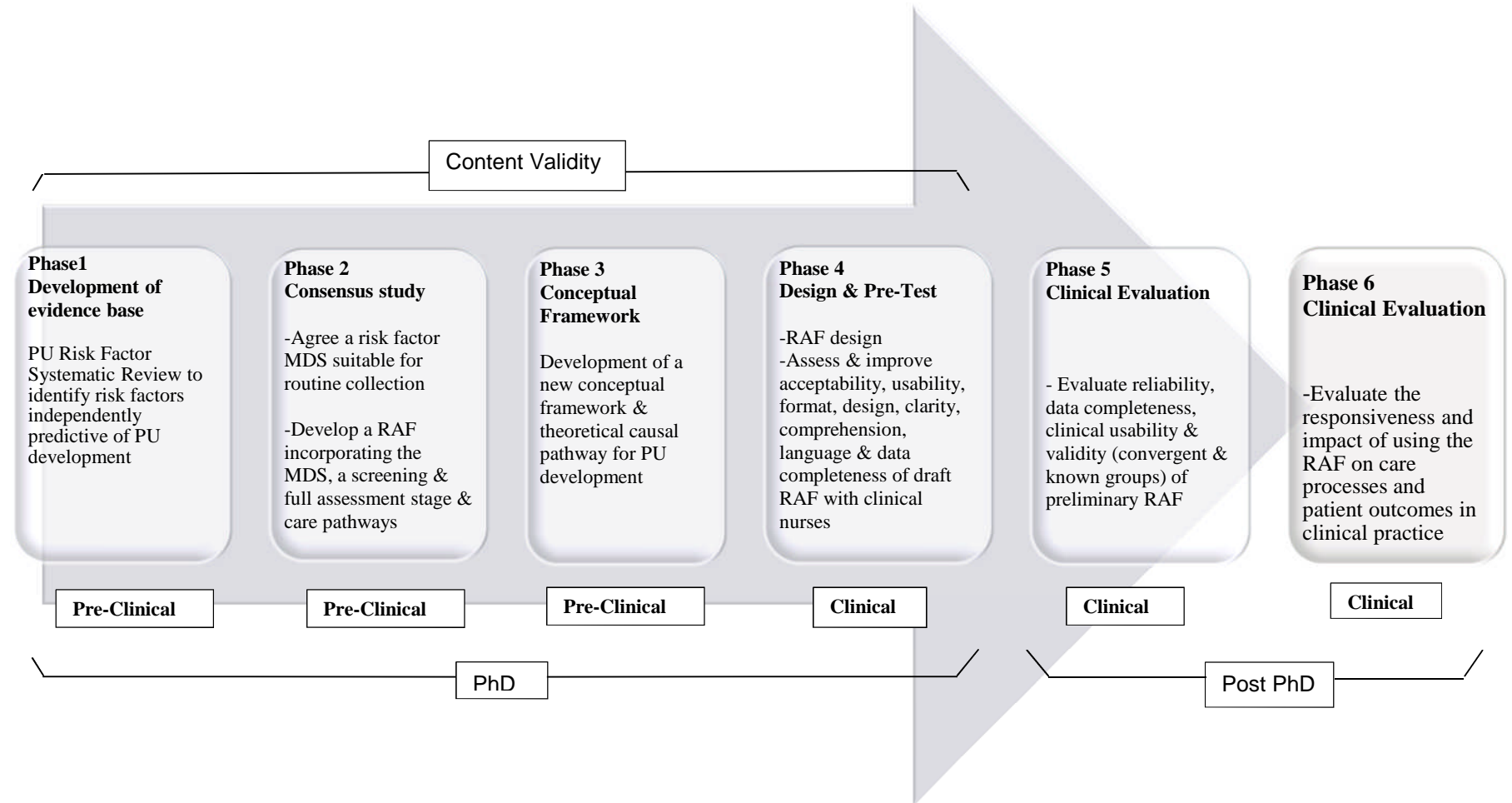


Figure 2.1 Research Overview of Development and Measurement Properties

Chapter 3 Systematic Review of Pressure Ulcer Risk Factors

3.1 Introduction

This chapter discusses phase 1 of the development and validation of a Risk Assessment Framework and underpinning Minimum Data Set, the systematic review. This was undertaken to gain a clearer understanding of the risk factors most predictive of pressure ulcer development, using the best quality evidence. The chapter provides a detailed account of the methodological considerations, aims and methods of the review with particular focus on the development of the quality appraisal and data synthesis methods used. It goes on to present the results of the review and discusses the implications of the findings as well as the limitations of the review methods and literature.

3.2 Systematic reviews

Keeping up to date with relevant studies in a particular field is time consuming, requires individuals to identify all relevant research and then be able to critically appraise this, in order to decide whether it is credible and applicable to their area of practice. Individual studies within a specific field may generate conflicting results, due to bias, methodological flaws or by chance and this can make their interpretation difficult (CRD 2009). Systematic reviews facilitate an objective review of the literature and aim to identify, evaluate and summarise all relevant individual studies to make evidence more accessible to decision makers which could include health care workers, researchers and policy makers (Egger, Smith and O'Rourke 2001; Cochrane 2009; CRD 2009). Systematic reviews may also reveal inadequacies in the evidence base and the need for further research in the field under consideration (Egger, Smith and O'Rourke 2001). The key characteristics of a systematic review are (Cochrane 2009), Section 1.22):

- A clearly stated set of objectives with pre-defined eligibility criteria for studies
- An explicit, reproducible methodology.
- A systematic search that attempts to identify all studies that would meet the eligibility criteria.
- An assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias.

- A systematic presentation, and synthesis, of the characteristics and findings of the included studies.

Guidance for undertaking each stage of a systematic review is available, though this is weighted towards those related to interventions, rather than observational studies (Cochrane 2009; CRD 2009). In addition there are also standards for the preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement (Moher *et al.* 2009) which superseded the QUOROM (Quality Of Reporting Of Meta-analyses) statement (Moher *et al.* 1999). These guidelines are not in themselves is for assessing the quality of research.

3.3 The need for a systematic review in this PhD

Systematic reviews in the pressure ulcer field have been undertaken previously, concerning Risk Assessment Instruments (Cullum *et al.* 1995; McGough 1999; Pancorbo-Hidalgo *et al.* 2006; Moore and Cowman 2010; Moore and Cowman 2014; NICE 2014). While of relevance to this PhD the systematic reviews of Risk Assessment instruments focus on sensitivity and specificity and clinical effectiveness of the instrument overall, rather than considering the predictive ability of their risk factor components. The systematic review undertaken as part of this PhD is concerned with identifying risk factors predictive of pressure ulcer development, which will involve consideration of wider epidemiological literature, incorporating a comprehensive range of risk factors. In the absence of an existing pressure ulcer risk factor systematic review, this was considered a necessary step to ensure all important risk factors were considered in order to develop a clear conceptual basis and facilitate content validity of the Minimum Data Set and Risk Assessment Framework.

3.4 Aim

The aim of this study was to identify and consider risk factors independently predictive of pressure ulcer development in adult patient populations.

3.5 Methodological Considerations

To inform the development of the systematic review methodology a review of papers identified in previous publications was undertaken (Nixon and McGough 2001; Nixon *et al.* 2006b; NICE 2014). This identified some key methodological issues including:

- Poor general reporting of methods and results making it difficult to assess the quality of some studies.
- A large number of poorly reported studies reporting univariate analyses.
- Different study designs considering pressure ulcer risk factors.
- Poor statistical design, e.g. insufficient number of events which is problematic as it can produce overestimation and underestimation of the true effect (Peduzzi *et al.* 1995).
- The unit of analysis not at the patient level, rather at ulcer or multiple time point level without appropriate statistical adjustment. This presents a potential problem as the number of events may be inflated and demonstrate spurious statistical significance (Altman and Bland 1997).
- Inclusion of patients with and without pressure ulcers at cohort inception (and different Grades/Stage), though it is recommended that systematic reviews of prognostic studies should involve patients at the same starting point in the disease (Altman 2001).
- Lack of comparable data fields for risk factors impacting on interpretation and further use of the data in meta-analysis.

The review of papers identified in previous publications (Nixon and McGough 2001; Nixon *et al.* 2006b) proved particularly useful for planning the eligibility criteria and quality appraisal methods for the review.

3.5.1 Study Design Considerations

A key consideration of the eligibility criteria was identifying studies with appropriate design. There are many types of studies which may inform our understanding of risk factors. In many areas of medicine, the first step involves cross-sectional or prevalence studies which allow the comparison of patient characteristics for those with and without the disease. They provide the basis for hypothesis testing, but do not identify which characteristics are predictive of the disease, nor can they differentiate cause and effect from association (Mann 2003). Case control studies are useful for rare conditions,

when there is an extended latent period between the exposure and the disease and can help to determine hypotheses for future study (Mann 2003). This type of study is prone to sampling and recall bias as well as confounding. Due to these limitations, cross-sectional and case control designs were excluded from the review.

While RCTs are designed specifically to answer questions of treatment effectiveness (CRD 2009), they can also provide risk factor evidence. However, patients enrolled in RCTs often differ to those seen in everyday practice for a number of reasons including the exclusion of minority groups such as women and the elderly (Gurwitz, Col and Avorn 1992) and the setting in which they are undertaken is often different to general treatment settings (Egger, Smith and Schneider 2001). In addition, patients have to meet intervention related inclusion and exclusion criteria, which may make the sample unrepresentative of the normal population, e.g. a limitation of studies considering support surfaces for the prevention of pressure ulcers is that weight limits on some mattresses, precludes the inclusion of patients with very low and very high weights. However, a major advantage of RCTS is that all patients are recruited and followed up prospectively and they can be a good source of high quality data (e.g. where attrition is low and intention to treat analysis is undertaken (CRD 2009). So, despite the limitation of RCTs, they were included in the review with quality related exclusion criteria.

Cohort studies are considered the most appropriate study design for determining the incidence and natural history of a condition and are the predominant study design in risk factor research (Mann 2003; Altman 2009; Moons *et al.* 2009; Jones 2010). Cohort studies allow the measurement of potential causes (risk factors) before the outcome occurs, enabling statistical analysis to calculate the effect of each variable on the probability of the outcome (Mann 2003). As cohort studies are at risk of confounding, it is important that all potentially relevant variables are considered to avoid any being missed.

The advantages and disadvantages of prospective and retrospective cohort studies were carefully considered. Prospective cohort studies allow the collection of risk factor data that might not be available in medical records and allow the inclusion of potential confounders. They also allow researchers to ensure the data is collected in an standardised manner to reduce the risk of measurement bias (Moons *et al.* 2009; Fletcher, Fletcher and Fletcher 2014). A potential area of bias for prospective studies is

the need for patients to consent for inclusion in the research, which affects the generalisability of study populations, e.g. the exclusion of patients who lack capacity to consent or are very ill. This is not a problem for retrospective data sets, where patient consent is not usually required. Prospective cohort studies can also be inefficient where the incidence of the outcome of interest is low (Mann 2003). This can be a problem in the pressure ulcer field, resulting in the need for large sample sizes, which are often precluded by cost. As a consequence prospective studies in the field tend to be small which limits the generalisability of the results.

Retrospective studies, often referred to as record reviews, are cheaper and easier to conduct, as the data has already been collected, with the potential for making use of existing computerised data bases (Mann 2003; Fletcher, Fletcher and Fletcher 2014). Studies that use large institutional data sets also tend to have the added advantage of longer follow-up periods (Altman 2009). Patient consent is often not required for this type of study, facilitating a more representative sample. However, selection bias can be a problem as the studies tend to be undertaken only where the data bases are available and there is no opportunity to chase-up missing data. Other limitations associated with this type of research include inadequacies of the data base fields used (i.e. lack of comprehensive inclusion potential risk factors and confounding variables) and that the information might not be collected in a standardised manner. However, this is not always the case and the use of large comprehensive databases can be particularly useful for studying potential risk factors (Fletcher, Fletcher and Fletcher 2005).

While there are advantages and disadvantages to prospective and retrospective approaches, both were considered relevant to this review and were included in the inclusion criteria (section 3.6.1.1). The overall quality of the study needs to be informed by the thoroughness with which the study is conducted rather than solely on the basis of the research design (CRD 2009; Mann 2003). Even the highest regarded study designs can be poorly conducted and there is inconsistent use of study design 'labels' in the literature. It is therefore important that the specific aspects of the study design that may introduce bias are considered when assessing the quality of any study in order to make judgement about the credibility of the research (CRD 2009).

3.5.2 Quality Appraisal Considerations

Various tools have been developed to assess the quality of primary research studies which are often linked to the specific design of the study. The most developed area is for RCTs where a review identified 25 scales and 9 checklists to assess the quality of evidence about treatment effectiveness (Moher *et al.* 1995). The scales and checklists include composite scales incorporating a range of quality components which are combined in a single numerical score and have been criticized in relation to the varying dimensions included, their size and complexity as well as the lack of transparency and reliability (Juni, Altman and Egger 2001; Cochrane 2009). Presently a more transparent approach to appraising study quality is advocated incorporating consideration of the risk of bias in a number of domains e.g. for RCTs, selection bias, performance bias, detection bias, attrition bias, reporting bias (GRADE Working Group 2004; Guyatt *et al.* 2008; Cochrane 2009).

For observational studies a systematic review for assessing study quality identified 53 checklists and 33 scales (Sanderson, Tatt and Higgins 2007). Of these one third were designed for study specific reviews and one third for critical appraisal. In keeping with tools for RCTs the review found that the inclusion of quality criteria and their weighting was inconsistent and there was a lack of an obvious single tool for assessing the quality of observational studies. The review authors concurred with those from other fields about avoiding the use of summary scores and taking into account the particular study design and topic area (Sanderson, Tatt and Higgins 2007). The review highlighted the need for a rigorous development process for tool design and the need to reach consensus on the quality domains that should be included.

When considering the quality appraisal method for this systematic review it was recognised that specific design related aspects of quality would need to be addressed. However as the aim of the study was to identify risk factors independently predictive of pressure ulcer development, it was concluded that the detailed quality appraisal needed to focus on the assessment of bias relating to risk factors. These type of studies fall into the prognosis studies category and include 'clinical studies of variables predictive of future events as well as epidemiological studies of aetiological risk factors' (Altman 2001). Though, there is no widely agreed quality criteria for the assessment of prognostic studies (Altman 2001), following a review which evaluated the quality of

prognosis studies in systematic reviews, a framework for the assessment of study quality was proposed. This incorporates a total of 28 items organised into 6 key domains including study participation, attrition, prognostic factor measurement, outcome measurement, confounding measurement and account and analysis (Hayden, Côté and Bombardier 2006). The framework incorporates principles of quality and bias that were relevant for the risk factor studies of this review. These principles, in addition to design related criteria and methodological considerations in the analysis, meta-analysis and publication of observational studies provided the basis for the overall approach to quality appraisal for this review (Harrell *et al.* 1985; Simon and Altman 1994; Peduzzi *et al.* 1995; Altman 2001; Egger, Smith and Schneider 2001; Mak and Kum 2005; Maltoni *et al.* 2005; von Elm *et al.* 2007; Royston, Altman and Sauerbrei 2006; CRD 2009; Schulz *et al.* 2010; Steyerberg 2010; Altman 2009; Mallett *et al.* 2010). The application of these would be addressed in two ways; firstly through the inclusion and exclusion criteria of the review, allowing studies with aspects of quality and bias that was considered unacceptable to be screened out and; secondly, through a detailed and consistent quality appraisal.

3.6 Methods

A systematic review of primary research was undertaken. The methodological approach was based upon the systematic review methods recommended for questions of effectiveness (Cochrane 2009; CRD 2009), and adapted to identify risk factor studies with consideration of the methodological limitations including bias and confounding associated with observational studies of prognosis (Harrell *et al.* 1985; Simon and Altman 1994; Peduzzi *et al.* 1995; Altman 2001; Egger, Smith and Schneider 2001; Mak and Kum 2005; Maltoni *et al.* 2005; von Elm *et al.* 2007; Hayden, Côté and Bombardier 2006; Royston, Altman and Sauerbrei 2006; CRD 2009; Schulz *et al.* 2010; Steyerberg 2010; Altman 2009; Mallett *et al.* 2010) and the PRISMA statement (Appendix 5) (Moher *et al.* 2009).

3.6.1 Study Eligibility

Key aspects of methodological quality were considered in the eligibility criteria of the systematic review:

- The representativeness of the source and study population and that the level of participation in the study by eligible patients was adequate (Altman 2001; Mak and Kum 2005; Hayden, Côté and Bombardier 2006).
- Clearly defined outcome of interest to ensure this is the same for all patients included in the study (Altman 2001; Mak and Kum 2005; Hayden, Côté and Bombardier 2006).
- Sufficient length of follow-up to allow that the outcome of interest to manifest (Altman 2001; Mak and Kum 2005; Hayden, Côté and Bombardier 2006).
- Study attrition for cohort studies including prospective and record reviews were considered to ensure the proportion of the study sample completing the study and providing outcome data adequately represented the sample (Altman 2001; Mak and Kum 2005; Maltoni *et al.* 2005; von Elm *et al.* 2007; Hayden, Côté and Bombardier 2006).
- Randomised allocation to treatment for RCT, to ensure that the intervention is allocated by a play of chance and the groups are comparable with respect to any known or unknown confounding factors analyses (CRD 2009; Schulz *et al.* 2010).
- Intention to treat analyses for RCTs, to ensure that all randomized patients (whether they adhere to the study protocol or not) are included and analysed in their original allocated group to avoid attrition bias (CRD 2009; Schulz *et al.* 2010).
- Multivariable analyses - to identify factors that are independently associated with pressure ulcer development.

3.6.1.1 Inclusion criteria

- i) primary research.
- ii) adult study populations in any setting.
- iii) outcome was the development of a new pressure ulcer(s).
- vi) outcome clearly defined as \geq grade/stage 1 (AHCPR 1992; EPUAP 1999) or equivalent.
- iv) prospective cohort, retrospective record review or a controlled trial.
- v) length of follow-up at least 3 days, with exception of operating room studies for which no minimum was set.
- vii) multivariable analyses were undertaken to identify factors affecting pressure ulcer outcome.

viii) the unit of analysis was the patient.

3.6.1.2 Exclusion criteria

i) paediatric study populations.

ii) cross-sectional, case-study.

iii) patient recall, patient self-report or analysis of General Practitioner records (due to issues of reliability).

iii) duplicate publication of patient dataset.

iv) cohort studies (prospective and record reviews) were excluded from the review if >20% of the study sample were excluded from analysis for reasons including withdrawal, death, loss to follow-up and missing records (Altman 2001; Egger, Smith and Schneider 2001; Maltoni *et al.* 2005; von Elm *et al.* 2007).

v) Controlled trials were excluded unless both the following minimum criteria applied: randomised allocation to treatment and intention to treat analyses (CRD 2009; Schulz *et al.* 2010).

No language restriction was applied.

3.6.2 Search and Data Sources

Fourteen electronic databases were searched, each from inception until March 2010 (Appendix 6): AMED, British Nursing Index, MEDLINE, EMBASE, PsycINFO, CINAHL, Cochrane Library, Proquest, Networked Digital Library of Theses and Dissertations, International Theses in Progress, Theses Canada Portal, Australian Digital Theses Program, and Russian Academy of Sciences Bibliographies and Index to Theses. The search strategy 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 includes pressure ulcer search terms (Cullum *et al.* 2001), OVID maximum sensitivity filters for Prognosis and Aetiology or Harm and OVID maximum sensitivity filter for RCTs (CRD 2009). In 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 (Appendix 6).

3.6.3 Data extraction

Abstracts were screened for relevance by one reviewer (CG) and checked by a second (JN). Abstracts assessed as potentially relevant were obtained in full and reviewed

against the eligibility criteria by one reviewer (CG or SC) and checked by a third (JN). Where the statistical methods were unclear and eligibility could not be determined, statistical review was undertaken (JB). Disagreements were dealt with through consensus.

Where studies fulfilled the eligibility criteria data were extracted by a single reviewer (CG or SC) and checked by a second reviewer (JN). Where data was missing from the publication attempts were made to contact the authors. Where duplicate publications of patient datasets 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.

3.6.4 Quality Assessment

The studies that met the inclusion criteria were subject to further detailed quality appraisal based upon a framework for assessing the quality of prognostic studies (Hayden, Côté and Bombardier 2006) and methodological guidance in the conduct of multivariable analysis (Harrell *et al.* 1985; Simon and Altman 1994; Peduzzi *et al.* 1995; Altman 2009; Steyerberg 2010; Mallett *et al.* 2010).

To prevent duplication, the aspects of quality that had already been considered during study eligibility assessment (section 3.6.1), were not repeated in the detailed quality appraisal. The detailed quality appraisal comprised 7 quality criteria and 4 key quality domains. The 7 quality criteria are as follows:

1. The baseline study sample (i.e. individuals entering the study) is adequately described for key characteristics.
2. A clear definition or description of the risk factor measured is provided (e.g. including dose, level, duration of exposure and clear specification of the method of measurement).
3. Continuous variables are reported or appropriate (i.e. not data-dependent) cut points are used.
4. Adequate proportion of sample has complete data for risk factors
5. Range of potential risk factors are measured (i.e. Key variables in conceptual model).
6. Range of potential risk factors are accounted for in the analysis (i.e. appropriate the adjustment).

7. There is no selective reporting of results.

The 4 key quality domains are detailed below:

- A. There is sufficient number of events (rule of thumb ≥ 10 events per risk factor.)
- B. There is sufficient presentation of data to assess the adequacy of method and analysis.
- C. The strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework.
- D. The selected model is adequate for the design of the study.

Domain A (sufficient number of events) was critical because the results from fitted regression models may not be accurate or precise if the number of events per risk factor variable in the multivariable analysis is too small, with the risk of producing an overestimation and underestimation of the true effect (Harrell *et al.* 1985; Simon and Altman 1994; Peduzzi *et al.* 1995; Altman 2009; Steyerberg 2010; Mallett *et al.* 2010). Domains B-D were based on the analysis section of the framework for assessing quality in prognostic studies (Hayden, Côté and Bombardier 2006). Domain B (sufficient presentation of data) was considered central as poor presentation of data makes it difficult to assess adequacy of the method of analysis. Domain C (strategy for model building) was valuable in ensuring all potential risk factors are considered in the model. Failure to do this could result in the exclusion of important potential risk factors and an overestimation of the effect of other risk factor variables included in the model. Domain D (selected model adequate for the design), was important in giving an indication of the overall confidence in the validity of the results of the study.

The contribution of the quality criteria to the assessment of the key quality domains is detailed in Table 3.1. It should be noted that the key quality domains are not independent and their inter-dependent relationships are detailed in Table 3.2. As an example, in order to assess whether there is sufficient number of events (A), the strategy for model building including the number of risk factors entered into the multivariable model (C) must be considered (Table 3.2).

The detailed quality appraisal was undertaken by two reviewers (JN, SC) and compliance for each criteria and domain was assessed with four possible outcomes

(i.e. yes, no, partial or uncertain). In addition, some limitations of the criteria and domains were also noted (poor/partial reporting for baseline study sample characteristics, use of inappropriate cut points, absence of p value and CIs, inappropriate inclusion of time dependent co-variates and record review), in order to provide a synopsis of key limitations.

3.6.5 Study Classification

Following quality appraisal studies were classified as high, moderate, low and very low quality using 4 key domains and the following criteria:

- High quality studies: yes for all key domains A-D
- Moderate quality studies: yes for key domain A and 2 other key domains
- Low quality studies: no for key domain A and no or partial for 1 or 2 other key domains
- Very low quality studies: no for key domain A and no or partial for all 3 other key domains.

3.6.6 Data Synthesis

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 those factors and pressure ulcer development, a narrative synthesis was carried out (CRD 2009).

For each study all factors entered into multivariable modelling and those which emerged as significant ($p \leq 0.05$) were identified. For studies using stepwise regression we included non-significant factors ($p \geq 0.05$) if these were reported in the final model as being independently associated with pressure ulcer development. Risk factors were categorised into domains and sub-domains which were developed following review of the risk factors reported in the primary studies. Evidence tables were generated for each risk factor sub-domain, with a summary narrative synthesis by sub-domain and domain. For each sub-domain the total number of studies entering the variable and the total number where the variable emerges in the multivariable analyses and the quality of studies are summarised. In the evidence tables Grade and Stage are recorded as reported in individual studies.

Table 3.1 Relationship between the Quality Criteria and Domains

Criteria contributing to the assessment of key quality domains	Key Quality Domains			
	A. There is sufficient Number of events (rule of thumb ≥ 10 events per risk factor)	B. There is sufficient presentation of data to assess the adequacy of method and analysis	C. The strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework	D. The selected model is adequate for the design of the study
1. The baseline study sample (i.e. individuals entering the study) is adequately described for key characteristics		X		
2. A clear definition or description of the risk factor measured is provided		X	X	X
3. Continuous variables are reported or appropriate (i.e. not data-dependent) cut points are used.		X	X	
4. Adequate proportion of sample has complete data for risk factors		X	X	X
5. Range of potential risk factors are measured (i.e. Key variables in conceptual model)			X	X
6. Range of potential risk factors are accounted for in the analysis (i.e. appropriate the adjustment).			X	X
7. There is no selective reporting of results		X	X	X

Table 3.2 Relationship between Key Quality Domains

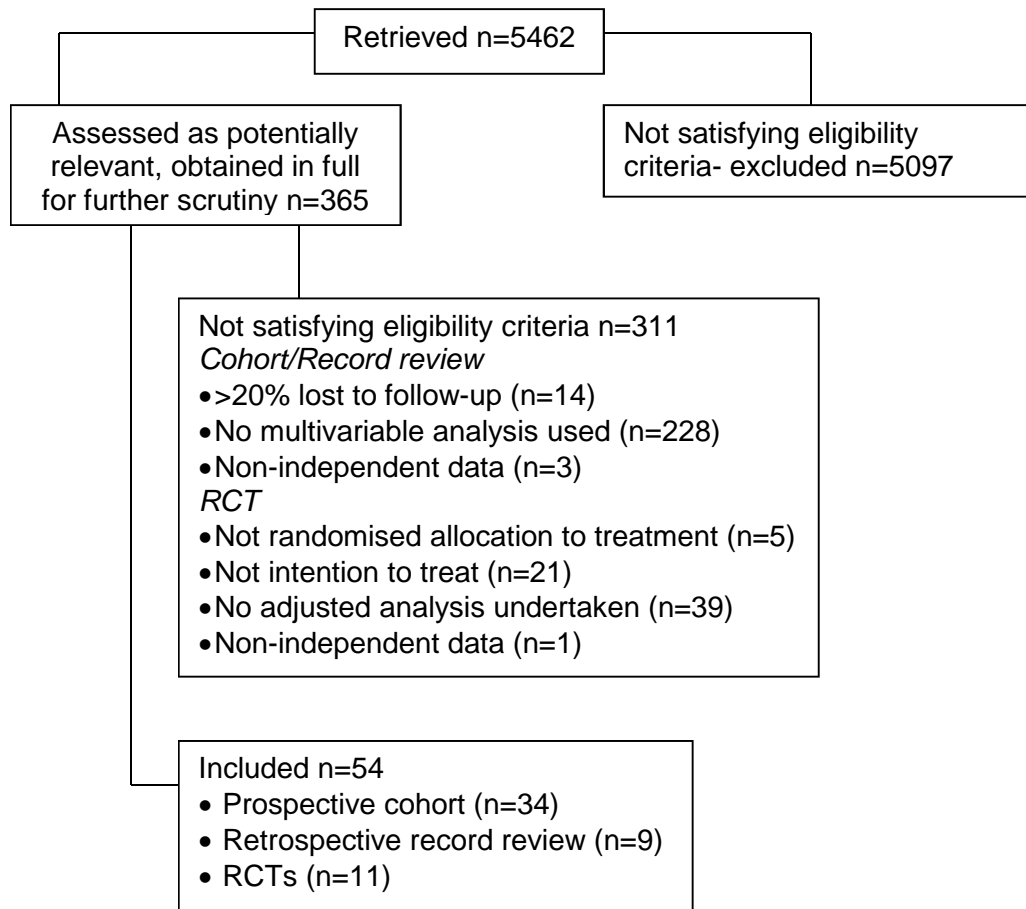
Other Impacting Key Quality Domain Assessment	Key Quality Domains			
	A. There is sufficient Number of events (rule of thumb ≥ 10 events per risk factor)	B. There is sufficient presentation of data to assess the adequacy of method and analysis	C. The strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework	D. The selected model is adequate for the design of the study
A. There is sufficient Number of events (rule of thumb ≥ 10 events per risk factor)	X		X	X
B. There is sufficient presentation of data to assess the adequacy of method and analysis		X	X	X
C. The strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model	X		X	X
D. The selected model is adequate for design of the study				X

Gray shading indicates same key quality domain

3.7 Results

3.7.1 General Study Characteristics

Of 5462 abstracts retrieved, 365 were identified as potentially eligible. Of these 54 fulfilled the eligibility criteria including 34 prospective cohort, 9 retrospective record reviews and 11 RCTs (Figure 3.1). A summary of included studies are detailed in Table 3.3.



Reprinted from the international Journal of Nursing Studies, Coleman S, Nelson E A, Closs SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J. Patient risk factors for pressure ulcer development: systematic review. 2013, 50; 794-1003.

Figure 3.1 PRISMA Flow Chart of Studies

Table 3.3 Summary of included studies

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
Allman et al (1995) USA	286 pts Setting: acute care hospital; Speciality: multiple	Admitted to hospital within previous 3 days, aged ≥ 55 yrs, expected LOS in bed or chair ≥ 5 days, had a hip fracture, expected LOS (hospital) ≥ 5 days. Excluded pts with Stage ≥ 2 PU, Friday admission, active skin disease that would interfere with PU assessment and previous enrolment to study. Consent required.	Cohort Backward stepwise Cox regression	286 (12.9%), 37 Stage ≥ 2 PU	9 (5) Nonblanchable erythema if intact sacral skin Immobility Dry sacral skin Decreased body weight Lymphopenia	0.05 0.02 0.04 0.03 0.003	7.5 2.4 2.3 2.2 4.9	1.0-59.1 1.1-4.9 1.0-5.2 1.1-4.5 1.7-13.9	LQS Insufficient number of events.
Baldwin & Ziegler (1998) USA	36 pts Setting: acute care hospital; Speciality: trauma	Adults aged 15-60 yrs, hospitalised due to severe trauma, previously healthy, did not require burn fluid resuscitation, and expected LOS (hospital) ≥ 1 wk	Cohort Forward logistic regression	36 (30.6%), 11 Stage ≥ 1 PU	7 (2) Braden mobility subscore Braden moisture subscore	0.02 0.04	0.3 3.0	0.1-0.8 1.1-8.3	VLQS Baseline characteristics are not reported. The sample size is too small and insufficient number of events.
Bates-Jensen et al (2007) USA	35 non-surgical pts Setting: NH; Speciality:	Long-stay residents in 2 NH eligible for a larger nutrition trial (not referenced) and provided informed	Cohort Generalised logistic regression	35 (45.7%), 16 Stage ≥ 2 PU	5 (2) Subepidermal moisture (at 1 wk) Total Braden score	≤ 0.05 ≤ 0.05	1.0 6.8	1.004-1.012 0.6-72.3	LQS Inadequate sample size resulting in wide CI.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
	elderly/geriatric	written consent.							
Baumgarten et al (2004)	2285 non-surgical pts Setting: long-term nursing care/NH; Speciality: NR	Pts aged ≥65, newly admitted to NH, black or white skin colour, consent or relative assent. Excluded if previously resided in a NH or chronic care facility for ≥8 days in the yr before the NH admission.	Cohort Cox proportional hazards model	1938 (23.2%), 450 Stage ≥ 2 PU	12 (3) Black race n of ADL dependencies PU on admission	0.032 0.001 0.001	1.3 1.4 1.8	1.0-1.7 1.3-1.5 1.4-2.3	MQS All risk factors are categorical data rather than continuous. 20% missing data from final model.
Bergquist, & Frantz (1999) USA	1711 non-surgical pts Setting: community/homecare; Speciality: elderly/geriatric	Home healthcare agency, aged ≥60, no PU on admission, non-hospice, non-IV therapy. Consent not required.	Record review Stepwise Cox proportional hazards	1567 (3.2%), 55 Stage ≥2 PU	45 (10) Limited to wheelchair ADL dressing Incontinence bowel &/or bladder Braden mobility Anaemia Adult child primary caregiver Male Recent fracture Oxygen use Skin drainage	0.0198 <0.001 0.0195 <0.001 0.0021 <0.001 0.0281 0.0019 <0.001 <0.001	2.8 2.7 2.8 5.2 4.0 5.8 1.9 3.5 3.9 6.6	1.2-6.5 1.5-4.8 1.2-6.8 2.4-11.1 1.6-9.5 2.1-15.9 1.1-3.2 1.6-7.6 2.1-7.6 2.3-19.2	LQS Record review and insufficient number of events. Inadequate measurement of risk factors (record review).
Bergstrom, & Braden (1992) USA	200 non-surgical pts Setting: long-term nursing care/NH; Speciality: elderly/geriatric	Consecutive pt admissions to teaching NH were screened and included if >65 yrs, at risk of PU development (Braden score <17), free of existing PU, estimated LOS	Cohort, logistic regression (backward elimination)	200 (73.5%), 147 Stage ≥1 PU, (38.5%), 77 Stage ≥2 PU Model 1 Stage ≥1 Model 2	<u>Model 1</u> 10 (5) Braden score Diastolic BP Temperature Age Protein (%RDA) <u>Model 2</u> 10 (4) Braden score	<0.01 <0.01 ns ns <0.05 <0.001	NR NR NR NR NR NR NR	NR NR NR NR NR NR NR	MQS No CI reported.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
		>10 days. Consent required from pts or family.		Stage ≥2 Model 3 Stage = 1	Age Systolic BP Protein (%RDA) <u>Model 3</u> 10 (4) Braden score Diastolic BP Temperature Iron (%RDA)	<0.05 <0.01 ns <0.01 <0.01 <0.05 <0.01	NR NR NR NR NR NR NR		
Bergstrom et al (1996) USA	843 pts Setting: multiple; Speciality: multiple	Pts from 2 NHs, 2 university hospitals and 2 VAMCs, ≥19 yrs, no PU on admission, admitted for care within 72 hours.	Cohort Logistic regression	843 (12.8%), 108 Stage ≥1 PU Model 1 age, gender, race, Braden Scale and preventive measures; Model 2 mobility, activity and primary diagnoses (13); Model 3 Braden total score and primary diagnoses (13)	<u>Model 1</u> 6 (3) Braden scale score Age Race <u>Model 2</u> 15 (3) Braden mobility Braden activity Cardiovascular disease <u>Model 3</u> 14 (1) Braden total	<0.001 <0.001 0.012 <0.001 0.004 0.023 <0.001	1.3 1.0 2.7 1.7 1.5 2.5 1.4	1.2-1.4 0.95-0.98 1.3-6.0 1.3-2.3 1.1-1.9 1.1-5.5 1.3-1.5	HQS
Berlowitz, & Wilking (1989) USA	185 non-surgical pts Setting: chronic	All admissions to chronic care hospital (requiring medical, skilled nursing,	Cohort Stepwise logistic	185 (10.8%), 20 Stage ≥2 PU	11 (3) Cerebrovascular accident Bed or chair bound Impaired nutritional intake	<0.05 <0.05 <0.05	5.0 3.8 2.8	1.7-14.5 1.0-14.0 1.0-17.9	LQS Insufficient number of events. Data collection relied on clinical staff and only partial reporting of

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
	care hospital; Speciality: medicine	rehabilitative services) with chronic medical conditions. Pt excluded if died or discharged within 1 wk of admission or required transfer to an acute care hospital within 24 hrs of admission (i.e. had PU at baseline). Consent not required - record review	regression						baseline characteristics.
Bostrom et al (1996) USA	112 pts Setting: multiple; Speciality: multiple	Medical and surgical pts admitted to 3 hospitals (tertiary, general, community) aged ≥18 yrs, able to give consent and expected LOS (hospital) ≥48 hrs	Cohort Logistic regression	112 (8.04%), 9 Stage ≥1 PU	7 (1) N of layers between pt & mattress	0.001	NR		VLQS Insufficient number of events. Analysis reporting inadequate. No CI intervals reported. Time dependent variables included in the analysis.
Bourdel-Marchasson et al (2000) France	672 pts Setting: acute care hospital; Speciality: elderly/geriatric	Pts recruited from University hospital wards and geriatrics units (>40% of in-pts aged >65 yrs), including neurology, gastroenterology, orthopaedic or vascular surgery, internal and geriatric medicine.	RCT Cox proportional hazards model	672 (44.5%), 299 stage ≥1 PUs	NR (5) Hypoalbuminemia Lower limb fracture Norton score 5-10 vs. >14 Kuntzman score Control vs. nutritional intervention	<0.001 <0.001 0.04 0.003 0.04	1.1 2.7 1.3 1.2 1.6	1.0-1.1 1.8-4.1 1.0-1.6 0.3-4.6 1.0-2.4	MQS Full details of modelling not provided. Adequate number of events is assumed as large number of events (299).

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
		Pts aged >65 yrs, in acute phase of a critical illness, unable to move or eat independently, no PU on admission. Consent requirement not reported.							
Boyle & Green (2001) UK	534 pts Setting: ICU	ICU pts not consented. PUs developing after day 1 admission included in analysis; PU on admission excluded.	Cohort Parametric survival regression (Weibull)	534 (5.2%), 28 Grade ≥1 PU	7 (2) Coma/unresponsiveness/paralysed & sedated Cardiovascular instability	0.001 0.035	4.2 2.7	30-77 4-70	LQS Baseline characteristics not reported. Insufficient number of events.
Brandeis et al (1994) USA	4232 non-surgical pts Setting: long-term nursing care/NH; Speciality: elderly/geriatric	Residents >60 yrs, admitted to NHC NHs during 1988 and 1989, no PU on admission and at 3-mth FU (baseline assessment) Eligible residents remained in the home for ≥3 mths after baseline assessment up to 21 mths. Consent not required record review	Cohort Pooled logistic regression	4232 (12.9%), 546 Stage ≥2 Model 1 High incidence Homes 1322 (19.3%), 255 Stage ≥2 PU ; Model 2 Low Incidence Homes 1365 (6.5%) 89 Stage ≥2 PU	<u>Model 1</u> 15 (4) Ambulation difficulty Faecal incontinence Diabetes Feeding ADL <u>Model 2</u> 15 (3) Ambulation difficulty Feeding ADL Male	<0.001 <0.001 <0.006 <0.001 <0.001 <0.001 <0.007	3.3 2.5 1.7 2.2 3.6 3.5 1.9	2.0-5.3 1.6-4.0 1.2-2.5 1.5-3.3 1.7-7.4 2.0-6.3 1.2-3.6	HQS Record review.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
Chan et al (2005) Singapore	666 pts Setting: acute care hospital; Speciality: multiple	All hospital in-pts on census date, aged >18. Excluded infectious disease wards, aggressive psychiatric or airborne infectious pts, pts with existing ulcers.	Cohort Logistic regression	666 (8.1%), 54 Stage ≥1 PU	23 (1) Braden score (Braden score 12-15) (Braden score 6-11)	0.001 0.001 0.001	7.0 12.5	3.5-17.1 4.5-34.6	LQS Only partial reporting of baseline characteristics. Inadequate reporting of analysis and modelling. Inadequate number of events.
Cobb et al (1997) USA)	123 pts Setting: acute care hospital; Speciality: ICU	Aged >18 yrs, weighed ≤290 pounds, no pre-existing PU, expected LOS 1-2 wks, determined at-risk based on Braden scale. Consent required. All hospital wards and ICU of large military hospital	RCT Wilcoxon test	123 (16.3%), 20 Stage ≥1 PU	4 (2) Hypertension Weight	0.03 0.05	NR NR	NR NR	VLQS Inadequate reporting of analysis methods. No CI reported. Insufficient number of events.
Compton et al (2008) German	713 pts Setting: Acute care hospital, non-surgical; Speciality: ICU	Pts without PU on admission to the medical ICU between Apr 2001 and Dec 2004. Pts in ICU for <72 hrs were excluded from analysis.	Record Review	698 (17%) 121 grade 2-4	32 (6) Male gender Moist skin Oedematous skin Centralised circulation Mottled skin Reddened skin	0.014 0.001 0.002 0.001 0.016 0.001	1.8 2.4 2.2 2.4 2.0 2.3		LQS Record review. Large number of events but it used 32 variables in model. No CI reported.
Defloor & Grypdonck (2005) Belgium)	1772 non-surgical pts Setting: long-term nursing care/NH; Speciality:	All in-pts in 11 long-term care facilities during the 4-wk study period	RCT Stepwise logistic regression	1458 Model 1 Grade ≥1, 302/1458 (20.7%) Model 2 Grade ≥2 =171/	<u>Model 1 19</u> (3) Braden sensory perception Skin condition Existing PU <u>Model 2 19</u> (4) Braden activity	0.02 <0.001 <0.001 0.03	0.8 1.5 2.3 0.7	0.6-1.0 1.2-1.9 1.4-3.5 0.5-1.0	HQS Limitation partial reporting of baseline.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
	elderly/geriatric			1458 (11.7%)	Braden sensory perception Skin condition Existing PU	0.02 <0.001 0.01	0.7 1.6 1.9	0.6-1.0 1.3-2.1 1.1-3.0	
De Laat et al (2007) Netherlands	399 pts Setting: acute care hospital; Speciality: ICU	Pts admitted into ICU, with expected LOS >48 hours, without PU on admission, and screened within 48 hrs of admission. Consent not required.	Cohort Cox proportional hazards model	399 (35.1%), 140 Grade ≥2 PU	11 (3) Preventive transfers Shock/resus Friction/shear	<0.001 <0.001 0.02	0.2 1.5 1.3	NR	MQS Ward staff recording data and no CI reported. Time dependent covariates included in the analysis.
Donnelly (2006) UK	240 hip fracture pts Setting: acute care hospital; Speciality: elderly/ geriatric	Aged ≥65 yrs on day of injury, new fractured hip (injury < 48 hrs "old"), able to undergo tests and assessment procedures. Patient consent required.	RCT Cox proportional hazards model	239 (16.3%), 39 Grade ≥1 PU	20 (1) Control group (standard mattress)	0.001	4.6	NR	LQS Insufficient number of events and no CI reported.
Ek (1987) Sweden	515 non-surgical pts Setting: Chronic care hospital; Speciality: medicine	Consecutive pts admitted to a long-term medical ward who were hospitalised for >3 days, with or without PU at baseline. Consent requirement not reported	Cohort Logistic regression	515 (7.6%), 39 ≥Stage 1 equivalent PU Model 1 Baseline measures; Model 2 variables on day of PU or if PU free on 4 th wk of care	<u>Model 1 8</u> (1) Norton mobility <u>Model 2 8</u> (2) General physical condition Norton activity	<0.05 <0.01 <0.01	NR NR NR	NR NR NR	VLQS Partial reporting of baseline. Inadequate reporting of methods. Insufficient number of events and no CI reported.
Ek et al (1991) Sweden	501 non-surgical pts	Newly admitted long-term medical ward admissions	RCT Multiple	495 (10.1%), 51 stage ≥1 equivalent	NR (4) Albumin Norton mobility	<0.001 <0.001	NR	NR	VLQS Partial reporting of baseline. Inadequate

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
	Setting: Acute care hospital; Speciality: Medicine	who remained in hospital >3 wks. Patient consent required.	regression	PU	Norton activity Food intake	<0.001 <0.05			reporting of methods and analysis. No CI reported. Adequacy of number of events cannot be assessed.
Feuchtinger et al (2006) Germany	175 surgical pts Setting: acute care hospital; Speciality: cardiac surgery	Aged ≥18 yrs, scheduled for cardiac surgery with ECC, not included in another study, consent required.	RCT Logistic regression	175 (14.3%), 25 Grade ≥1 PU	13 (1) Renal insufficiency	0.05	NR	NR	LQS Inadequate reporting of analysis and insufficient number of events. No CI reported.
Fife et al (2001) USA	186 pts Setting: ICU	Pts admitted to Neuro ICU (acute SCI/head injuries/gunshot wounds/CVAs). No consent required (apart for photographs). Excluded if >2 PU on initial assessment, discharge from unit <24 hrs after admission, diagnosis of brain death or life support pending organ donation, no evaluation by nursing staff within 12 hrs after admission.	Cohort Stepwise, logistic regression	149 (15.4%), 23 Stage ≥2 PU	11 (2) Braden score Age	0.002 0.043	NR	NR	LQS Insufficient number of events. OR and CI not reported.
Goodridge et al (1998) Canada	330 non-surgical pts Setting: acute	Care-setting: medical/elderly of tertiary care and long-term care facilities, >65 yrs,	Cohort Stepwise logistic	330 (9.7%), 32 Stage ≥1 PU	5 (1) N of prevention strategies used prior to PU appearance	<0.001	1.4	NR	VLQS Partial presentation of baseline data. Nutritional factors collected but not analysed. Analysis

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
	care hospital; Speciality: elderly/geriatric	within 48-96 hours of admission. Excluded pre-existing dermal ulcers, terminal stage cancer, acute/ chronic renal failure	regression						reporting inadequate. No CI or p values reported. Insufficient number of events. Time dependent variable included in the analysis.
Gunningberg et al (2001) Sweden	146 hip fracture pts Setting: acute care hospital; Speciality: trauma	Pts with hip fracture, ≥65 yrs, admitted without a PU carried out in the A&E or orthopaedics departments. Not sure about consent - assume not	Record review Logistic regression	146 (36.9%), 54 stage ≥1 PU	3 (1) Advanced age	0.03	1.1	NR	MQS Partial reporting of baseline characteristics and analysis reporting inadequate. No CI reported.
Halfens et al (2000) Netherlands	320 pts Setting: acute care hospital; Speciality: multiple	No PU on admittance, Caucasian, probable LOS (hospital) ≥10 days. Consent required. 3 hospitals; pts from surgical, neurological, orthopaedic and internal medicine	Cohort Stepwise logistic regression	320 (14.7%), 47 Grade ≥ 1 PU	16 (4) Braden sensory perception Age Braden friction/shear Braden moisture	<0.01 <0.01 <0.01 <0.01	3.7 2.3 2.3 2.1	1.4-9.3 1.4-3.9 1.4-4.0 1.2-3.5	LQS Partial reporting of baseline characteristics and insufficient number of events.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
Hatanaka et al (2008) Japan	149 non-surgical pts Setting: Acute Care Hospital; Speciality: Respiratory	Bedridden pts hospitalised for a respiratory disorder, required constant attentive care or needed a considerable amount of assisted care.	Cohort Cox proportional hazards model	149 (25.5 %) 38 Grade ≥ 2	NR(5) Hb CRP Alb Age Gender	0.006 0.042 0.021 0.953 0.379	1.2 1.9 0.4 1.0 0.7	1.1-1.4 1.0-3.9 0.2-0.9 0.97-1.03 0.3-1.7	LQS Clinical data collection method not reported and number of factors entered into the stepwise procedure not reported, therefore adequacy of number of events cannot be assessed.
Inman et al (1999) Canada	149 pts Setting: ICU	Aged ≥ 17 yrs, an APACHE II score ≥ 15 , expected LOS (ICU) ≥ 3 days. Pts excluded if PUs at baseline, not expected to survive, admitted for compassionate care or ICU transfer. Consecutive admissions randomised - not concealed allocation, consent procedure not detailed.	RCT Stepwise logistic regression	144 (25.7%), 37 Stage ≥ 1 PU	9 (2) LOS in ICU Increasing SURE score	NR	NR	NR	VLQS Poor quality reporting and insufficient number of events. Limited number of risk factors. Inadequate stats reporting and the independent variable is a composite score which includes the dependent variable. P values, OR or CI not reported. Data reporting by ward staff. Time dependent variable included in the analysis (LOS and increase SURE score).
Kemp et al (1993) USA	84 non-surgical pts Setting: multiple; Speciality: elderly/medical	Pts recruited from hospital in-pt (general medicine and geriatric medicine) and long-term care facilities. Included if aged ≥ 65 yrs, Braden score ≤ 16 and PU free.	RCT Cox regression	84 (39.3%), 33 Stage ≥ 1 PU	11 (2) Overlay type Average Braden mobility	0.018 <0.001	NR	NR	LQS Inadequate number of events; CI not reported.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
		Consent requirements not detailed.							
Lindgren et al (2004) Sweden	548 mixed pts Setting: acute care hospital; Speciality: multiple	Elective and acute medical or surgical pts admitted to 21 wards in University hospital, aged >17 yrs, expected LOS (hospital) ≥5 days, for pts undergoing surgery expected time on operating table of ≥1 hour and PU free. Verbal consent required (patient or relative). Consecutive pts admitted in 3 defined days included up to max 9 per wk.	Cohort Multiple stepwise logistic regression	530 (11.7%) 62 Stage ≥1, Model 1 Total sample 530 (11.7%) 62 Model 2 Medical patients 244 (8.6%) 21 Model 3 Surgical patients 286 (14.3%) 41	<u>Model 1</u> 13 (5) Mobility RAPS Length of hospitalisation Age Weight Surgical treatment <u>Model 2</u> 13 (3) Mobility RAPS Length of hospitalisation Diastolic BP <u>Model 3</u> 13 (3) Serum albumin RAPS Length hospitalisation Weight	0.011 0.002 0.014 0.006 <0.001 0.001 0.029 0.026 0.029 0.027 0.002	0.5 1.0 1.0 1.0 4.8 0.4 1.0 1.0 0.5 1.0 1.0	0.3-0.9 1.0-1.1 1.0-1.1 0.9-1.0 2.0-11.4 0.2-0.6 1.00-1.04 0.9-1.0 0.3-0.9 1.0-1.1 0.9-1.0	LQS Insufficient number of events. Time dependent covariate was included in the analysis.
Marchette et al (1991) USA	161 surgical pts Setting: acute care hospital; Speciality: ICU	Pts aged >59 yrs in ICU after a surgery. Consent not required.	Record review Discriminant analysis	161 (39.1%), 63 Stage ≥2 equivalent PU	NR (5) Skin redness Days static air mattress for prevention Fecal incontinence Diarrhea Preoperative albumin	<0.001 <0.001 0.0013 0.0019 0.0028	NR NR	NR NR	VLQS Inadequate reporting of methods and analysis. No CI. Included time dependent variables in the analysis. Adequacy of number of events cannot be assessed.
Nijs et al (2009) Belgium	520 pts Setting: acute care hospital , surgical; Speciality: ICU	Pts expected LOS in surgical ICU of an acute hospital >24hrs. Excluded <16 yrs old and admitted for burn	Cohort Multivariate logistic regression	463 (28.9%) 134 Grade 2-4	19 (9) Dopamine <5mcg/km/min Medical history of vascular disease IHD or CVVH Adequate prevention	0.003 <0.001 0.045 0.002	6.1 4.5 3.8 6.0	1.9-19.5 2.0-10.2 1.0-13.9 1.9-18.6	MQS Full details of modelling not provided. Adequate number of events is assumed as large number of events.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
		injuries.			Frequency of turning ≥ 6 x/day or alternating mattress Turning Use of sedatives Body Temp ≥ 38.5 C Sitting in chair	<0.001 <0.001 0.006 0.029 <0.001	30.2 6.7 0.3 0.2 0.1	12.2-74.8 2.7-16.4 0.1-0.7 0.2-0.9 0.0-0.3	
Nixon et al (2006) UK	1972 pts Setting: acute care hospital; Speciality: multiple	Aged ≥ 55 yrs, admitted to orthopaedic, vascular, medical or care of elderly wards, acute or elective, expected LOS ≥ 7 days, limited activity or mobility, existing Grade 2 PU. Consent required	RCT, Logistic regression	1971 (10.5%), 207 Grade ≥ 2 PU	13 (7) Hospital Acute admission Baseline wound Baseline skin trauma Baseline grade 1 Age Diabetes	0.02 <0.001 <0.001 0.05 0.001 0.03 0.047	3.7 3.0 1.7 2.0 1.0 1.6	2.3-5.9 1.7-5.1 1.0-2.8 1.3-2.9 1.002-1.04 1.0-2.6	HQS Minor limitation - number of pts in final model not reported.
Nixon et al (2007) UK	109 surgical pts Setting: acute care hospital; Speciality: multiple	Aged >55 yrs, expected LOS ≥ 5 days, scheduled for elective major general or vascular surgery OR acute orthopaedic (avg. surgical time ≥ 90 mins), with or without PU at baseline. Consent required	Cohort Forward stepwise logistic regression	97 (15.5%), 15 Grade ≥ 2 PU	8 (4) Pre-op albumin Grade 1 equivalent Weight loss Diastolic Bp min.	0.009 0.008 0.092 0.205	0.8 7.0 0.3 1.0	0.7-1.0 1.7-29.5 0.1-1.2 0.9-1.0	LQS Inadequate number of events. Included time dependent variables in the analysis.
Okuwa et al (2006) Japan	259 non-surgical pts Setting: long-term nursing care/NH;	Pts admitted to long-term care facility, aged ≥ 65 yrs, bedfast, without lower extremity PU, LOS (hospital) ≥ 14	Cohort Forward stepwise Cox regression	259 (12.7%), 33 stage ≥ 2 PU	9 (3) Ankle brachial index Length of bedfast period Male gender	<0.001 0.003 0.001	0.1 3.0 1.0	0.0-0.2 1.5-6.0 1.004-1.015	LQS Inadequate number of events. Time dependent variables reported.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
	Speciality: elderly/geriatric	days, at risk of developing PU. Consent required (patient or family).							
Olson et al (1996) USA	149 pts Setting: acute care hospital; Speciality: multiple	Medical and surgical in-pts aged ≥18 yrs, no PU on admission, expected LOS (hospital) ≥5 days, consent required.	Cohort Stepwise logistic regression	143 (13.9%), 20 Stage ≥1 PU	11 (3) Haemoglobin Hours in bed Pulse pressure	0.0731 0.0551 0.3022	NR	NR	LQS Insufficient number of events.
Ooi et al (1999) USA	5518 non-surgical pts Setting: long-term nursing care/NH; Speciality: elderly/geriatric	NH residents free from PUs at baseline and 3 mth FU assessment. Excluded residents in homes <50. Consent not required record review	Record review Logistic regression backward elimination	5518 (11.4%), 629 Stage ≥2 PU	6 (6) Age Diabetes Faecal/urine incontinence Transfers Medicaid payments Facility effects (facility effects intermediate) (facility effects high risk)	0.0081 0.0106 <0.001 <0.001 0.0623 <0.001 <0.001	1.0 1.4 1.6 1.5 1.2 1.6 1.9	1.00-1.03 1.1-1.7 1.2-2.0 1.2-1.8 1.0-1.4 1.3-2.0 1.5-2.4	MQS Record review and limited range of risk factors considered (e.g. do not have mobility in the model).
Pancorbo-Hidalgo & Garcia-Fernandez (2001) Spain	187 pts Setting: acute care hospital; Speciality: multiple	Pts at risk of PUs (Gosnell score ≤12) and aged >70 yrs, admitted to internal medicine, ICU, general surgery, and orthopaedic wards	Cohort Logistic regression	187 (16.6%), 31 Stage ≥1 Model 1 Stage ≥1 Model 2 Stage ≥2	<u>Model 1</u> 16 (9) LOS Gosnell score Incontinence Skin alterations diminished Highest systolic BP Lowest diastolic BP Low skin fold thickness Diminished lymphocytes Low haemoglobin <u>Model 2</u> 10 Length of Stay Gosnell score Incontinence	<0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05	1.1 1.2 2.2 1.4 1.0 1.1 1.3 1.2 2.2 1.2 1.1 1.2	1.1-1.2 1.1-1.2 1.7-2.9 1.0-1.9 0.9-1.0 1.06-1.13 1.0-1.6 1.0-1.5 1.3-3.9 1.1-1.2 1.1-1.2 1.1-1.2	LQS Article was translated so unable to undertake detailed quality assessment. Limitations based on inadequate number of events. Time dependent variables included in the analysis.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
					NOVA activity diminished Highest systolic BP Lowest diastolic BP Low skin fold thickness Diminished lymphocytes Low haemoglobin Use of alternating overlay (at risk pts)	<0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05	2.0 1.0 1.1 1.4 1.5 3.0 2.7	1.2-3.5 0.9-1.0 1.0-1.1 1.0-1.9 1.1-2.0 1.5-6.1 1.0-6.9	
Perneger et al (2002) Switzerland	1190 pts Setting: acute care hospital; Speciality: multiple	All newly admitted patients admitted to mixed specialties within a teaching hospital (with or without PU at baseline). Consent not required	Cohort Multivariate proportional hazards model	1190 (10.8%), 129 stage ≥1 PU	10 (3) Braden/Norton mobility Braden friction/shear Age (16-59) (age 60-69) (age 70-79) (age 80-89) (age 90-96)	0.006 0.034	1.4 1.5 1.5 2.5 3.8 5.2	1.1-1.8 1.0-1.8 0.8-2.2 1.5-4.4 2.3-6.4 2.6-10.6	HQS Limitation partial reporting of baseline.
Rademakers et al (2007) Netherlands	722 hip fracture pts Setting: acute care; Speciality: Trauma	Hip fracture pts admitted to level-1 trauma centre. Excluded aged <60 yrs, (multiple) high energy trauma (fall from higher than ground level; road traffic accident), initial conservative treatment, inter-hospital transfer, presence of PUs on admission, pathological fractures and recurrent fractures	Record review, Multivariate logistic regression	722 (29.6%), 214 Stage ≥2 PU	10 (5) Diabetes post-op urinary tract infection post-op hip dislocation ASA class III/IV time to surgery >12 hours	0.021 0.004 0.009 0.001 0.008	1.7 1.9 2.7 4.2 1.7	1.1-2.7 1.2-2.9 1.3-5.6 2.9-6.1 1.2-2.6	MQS Large sample size but limited number of risk factors considered and not based on a conceptual framework (no nutrition or skin moisture factors). Inadequate measurement of risk factor. (Record review).
Reed et al (2003)	2771 non-surgical pts	Record review identifying:	Record review	2771 (14.7%), 406	7 (6)				HQS

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
USA	Setting: chronic care hospital; Speciality: medicine	mobility impaired, admitted to the chosen hospital wards between Jul 1 st , 1994 to Oct 1 st , 1997, LOS \geq 1 wk. Consent not required - record review, Grade 3 and 4 PUs reported	Forward stepwise logistic regression	Stage \geq 2 PU	Low albumin levels Confusion DNR Urinary catheter on admission Malnutrition Stage 1 PU	0.014 0.001 <0.001 <0.001 <0.001 <0.001	1.4 1.5 1.5 1.6 1.7 3.1	1.1-1.8 1.2-1.8 1.2-1.9 1.4-1.8 1.3-2.2 2.4-4.1	Record review.
Rose et al (2006) Canada	111 pts Setting: acute care hospital; Speciality: ICU	Consecutive admissions to university hospital ICU. Consent not reported	Cohort Multiple regression	111 (43.2%), 48 stage \geq 1 PU	NR (3) Skin quality Restricted movement Temperature	NR	NR	NR	VLQS Abstract only. Inadequate information on methodology and analysis. No p values or CI reported.
Salzberg et al (1999) USA	226 SCI pts Setting: acute care hospital; Speciality: trauma	SCI with a neurological deficit attributable to damage of the spinal cord; excluding the cortices and brainstem, defined by ICD-9CM, acute SCI due to a trauma, survival \geq 14 days following acute SCI, and level of SCI between C4-S1.	Record review Model 1 forward stepwise linear regression Model 2 Cox proportional hazards	226 (38.5%), 87 Stage \geq 1 PU	<u>Model 1</u> 8 (3) Extent of paralysis Moisture Serum creatinine <u>Model 2</u> 8 (8) Extent of paralysis Moisture Serum creatinine Incontinence Albumin Mobility Pulmonary disease Level of activity	<0.001 <0.001 0.007 <0.001 0.003 0.006 <0.001 0.028 0.002 0.014 0.036	NR NR NR NR NR NR NR NR NR NR	MQS Limited because of record review and no CI reported.	
Sayar et al (2009) Turkey	140 pts Setting: acute	Surgical and medical ICU pts. Within 1-2 hrs	Cohort Multiple	140 (14.3%) 20 Stage \geq 1 PU	6 (2) LOS Activity level	<0.001 0.005	1.2 0.3	1.1-1.3 0.2-0.7	LQS Insufficient number of events.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
	care hospital; Specialty: ICU	after admission to ICU waterlow was administered. Pts scoring 'at risk' and 'very high risk' included	stepwise logistic regressions						
Schnelle et al (1997) USA	105 non-surgical pts Setting: long-term nursing care/NH; Speciality: elderly/geriatric	Incontinent NH residents, consent required, exclusion criteria presence of stage ≥ 2 PU at baseline, catheters, <60 day LOS	Cohort Stepwise multiple regression	91 (20.9%), 19 Stage ≥ 1 PU Model 1 Stage ≥ 1 severity index = NR; Model 2 Stage ≥ 1 only = NR	Model 1 NR (2) Bed mobility Blanchable erythema severity Model 2 NR (1) Blanchable erythema severity	NR	NR	NR	LQS Insufficient number of events and analysis reporting inadequate. No p values or CI reported.
Schoonhoven et al 2002 Netherlands	223 surgical pts Setting: acute care hospital; Speciality: multiple	Pts scheduled for surgery expected to exceed 4 hrs (post recruitment exclusion if surgery lasted <4 hrs)	Cohort Multiple logistic regression	208 (10.1), 21 Grade ≥ 2 PU	12 (1) Length of surgery (in minutes)	<0.05	1.0	1.0035-1.0087	LQS Baseline characteristics not reported. Insufficient number of events.
Schultz et al (1999) USA	413 surgical pts Setting: acute care hospital; Speciality: mixed	Pts scheduled for inpatient care, aged ≥ 18 yrs, with surgery scheduled to last >2 hrs in lithotomy or supine position. Excluded PUs at baseline, severe chronic skin problems, or receiving only local anaesthesia.	RCT Logistic regression	413 (21.5%), 89 Stage ≥ 1 PU	7 (5) Age Presence of diabetes Less body mass Use of the study mattress Admission Braden score	0.005 0.013 0.015 0.044 0.013	1.1 2.5 0.9 1.9 0.8	1.0-1.1 1.2-5.3 0.9-1.0 1.0-3.7 0.7-1.0	HQS Risk factors were recorded by OR and ward staff, although outcome data was assessed by research assistants.

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
Serpa & Santos (2007) Brazil	170 pts Setting: private hospital; Speciality: NR	Age ≥18 yrs, no PU at admission, hospitalised for ≥24 hrs, total Braden score, admitted to 2 private hospitals, agreed to participate. Excluded chronic renal failure, dialysis treatment for >1 mth, presence of hepatic insufficiency accompanied by ascites.	Cohort Multivariate logistic regression	170 NR	16 (5) Sub Global Nut Assess Albumin Ureas Age Institution	<0.001 <0.001 <0.001 <0.001			LQS Unable to assess in detail, abstract & author communication available only. Low quality study based on assumed inadequate no events. Stage of PU definition unknown.
Stordeur et al (1998) Belgium	174 surgical pts Setting: acute care hospital; Speciality: cardiac/vascular	Consecutive pts, aged ≥16 yrs, who underwent cardiac or vascular surgery, min LOS (hospital) >5 days. Excluded pts who died. Not sure about consent - assume not	Cohort Stepwise logistic regression	163 (29.5%), 48 Stage ≥2 PU	16 (3) Postoperative Braden score Haemoglobin concentration at admission Postoperative steroid therapy	<0.001 <0.001 0.020	NR	NR	LQS Insufficient number of events and CI not reported.
Suriadi et al (2008) Japan	253 pts: Setting: acute care hospital; Specialty: ICU	Aged >18yrs, ICU pts, admitted at least 24hrs before study enrolment, bedfast, no existing PU, able to give informed consent and Indonesian origin.	Cohort Logistic regression model	253 (28.4%) 72 Stage ≥1	Unknown (3) Interface pressure Body Temperature Cigarette smoking		2.2 2.0 1.6	1.6-2.9 1.7-2.5 1.1-2.5	MQS Inadequate reporting of analysis and modelling. Adequate number of events is assumed as large number of events.
Suriadi et al	105 pts	Admitted to ICU for ≥24 hrs and	Cohort	105 (33.3%), 35 stage ≥1	6 (4)				LQS

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
(2007) Indonesia	Setting: ICU	expected LOS (ICU) ≥3 days, bedfast or unable to walk, free from PUs, informed consent (by patient or family). Excluded pts physically incapable of participating (difficult to identify skin condition daily as pt could not be manipulated) or did not wish to participate.	Multivariate logistic regression	PU	Interface pressure Skin moisture Smoking >10/day Body temperature	<0.001 0.002 0.001 0.001	17.6 8.2 12.7 102.0	4.1-74.3 2.2-30.9 2.8-56.7 7.7-98.8	Insufficient number of events.
Tourtual et al (1997) USA	291 non-surgical pts Setting: acute care hospital; Speciality: medicine: elderly/geriatric	All pts admitted to 4 nursing units within an acute hospital and gave consent. Baseline PU status not recorded.	Cohort Forward stepwise logistic regression	291 (21.6%), 63 Stage ≥1 heel PU	17 (2) Braden friction & sheer Braden moisture	0.01 0.007	NR NR	NR NR	LQS Insufficient number of events and CI not reported.
Vanderwee et al (2009)	235 pts Setting: NH; Specialty: elderly non-surgical	NH pts with no PU (Grade 2-4, EPUAP), if could be repositioned, expected LOS >3 days in NH and with non-blanchable erythema at pressure point on the skin.	RCT Multivariate Cox regression analysis	235 (18.7%) 44 Grade ≥2 PU	16 (6) Age >80-90 Age >90 CVA Urinary inc Dual inc Contractures Hypotension	0.16 0.015 0.042 0.004 0.086 0.04 0.002	0.6 0.4 1.9 0.2 0.5 2.0 3.4	0.3-1.2 0.2-0.8 1.1-3.7 0.1-0.6 0.2-1.1 1.0-4.0 1.6-7.5	LQS Insufficient number of events.
Watts et al	148 pts	Victims of blunt or	Cohort	148 (20.	20 (1)				VLQS

Study, Country and reference	Study population (n recruited & type)	Other inclusion criteria	Design and analysis method	n final model (PU%), n PU dev & Stage/Grade	Results: n risk factors (n in model), model risk factor names	P value	OR	CI	Overall study quality and limitation notes
(1998) USA	Setting: acute care; Speciality: trauma	penetrating injury, aged ≥15 yrs, with traumatic injuries, LOS ≥2 days and no pre-existing PU.	Logistic regression	3%), 30 Stage ≥1 PU	Braden mobility	NR	7.5	NR	Baseline characteristics not reported. Insufficient number of events and presentation of analysis. Inadequate measurement of risk factors. No CI or p values reported.
Yepes et al (2009)	150 pts Setting: acute care hospital; Specialty: ICU	Pts without PU on admission hospitalised >48 hrs in ICU and with any of the following risk factors for PUs: intubated and on mechanical ventilation, with vasopressor support.	Cohort Multivariate logistic regression	150 (26.7%) 40 stage ≥2	8 (3) Infection ICU LOS APACHE II	 0.023 0.005 0.044	 2.9 1.1 1.1	 1.2-7.2 1.1-1.2 1-1.1	LQS Insufficient number of events. Time dependent variable included in the analysis.

RCT Randomised Controlled Trial; PU Pressure Ulcer; ADL Activities of Daily Living; ICU Intensive Care Unit; SCI Spinal Cord Injury; LOS Length Of Stay; NR Not Reported; APACHE Acute Physiology & Chronic Health Evaluation; ns not significant; NH nursing home; n number; pts patients; wks weeks; mth month; yrs years; FU follow-up; CI confidence interval; OR odds ratio; BP blood pressure. Overall study quality: HQS (High Quality Study); MQS (Moderate Quality Study); LQS (Low Quality Study); VLQS (Very Low Quality Study). P values <0.001 reported as such. Odds Ratio and Confidence Intervals reported to one decimal place (where appropriate)

Reprinted from the International Journal of Nursing Studies, 50, Coleman S, Gorecki C, Nelson EA, Close SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J. Patient risk factors for pressure ulcer development: systematic review. 2013; 974–1003

The 54 studies (Table 3.3) include a total of 34,449 patients (median 237 per study). Median pressure ulcer incidence was 16.6 (range 3.2% to 73.5%). Study patient populations include intensive care, surgery, trauma, various mixed specialty acute care environments, long-term rehabilitation and nursing home populations, community populations and specific diagnostic groups (e.g. fractured hip and spinal cord injured).

Twenty eight studies defined pressure ulcer outcome as Grade ≥ 1 (Ek 1987; Ek *et al.* 1991; Kemp *et al.* 1993; Bergstrom *et al.* 1996; Bostrom *et al.* 1996; Olson *et al.* 1996; Cobb, Yoder and Warren 1997; Schnelle *et al.* 1997; Tourtual *et al.* 1997; Baldwin and Ziegler 1998; Goodridge *et al.* 1998; Watts *et al.* 1998; Inman *et al.* 1999; Salzberg *et al.* 1999; Schultz *et al.* 1999; Bourdel-Marchasson *et al.* 2000; Halfens, Van Achterberg and Bal 2000; Boyle and Green 2001; Gunningberg *et al.* 2001; Perneger *et al.* 2002; Lindgren *et al.* 2004; Chan *et al.* 2005; Donnelly 2006; Feuchtinger *et al.* 2006; Rose, Cohen and Amsel 2006; Suriadi *et al.* 2007; Suriadi *et al.* 2008; Sayar *et al.* 2009), 22 define pressure ulcer outcome as a Grade ≥ 2 (Marchette, Arnell and Redick 1991; Brandeis *et al.* 1994; Allman *et al.* 1995; Bergquist and Frantz 1999; Berlowitz and Wilking 1989; Stordeur, Laurent and D'Hoore 1998; Ooi *et al.* 1999; Fife *et al.* 2001; Schoonhoven *et al.* 2002; Reed *et al.* 2003; Baumgarten *et al.* 2004; Nixon *et al.* 2006b; Okuwa *et al.* 2006; Bates-Jensen *et al.* 2007; De Laat *et al.* 2007; Nixon, Cranny and Bond 2007; Rademakers *et al.* 2007; Compton *et al.* 2008; Hatanaka *et al.* 2008; Nijs *et al.* 2009; Vanderwee *et al.* 2009; Yepes *et al.* 2009), 3 report both (Bergstrom and Braden 1992; Pancorbo Hidalgo and Garcia Fernandez 2001; Defloor and Grypdonck 2005) and 1 is unknown (Serpa and Santos 2007).

The majority of studies reported a dichotomous outcome, with fifteen reporting time to the development of new pressure ulcers (Kemp *et al.* 1993; Allman *et al.* 1995; Cobb, Yoder and Warren 1997; Bergquist and Frantz 1999; Salzberg *et al.* 1999; Bourdel-Marchasson *et al.* 2000; Boyle and Green 2001; Perneger *et al.* 2002; Baumgarten *et al.* 2004; Okuwa *et al.* 2006; Donnelly 2006; De Laat *et al.* 2007; Hatanaka *et al.* 2008; Sayar *et al.* 2009; Vanderwee *et al.* 2009) in modelling .

Eleven studies reported more than one multivariable analysis (Ek 1987; Bergstrom and Braden 1992; Brandeis *et al.* 1994; Bergstrom *et al.* 1996; Schnelle *et al.* 1997; Salzberg *et al.* 1999; Pancorbo Hidalgo and Garcia Fernandez 2001; Lindgren *et al.* 2004; Defloor and Grypdonck 2005; Bates-Jensen *et al.* 2007; Nijs *et al.* 2009). Where

more than one model was reported a primary model was identified based upon the following hierarchy: primary endpoint of \geq Grade 1, primary endpoint development of new pressure ulcer(s), model with the most comprehensive range of variables, total sample or largest sub-groups of patients, largest number of pressure ulcers and models with baseline values not time dependent variables.

3.7.2 Study Quality

The detailed quality appraisal for each included study is shown in Table 3.4. Seven studies fulfilled all 4 quality criteria and were classified as high quality and a further 10 studies had sufficient numbers of event and were classified as moderate quality studies. The remaining 37 studies (68.5%) had inadequate numbers of pressure ulcers and other methodological limitations and comprised 27 low quality studies and 10 very low quality studies (Table 3.4).

3.7.3 Risk Factor Domains and Sub-domains

Forty seven (87.0%) studies reported of the risk factors entered into multivariable modelling and those which emerged as significant (independently predictive of pressure ulcer outcome). Seven studies (Schnelle *et al.* 1997; Bourdel-Marchasson *et al.* 2000; Ek *et al.* 1991; Rose, Cohen and Amsel 2006; Marchette, Arnell and Redick 1991; Serpa and Santos 2007; Hatanaka *et al.* 2008) only reported the risk factors which emerged from multivariable modelling. The forty seven studies evaluated a median of 11 (range 3-45) potential risk factors in multivariable analyses and identified a median of 3 (range 1-10) factors as independently predictive of pressure ulcer outcome.

A summary of risk factors entered into multivariable modelling (where known) and those which emerged as significant are summarised by study (Table 3.3) and by risk factor domain/sub-domain (Table 3.5). An example of the underpinning evidence tables relating to skin condition are shown in Appendix 7 (full evidence tables are available at <http://ctru.leeds.ac.uk/PURE>).

Table 3.4 Quality Assessment of Included Studies

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
Defloor & Grypdonck 2005	P	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Limitation partial reporting of baseline.	HQS
Schultz et al 1999	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Risk factors were recorded by OR and ward staff, although outcome data was assessed by research assistants.	HQS
Reed et al 2003	P	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	Record review.	HQS
Perneger et al 2002	P	Y	N	U	Y	Y	Y	Y	Y	Y	Y	Limitation partial reporting of baseline.	HQS
Brandeis et al 1994	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Record review.	HQS
Nixon et al 2006	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	Minor limitation - number of patient in final model not reported.	HQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
Bergstrom et al 1996	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	Y		HQS
Rademakers et al 2007	Y	Y	Y	U	N	N	Y	Y	Y	N	Y	Large sample size but limited number of risk factors considered and not based on a conceptual framework (no nutrition or skin moisture factors). Inadequate measurement of risk factor. (Record review).	MQS
Baumgarten et al 2004	Y	Y	U	N	Y	Y	Y	Y	Y	P	Y	all risk factors are categorical data rather than continuous. 20% missing data from final model.	MQS
Nijs et al 2009	P	Y	Y	Y	Y	Y	Y	Y	P	P	Y	Full details of modelling not provided. Adequate number of events is assumed as large number of events.	MQS
Suriadi et al 2008	P	Y	Y	U	Y	Y	Y	Y	N	Y	P	Inadequate reporting of analysis and modelling. Adequate number of events is assumed as large number of events.	MQS
Gunningberg et al 2001	P	Y	Y	U	Y	U	U	Y	P	Y	U	Partial reporting of baseline characteristics and analysis reporting inadequate. No confidence intervals reported.	MQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
Ooi et al 1999	Y	Y	Y	U	P	P	Y	Y	Y	P	Y	Record review and limited range of risk factors considered (eg do not have mobility in the model).	MQS
Bergstrom and Braden 1992	Y	Y	Y	U	Y	Y	Y	Y	N	Y	Y	No confidence intervals reported.	MQS
Salzberg et al 1999	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Limited because of record review and no confidence intervals reported.	MQS
Bourdel-Marchasson et al 2001	P	Y	Y	Y	Y	Y	N	Y	N	Y	U	Full details of modelling not provided. Adequate number of events is assumed as large number of events (299).	MQS
De Laat et al 2007	Y	Y	Y	U	Y	Y	Y	Y	P	Y	Y	Ward staff recording data and no confidence intervals reported. Time dependent covariates included in the analysis.	MQS
Bates-Jensen et al 2007	Y	Y	Y	U	Y	N	U	N	Y	Y	N	Inadequate sample size resulting in wide confidence intervals.	LQS
Chan et al 2005	P	N	U	U	U	U	U	N	N	U	N	Only partial reporting of baseline characteristics. Inadequate reporting of analysis and modelling. Inadequate number of events.	LQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
Serpa and Santos 2007	N	N	U	U	Y	N	U	N	P	N	N	Unable to assess in detail, abstract & author communication available only. Low quality study based on assumed inadequate no events. Stage of PU definition unknown.	LQS
Yepes et al 2009	Y	Y	Y	U	Y	Y	Y	N	Y	Y	N	Insufficient number of events. Time dependent variable included in the analysis.	LQS
Hantanaka et al 2008	Y	Y	Y	U	Y	Y	Y	U	P	Y	U	Clinical data collection method not reported and number of factors entered into the stepwise procedure not reported, therefore adequacy of number of events cannot be assessed.	LQS
Schoonhoven et al 2002	N	Y	Y	U	P	Y	Y	N	Y	Y	N	Baseline characteristics not reported. Insufficient number of events.	LQS
Boyle and Green 2001	P	Y	N/A	U	Y	Y	Y	N	Y	Y	P	Baseline characteristics not reported. Insufficient number of events.	LQS
Fife et al 2001	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Insufficient number of events. Odds ratios and confidence levels not reported.	LQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
Suriadi et al 2007	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	P	Insufficient number of events.	LQS
Compton et al 2008	Y	Y	Y	U	Y	Y	Y	N	Y	Y	P	Record review. Large number of events but it used 32 variables in model. No confidence intervals reported.	LQS
Bergquist and Frantz 1999	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Record review and insufficient number of events. Inadequate measurement of risk factors (record review).	LQS
Sayar et al 2009	Y	Y	Y	U	Y	Y	Y	N	Y	Y	N	Insufficient number of events.	LQS
Vanderwee et al 2009	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	P	Insufficient number of events.	LQS
Tourtual et al 1997	Y	Y	Y	U	Y	Y	Y	N	Y	Y	P	Insufficient number of events and confidence intervals not reported.	LQS
Schnelle et al 1997	Y	Y	Y	Y	Y	U	U	N	N	Y	N	Insufficient number of events and analysis reporting inadequate. No P values or confidence intervals reported.	LQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
Olson et al 1996	Y	Y	Y	Y	Y	Y	Y	N	Y	U	N	Insufficient number of events.	LQS
Allman et al 1995	Y	Y	Y	U	Y	Y	Y	N	Y	Y	P	Insufficient number of events.	LQS
Berlowitz & Wilking 1989	P	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Insufficient number of events. Data collection relied on clinical staff and only partial reporting of baseline characteristics.	LQS
Stordeur et al 1998	Y	Y	Y	U	Y	Y	Y	N	Y	Y	N	Insufficient number of events and confidence intervals not reported.	LQS
Pancorbo Hidalgo & Garcia Fernandez 2001	U	U	U	U	Y	Y	U	N	Y	U	N	Article was translated so unable to undertake detailed quality assessment. Limitations based on inadequate number of events. Time dependent variables included in the analysis.	LQS
Halfens et al 2000	P	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Partial reporting of baseline characteristics and insufficient number of events.	LQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
Feuchtinger et al 2006	Y	Y	Y	U	Y	Y	P	N	P	Y	N	Inadequate reporting of analysis and insufficient number of events. No confidence intervals reported.	LQS
Lindgren et al 2004	Y	Y	Y	U	Y	Y	Y	N	Y	Y	N	Insufficient number of events. Time dependent covariate was included in the analysis.	LQS
Kemp et al 1993	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Inadequate number of events, Confidence intervals not reported.	LQS
Nixon et al 2007	P	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Inadequate number of events. Included time dependent variables in the analysis.	LQS
Okuwas et al 2006	Y	Y	Y	U	Y	Y	Y	N	Y	Y	N	Inadequate number of events. Time dependent variables reported.	LQS
Donnelly 2006	Y	Y	N/A	U	Y	Y	Y	N	P	Y	N	Insufficient number of events and no confidence intervals reported.	LQS
Inman et al 1999	Y	Y	Y	U	N	N	U	N	N	N	P	Poor quality reporting and insufficient number of events. Limited number of risk factors. Inadequate stats reporting and the independent variable is a composite score which includes the dependent	VLQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
												variable. P values, Odds ratios or confidence intervals not reported. Data reporting by ward staff. Time dependent variable included in the analysis (LOS and increase SURE score).	
Baldwin and Ziegler 1998	N	Y	N/A	U	Y	P	Y	N	N	P	N	Baseline characteristics are not reported. The sample size is too small and insufficient number of events.	VLQS
Watts et al 1998	P	Y	U	U	Y	Y	Y	N	N	P	N	Baseline characteristics not reported. Insufficient number of events. Insufficient presentation of analysis. Inadequate measurement of risk factors. No confidence intervals or p values reported.	VLQS
Goodridge et al 1998	P	Y	N/A	U	Y	P	P	N	N	N	P	Partial presentation of baseline data. Nutritional factors collected but not analysed. Analysis reporting inadequate. No confidence intervals or p values reported. Insufficient number of events. Time dependent variable included in the analysis.	VLQS
Bostrom et al 1996	P	Y	N/A	U	P	N	y	N	N	N	N	Insufficient number of events. Analysis reporting inadequate. No confidence intervals reported. Time dependent variables	VLQS

Author and Year	1. The baseline study sample (individuals entering the study) is adequately described for key characteristics	2. A clear definition or description of the risk factor measured is provided	3. Continuous variables are reported or appropriate (not data-dependent) cut points are used.	4. Adequate proportion of the study sample has complete data for risk factors	5. Range of potential risk factors are measured (i.e. key variables in conceptual model)	6. Range of potential risk factors are accounted for in analysis (i.e. appropriate adjustment)	7. There is no selective reporting of results	8. Sufficient number of events (≥ 10 event per risk factor) (Key domain A)	9. There is sufficient presentation of data to assess the adequacy of the method and analysis (Key Domain B)	10. Strategy for model building (i.e. inclusion of variables) is appropriate and is based on a conceptual framework or model (Key Domain C)	11. Selected model is adequate for the design of the study (Key Domain D)	Limitations	Quality level allocation
												included in the analysis.	
Cobb et al 1997	Y	Y	Y	U	Y	U	P	N	N	U	N	Inadequate reporting of analysis methods. No confidence intervals. Insufficient number of events.	VLQS
Ek 1987	P	Y	N	U	Y	Y	Y	N	N	N	N	Partial reporting of baseline. Inadequate reporting of methods. Insufficient number of events and no confidence intervals reported.	VLQS
Ek et al 1991	P	Y	Y	U	Y	Y	N	U	N	N	N	Partial reporting of baseline. Inadequate reporting of methods and analysis. No confidence intervals. Adequacy of number of events cannot be assessed.	VLQS
Marchette et al 1991	P	N	Y	U	Y	U	U	U	N	N	N	Inadequate reporting of methods and analysis. No confidence intervals. Included time dependent variables in the analysis. Adequacy of number of events cannot be assessed.	VLQS
Rose et al 2006	N	N	U	U	U	U	U	U	N	N	N	Abstract only. Inadequate information on methodology and analysis. No p values or confidence intervals.	VLQS

Study quality: HQS (High Quality Study), MQS (Moderate Quality Study), LQS (Low Quality Study), VLQS (Very Low Quality Study).

Y: Yes; N:No; P:Partial, U: uncertain; PU: pressure ulcer. Gray Shading indicates Key Quality Domains.

Table 3.5 Summary of evidence for risk factor domains/sub-domains

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Mobility/Activity Sub-Domains		
RAS Mobility subscale 8 of 14 studies (57.1%)	1 HQS - Perneger et al 2002 3 LQS - Bergquist & Frantz 1999; Lindgren et al 2004; Kemp et al 1993 4 VLQS - Baldwin & Ziegler 1998; Watts et al 1998; Ek 1987; Ek et al 1991	1 MQS - Salzberg et al 1999 4 LQS - Vanderwee et al 2009; Tourtual et al 1997; Pancorbo Hidalgo & Garcia Fernandez 2001; Halfens et al 2000 1 VLQS - Bostrom et al 1996
RAS Activity subscale 1 of 16 studies (6.2%)	1 VLQS - Ek et al 1991	3 HQS - Defloor & Grypdonck 2005; Perneger et al 2002; Nixon et al 2006 1 MQS - Salzberg et al 1999 7 LQS - Bergquist & Frantz 1999; Vanderwee et al 2009; Tourtual et al 1997; Pancorbo Hidalgo & Garcia Fernandez 2001; Halfens et al 2000; Lindgren et al 2004; Kemp et al 1993 4 VLQS - Baldwin & Ziegler 1998; Watts et al 1998; Bostrom et al 1996; Ek 1987
Activity (Bed/ Chairfast/immobile) descriptors 6 of 11 (54.5%)	1 MQS - Nijs et al 2009 5 LQS - Schnelle et al 1997; Olson et al 1996; Allman et al 1995; Berlowitz & Wilking 1989; Okuwa et al 2006	2 MQS - De Laat et al 2007; Baumgarten et al 2004 3 LQS - Fife et al 2001; Bergquist & Frantz 1999; Donnelly 2006

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Mobility/Activity ADL 4 of 7 (57.1%)	1 HQS - Brandeis et al 1994 1 MQS - Ooi et al 1999 1 LQS - Sayar et al 2009 1 VLQS - Rose et al 2006	1 MQS - Rademakers et al 2007 2 LQS - Bergquist & Frantz 1999; Donnelly 2006
General ADL 2 of 4 (50%)	1 MQS - Baumgarten et al 2004. 1 LQS - Bergquist & Frantz 1999	1 HQS - Brandeis et al 1994 1 LQS - Berlowitz & Wilking 1989
RAS Friction and shear 4 of 12 (33.3%)	1 HQS - Perneger et al 2002 1 MQS - De Laat et al 2007 2 LQS - Tourtual et al 1997; Halfens et al 2000	1 HQS - Defloor & Grypdonck 2005 4 LQS - Bergquist & Frantz 1999; Vanderwee et al 2009; Lindgren et al 2004; Kemp et al 1993 3 VLQS - Baldwin & Ziegler 1998; Watts et al 1998; Bostrom et al 1996
Factors affecting mobility 6 of 13 (46.1%)	3 MQS - Rademakers et al 2007; Salzberg et al 1999; Bourdel-Marchasson et al 2000 3 LQS - Boyle & Green 2001; Bergquist & Frantz 1999; Vanderwee et al 2009	1 HQS - Defloor & Grypdonck 2005 1 MQS - De Laat et al 2007 5 LQS - Fife et al 2001; Sayar et al 2009; Tourtual et al 1997; Berlowitz & Wilking 1989; Feuchtinger et al 2006
Interface pressures 2 of 2 (100%)	1 MQS - Suriadi et al 2008 1 LQS - Suriadi et al 2007	
Skin/PU Status Sub-Domains		
Stage/Grade 1 4 of 4 (100%)	2 HQS - Reed et al 2003; Nixon et al 2006 2 LQS - Allman et al 1995; Nixon et al 2007	
Existing PU 2 of 5 (40%)	1 HQS - Defloor & Grypdonck 2005 1 MQS - Baumgarten et al 2004	1 HQS - Nixon et al 2006 2 LQS - Tourtual et al 1997; Stordeur et al 1998

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Previous PUs 0 of 2 (0%)		2 LQS - Allman et al 1995; Halfens et al 2000
General skin status 9 of 10 (90%)	2 HQS - Defloor & Grypdonck 2005 Nixon et al 2006 5 LQS - Compton et al 2008; Schnelle et al 1997; Allman et al 1995; Pancorbo Hidalgo & Garcia Fernandez 2001; Bates-Jensen et al 2007 2 VLQS - Rose et al 2006; Marchette et al 1991	1 LQS - Boyle & Green 2001
Perfusion Sub-Domains		
Diabetes 5 of 12 (41.6%)	3 HQS - Schultz et al 1999; Brandeis et al 1994; Nixon et al 2006 2 MQS - Rademakers et al 2007; Ooi et al 1999	7 LQS - Compton et al 2008; Vanderwee et al 2009; Berlowitz & Wilking 1989; Stordeur et al 1998; Halfens et al 2000; Feuchtinger et al 2006; Donnelly 2006
Vascular disease 4 of 6 (66.6%)	1 MQS - Nijs et al 2009 3 LQS - Vanderwee et al 2009; Berlowitz & Wilking 1989; Feuchtinger et al 2006	2 LQS - Tourtual et al 1997; Donnelly 2006
Circulation 3 of 6 (50%)	3 LQS - Compton et al 2008; Olson et al 1996; Okuwa et al 2006	1 HQS - Defloor & Grypdonck 2005 2 LQS - Tourtual et al 1997; Feuchtinger et al 2006

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Blood Pressure 6 of 11 (54.5%)	1 MQS - Bergstrom & Braden 1992 4 LQS - Boyle & Green 2001; Vanderwee et al 2009; Pancorbo Hidalgo & Garcia Fernandez 2001; Nixon et al 2007 1 VLQS - Cobb et al 1997	5 LQS - Fife et al 2001; Suriadi et al 2007; Olson et al 1996; Lindgren et al 2004; Donnelly 2006
Smoking 2 of 4 (50%)	1 MQS - Suriadi et al 2008 1 LQS - Suriadi et al 2007	2 LQS - Feuchtinger et al 2006; Donnelly 2006
Oedema 1 of 4 (25%)	1 LQS - Compton et al 2008	1 MQS - Nijs et al 2009 2 LQS - Bergquist & Frantz 1999; Donnelly 2006
Haematological Measures Sub-Domains		
U&Es 2 of 4 (50%)	1 MQS - Salzberg et al 1999 1 LQS - Serpa & Santos 2007	2 LQS - Berlowitz & Wilking 1989; Okuwa et al 2006
Protein 1 of 3 (33.3%)	1 LQS - Hatanaka et al 2008	1 LQS - Sayar et al 2009 1 VLQS - Marchette et al 1991
Albumin 7 of 11 (63.6%)	1 HQS - Reed et al 2003 1 MQS - Bourdel-Marchasson et al 2000 3 LQS - Serpa & Santos 2007; Hatanaka et al 2008; Nixon et al 2007 2 VLQS - Ek et al 1991; Marchette et al 1991	2 MQS - Bergstrom & Braden 1992; Salzberg et al 1999 2 LQS - Lindgren et al 2004; Kemp et al 1993
Lymphopenia 2 of 2 (100%)	2 LQS - Allman et al 1995; Pancorbo Hidalgo & Garcia Fernandez 2001	

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Haemoglobin (Hb) 6 of 11 (54.5%)	1 HQS - Nixon et al 2006 5 LQS - Hatanaka et al 2008; Bergquist & Frantz 1999; Olson et al 1996; Stordeur et al 1998; Pancorbo-Hidalgo & Garcia Fernandez 2001	1 MQS - Gunningberg et al 2001 4 LQS - Serpa & Santos 2007; Feuchtinger et al 2006; Nixon et al 2007; Okuwa et al 2006
Moisture Sub-Domains		
Moisture Subscales 4 of 12 (33.3%)	1 MQS - Salzberg et al 1999 2 LQS - Tourtual et al 1997; Halfens et al 2000 1 VLQS - Baldwin & Ziegler 1998	2 HQS - Defloor & Grypdonck 2005; Perneger et al 2002 3 LQS - Bergquist & Frantz 1999; Vanderwee et al 2009; Kemp et al 1993 3 VLQS - Watts et al 1998; Bostrom et al 1996; Ek 1987
Urinary incontinence 1 of 7 (14.3%)	1 LQS - Vanderwee et al 2009	1 HQS - Brandeis et al 1994 2 MQS - Salzberg et al 1999; Baumgarten et al 2004. 3 LQS - Bergquist & Frantz 1999; Halfens et al 2000; Donnelly 2006
Faecal incontinence 2 of 11 (18.2%)	1 HQS - Brandeis et al 1994 1 VLQS - Marchette et al 1991	1 HQS - Reed et al 2003 1 MQS - Baumgarten et al 2004. 7 LQS - Boyle & Green 2001; Fife et al 2001; Suriadi et al 2007; Olson et al 1996; Allman et al 1995; Halfens et al 2000; Donnelly 2006

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Dual incontinence 3 of 5 (60.0%)	1 MQS - Ooi et al 1999 2 LQS - Bergquist & Frantz 1999; Vanderwee et al 2009	1 MQS - Baumgarten et al 2004. 1 LQS - Tourtual et al 1997
Incontinence other 1 of 1 (100%)	1 LQS - Pancorbo Hidalgo & Garcia Fernandez 2001	
Urinary Catheter 1 of 3 (33.3%)	1 HQS - Reed et al 2003	2 LQS - Compton et al 2008; Berlowitz & Wilking 1989
Skin moisture 3 of 5 (60.0%)	3 LQS - Suriadi et al 2007; Compton et al 2008; Bergquist & Frantz 1999	1 MQS - De Laat et al 2007 1 LQS - Halfens et al 2000
Body Temperature Domain		
Body Temperature 5 of 8 (62.5%)	3 MQS - Nijs et al 2009; Suriadi et al 2008; Bergstrom & Braden 1992 1 LQS - Suriadi et al 2007 1 VLQS - Rose et al 2006	2 LQS - Vanderwee et al 2009; Feuchtinger et al 2006 1 VLQS - Ek 1987
Nutrition Sub-Domains		
Nutritional Scales 1 of 14 (7.1%)	1 LQS - Serpa & Santos 2007	3 HQS - Defloor & Grypdonck 2005; Perneger et al 2002; Nixon et al 2006 6 LQS - Vanderwee et al 2009; Tourtual et al 1997; Pancorbo Hidalgo & Garcia Fernandez 2001; Halfens et al 2000; Lindgren et al 2004; Kemp et al 1993 4 VLQS - Baldwin & Ziegler 1998; Watts et al 1998; Bostrom et al 1996; Ek 1987

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Food intake 4 of 7 (57.1%)	1 HQS - Brandeis et al 1994 1 MQS - Bergstrom & Braden 1992 1 LQS - Berlowitz & Wilking 1989 1 VLQS - Ek et al 1991	1 HQS - Defloor & Grypdonck 2005 1 MQS - De Laat et al 2007 1 LQS - Bergquist & Frantz 1999
Malnourishment 1 of 3 (33.3%)	1 HQS - Reed et al 2003	2 LQS - Schoonhoven et al 2002; Donnelly 2006
Weight 4 of 12 (33.3%)	3 LQS - Allman et al 1995; Lindgren et al 2004; Nixon et al 2007 1 VLQS – Cobb et al 1997	1 MQS - Bergstrom & Braden 1992 5 LQS - Yepes et al 2009; Boyle & Green 2001; Compton et al 2008; Olson et al 1996; Kemp et al 1993 2 VLQS - Inman et al 1999; Watts et al 1998
BMI 2 of 9 (22.2%)	1 HQS - Schultz et al 1999 1 LQS - Fife et al 2001	2 HQS - Defloor & Grypdonck 2005; Brandeis et al 1994 5 LQS - Serpa & Santos 2007; Compton et al 2008; Vanderwee et al 2009; Feuchtinger et al 2006; Lindgren et al 2004
Arm measurements 1 of 3 (33.3%)	1 LQS - Pancorbo Hidalgo & Garcia Fernandez 2001	2 LQS - Serpa & Santos 2007; Allman et al 1995
Other measures 0 of 4 (0%)		2 LQS - Yepes et al 2009; Compton et al 2008 2 VLQS - Inman et al 1999; Watts et al 1998
Age Domain		

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Increasing Age 12 of 32 (37.5%)	<p>4 HQS - Schultz et al 1999; Perneger et al 2002; Bergstrom et al 1996; Nixon et al 2006</p> <p>3 MQS - Ooi et al 1999; Bergstrom & Braden 1992; Gunningberg et al 2001</p> <p>5 LQS - Serpa & Santos 2007; Hatanaka et al 2008; Vanderwee et al 2009; Halfens et al 2000; Lindgren et al 2004</p>	<p>2 HQS - Defloor & Grypdonck 2005; Brandeis et al 1994</p> <p>2 MQS - De Laat et al 2007; Baumgarten et al 2004.</p> <p>12 LQS - Chan et al 2005; Yepes et al 2009; Fife et al 2001; Compton et al 2008; Bergquist & Frantz 1999; Tourtual et al 1997; Olson et al 1996; Allman et al 1995; Berlowitz & Wilking 1989; Feuchtinger et al 2006; Kemp et al 1993; Nixon et al 2007</p> <p>4 VLQS - Inman et al 1999; Watts et al 1998; Goodridge et al 1998; Cobb et al 1997</p>
Sensory Perception Domain		
Sensory perception Braden subscale 2 of 9 (22.2%)	<p>1 HQS - Defloor & Grypdonck 2005</p> <p>1 LQS - Halfens et al 2000</p>	<p>1 HQS - Perneger et al 2002</p> <p>3 LQS - Vanderwee et al 2009; Tourtual et al 1997; Kemp et al 1993</p> <p>3 VLQS - Baldwin & Ziegler 1998; Watts et al 1998; Bostrom et al 1996</p>
Mental Status Sub-Domains		
Mental Status Subscales 1 of 5 (20%)	<p>1 HQS - Perneger et al 2002</p>	<p>1 HQS - Defloor & Grypdonck 2005</p> <p>2 LQS - Pancorbo Hidalgo & Garcia Fernandez 2001; Donnelly 2006</p> <p>1 VLQS - Ek 1987</p>

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Mental status study specific measures 1 of 8 (12.5%)	1 HQS - Reed et al 2003	1 HQS - Brandeis et al 1994 1 MQS - Baumgarten et al 2004. 5 LQS - Bergquist & Frantz 1999; Sayar et al 2009; Pancorbo Hidalgo & Garcia Fernandez 2001; Halfens et al 2000; Donnelly 2006
Race Domain		
Race 2 of 5 (40%)	1 HQS - Bergstrom et al 1996 1 MQS - Baumgarten et al 2004	1 HQS - Brandeis et al 1994 2 LQS - Bates-Jensen et al 2007; Chan et al 2005
Gender Domain		
Gender 4 of 15 (26.6%)	4 LQS - Compton et al 2008; Bergquist & Frantz 1999; Okuwa et al 2006; Hatanaka et al 2008	2 HQS - Brandeis et al 1994; Bergstrom et al 1996 1 MQS - Baumgarten et al 2004. 6 LQS - Chan et al 2005; Serpa & Santos 2007; Boyle & Green 2001; Fife et al 2001; Lindgren et al 2004; Donnelly 2006 2 VLQS - Inman et al 1999; Goodridge et al 1998
General Health Status Sub-Domains		
ASA 1 of 2 (50%)	1 MQS - Rademakers et al 2007	1 LQS - Donnelly 2006
APACHE 2 1 of 4 (25%)	1 LQS - Yepes et al 2009	1 MQS - Nijs et al 2009 1 LQS - Compton et al 2008 1 VLQS - Inman et al 1999

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Norton score measures 0 of 3 (0%)		2 HQS - Defloor & Grypdonck 2005; Perneger et al 2002 1 VLQS - Ek 1987
Chronic wounds 1 of 2 (50%)	1 HQS - Nixon et al 2006	1 LQS - Nixon et al 2007
Other factors 8 of 26 (30.8%)	3 HQS - Schultz et al 1999; Reed et al 2003; Nixon et al 2006 2 MQS - Rademakers et al 2007; Nijs et al 2009 2 LQS - Yepes et al 2009; Lindgren et al 2004 1 VLQS - Marchette et al 1991	2 HQS - Defloor & Grypdonck 2005; Brandeis et al 1994 2 MQS - Salzberg et al 1999; De Laat et al 2007 12 LQS - Bates-Jensen et al 2007; Chan et al 2005; Serpa & Santos 2007; Schoonhoven et al 2002; Fife et al 2001; Compton et al 2008; Bergquist & Frantz 1999; Halfens et al 2000; Feuchtinger et al 2006; Nixon et al 2007; Okuwa et al 2006; Donnelly 2006 2 VLQS - Inman et al 1999; Watts et al 1998
Medication Domain		
Medication 3 of 10 (30%)	1 MQS - Nijs et al 2009 2 LQS - Bergquist & Frantz 1999 Stordeur et al 1998	1 HQS - Brandeis et al 1994 6 LQS - Yepes et al 2009; Schoonhoven et al 2002; Compton et al 2008; Vanderwee et al 2009; Olson et al 1996; Donnelly 2006
Risk Factor Sub-Domains		

Domain summary: Variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model	Number and quality of studies variable non-significant in multivariable model
Braden Scale total score 7 of 16 (43.75%)	2 HQS - Schultz et al 1999; Bergstrom et al 1996 1 MQS - Bergstrom & Braden 1992 4 LQS - Bates-Jensen et al 2007; Chan et al 2005; Fife et al 2001; Stordeur et al 1998	6 LQS - Yepes et al 2009; Serpa & Santos 2007; Bergquist & Frantz 1999; Tourtual et al 1997; Kemp et al 1993; Donnelly 2006 3 VLQS - Baldwin & Ziegler 1998; Watts et al 1998; Goodridge et al 1998
Other scales 3 of 7 (42.8%)	1 MQS - Bourdel-Marchasson et al 2000 1 LQS - Pancorbo Hidalgo & Garcia Fernandez 2001 1 VLQS - Inman et al 1999	4 LQS - Compton et al 2008; Sayar et al 2009; Stordeur et al 1998; Lindgren et al 2004

Study quality: HQS (High Quality Study), MQS (Moderate Quality Study), LQS (Low Quality Study), VLQS (Very Low Quality Study).

ASA: American Society of Anesthesiologists; APACHE: Acute Physiology & Chronic Health Evaluation; PU: pressure ulcer; RAS: Risk Assessment Scale; BMI: Body Mass Index. Reprinted from the International Journal of Nursing Studies, 50, Coleman S, Gorecki C, Nelson EA, Close SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J. Patient risk factors for pressure ulcer development: systematic review. 2013; 974–1003.

3.7.3.1 Mobility/Activity

Mobility/activity variables were classified into 8 sub-domains including activity risk assessment scale subscales, mobility risk assessment scale subscales, activity descriptors (bedfast/chair fast/immobility), mobility/activity ADL (Activities of Daily Living), general ADL, friction and shear, factors affecting mobility and interface pressures. Activity subscales categorize patients as bedfast, chair fast, walking with limitations, walking with no limitations, whilst mobility subscales tend to categorize frequency or magnitude of movement.

Overall 36 studies entered one or more mobility/activity related variables into their statistical models (Table 3.5). In 29 (80.5%) of these studies a mobility /activity related variable emerged as statistically significant (this included 2 large, high quality studies). The variables that emerged most consistently were mobility subscales (8 of 14 studies), mobility/activity ADL (4 of 7 studies) and activity (bedfast/chairfast/immobile descriptors (6 of 11 studies). In all studies the direction of the relationship was that poorer mobility/activity increased the risk of pressure ulcer development.

Study specific activity descriptors were used in 11 studies and the use of non-standardised measures also impacts upon interpretation and clinical application of findings. A distinction is found in the literature between measures of activity which are at the macro level (that is, bedfast, chairfast, ambulation) and mobility which capture frequency and magnitude of movement. An important observation is that 14 studies used standardised measures (risk assessment scale subscales) and included both activity and mobility subscales in multivariable modelling. Both subscales emerged in 1 very poor quality study (Ek *et al.* 1991), in 7 the mobility subscale rather than the activity subscale emerged (Ek 1987; Kemp *et al.* 1993; Baldwin and Ziegler 1998; Bergquist and Frantz 1999; Watts *et al.* 1998; Perneger *et al.* 2002; Lindgren *et al.* 2004) illustrating that mobility measures are more able to distinguish between patients who will or will not develop pressure ulcers.

3.7.3.2 Skin/Pressure Ulcer Status

Skin/ pressure ulcer status were categorised into 5 areas comprising general skin status (relating to factors which may make the skin more vulnerable to pressure ulcer development, e.g. redness, blanching erythema, dryness), stage/grade 1 equivalent, existing pressure ulcers, and previous pressure ulcers. Overall sixteen studies entered one or more skin/ pressure ulcer status related variables into their

statistical models (Table 3.5). In 12 (75.0%) of these studies skin/pressure ulcer status related variables emerged in multivariable modelling as independently predictive of pressure ulcer development, and this included 3 high quality studies.

There is strong association between Stage/Grade 1 pressure ulcers (Allman *et al.* 1995; Reed *et al.* 2003; Nixon *et al.* 2006b; Nixon, Cranny and Bond 2007) and subsequent \geq Stage/Grade 2 pressure ulcers. All of the studies reported odds ratios and confidence intervals and the 2 large high quality studies (Reed *et al.* 2003; Nixon *et al.* 2006b) suggest that the presence of a Stage/Grade 1 pressure ulcer increases the odds of subsequent Stage/Grade 2 by 2-3 fold.

General skin status also appears to be important and emerged in 9 of the 10 studies which considered it (Marchette, Arnell and Redick 1991; Allman *et al.* 1995; Schnelle *et al.* 1997; Pancorbo Hidalgo and Garcia Fernandez 2001; Defloor and Grypdonck 2005; Nixon *et al.* 2006b; Rose, Cohen and Amsel 2006; Bates-Jensen *et al.* 2007; Compton *et al.* 2008) including 2 high quality studies (Defloor and Grypdonck 2005; Nixon *et al.* 2006b). However, the large number of descriptors and more recent technologies to quantify underlying inflammation (e.g. Sub-Epidermal Moisture Bates-Jensen *et al.* 2007), make interpretation difficult. The presence of existing pressure ulcers emerged only in long-term elderly patient populations (Baumgarten *et al.* 2004; Defloor and Grypdonck 2005), whilst the presence of existing pressure ulcer and previous pressure ulcer did not emerge in acute hospital patient studies.

3.7.3.3 Perfusion

Perfusion related variables were categorised into diabetes, vascular disease, circulation, blood pressure, smoking and oedema. Overall twenty seven studies considered 1 or more perfusion related variables within their analysis (Table 3.5). Of these, in 19 studies (70.4%) a perfusion related variable emerged.

There is strong evidence that diabetes increases the probability of pressure ulcer development. Twelve studies (Berlowitz and Wilking 1989; Brandeis *et al.* 1994; Stordeur, Laurent and D'Hoore 1998; Ooi *et al.* 1999; Schultz *et al.* 1999; Halfens, Van Achterberg and Bal 2000; Feuchtinger *et al.* 2006; Nixon *et al.* 2006b; Donnelly 2006; Rademakers *et al.* 2007; Compton *et al.* 2008; Vanderwee *et al.* 2009) included the diagnosis of diabetes in multivariable modelling. Of these 5 studies comprising of 3 high quality studies (Brandeis *et al.* 1994; Schultz *et al.* 1999; Nixon *et al.* 2006b) and 2 moderate quality studies (Ooi *et al.* 1999; Rademakers *et al.*

2007) including both acute and long-term care patient populations found diabetes to be associated with pressure ulcer development. The 7 studies where diabetes did not emerge were all of low quality having serious limitations, including insufficient number of events. Where diabetes emerged, the odds ratios associated with diabetes ranged from 1.35 to 2.52.

Evidence from the wide range of other 'perfusion-related' variables suggest that factors which impair circulation increase the probability of pressure ulcer development, but the evidence is limited by study quality – only 4 of 20 studies are high/moderate quality studies and interpretation is limited by the large range of variable descriptors. Further confirmatory research in this area is required.

3.7.3.4 Haematological Measures

Haematological measures were categorised into U&Es, Protein, Albumin, Lymphopenia and Haemoglobin (Hb). Overall, twenty two studies considered 1 or more haematological measures within their analysis (Table 3.5).

Eleven studies (Ek *et al.* 1991; Marchette, Arnell and Redick 1991; Bergstrom and Braden 1992; Kemp *et al.* 1993; Salzberg *et al.* 1999; Bourdel-Marchasson *et al.* 2000; Reed *et al.* 2003; Lindgren *et al.* 2004; Nixon, Cranny and Bond 2007; Serpa and Santos 2007; Hatanaka *et al.* 2008) included albumin as a variable in multivariable modelling. In 7 studies (63.6%) (Ek *et al.* 1991; Marchette, Arnell and Redick 1991; Bourdel-Marchasson *et al.* 2000; Reed *et al.* 2003; Nixon, Cranny and Bond 2007; Serpa and Santos 2007; Hatanaka *et al.* 2008) including 1 high quality (Reed *et al.* 2003) and 1 moderate quality study (Bourdel-Marchasson *et al.* 2000) albumin emerged as significant, the direction of the relationship suggesting that lower albumin levels are associated with pressure ulcer development. Analyses are limited by the use of categorical data.

Eleven studies (Olson *et al.* 1996; Stordeur, Laurent and D'Hoore 1998; Bergquist and Frantz 1999; Gunningberg *et al.* 2001; Pancorbo Hidalgo and Garcia Fernandez 2001; Feuchtinger *et al.* 2006; Nixon *et al.* 2006b; Nixon, Cranny and Bond 2007; Okuwa *et al.* 2006; Serpa and Santos 2007; Hatanaka *et al.* 2008) involving acute hospital, community and nursing home patient populations included haemoglobin or anaemia as a variable in multivariable analyses and in 6 studies (54.5%) (Olson *et al.* 1996; Stordeur, Laurent and D'Hoore 1998; Bergquist and Frantz 1999; Pancorbo Hidalgo and Garcia Fernandez 2001; Nixon *et al.* 2006b; Hatanaka *et al.* 2008) haemoglobin/anaemia emerged as a significant factor. The

direction of the relationship reported in 6 studies, which comprised of 1 high quality study (Nixon *et al.* 2006b) and 5 low quality studies (Olson *et al.* 1996; Stordeur, Laurent and D'Hoore 1998; Bergquist and Frantz 1999; Pancorbo Hidalgo and Garcia Fernandez 2001) was that reduced haemoglobin/ anaemia is associated with pressure ulcer development. However, in one study (Hatanaka *et al.* 2008) the relationship was reversed but the study population comprised of respiratory patients where an increased haemoglobin level is indicative of severity of respiratory disease.

Four studies (Berlowitz and Wilking 1989; Salzberg *et al.* 1999; Okuwa *et al.* 2006; Serpa and Santos 2007) included a variety of serum blood measures (creatinine, urea, chloride, and sodium) as variables in multivariable analysis and in 1 moderate quality study (Salzberg *et al.* 1999) and 1 low quality study (Serpa and Santos 2007) the variable emerged as significant (creatinine and urea). C-reactive protein was modelled in 2 low quality studies (Hatanaka *et al.* 2008; Sayar *et al.* 2009) and emerged in 1 (Hatanaka *et al.* 2008). Another very low quality study (Marchette, Arnell and Redick 1991) considered pre op protein but this did not emerge in the multivariable analyses. Two low quality studies (Allman *et al.* 1995; Pancorbo Hidalgo and Garcia Fernandez 2001) included the variables lymphopenia and diminished lymphocytes within their multivariable analysis and both emerged as significant. Both studies were in acute hospital patient populations.

3.7.3.5 Moisture

Moisture related variables were categorised as moisture subscales of risk assessment scales, urinary incontinence, faecal incontinence, dual incontinence, incontinence other, urinary catheters and measures of skin moisture. Overall twenty seven studies entered one or more moisture related variables into their statistical models. In 13 (48 %) of these studies including 2 high quality studies (Brandeis *et al.* 1994; Reed *et al.* 2003) and 2 moderate quality studies (Salzberg *et al.* 1999; Ooi *et al.* 1999) a moisture related variable emerged as statistically significant (Table 3.5). Overall, there is some evidence that moisture is a factor in pressure ulcer development with the measures relating to dual incontinence and skin moisture emerging more consistently compared to moisture risk assessment subscales, urinary and faecal incontinence.

3.7.3.6 Body Temperature

Eight studies included temperature within their multivariable analysis (Table 3.5). In 5 studies, including 3 moderate quality studies (Suriadi *et al.* 2008; Bergstrom and

Braden 1992; Nijs *et al.* 2009), 1 low quality study (Suriadi *et al.* 2007) and 1 very low quality study (Rose, Cohen and Amsel 2006) temperature emerged in multivariable modelling as independently predictive of pressure ulcer development. In 3 of these studies (Bergstrom and Braden 1992; Suriadi *et al.* 2007; Suriadi *et al.* 2008) the direction of the relationship linked increased body temperature with pressure ulcer development; in 1 study increased temperature reduced the risk (Nijs *et al.* 2009), and in 1 study (Rose, Cohen and Amsel 2006) the direction of the relationship was not reported. It is noteworthy that temperature emerged in all 4 ICU patient studies (Rose, Cohen and Amsel 2006; Suriadi *et al.* 2007; Suriadi *et al.* 2008; Nijs *et al.* 2009). There are methodological limitations with the studies which limit interpretation. The majority of studies defined the temperature variable categorically. Only 3 of the 4 studies reporting statistical significance included odds ratios and confidence intervals (Suriadi *et al.* 2007; Suriadi *et al.* 2008; Nijs *et al.* 2009). Overall, there is some evidence that increased body temperature may be an important predictor of pressure ulcer development, but further confirmatory research is required.

3.7.3.7 Nutrition

Nutrition related variables were categorised into nutritional scales, food intake, malnourishment, weight, BMI, arm measurement and other measurement. Overall 34 studies included 1 or more nutrition related variable in their analyses and in 13 (38.2%) a nutrition related variable emerged as an important predictor of pressure ulcer development (Table 3.5).

The variables that emerged most consistently were related to food intake and weight. Of 7 studies considering food intake 4 studies emerged in multivariable modelling comprising 1 high quality study (Brandeis *et al.* 1994), 1 moderate quality study (Bergstrom and Braden 1992), 1 low quality study (Berlowitz and Wilking 1989) and 1 very low quality study (Ek *et al.* 1991). Of 12 studies considering weight 4 studies comprising 3 low quality studies and 1 very low quality study emerged in multivariable modelling. Fourteen studies (Ek 1987; Kemp *et al.* 1993; Bostrom *et al.* 1996; Tourtual *et al.* 1997; Baldwin and Ziegler 1998; Watts *et al.* 1998; Halfens, Van Achterberg and Bal 2000; Pancorbo Hidalgo and Garcia Fernandez 2001; Perneger *et al.* 2002; Lindgren *et al.* 2004; Nixon *et al.* 2006b; Defloor and Grypdonck 2005; Serpa and Santos 2007; Vanderwee *et al.* 2009) involving (in the main) acute care hospital patient populations, included nutritional scales which comprised of the Braden Nutrition subscale (10 studies), other nutrition subscales (3 studies) and one study that considered both the Subjective

Global Nutrition Assessment (SGNA) and the Braden subscale. In only one low quality study (Serpa and Santos 2007) did the nutrition scale (SGNA) emerge as independently associated with pressure ulcer development. The studies where nutritional scales did not emerge in multivariable modelling included 3 large high quality studies.

Of note is that 13 studies entered other subscales of the risk assessment instruments in the multivariable analysis and the nutrition subscale was not found to be important in the presence of other key risk factors. In three studies none of the risk assessment subscales emerged in the model (Bostrom *et al.* 1996; Pancorbo Hidalgo and Garcia Fernandez 2001; Vanderwee *et al.* 2009), and in 10 studies one or more other subscales including mobility (Ek 1987; Kemp *et al.* 1993; Baldwin and Ziegler 1998; Watts *et al.* 1998; Perneger *et al.* 2002; Lindgren *et al.* 2004), moisture (Tourtual *et al.* 1997; Baldwin and Ziegler 1998; Halfens, Van Achterberg and Bal 2000), friction and shear (Tourtual *et al.* 1997; Halfens, Van Achterberg and Bal 2000) and sensory perception (Halfens, Van Achterberg and Bal 2000; Defloor and Grypdonck 2005) did emerge as important predictors of pressure ulcer development.

3.7.3.8 Increasing Age

Thirty two studies evaluated age as a variable in their analysis (Table 3.5). Of these increased age emerged in 12 (37.5%) studies (Bergstrom and Braden 1992; Bergstrom *et al.* 1996; Ooi *et al.* 1999; Schultz *et al.* 1999; Halfens, Van Achterberg and Bal 2000; Gunningberg *et al.* 2001; Perneger *et al.* 2002; Lindgren *et al.* 2004; Nixon *et al.* 2006b; Serpa and Santos 2007; Hatanaka *et al.* 2008; Vanderwee *et al.* 2009). It was anticipated that age would not emerge in homogenous study populations, however, reporting of mean age and age range of study populations is not comprehensive. The trend of increasing age and risk is noted in the high and moderate quality studies. Seven high and moderate quality studies included heterogeneous study populations and in six (Bergstrom and Braden 1992; Bergstrom *et al.* 1996; Ooi *et al.* 1999; Schultz *et al.* 1999; Perneger *et al.* 2002; Nixon *et al.* 2006b) age emerged in multivariable modelling as an important predictor of pressure ulcer development, whilst in two high quality studies of very aged homogenous patient populations (Brandeis *et al.* 1994; Defloor and Grypdonck 2005), age did not emerge as an important factor in the presence of other risk factors in multivariable modelling.

3.7.3.9 Sensory Perception

Nine studies involving acute care hospital, long-term and ICU patient populations included the sensory perception subscale of the Braden scale within their multivariable analysis (Table 3.5). In two studies comprising 1 high quality study (Defloor and Grypdonck 2005) and 1 low quality study (Halfens, Van Achterberg and Bal 2000) this factor emerged as statistically significant. However, it did not emerge in the remaining 7 studies.

3.7.3.10 Mental Status

Overall eleven studies considered mental status, using a range of measures and descriptors in multivariable analysis and 2 (18.2%) high quality studies (Perneger *et al.* 2002; Reed *et al.* 2003) found mental health variables to be of significance (Table 3.5). Mental status did not emerge as a key risk factor in pressure ulcer development.

3.7.3.11 Race

Five studies considered race as a variable in modelling (Table 3.5). In two studies comprising 1 high quality study (Bergstrom *et al.* 1996) and 1 moderate quality study (Baumgarten *et al.* 2004) race emerged as an independent predictor of pressure ulcer development, however findings were contradictory, since in one study white race was associated with increased risk (Bergstrom *et al.* 1996) and in the other black race was associated with increased risk (Baumgarten *et al.* 2004). In the remaining three studies race did not emerge as being significant. Overall there is limited evidence relating to the relationship between race and pressure ulcer development.

3.7.3.12 Gender

Fifteen studies included gender in multivariable modelling (Table 3.5). Only 4 low quality studies (Bergquist and Frantz 1999; Okuwa *et al.* 2006; Hatanaka *et al.* 2008; Compton *et al.* 2008) demonstrated a relationship between gender and pressure ulcer development, with 3 (Bergquist and Frantz 1999; Okuwa *et al.* 2006; Compton *et al.* 2008) identifying males at increased risk and 1 (Hatanaka *et al.* 2008) suggesting that males were at reduced risk. Eleven studies, including 2 high quality and 1 moderate quality did not find gender to be a significant factor in pressure ulcer development. Overall there is minimal evidence to suggest that gender is a risk factor associated with pressure ulcer development.

3.7.3.13 General Health Status

We categorised General Health Status into ASA (American Society of Anaesthesiologists) classification, APACHE 2 (Acute Physiology and Chronic Health Evaluation), Norton measures, chronic wounds and other factors. Overall twenty eight studies considered 1 or more general health status measures within their analysis (Table 3.5). In 8 studies (28.6%) a general health status measure emerged as important in modelling. The presence of chronic wound also emerged in 1 of the 2 studies that included it in the statistical model. The variety of measures used has made it difficult to consider the overall importance of the findings.

3.7.3.14 Medication

Ten studies included various medication therapies in multivariable modelling (Table 3.5). In three studies (Stordeur, Laurent and D'Hoore 1998; Bergquist and Frantz 1999; Nijs *et al.* 2009) medication emerged as a significant variable and these included, use of sedatives, dopamine 5mcg/kg/min, oxygen use and post-operative steroid therapy. In one study (Nijs *et al.* 2009) of an ICU population use of sedative emerged as significant, however, the direction of the relationship was that it acted as a protective factor.

Overall there is limited evidence that any particular medication predisposes patient to develop pressure ulcers, rather they are likely to be a surrogate indicator of underlying disease pathology which may contribute to risk.

3.7.3.15 Risk Assessment Instruments

Overall, 22 studies included a risk assessment scales total score within their analysis and in 10 (45.4%) the risk assessment instrument total score emerged as statistically significant (Table 3.5). The risk assessment total score emerged in all the high quality (Bergstrom *et al.* 1996; Schultz *et al.* 1999) and moderate quality (Bergstrom and Braden 1992; Bourdel-Marchasson *et al.* 2000) studies which included this variable. However, it is also noteworthy that in general, where studies included both total score and subscales of the Risk Assessment Instrument (Kemp *et al.* 1993; Tourtual *et al.* 1997; Baldwin and Ziegler 1998; Watts *et al.* 1998; Bergquist and Frantz 1999; Pancorbo Hidalgo and Garcia Fernandez 2001; Lindgren *et al.* 2004) a subscale emerged as independently predictive of pressure ulcer development (Kemp *et al.* 1993; Tourtual *et al.* 1997; Baldwin and Ziegler 1998; Watts *et al.* 1998; Bergquist and Frantz 1999; Lindgren *et al.* 2004) rather than the total score.

3.8 Discussion

This is the first systematic review of risk factors related to pressure ulcer development. A strength of the review was that each of the included studies were subject to detailed quality assessment allowing limitations to be identified and taken into consideration in interpretation. This was informed by consideration of the assessment of limitations and bias of risk factor and prognostic factor studies and methodological considerations in the analysis, meta-analysis and publication of observational studies prognosis (Harrell *et al.* 1985; Simon and Altman 1994; Altman 2001; Peduzzi *et al.* 1995; Egger, Smith and Schneider 2001; Mak and Kum 2005; Maltoni *et al.* 2005; Hayden, Côté and Bombardier 2006; Royston, Altman and Sauerbrei 2006; von Elm *et al.* 2007; Altman 2009; CRD 2009; Mallett *et al.* 2010; Schulz *et al.* 2010; Steyerberg 2010) enabling the development of a two staged approach to quality assessment. The first stage was integrated into the eligibility criteria and the second stage involved detailed quality appraisal of included studies. This provided an efficient method for quality appraisal, as the eligibility criteria allowed studies with bias that was considered unacceptable to be screened out, ensuring a minimum standard of quality for included studies. The integration of critical design specific aspects of quality (e.g. exclusion of controlled trials without randomised allocation to treatment and intention to treat analyses) in the eligibility criteria also meant that the detailed quality appraisal could focus on risk factor measurement rather than study design. This allowed a consistent approach to the overall assessment of study quality to be achieved.

The detailed quality appraisal provided information on each criteria and key domain for each study in keeping with other other quality appraisal systems (GRADE Working Group 2004; Guyatt *et al.* 2008; Cochrane 2009). In addition, each study was classified to provide an overall summary of study quality to facilitate the development of the evidence tables, interpretation of the results and to give an indication of the strength of evidence for each risk factor. However, there were some potential limitations that should be acknowledged. In the absence of published guidance for the classification of study quality for risk factor research, an approach was developed for this review. This was not specified prior to the quality assessment, rather it was developed following appraisal of all criteria. While this approach could be criticised, it was required to assist in identifying the differences between high and low quality studies in the context of the pressure ulcer field and in developing the classification system.

The key domains that were identified focussed on the analysis methods of the included studies and this could be viewed as not being balanced with regard to other important aspects of quality i.e. study participation, attrition, risk factor measurement and outcome measurement (Hayden, Côté and Bombardier 2006). The focus on analysis was considered necessary to emphasise the fundamental importance for ensuring the validity of the results. While the other quality criteria (items 1-7 Table 3.1) were viewed as very important (and contributed to the assessment of the key quality domains), all of these could be achieved, but poor methods of analysis would still result in a poor quality study, in which there was a high degree of uncertainty about the validity of the results (Kemp *et al.* 1993; Olson *et al.* 1996; Bergquist and Frantz 1999; Fife *et al.* 2001; Suriadi *et al.* 2007; Vanderwee *et al.* 2009). In addition, the studies which were classified as high or moderate quality tended to meet most of the quality criteria (items 1-7 Table 3.1). Others could view the analysis appraisal as superficial as there are specific statistical considerations that could have been considered, for example, the appropriateness of the multivariate analysis used, or whether the number of patients in the final model was reported.

The study classification system was also limited as it did not cover all potential combinations of compliance with the four key domains (i.e. whether they met - yes, no, partial, uncertain). This meant that 8 studies (Ek *et al.* 1991; Marchette, Arnell and Redick 1991; Cobb, Yoder and Warren 1997; Bourdel-Marchasson *et al.* 2000; Gunningberg *et al.* 2001; Rose, Cohen and Amsel 2006; Suriadi *et al.* 2008; Nijs *et al.* 2009) did not actually fall into the strict classification definitions, e.g. four moderate quality studies (Gunningberg *et al.* 2001; Bourdel-Marchasson *et al.* 2000; Suriadi *et al.* 2008; Nijs *et al.* 2009) met domain A but only fully met 1 other quality domain rather than 2 (the third being partially met). On these occasions the decision to allocate the study to the moderate quality category was influenced by the importance of key domain A, or the adequacy of the number of pressure ulcers developed in relation to the number of risk factors considered and emerging in the model. Difficulties in the derivation of studies also led to one study being misclassified as a low quality study (Serpa and Santos 2007) when it should have been allocated as very low quality. Fortunately this did not affect the interpretation of the results. It is acknowledged that if this system is to be used in future work, further development is required to accommodate all potential outcomes in the classification of study quality.

It is also important to note that some of the included key quality domains are not independent of one another and require informed judgements to be made by those undertaking the appraisal and classification of study quality. Judgements were also made where the reporting of methods were lacking, in determination of Domain A (whether there was sufficient number of events (rule of thumb ≥ 10 events per risk factor)). There were 9 studies (Ek *et al.* 1991; Marchette, Arnell and Redick 1991; Bourdel-Marchasson *et al.* 2000; Serpa and Santos 2007; Rose, Cohen and Amsel 2006; Hatanaka *et al.* 2008; Suriadi *et al.* 2008; Nijs *et al.* 2009) where the number of risk factors entered into the model was not clearly specified and judgements were made based on 3 sources of information incorporating the number of events reported, the number of risk factors described in the methods and the number of risk factors in the final model. Judgements were then made as 'probably yes' (i.e. very large number of events and maximum number of possible risk factors does not exceed >10 events per risk factor), 'definitely no' (i.e. the model itself has <10 events per risk factor) and 'uncertain'. Further judgement was then required in three studies (Ek *et al.* 1991; Marchette, Arnell and Redick 1991; Rose, Cohen and Amsel 2006) where there was uncertainty for key domain A. As none of the other key criteria were met the studies were allocated to the very low quality study category.

Despite these noted limitations the quality appraisal method provides a pragmatic approach that was integrated into the evidence tables of the review and helped to clarify the overall strength of evidence for each risk factor which facilitated interpretation of the results. While the approach may be of relevance to researchers in other fields, it is acknowledged that further work should be undertaken with methodological experts to reach consensus on the most important criteria required to assess the quality of exploratory risk factor studies to develop and validate a tool to specifically for this.

The results of the review are consistent with pressure ulcer aetiology conceptual frameworks confirming major domains of mobility/activity, and perfusion (Defloor 1999), whilst identifying for the first time the importance of skin/pressure ulcer status and diabetes. However, the review also highlights important limitations with the current evidence and methodological challenges associated with the conduct and interpretation of risk factor reviews in the absence of clear guidelines. A key limitation is the large number of descriptor variables used to describe risk factors which impacts upon interpretation and further use of the data in meta-analysis,

highlighting the need for an internationally agreed minimum data set. Study quality is also generally poor (sample size considerations, analysis methods and standards of reporting). In general, sample size considerations for multivariable analyses have not been used to inform study design and only seventeen studies fulfilled the 'rule of thumb' sample size estimate of 10 events (or pressure ulcers) per variable in the multivariable model (Harrell *et al.* 1985; Simon and Altman 1994; Peduzzi *et al.* 1995; Altman 2009; Mallett *et al.* 2010; Steyerberg 2010). The impact of this is demonstrated in studies which report Confidence Intervals (CIs). For example, four studies report non-blanchable erythema as an independent predictor of Grade ≥ 2 pressure ulcer development (Allman *et al.* 1995; Reed *et al.* 2003; Nixon *et al.* 2006b; Nixon, Cranny and Bond 2007). Two studies had inadequate numbers of pressure ulcers and reported large odds ratios with wide CIs (Allman *et al.* 1995; Nixon, Cranny and Bond 2007), whereas the two larger studies (Reed *et al.* 2003; Nixon *et al.* 2006b) with adequate numbers of pressure ulcers reported lower odds ratios and narrow CIs. Future research should ensure adequate numbers of pressure ulcers to maximise the validity of study results.

Continuous data has been analysed as continuous data (Olson *et al.* 1996; Stordeur, Laurent and D'Hoore 1998; Nixon *et al.* 2006b; Nixon, Cranny and Bond 2007; Hatanaka *et al.* 2008), but also as categorical data (Bergquist and Frantz 1999; Bourdel-Marchasson *et al.* 2000; Pancorbo Hidalgo and Garcia Fernandez 2001; Reed *et al.* 2003; Serpa and Santos 2007; Nijs *et al.* 2009), with no standardisation of category values. Continuous data allows comparability of results from various studies. Categorisation of continuous data should be avoided in regression models since it leads to a loss of power and residual confounding. In addition, the use of data-derived cut points can lead to serious bias (Altman *et al.* 1994; Royston, Altman and Sauerbrei 2006).

A further consideration is the recommendation that systematic reviews of prognostic factors studies are limited to those with patients at the same 'starting point' in the disease trajectory (Altman 2001). However, as this was the first systematic review of pressure ulcer risk factors, the emphasis was to explore the breadth of available evidence and studies of patients with and without pressure ulcers at baseline, from acute, rehabilitation, long-term care and community populations, including heterogeneous and homogeneous patient populations were included. Interpretation was complicated by poor reporting of patient baseline characteristics and hence difficulty in assessing heterogeneity. It is important to note that the heterogeneity of

study populations will impact upon multivariable analysis and also other factors entered into models for example, some studies included only bed/chairfast/ mobility restricted patients (Kemp *et al.* 1993; Allman *et al.* 1995; Inman *et al.* 1999; Salzberg *et al.* 1999; Bourdel-Marchasson *et al.* 2000; Boyle and Green 2001; Fife *et al.* 2001; Gunningberg *et al.* 2001; Reed *et al.* 2003; Defloor and Grypdonck 2005; Donnelly 2006; Nixon *et al.* 2006b; Okuwa *et al.* 2006; Suriadi *et al.* 2007; Rademakers *et al.* 2007; De Laat *et al.* 2007; Compton *et al.* 2008; Hatanaka *et al.* 2008; Suriadi *et al.* 2008; Nijs *et al.* 2009; Yepes *et al.* 2009; Sayar *et al.* 2009; Vanderwee *et al.* 2009) therefore it is unlikely that a relationship between mobility/activity and pressure ulcer development would be observed, as all patients were similarly immobile. Future work should be undertaken to identify a sub-set of studies deemed similar enough and of good quality, and the potential for meta-analysis explored with or without individual patient data.

In general researchers did not consider a comprehensive range of key risk factors in multivariable analyses and this limits interpretation and overall conclusions. For example, the study by Serpa and Santos includes 10 descriptors relating to nutrition, but no variables relating to activity/mobility or perfusion (Serpa and Santos 2007). Similarly a large number of studies do not include a mobility/activity factor in their analysis even where the study population is heterogeneous for activity/mobility (Cobb, Yoder and Warren 1997; Goodridge *et al.* 1998; Ooi *et al.* 1999; Chan *et al.* 2005). Furthermore, the primary studies of the review do not test for statistical interaction between risk factors within their regression models. The review is therefore limited to the confines of the original study analysis. Future primary research should consider which risk factor interactions are most predictive of pressure ulcer development.

A number of studies use only the Risk Assessment Instrument total score in the multivariable analysis (Bergstrom and Braden 1992; Stordeur, Laurent and D'Hoore 1998; Inman *et al.* 1999; Schultz *et al.* 1999; Fife *et al.* 2001; Bourdel-Marchasson *et al.* 2000; Chan *et al.* 2005; Bates-Jensen *et al.* 2007; Compton *et al.* 2008; Yepes *et al.* 2009). This does not enable the dominant risk factors to be identified. Future research should ensure that key risk factors are included in multivariable analyses, so that validation of the core set of risk factors can be achieved and prognostic variables can be utilised widely.

In addition general standards for the reporting of risk factor studies do not meet basic criteria recommended by international guidelines on the reporting of observational studies (von Elm *et al.* 2007). A large number of studies were excluded due to two key criteria – loss to follow-up rates and use of multivariable analysis. Of the 45 cohort studies and RCTs included in the review only eighteen fulfilled basic reporting requirements (Hayden, Côté and Bombardier 2006; von Elm *et al.* 2007), including reporting of baseline study population characteristics, levels of significance and CIs (Brandeis *et al.* 1994; Bergquist and Frantz 1999; Allman *et al.* 1995; Ooi *et al.* 1999; Fife *et al.* 2001; Baumgarten *et al.* 2004; Lindgren *et al.* 2004; Nixon *et al.* 2006b; De Laat *et al.* 2007; Okuwa *et al.* 2006; Sayar *et al.* 2009; Schultz *et al.* 1999; Bates-Jensen *et al.* 2007; Rademakers *et al.* 2007; Suriadi *et al.* 2007; Hatanaka *et al.* 2008; Vanderwee *et al.* 2009; Yepes *et al.* 2009). These are essential components for the interpretation of results. Future researchers should ensure adequate reporting of risk factor studies to improve the validity and generalisability of study results. This may be assisted by published standards of reporting for primary research of different designs including CONSORT Statement, guidelines for reporting parallel group randomized trials (Begg *et al.* 1996; Moher *et al.* 2001; Schulz *et al.* 2010) and STROBE Statement: guidelines for reporting observational studies (von Elm *et al.* 2007).

The methodological limitations are further complicated by the use of different outcome measures, that is both Grade ≥ 1 and Grade ≥ 2 outcomes are utilised. Some might suggest that risk factors associated with Grade 1 pressure ulcers are different to risk factors associated with Grade 2 pressure ulcers but this was outside the scope of this review and requires formal review and further analysis to inform future research and clinical practice. The majority of pressure ulcer development in the studies of the review are superficial pressure ulcers since cohort studies fail to recruit patients who develop severe pressure ulcers; therefore the review is limited to risk factors associated with superficial pressure ulcer development.

The strong association between Stage/Grade 1 pressure ulcers and subsequent \geq Stage/Grade 2 pressure ulcers resonates with what is experienced in clinical practice and nurses often see the presence of non-blanching erythema as a warning of potential further deterioration. Additionally the presence of an existing \geq Stage/Grade 2 pressure ulcer would alert the nurse of the possibility of additional pressure ulcer development and the need for secondary prevention.

Another potential area of uncertainty is whether the superficial pressure ulcers reported in the studies of the systematic review are incontinence associated dermatitis (IAD) rather than pressure ulcers. Historically trunk wounds have been labelled as pressure ulcers but there is confusion between IAD and superficial pressure ulcers (Beeckman *et al.* 2011; Doughty 2012). Only 1 study specifically reported that the training of staff undertaking skin assessment incorporated the differentiation of IAD and pressure ulcers (Vanderwee *et al.* 2009). Moreover, there is a possibility that the importance of pressure ulcer risk factors may vary in relation to specific skin sites and this is still to be elucidated.

Finally, the methodological limitations within the pressure ulcer literature are similar to those reported in other areas of medicine (Altman 2001; Egger, Smith and Schneider 2001; Maltoni *et al.* 2005; Riley, Sauerbrei and Altman 2009). While it is recognized that as multiple similar studies accumulate it is important to identify and evaluate all of the relevant studies to develop a more reliable overall assessment (Altman 2001), the methodological limitations of the studies identified precluded combining study results using meta-analysis.

3.9 Conclusions

Overall there is no single factor which can explain pressure ulcer risk, rather a complex interplay of factors which increase the probability of pressure ulcer development. The review highlights the limitations of over-interpretation of results from individual studies and the benefits of reviewing results from a number of studies to develop a more reliable overall assessment of factors which are important in affecting patient susceptibility. This was assisted by the development of an efficient quality appraisal system to identify study quality. Study quality was integrated into evidence tables for each risk factor sub-domain, providing transparency and facilitating the interpretation of the results.

The risk factors which emerge most frequently as independent predictors of pressure ulcer development in studies using multivariable analyses are consistent with pressure ulcer aetiology conceptual frameworks, confirming major domains of mobility/activity and perfusion (including diabetes). In addition skin/ pressure ulcer status particularly relating to stage/grade 1, emerged as a major risk variable and this is an important finding of this systematic review.

Other factors including skin moisture, age, haematological measures, nutrition and general health status are also important, but do not emerge as frequently as the three main domains. Other factors which may be important but were included in only a small number of studies include body temperature and immunity and these require further confirmatory research. Our review shows that there is minimal or limited evidence that either race or gender is important.

The review provides a foundation for the further development of a conceptual framework of pressure ulcer development 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 will facilitate the development and content validity of a pressure ulcer minimum standard dataset and Risk Assessment Framework and inform future risk factor research.

Chapter 4 Using Consensus Methods to Develop a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework

4.1 Introduction

This chapter provides a general overview of consensus methods incorporating the Delphi method, nominal group technique, RAND/UCLA appropriateness method and consensus conference and critically examines the similarities and differences between these methods. It considers key methodological issues relating to validity, reliability, expert groups, patient involvement, consensus definitions and analysis and goes on to detail the rationale for undertaking a consensus study to agree a draft pressure ulcer risk factor minimum data set and Risk Assessment Framework. Following this the consensus study will be discussed, giving the rationale for the methods used, the results of the study and discussion.

4.2 Consensus Methods

Structured consensus methods are used to define levels of agreement on controversial subjects (Fink *et al.* 1984). Consensus methods incorporating the best available evidence and the views of experts are increasingly being used in the development of clinical guidelines and healthcare priorities, (Rycroft-Malone 2001; Washington *et al.* 2003; Hutchings and Raine 2006; Hutchings *et al.* 2006; Kadam *et al.* 2006; Jackson *et al.* 2009). They have advantages (Jones and Hunter 1995; Murphy *et al.* 1998; Raine *et al.* 2004) over informal approaches (e.g. committees) as they:

- Are carefully structured to reduce the influence of dominating personalities.
- Allow participants to change their opinion (or not) over the course of the process in light of group opinion/feedback.
- Provide privacy for individual participant judgements.
- Provide transparency with regard to the synthesis of judgements and group decisions based on pre-set methods of analysis.

The most frequently encountered consensus methods include the Delphi method, the nominal group technique and the Research and Development/ University of California at Los Angeles (RAND/ UCLA) appropriateness method, though there are

many variations in the application of these methods in the literature which are sometimes referred to as 'modified' consensus methods (Nair, Aggarwal and Khanna 2011). For completeness the consensus development conference is also mentioned, though this methodology has largely been discarded (Black 2006) in favour of the methodologies detailed above. The key characteristics of these methods and informal consensus methods are summarised in Table 4.1 and discussed in more detail in sections 4.3 to 4.6.

Table 4.1 Summary of characteristics of informal and formal consensus methods

Consensus method characteristic	Classi c Delphi	Classi c NGT	RAND/UCLA Appropriatene ss	Consensus developme nt conference	Informal consensu s
Explicit consideration of literature/systematic review evidence	X*	X*	√	√	X
Face-to-face contact	X	√	√	√	√
Structured interaction	√	√	√	X	X
Rating/voting	√	√	√	X	X
Mailed Questionnaires	√	X	√	X	X
Private decisions elicited	√	√	√	X	X
Formal feedback of group decisions	√	√	√	X	X
Opportunity to change opinion (re-rate)	√	√	√	X	X
Method of synthesis of judgement and group decisions explicit	√	√	√	X	X

* adapted versions of the method incorporate evidence

4.3 Delphi Method

The Delphi method was originally developed in the 1950's by the Research and Development (RAND) Corporation for forecasting in defence research in the US (Dalkey and Helmer 1963) and has since been used in healthcare settings to reach consensus on a variety of matters relating to healthcare, though not usually for clinical guideline development (Murphy *et al.* 1998). The Delphi method's objective is 'to obtain the most reliable consensus of opinion of a group of experts' (Dalkey and Helmer 1963). The method typically involves a series of intensive questionnaires which classically includes 4 rounds, but this can be adjusted to meet the investigators needs (Fink *et al.* 1984). The method includes controlled feedback but no face-to-face interaction between group members (Table 4.1). An overview of the process is detailed below (Jones and Hunter 1995):

- Round 1: development of the initial questionnaire by the researcher or in collaboration with experts.
- Round 2: participants rank their agreement with the questionnaire statement/cues using a Likert scale.
- Round 2 and subsequent rounds: results of the preceding round are summarised and participants are then able to re-rank their agreement with statements/cues in light of this feedback. Statements/cues where consensus is reached at round two may not be included in subsequent rounds.

Advantages of the Delphi method include that it facilitates information exchange in an iterative process and can incorporate the views of numerous and geographically dispersed participants cheaply (Jones and Hunter 1995; Murphy *et al.* 1998). It also encourages opinion that is free from peer pressure, though participants can alter their judgements in light of group feedback (Williams and Webb 1994). Additionally the controlled feedback avoids participants being side-tracked (McKenna 1994). Although the advantages have been highlighted, some believe that the lack of face to face interaction may prevent the identification of reasons for disagreement and diminish the opportunity for finding common ground (Murphy *et al.* 1998; Raine, Sanderson and Black 2005). Others have also suggested that it could lead to a lack of accountability for expressed views (Sackman 1974).

4.4 Nominal Group Technique

The nominal group technique was originally developed to facilitate effective committee decision making (Van de Ven and Delbecq 1971) but was also considered appropriate for use in the healthcare context (Van de Ven and Delbecq 1972). The nominal group technique is a structured face-to-face meeting that attempts to provide an orderly procedure for obtaining qualitative information from target groups who are most closely associated with a problem area (Van de Ven and Delbecq 1972). The key characteristics of the nominal group technique are summarised in Table 4.1. While in recent years there has been variations in the approach, classically the nominal group technique involves a group of 5 to 8 participants (who have direct experience or expertise of the problem area being explored) involved in the following process (Van de Ven and Delbecq 1972):

- Introduction.
- Silent generation of ideas by individual group participants with regard to barriers to achieving the task.
- Structured round robin listing of ideas with each participant suggesting an idea in turn until all ideas have been exhausted.
- Discussion of ideas to allow clarification or develop new ideas that may emerge through discussion.
- Private ranking of the top 10 priorities by participants which are tallied.
- Voting on the top 10 items.
- Discussion of vote.
- Private re- ranking and rating priorities.
- Conclusion.

The advantages of the nominal group approach are that the structured interaction of the group facilitates contributions by all participants and makes it more difficult for those with more dominant personalities to take control of the meeting (Murphy *et al.* 1998). As the generation of ideas elements are undertaken in a round robin format and are separated from the discussion element, it allows more ideas to be expressed, prevents pursuit of a single train of thought and avoids quick decision making (Van de Ven and Delbecq 1971; Gallagher *et al.* 1993). The structured discussion element of the process allows the ideas to be evaluated and where necessary to be clarified (Van de Ven and Delbecq 1971; Fink *et al.* 1984). Criticisms of the approach include the lack of explicit evidence integration (Vakil), though variations of classical nominal group technique methodology have been

used in healthcare to incorporate up to date evidence (see 4.5) RAND/UCLA appropriateness method (Fitch *et al.* 2001)). Other concerns relate to reliability, as the views of a small group may be unrepresentative of the wider community and practical issues relating to the time and financial resources required to undertake face-to-face meetings (Raine, Sanderson and Black 2005).

4.5 RAND/UCLA Appropriateness Method

The RAND/UCLA appropriateness method incorporates elements of both the nominal group technique and the Delphi method and was originally developed to measure overuse and underuse of surgical procedures (Fitch *et al.* 2001). It was developed in response to the lack of robust 'gold standard' or sufficiently detailed evidence often encountered to support clinical decision making regarding patient care in practice. It aimed to combine the best available scientific evidence with the collective judgements of experts relating to the appropriateness of performing surgical procedures for patient specific groups (in light of symptoms, medical history and test results) (Fitch *et al.* 2001). It has since been used more generally to rate appropriateness and develop criteria for wider healthcare treatment interventions, clinical guidelines and quality indicators (Buetow and Coster 2000; Rycroft-Malone 2001; Halbert *et al.* 2006; Kroger *et al.* 2007; To *et al.* 2010). The key characteristics of the RAND/UCLA appropriateness method are summarised in Table 4.1. An overview of the process is detailed below (Fitch *et al.* 2001):

- Literature review and synthesis of evidence.
- List of indications and definitions.
- The above are sent to expert panel members who are asked to rate the indications on a 9 point Likert scale prior to a face to face meeting.
- Face-to-face facilitated 1-2 day meeting of expert group members in which the results of the above are discussed with a focus on areas of disagreement and adjustments to the indications/definitions may be made, if required.
- Following the discussion the indications are privately re-rated by expert group members.
- Finally each indication is classified as 'appropriate', 'uncertain' or 'inappropriate' which is based on predetermined methods of analysis.

The outcomes are then used prospectively to aid clinical decision making to increase appropriateness and retrospectively to compare clinical records with the criteria outcomes (Fitch *et al.* 2001). The method combines some of the positive aspects of the classic nominal group technique and Delphi method i.e. private rating of questionnaires and the face-to-face meeting of participants at the second round where areas of disagreement can be discussed and clarified giving greater potential for eventual agreement. In addition, an important element which is more prominent than for the classic nominal group technique and Delphi method (though apparent in some adaptations of the methods) is the explicit consideration and synthesis of relevant research evidence.

4.6 Consensus Development Conference

The key characteristics of the consensus development conference are summarised in Table 4.1. It was originally developed by the US National Institute of Health and has developed over time. Typically the process involved a decision making group of about ten people who convened in a chaired meeting to reach consensus about the issue under consideration (Murphy *et al.* 1998). In the open meeting evidence from experts or various interest groups was presented. The decision making group then retired to consider the evidence and attempt to reach consensus.

4.7 Methodological Issues Concerning Consensus Methods

4.7.1 Validity

It has been recognised that it is difficult to determine the validity of consensus judgements (i.e. whether 'good judgements' are made) at the time the judgements are made (Murphy *et al.* 1998). Several possibilities for the assessment of validity have been considered including comparisons with gold standards, predictive validity, concurrent validity and internal logic (Murphy *et al.* 1998).

Consensus studies are undertaken when there is uncertainty and this usually means there is no conclusive evidence (i.e. no gold standard) of the best way to proceed for a given situation. Therefore the judgements made cannot be compared with a 'correct' answer as it does not exist at the time of undertaking the consensus study. Likewise in consensus studies that relate to forecasting (e.g. in the development of clinical Risk Assessment Instruments), predictive validity could be assessed as new evidence emerges, but not at the time of the consensus study. Concurrent validity can also be assessed by considering whether the group

judgements deviate from research evidence without good reason which could be considered invalid (Murphy *et al.* 1998).

Due to the difficulties associated with measuring the validity of consensus studies it is important that the consensus process is as rigorous as possible (Raine, Sanderson and Black 2005). This should be demonstrated by the application of good practice in the planning and delivery of each stage of the consensus process.

4.7.2 Reliability

Another criticism of consensus methods is the lack of reliability, that is the ability of the method (including the same information and questions) to produce the same results with different groups (Sackman 1974; Williams and Webb 1994; Keeney, Hasson and McKenna 2001; Hasson, Keeney and McKenna 2000; Raine, Sanderson and Black 2005). Indeed, a new approach has been suggested that checks the representativeness of the expert group views with the wider community (Raine, Sanderson and Black 2005).

4.7.3 Expert Groups

There is debate in the literature regarding expert groups, the most appropriate composition of participants in consensus studies and the effect this has on group decisions. Experts have been described as a panel of informed individuals (McKenna 1994) while others suggest that they incorporate characteristics relating to experience, credibility, continuing education and demonstrating an active contribution to educational needs (Williams and Webb 1994). Fink *et al.* suggests that consensus participants should comprise of participants who are representative of their professions, have power to implement findings, or because they are not likely to be challenged as experts in the field (Fink *et al.* 1984). Vakil suggests that the panel should incorporate enthusiasts and sceptics (Vakil 2011).

There is also concern of how to identify suitable experts (Hasson, Keeney and McKenna 2000) and the potential for selection bias (Jones and Hunter 1995; Keeney, Hasson and McKenna 2001). It is therefore important that this is carefully considered when developing the methodology and that the selection process is transparent. The nature of the consensus study will influence the required characteristics of participants e.g. studies of clinical matters should include clinicians practising in the field, but there may also be value in gaining the insight of a non-specialist to provide an alternative view (Jones and Hunter 1995). Indeed, a systematic review of consensus studies which considered the effects of speciality

mix on consensus judgements found that practitioners who perform the procedure under consideration are more likely to make judgements of appropriateness, compared with those who did not and that mixed groups rather than single specialty groups have a moderating effect on differences (Hutchings and Raine 2006). This suggests that mixed specialty groups rather than single speciality groups should be favoured, as they facilitate consideration of a wider range of opinions leading to some knowledge transfer between participants of different specialties (Hutchings and Raine 2006).

Another consideration relates to international differences and the effect multi-nationality panels, compared to single nationality panels have on levels of consensus. A systematic review incorporating six primary studies considered the differences in levels of consensus between groups from different countries (3 Swis v US, 1 UK v US, 1 Dutch v US, 1 UK v Israel) when comparing appropriateness ratings for various interventions. The results revealed varying differences in appropriateness ratings which are suggested to be related to the diversity of each country with regard to the organisation of health care and available resources (Hutchings and Raine 2006).

The review also identified two studies comparing differences in levels of consensus between national and multi-national groups. They concluded that the extent of bias (one group rating more favourably) was lower for multi-national studies than national studies (Hutchings and Raine 2006). One of the included studies compared the consensus ratings for the appropriateness of treatments for benign prostatic hyperplasia of a Dutch panel (of single specialty urologists) with a European panel (with urologist from Spain, the Netherlands, Germany, Sweden and England) (McDonnell *et al.* 2001). This study found that 84% of appropriateness indications (of 1152) were identical and only one indication was rated as inappropriate by the European panel compared to the appropriate rating of the Dutch panel which could be attributed to chance. They found statistically significant, but clinically minor differences relating to rating of uncertainty with the Dutch panel having fewer uncertain ratings and concluded that international panels 'can deliver essentially the same appropriateness ratings as national panels' which could save money and reduce undesirable practice variation (McDonnell *et al.* 2001). The other comparison study comparing a Dutch panel and multi-national panel regarding the appropriateness of coronary revascularisation came to similar conclusions with no

significant differences in appropriateness ratings between the two groups (Bernstein *et al.* 2002).

The number of group members involved in the consensus process is influenced by the type of consensus methodology employed. For groups that meet face-to-face consideration should be given to the co-ordination and facilitation of the group (Murphy *et al.* 1998). In practice group sizes tend to be between 9-12 (Scott and Black 1991; Rycroft-Malone 2001; Kadam *et al.* 2006; Carpenter *et al.* 2007) though larger groups (incorporating 15-23 members) have also been used (McDonnell *et al.* 2001; Shiffman *et al.* 2003). This appears to be based on practical experience and limited research of a peer review of medical care study, which showed that as the group size increased, over a range of 1 -10 members so did reliability (levelling off after 10) (Richardson 1972). This study also showed that on average 16, 21 and 28 participants were needed to generate judgements with a reliability of 0.95 suggesting that increased group membership may be favourable. However, when deciding group numbers a careful balance needs to be struck between maximising reliability, preventing co-ordination problems and diminishing returns (Murphy *et al.* 1998).

4.7.4 Use of Evidence

The information presented to participants in consensus studies is an important element of their decision making (Murphy *et al.* 1998). A lack of relevant synthesised evidence is more likely to result in participants relying solely on their own reading and experience which maybe limited (Fink *et al.* 1984). A study exploring the determinants of group judgements considered the effectiveness of mental-health interventions on three chronic conditions (Raine *et al.* 2004). The study involved 16 nominal groups, half of whom were provided with a relevant literature review and half who were not. The study demonstrated that where a literature review was provided the decisions made were more likely to be consistent (60% of 192 group median ratings) with the research evidence than if no review (42% of 192 group median ratings) was provided. If the evidence supported group member's clinical practice they were more likely to accept it. Divergence from the evidence related to weak or irrelevant evidence, clinical experience, patient preference, treatment availability, and reluctance to do nothing (Raine *et al.* 2004).

This provision of evidence has obvious implications for the validity of the decisions made in consensus studies. In practice, particularly in the area of clinical criteria/guideline development, consideration of systematic review evidence is

commonly incorporated into the process (Buetow and Coster 2000; Rycroft-Malone 2001; Halbert *et al.* 2006; Jackson *et al.* 2009).

4.7.5 Patient Involvement

While the involvement of patients and carers as key stakeholders are advocated in the consensus process (Fink *et al.* 1984; Black 2006), there is little evidence of this in the literature relating to clinical guideline development. Difficulties in involving patients and carers in the development of technical and clinical guidelines have been raised previously (Rolls and Elliott 2008). Of the few reported studies which incorporate patients/carers, the nature of their involvement mainly involves membership of the expert group (Rycroft-Malone 2001; Jackson *et al.* 2009). A limitation of this approach is the minimal number of patient/carer participants on the expert groups, which could be in part due to the small size of the groups. In addition, the complex nature of the research evidence considered in clinical guidelines could be a barrier for effective patient/carer involvement. These limitations could lead to under-representation of patients/carer views in guideline development. Of note in the Rycroft-Malone study is the additional patient/carer involvement at the end of the process where patient/care representatives (along with other stakeholders) were asked to comment on the draft guideline before it was finalised (Rycroft-Malone 2001). Using this approach may facilitate patient/carer endorsement of the guideline, but it could be argued that more rigorous involvement of patients and carers earlier in the consensus process could provide useful information to help shape the guideline and improve its acceptability to patients.

Looking at the wider literature there is some evidence of patient/carer involvement in health related priority setting which incorporate some, though less structured elements of consensus methodology. An example of such an initiative relates to establishing urinary incontinence research priorities and was undertaken by the James Lind Alliance (Buckley *et al.* 2010). This involved representation of patient/carer organisations as well as clinical organisations in identifying and ranking research priorities via questionnaires in adapted nominal group workshops. Limitations associated with this work from a consensus methods perspective was the unstructured nature in which the initial information and ranking information was obtained by the represented organisations i.e. there was no pre-specified methodology for obtaining this information, and represented organisations developed their own means of undertaking this, being asked only to describe the process and the people involved (Buckley *et al.* 2010). This increases the potential for introducing selection bias in the process and could impact on the validity and

reliability of the results. Nevertheless, the work provides an example of how patients/carers can be involved in a priority setting exercise. Another example of priority setting work relates to a study which considered patient-centred professionalism in community nursing. This used an adapted nominal group technique with five separate groups including two community nursing groups, one newly qualified group, one stakeholder group and one patients/carers (Hutchings *et al.* 2012). Each group meeting involved exemplar generation and ranking. This was followed up by a mixed group meeting where the outputs from the initial group meetings were discussed and privately ranked giving the final ranked list of the positive and challenging exemplars of patient-centred professionalism.

Of note in both the priority setting examples above is that patients/carers were not required to consider detailed complex research evidence, rather their input was sought to capture their personal experiences. It would seem that the role of patient/carer involvement in structured consensus studies which develop clinical guidelines needs to be clearer. This would help to determine how to most effectively incorporate their views into the process.

4.7.6 Defining Consensus

There are two main issues relating to the achievement of consensus, one relating to when consensus should be determined and the other relating to how it should be defined. When consensus is determined varies between methods, so in the Delphi methods there could be 4 rounds of consensus questionnaires (though often there are less) while for nominal group and the RAND/UCLA method there are only 2 rounds. Too many round potentiates participant fatigue (Hasson, Keeney and McKenna 2000). A crucial consideration about when consensus is determined is that participants should have the opportunity to change their views in light of discussion/feedback so a minimum of two rounds is necessary.

There is diversity regarding how consensus is defined in consensus studies (Fink *et al.* 1984; Murphy *et al.* 1998). When defining consensus consideration should be given to levels of agreement: this relates to agreement with the statement/cue/indication under consideration and the extent that participants agree with one another (Jones and Hunter 1995). So for example when individual group judgements are aggregated it could result in a lack of agreement with a statement/cue/indication, but agreement amongst participants (often referred to as within group agreement) regarding this decision. Clearly when considering the analysis methods the strictness of definitions used will influence the amount of

consensus reached and these should be determined prior to data collection and analysis (Black 2006).

When analysing the levels of agreement with the questionnaire statements/cues/indications a measure of central tendency is required. As group views are rarely normally distributed the group median rather than the mean is preferred (Black 2006). Generally if a 9 point Likert scale is used (this is the most frequently used as smaller scales give less information about levels of consensus) the group median responses for each statement are categorised into 3 tertiles so that group medians falling in the 1-3 tertile would indicate disagreement with the statement/cue/indication, group medians falling in the 4-6 tertile would indicate uncertainty and group medians falling in the 7-9 tertile would indicate agreement with the statement/cue/indication.

Many studies also require there to be within group agreement about the decisions made and this can be analysed using a measure of dispersion. Measures used in the literature include the interquartile range (Murphy *et al.* 1998; Black 2006), the mean absolute deviation from the median (Hutchings *et al.* 2005) and the RAND Disagreement index (Fitch *et al.* 2001). The mean absolute deviation from the median (MADM), rather than the standard deviation is preferred because it does not give extra weight to extreme observations (though they are included in the calculation) and it measures variations about the median, which is the most commonly used measure of central tendency for consensus studies (Hutchings *et al.* 2005). The disagreement index is a measure of dispersion which incorporates rules based on the classic definition of disagreement of the RAND/UCLA appropriateness method: in a 9-panel members group there is disagreement when at least three panellists rated the indication in the 1-3 tertile, and at least three panellists rate it in the 7-9 tertile (Fitch *et al.* 2001). The disagreement index was developed by investigators of the Carlos III Health Institute in Madrid due to problems in applying the classic definition to panels where membership was more or less than 9 and can be used for panels of any size.

4.8 Comparisons of Consensus Methods

Few studies have been undertaken to compare different consensus approaches on study outcomes. Of these some indicate there is little difference to study outcomes between in-person and mail only methods (Washington *et al.* 2003; Kadam *et al.* 2006) while others indicate important differences. Hutchings *et al.* undertook

research to compare the nominal group technique and the Delphi method in relation to clinical guideline development of four mental health treatments (Hutchings *et al.* 2006). The study incorporated four Delphi groups (comprising 2 GP only groups and 2 GPs and mental health practitioner groups) and 6 nominal groups (matched from a larger sample of nominal groups detailed in Raine *et al.* 2004) comprising of 3 GP only groups and 3 GP and mental health practitioner groups). Findings indicated that nominal groups have closer within group agreement, whilst the Delphi groups have improved reliability (k coefficients 0.88 and 0.89 compared with 0.41 and 0.65.) and concluded that a hybrid approach should be used (Hutchings *et al.* 2006). Such an approach was also suggested earlier by Raine, Sanderson and Black (2005). A hybrid approach would enable the nominal group and Delphi technique to work in a complementary manner, facilitating close consensus whilst maximising reliability.

4.9 The rationale for the Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework Consensus Study

The systematic review (Chapter 3) allowed the risk factors independently associated with pressure ulcer development to be identified providing a clearer notion of the critical pressure ulcer risk factors. However, there are remaining gaps in the literature for some potentially important risk factors which require further research. In addition, pressure ulcer risk factors were inconsistently represented in the modelling of the primary studies of the systematic review, and this limits both the interpretation and overall conclusions.

These shortfalls explain the lack of agreement of the key risk factors and data items to summarise patient risk and highlight the need to agree a pressure ulcer risk factor minimum data set. This is important from a research perspective as it will facilitate the standardised and consistent collection of data relating to pressure ulcer risk factors, facilitating future multivariable modelling and meta-analysis which was not possible in our systematic review (Chapter 3). From a clinical perspective the Minimum Data Set can be incorporated into a Risk Assessment Framework to provide the fundamental components for pressure ulcer risk assessment in practice and provide a standardised data set for case-mix adjustment. This may also have an economic impact in terms of resource allocation.

In the absence of absolute evidence relating to pressure ulcer risk factors, the need to consult with experts in the pressure field using a transparent and robust method was highlighted. This would require the experts to consider the systematic review evidence and other pertinent scientific (physiological and biomechanical) evidence and its relevance to clinical practice and risk assessment. This was undertaken using structured consensus methods.

4.10 Consensus study

4.11 Aim

To develop a draft pressure ulcer risk factor Minimum Data Set and Risk Assessment Framework for pre-testing and clinical evaluation. The new decision tool is intended to be used for the prevention and management of generic mobility related pressure ulcers. The objectives were:

1. To agree a list of patient characteristics to form a Minimum Data Set suitable for routine collection of key risk factors.
2. To develop a Risk Assessment Framework incorporating the Minimum Data Set and support for decision making with:
 - a) a simple *screening stage* to quickly identify not at risk patients.
 - b) a detailed *full assessment stage* for patients who are at potential/actual risk or have an existing pressure ulcer.
 - c) Decision pathways i.e. not currently at risk, primary prevention (at risk) or secondary prevention and treatment pathway (with pressure ulcer).

4.12 Design

To maximise content validity a consensus study using a modified nominal group technique based on the RAND/UCLA (Research and Development / University of California at Los Angeles) appropriateness method (Fitch *et al.* 2001) was used. This was favoured over other methods as it incorporates key characteristics of the Delphi method and the nominal Group Technique detailed in Table 4.1 (rating/voting, private decisions elicited, formal feedback of group decisions, opportunity to change opinion (re-rate), method of synthesis of judgement and group decisions explicit) and critically for this study it:

- incorporates the explicit integration of evidence which was an important element of the study.

- allows structured face-to-face interaction of the group (missing from the Delphi method) which was necessary given the complexity of the evidence and subject area.
- incorporates questionnaire completion using a 9 point Likert scale to give more information about levels of agreement (as opposed to simple voting in classic nominal group technique).

The approach in our study was also modified further to incorporate facilitated face-to-face interaction of a Patient and Public Involvement (PPI) service user group (Pressure Ulcer Research Service User Network: PURSUN). As pressure ulcer risk assessment practice is part of routine care, the aim of the PPI component was to explore the acceptability of proposed risk assessment elements with patients and carers. In light of the limitations of patient/carer involvement in structured consensus methods highlighted above (section 4.7.5) and the aim of their involvement in this study, there seemed to be more value in holding separate PURSUN meetings. This would allow more time to be devoted to patient/carer insights and the consideration of a larger number of service user views, than if we had a patient representative on the expert group. There was a need to ensure that PURSUN members' perspectives were integrated into the consensus process and this would be achieved by feedback at the expert group meetings or inclusion of PURSUN comments into questionnaires, so that the group could consider the patient/carer perspective alongside other evidence.

4.13 Sample/Participants

The expert group comprised internationally recognized clinical/academic leaders identified via their publication record in pressure ulcer or relevant research. The group was purposively sampled to include the perspectives of nurses (academic and clinical nurse specialists), doctors (diabetologist, vascular surgeon, elderly care medicine and public health), bioengineers, epidemiologist, and individuals with organisational development and decision science expertise. These characteristics were considered relevant to the aim of the study and a multi-specialty group was favoured in order to incorporate a wider range of opinions (Hutchings and Raine 2006). In addition the involvement of international participants within the group may facilitate wider use of the minimum data set in pressure ulcer research in the future. Seventeen members were recruited to allow for attrition, as twelve was considered the optimum number for the face-to-face meetings, in relation to preventing co-ordination problems whilst maximising reliability (Murphy *et al.* 1998). However co-

ordinating seventeen participants was considered manageable (with effective facilitation) should all be able to attend the face-to-face meetings.

The service user group, involved members of PURSUN UK, (web address: <http://www.pursun.org.uk/>) which was set up to improve the quality of PPI in pressure ulcer research. Seven members were involved in the study and included people with experience of having a pressure ulcer, people with experience of living with pressure ulcer risk and carers.

4.14 Data Collection

Data collection was undertaken between Dec 2010 and Dec 2011. The consensus process incorporated an initial expert group meeting and an initial PURSUN meeting, followed by 2 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 in 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 focussed on agreeing the risk factors to be included in the Minimum Data Set and Risk Assessment Framework, while the second consensus cycle focussed on agreeing the assessment items. Each cycle comprised an expert group face-to-face meeting and pre and post meeting consensus questionnaire completion (Figure 4.1). A PURSUN meeting was also undertaken at the end of cycle 1 (Figure 4.1).

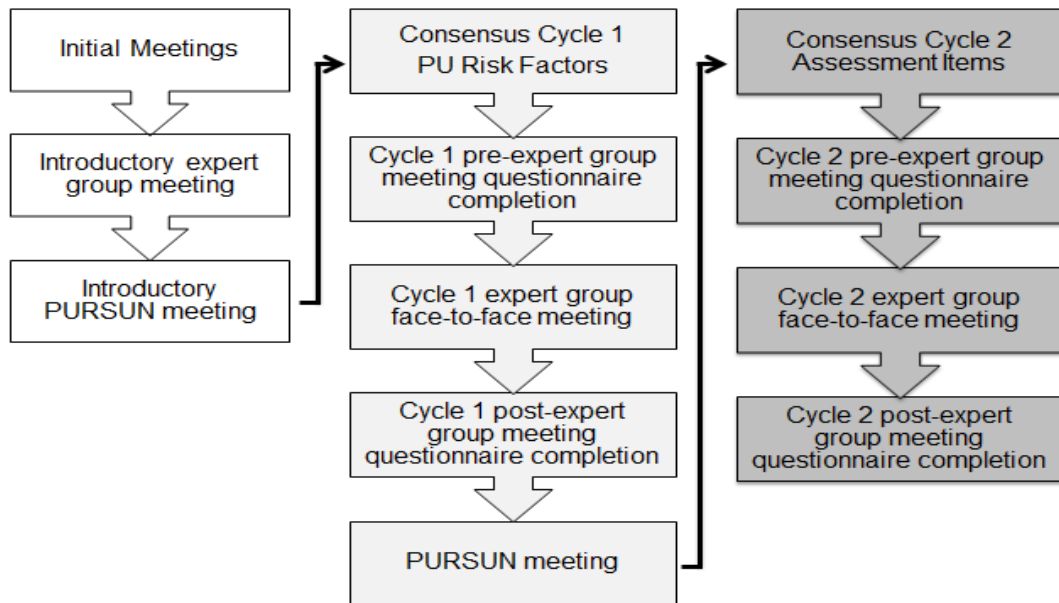


Figure 4.1 Overview Consensus Cycle

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online, DOI: 10.1111/jan.12444

Reviewing the pressure ulcer risk factor evidence was an important element of the study and was integrated throughout all cycles of the consensus process. The systematic review (Chapter 3) 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 was also considered by the group.

Questionnaires were completed by all expert group members privately before and after the cycle 1 and 2 meeting (Figure 4.1). In each questionnaire participants were asked to rate their level of support for statements (relating to the inclusion of risk factors/ assessment items to the Minimum Data Set and Risk Assessment Framework) on a 9 point Likert scale where 1 indicated strong disagreement and 9 indicated strong agreement (Figure 4.2). Each statement was preceded by the relevant summary of the pressure ulcer systematic review evidence as well as expert group discussions, summary of PURSUN 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. The completion of

the questionnaire after the meeting allowed individuals to change their ratings in light of discussions and/or where necessary for questionnaire items to be amended.

Statement Relating to Immobility										
After reviewing the above evidence please indicate your level of agreement with the following statement.										
1. Screening Stage:										
	Strongly disagree				Neutral: neither agree nor disagree				Strongly agree	
Data item(s)/clinical measure(s) relating to immobility status should be recorded for use at the screening stage of the PU risk assessment, i.e. for all patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 4.2 Example questionnaire items from the cycle 1 questionnaire

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online, DOI: 10.1111/jan.12444

Questionnaires were administered and completed via a commercial online survey platform (Survey Monkey). Participants were asked to complete the questionnaire within two weeks of initial posting. One or two reminders were sent (and on one occasion, due to a holiday period a third reminder was sent) to participants who had not completed the questionnaire within the allotted two week period. The surveys were closed to response at 10-weeks following initial posting.

In keeping with the RAND/UCLA Appropriateness method each expert group meeting was conducted over the course of the day (Fitch *et al.* 2001). The meetings were conducted in a pleasant room at the University of Leeds and regular refreshment breaks were provided throughout. The meetings were audio-recorded and led by trained facilitators to ensure a structured approach and that all participants were given the opportunity for discussion (Murphy *et al.* 1998). The researcher (SC) was the main facilitator with the support of two others (JN and EAN). There was also additional support to ensure the smooth running of the meetings (i.e. for scribing on flip charts and administration purposes).

Unlike a traditional RAND/UCLA method where 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 (Raine, Sanderson and Black 2005). At cycle 1 and 2 expert group meetings (Figure 4.1) 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.

At the initial PURSUN meeting (Figure 4.1) participants were introduced to the aims of the study, the purpose of the meetings and discussed potential assessment components of the Minimum Data Set and Risk Assessment Framework. Views were fed back to the expert group by the Patient and Public Involvement Officer (cycle 1). At the second PURSUN meeting (cycle 1, Figure 4.1) members were asked to consider the risk factors that the expert group had agreed should be included in the Minimum Data Set and Risk Assessment Framework, potential assessment items and the acceptability of collecting this information on a routine basis. Views were fed back to the expert group via the cycle 2 pre-meeting questionnaire (which included a summary PURSUN discussions) prompting discussion at the expert group meeting.

4.15 Ethical Considerations

The study was reviewed and approved by the University of Leeds School of Healthcare Research Ethics Committee (Appendix 8). Informed consent was gained from expert group members (Appendix 9 and 10) prior to participation and they remained free to withdraw from the study without giving reasons.

4.16 Data Analysis

The researcher (SC) listened to the audio-tapes and read the associated transcripts in total to ensure completeness. The data was then coded, with categories based on the pressure ulcer risk factor systematic review, in keeping with a directed content analysis approach (Hsieh and Shannon 2005). 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 a working group (sub-group of expert group) to ensure it reflected group discussions.

Careful notes were taken throughout the PURSUN meetings and a summary of discussions was written by the researcher (SC). The summary was circulated to the facilitator and group participants to ensure it reflected the discussions of 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 studies (Scott and Black 1991; Shiffman *et al.* 2003; Kroger *et al.* 2007; Fitch *et al.* 2001) Likert scale group median responses for each statement were categorised into 3 tertiles. For this study the categories were 1-3 disagree, 4-6 uncertain, 7-9 agree. Within-group agreement was measured using the RAND Disagreement index (Fitch *et al.* 2001), which considers the dispersion of individual scores to identify areas of disagreement (where panellists rate at both ends of the Likert Scale). This involves calculating the interpercentile range (IPR: 0.3-0.7) and the IPR adjusted for symmetry (IPRAS) to detect disagreement (if the IPR is larger than the IPRAS there is disagreement) (Fitch *et al.* 2001): by calculating the ratio of these an index of >1 indicates disagreement. This method of analysis was favoured over the MADM and the interquartile range as it pre-specifies the requirement for the classification of disagreement, in line with good statistical principles (ICH Expert Working Group 1998).

Consensus definitions were determined prior to data collection and analysis and were based on the RAND/UCLA Appropriate method criteria: 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 (Figure 4.1):

- Group medians of 1-3 without disagreement would be excluded
- Group medians of 7-9 without disagreement would be included
- Where the disagreement index was >1 or where the median was 4-6 they would be excluded but noted as potential areas for further research.

4.17 Validity and Reliability

As it is difficult to determine the validity of consensus judgements at the time the judgements are made (see section 4.7.1) it is important that the consensus process is as rigorous as possible (Raine, Sanderson and Black 2005). This study applied principles of good practice in the planning and delivery of the consensus process

incorporating the involvement of a mixed-speciality expert group (Hutchings and Raine 2006) and the views of service users (PURSUN). Other key principles included careful preparation and consideration of relevant evidence throughout the consensus process, questionnaire content informed by expert group discussions (and reviewed by a working group to ensure content validity), private completion of questionnaires by expert group members, facilitated face-to-face meetings and the inclusion of a measure of dispersion as well as central tendency in the reporting (Murphy *et al.* 1998). While the reliability of expert group judgements were not assessed in this study, future work is being planned to check the representativeness of the expert group views with the wider community (Raine, Sanderson and Black 2005).

4.18 Results

The expert group comprised of 17 international experts in the pressure ulcer field, comprising 9 female and 8 male participants. There was 100% completion of all questionnaires, 77.9% (n=53/68) were completed within the 2-week allotted time period; 13.2% (n=9/68) were completed up to 1-week late; 2.9% (n=2/68) up to 4-weeks late; 1.5% (n=1/68) up to 6-weeks late; 1.5% (n=1/68) up to 7-weeks late; and 2.9% (n=2/68) up to 8-weeks late) and 86.3% attendance at the face to face meetings (n=17/17 attended the first meeting, n=13/17 attended the second meeting, and n=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 below.

4.19 Cycle 1 Risk Factors

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 and comprised immobility, existing and previous pressure ulcer. Table 4.2 indicates the questionnaire responses before and after the expert group meetings. In the pre-meeting questionnaire responses there was support for inclusion of 3 risk factors and exclusion of 13 risk factors, with uncertainty for 10 risk factors (3 with disagreement). Following the consensus meeting and discussion of the areas of uncertainty and disagreement the post meeting questionnaire responses indicated agreement for inclusion of 3 risk factors and exclusion of 21 risk factors (Table 4.2)

Table 4.2 Risk Factors for Screening Stage of Minimum Data Set and Risk Assessment Framework

	Pre-meeting Questionnaire Responses		Post-meeting Questionnaire Responses	
	Group Median	Disagreement Index	Group Median	Disagreement Index
Immobility status	9.00	0.00	9.00	0.00
Existing pressure status	9.00	0.13	9.00	0.00
Previous pressure ulcer status	7.00	0.29	8.00	0.29
General skin status	5.00	1.87*	3.00	0.74
Sensory perception	4.00	0.68	3.00	0.72
Acute illness	5.00	0.59	3.00	0.54
Infection	5.00	0.98	2.00	0.33
Body temperature	5.00	0.97	2.00	0.29
Nutrition	5.00	0.55	2.00	0.75
Friction and shear	2.00	0.16	2.00	0.29
Chronic wounds	3.00	0.65	2.00	0.29
Diabetes	4.00	0.55	2.00	0.37
Summary measure of general health status.	2.00	0.20	2.00	0.13
Perfusion	-	-	2.00	0.75
Albumin	3.00	0.48	2.00	0.29
Skin moisture	4.00	1.61*	2.00	0.29
Dual incontinence	5.00	1.70*	2.00	0.33
Medication	3.00	0.33	1.00	0.02
Mental status	2.00	0.65	1.00	0.13
Age	4.00	0.67	1.00	0.16
Race	2.00	0.49	1.00	0.02
Gender	1.00	0.29	1.00	0.02
Haemoglobin	2.00	0.37	1.00	0.16
Pitting oedema	3.00	0.67	1.00	0.13
BP	3.00	0.67	-	-
Smoking	2.00	0.37	-	-
Cardiovascular disease	3.00	0.67	-	-

Dark grey: group median 1-3 (inclusion not supported), Mid grey: group median 4-6 (uncertain), Light grey: group median 7-9 (inclusion supported)*disagreement

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online, DOI: 10.1111/jan.12444

The expert group agreed that eleven risk factors namely immobility, existing and previous pressure ulcer, general skin status, perfusion, skin moisture, dual incontinence, diabetes, sensory perception, nutrition and albumin 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 have an existing pressure ulcer from the screening stage.

Table 4.3 indicates the questionnaire responses before and after the expert group meetings. In the pre-meeting questionnaire responses there was support for inclusion of 12 risk factors and exclusion of 2 risk factors, with uncertainty for 12 risk factors (2 with disagreement). Following the consensus meeting and discussion of the areas of uncertainty and disagreement the post meeting questionnaire responses indicated agreement for inclusion of 11 risk factors, exclusion of 4 risk factors and uncertainty for 9 risk factors (1 with disagreement). A summary of the key discussion points relating to the uncertain risk factors is detailed in Table 4.4. After reviewing the evidence the post meeting questionnaire was revised and Blood Pressure (BP), smoking and cardiovascular disease were combined into a general category of 'perfusion'.

Using the decision rules highlighted in section 4.16 the Minimum Data Set and Risk Assessment Framework comprised only those risk factors where there was agreement (group median 7-9 without disagreement). The progression of risk factors through the consensus study are detailed in Figure 4.3. This shows that of the original 15 risk factor domains and 46 sub-domains identified through the systematic review (Chapter 3), 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 recognised that albumin emerged strongly in the systematic review and that it was important in relation to potential changes in oncotic pressure and the development of oedema. Some also thought it was linked to nutritional status. The expert group agreed that albumin should be included at the

Table 4.3 Risk Factors for the Full Assessment Stage of Minimum Data Set and Risk Assessment Framework

	Pre-meeting Questionnaire Responses		Post-meeting Questionnaire Responses	
	Group Median	Disagreement Index	Group Median	Disagreement Index
Immobility status	9.00	0.16	9.00	0.00
Existing pressure ulcer status	9.00	0.13	9.00	0.16
Previous pressure ulcer status	7.00	0.40	8.00	0.16
General skin status	8.00	0.23	8.00	0.29
Skin moisture	8.00	0.29	8.00	0.33
Diabetes	8.00	0.29	8.00	0.33
Nutrition	7.00	0.67	8.00	0.16
Perfusion	-	-	8.00	0.40
Albumin	7.00	0.20	7.00	0.45
Sensory perception	8.00	0.29	7.00	0.29
Dual incontinence	8.00	0.19	7.00	0.33
Friction and shear	5.00	1.10*	6.00	0.52
Chronic wounds	6.00	0.42	6.00	0.37
Medication	5.00	0.41	5.00	0.08
Acute illness	7.00	0.07	5.00	0.59
Infection	5.00	1.10*	5.00	0.41
Body temperature	7.00	0.52	5.00	0.88
Pitting oedema	6.00	0.30	5.00	1.04*
Age	5.00	0.49	5.00	0.50
Summary measure of general health status	4.00	0.62	4.00	0.65
Haemoglobin	5.00	0.32	3.00	0.72
Mental status	5.00	0.72	2.00	0.75
Race	2.00	0.49	1.00	0.13
Gender	2.00	0.29	1.00	0.02
BP	5.00	0.52	-	
Smoking	5.00	0.59	-	-
Cardiovascular disease	6.00	0.42	-	-

Dark grey: group median 1-3 (inclusion not supported), Mid grey: group median 4-6 (uncertain), Light grey: group median 7-9 (inclusion supported) *disagreement

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online, DOI: 10.1111/jan.12444

Table 4.4 Uncertain risk factors

Uncertain Risk Factors	Key Discussion Points
Friction and shear	<ul style="list-style-type: none"> • Important concept in relation to biomechanics and tissue loading • Debate about whether a patient characteristic • Difficult to measure in practice • Different definition of terms (e.g. nurses and bioengineers) • Interlinked with immobility • Should to be minimised in care
Acute illness Infection Body temperature (elements of general health status)	<ul style="list-style-type: none"> • Felt to be important clinically • Links between the 3 elements recognised • Impact on mobility, perfusion and moisture acknowledged
Chronic Wound	<ul style="list-style-type: none"> • Did not emerge as a strong risk factor in the systematic review • Link to other factors including nutritional depletion, moisture (exudate), oedema, diabetes and general skin condition recognised • Would be captured by other key risk factors e.g. general 'skin status', nutrition, moisture and diabetes
Pitting oedema	<ul style="list-style-type: none"> • Relatively unexplored area in the literature • Leads to changes in the mechanical properties of the tissues • May result in reduced mobility due to heavy oedematous legs • Some felt that oedema should be considered under the skin status umbrella
Medication	<ul style="list-style-type: none"> • Acknowledged that the systematic review evidence associated with medication was weak. • Links between specific medications and risk factors were made e.g. the effects of sedation, epidurals and analgesia on sensation and movement which, steroids on skin condition (tissue paper skin) • Use of vasoconstrictors in specialist areas important • Complicated by dose-dependent effects • Difficult to measure
Age	<ul style="list-style-type: none"> • Some felt that age formed an important element of assessment • Others felt it was a proxy for other measures e.g. skin condition and immobility

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online, DOI: 10.1111/jan.12444

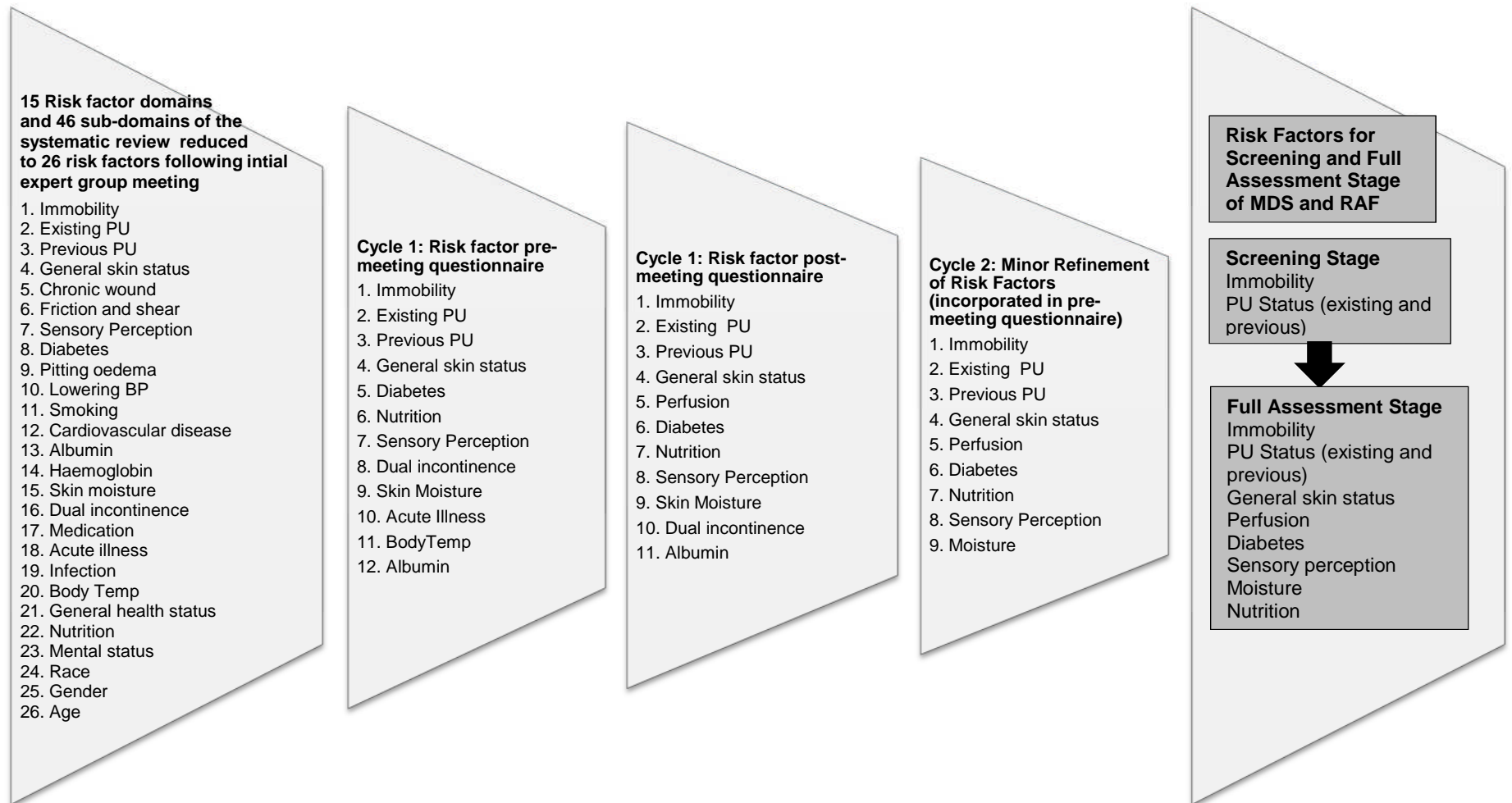


Figure 4.3 Risk Factor Progression

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online. DOI: 10.1111/ian.12444

second stage of the assessment (Table 4.3). However at a subsequent PURSUN meeting concern was raised about the need to undertake an additional blood test for assessment of albumin. This concern was fed-back to the expert group in the cycle 2 pre-meeting questionnaire and members were asked whether there was a clinical indication for undertaking an additional blood test to measure albumin for patients to establish level of pressure ulcer risk. It was concluded that this was unnecessary and would not be included in the Minimum Data Set and Risk Assessment Framework. The expert group also concluded that skin moisture and dual incontinence could be combined into one measure.

4.20 Cycle 2: Assessment Items for Risk Factors

There was support (group median 7-9 without disagreement) for all statements in the cycle 2 questionnaire concerning the assessment items of Minimum Data Set and Risk Assessment Framework. However, following group discussion at the cycle 2 meeting it was felt that some changes were necessary 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 focussed on items that required adjustment. The agreed assessment items for the screening and full assessment stage are detailed in Table 4.5. 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.

4.21 Draft Risk Assessment Framework

Using the results from cycle 1 and 2 of the study an initial draft of the Risk Assessment Framework (Figure 4.4) was made incorporating the screening and full assessment stage and decision pathways of the assessment process i.e. not currently at risk, primary prevention (at risk) or secondary prevention and treatment pathway (existing pressure ulcer or scarring from a previous pressure ulcer). This will undergo further graphic design in preparation for pre-testing.

Table 4.5 Minimum Data Set (to be incorporated in Risk Assessment Framework)

Screening Stage
Mobility: a. Does the patient walk without help? b. Does the patient change position?
PU status: a. Current PU (≥ 1 category) b. Reported history of PU
Full Assessment stage
Immobility items to incorporate the frequency of independent movement e.g.: a. Doesn't move b. Moves occasionally c. Moves frequently
Immobility items to incorporate the magnitude of independent movement e.g. a. Doesn't move b. Slight position changes c. Major position changes
Immobility items to incorporate general, clinically relevant descriptions of movement e.g.: a. Bedfast b. Chairfast c. Walks with assistance
Sensory perception: a. Does the patient feel and respond appropriately to discomfort from pressure
PU (existing and previous PU): a. Category of PU (where possible for previous PU) b. Site of PU c. Presence of scar tissue (for previous PU)
General skin status: a. Confirmation of vulnerable skin, e.g. dryness, paper thin and redness b. Pressure area skin site
Perfusion: a. Conditions affecting central circulation, e.g. shock, heart failure and hypotension b. Conditions affecting peripheral circulation, e.g. peripheral vascular/arterial disease.
Diabetes: a. Presence of diabetes
Moisture: a. Presence of moisture due to perspiration, urine, faeces or exudate. Frequency: b. Frequent (1 or 2 times a day) c. Constant
Nutrition: a. Unplanned weight loss b. Poor nutritional intake c. Low BMI d. High BMI

PU: pressure ulcer

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online, DOI: 10.1111/jan.12444

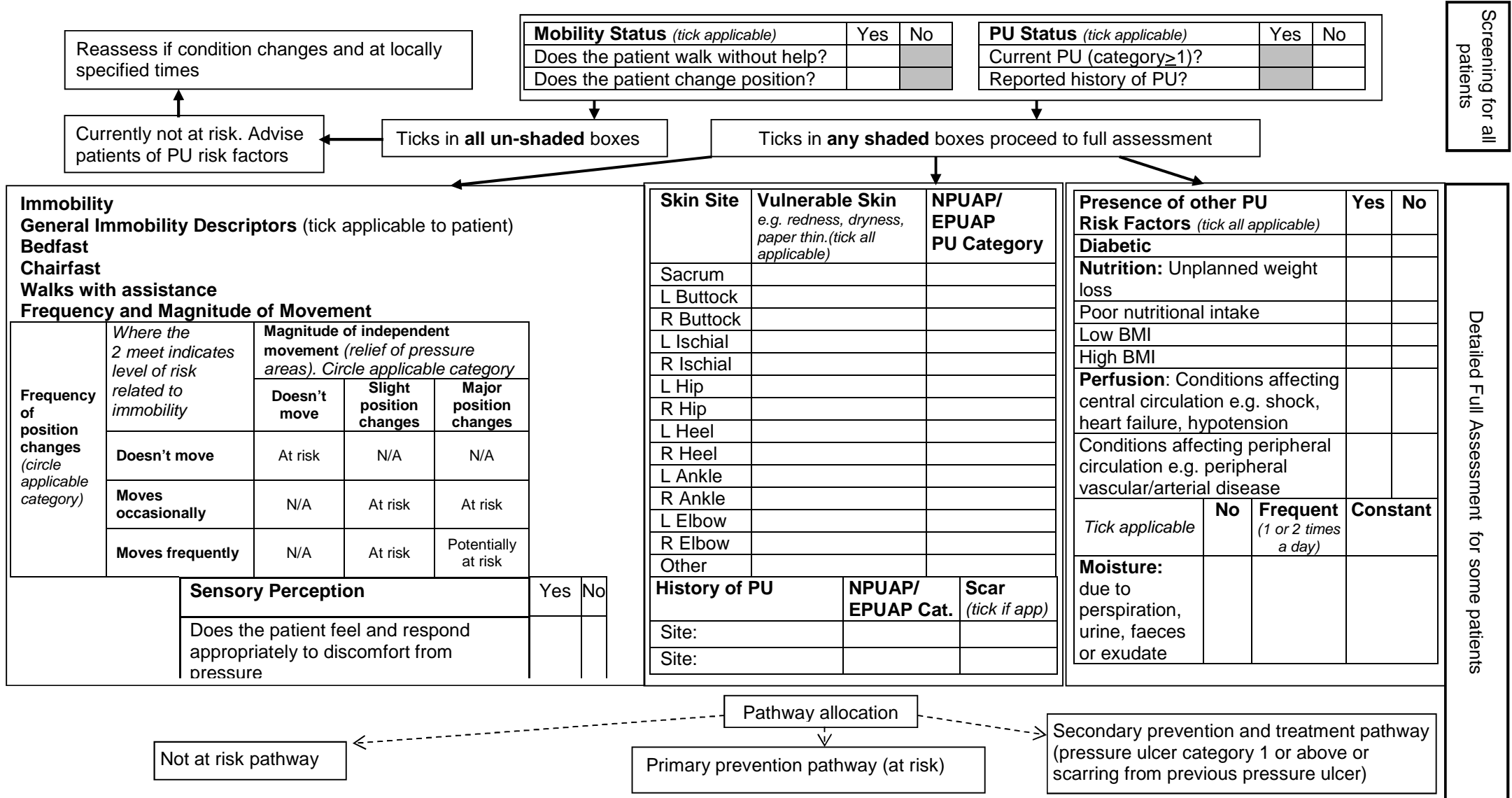


Figure 4.4 Draft Risk Assessment Framework with Underpinning Minimum Data Set

Reprinted from Journal of Advanced Nursing, Coleman, S., Nelson, E., A., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Muir, D., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Bader, D.L., Gefen, A., Oomens, C.W.J., Schoonhoven, L. & Nixon, J. Developing a Pressure Ulcer Risk Factor Minimum Data Set and Risk Assessment Framework. 2014 Online. DOI: 10.1111/ian.12444

4.22 Discussion

The consensus study allowed the evidence of the systematic review to be carefully reviewed by an expert group, taking into account the wider scientific evidence, its relevance to clinical practice, and the views of PURSUN UK. It allowed the risk factors and assessment items for a draft Minimum Data Set and Risk Assessment Framework to be agreed establishing the content validity of the tool. The consensus methods were particularly useful in allowing identification of risk factors for inclusion in the Risk Assessment Framework and Minimum Data Set. While they were also useful in identifying the key principles of the assessment items, the method was inappropriate for considering the specific wording of items. Of note was the agreement that the risk factors and assessment items should be the same for the Minimum Data Set and the Risk Assessment Framework i.e. no additional risk factor information to supplement the Minimum Data Set was considered necessary for a Risk Assessment Framework for assessment in clinical practice. The draft Risk Assessment Framework differs from other Risk Assessment Instruments in two main ways: the incorporation of a screening stage within the Risk Assessment Framework will allow 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 practice. The integration of existing pressure ulcer (and/or scarring from a previous pressure ulcer) and the secondary prevention and treatment pathway within the Risk Assessment Framework has the potential to facilitate escalation of interventions to prevent deterioration and promote healing. Further research is required to confirm this.

Being well organised and prepared for the expert group face-to-face meetings helped the meetings to run smoothly. Effective facilitation ensured all participants were involved in the process even when all members of the expert group were in attendance. Of note to others when preparing such a meeting is the benefit of having additional facilitators involved, who can step in to ensure optimum facilitation at all times throughout the course of the meeting. There was strong commitment from the expert group to be involved throughout the study, though there were a few occasions where participants were unable to attend the face-to-face meetings (13/17 attended the second meeting and 14/17 attended the third meeting). On these occasions special arrangements were made to ensure they were properly updated and could continue to participate in the process. One to one telephone meetings were organised between the researcher and these individuals after the

expert group meeting. The participant was sent the same information considered at the expert group meeting and the researcher presented the same power point presentations and summarised the discussions of the expert group meeting. The participant then completed the online questionnaire (all completed the pre-meeting questionnaires at the same time as the rest of the group). Every effort was made to ensure that these participants remained engaged in the consensus process but there remains the possibility that these participants might have made different questionnaire responses had they been subject to the actual expert group discussions.

The use of the systematic review evidence (Chapter 3) provided the foundation for the evidence base of the consensus study, but the expert group also considered wider scientific evidence, clinical and practical implications as well as the views of PURSUN when deciding which risk factors should be included at the screening stage and the full assessment stage of the Minimum Data Stand Risk Assessment Framework. The expert group meetings allowed facilitated exploration of the risk factors and assessment items considered important for summarising patient risk. The post meeting questionnaire completion element of the consensus process allowed expert group members to privately rate their level of support for including risk factors and assessment items in the Risk Assessment Framework in light of the expert group discussions. The private rating of the questionnaires and subsequent anonymised results allowed expert group members to make their ratings, free from peer pressure. In addition, the pre-defined consensus definitions based on the RAND/UCLA Appropriateness method gave clarity on the levels of support required for risk factor and assessment item inclusion i.e. only those with group medians of 7-9 without disagreement in the post-meeting questionnaire would be included in the Risk Assessment Framework (Fitch *et al.* 2001). The approach worked well and enabled the expert group to agree the key risk factors and assessment items to be included in the Risk Assessment Framework.

However it was recognised that other risk factors that did not reach the required levels of support and were excluded may still have a role in the pressure ulcer causal pathway via their relationship with the primary risk factors and may be important at an individual patient level e.g. the use of inotropes impacts on perfusion. Pressure ulcer causal pathways were considered more closely in a follow-up piece of work which developed a conceptual framework (Chapter 5).

As with all consensus studies the measurement of validity at the time of conducting the study is problematic. The methodology and conduct of the study was undertaken in as rigorous a manner as possible and took into account the evidence and service user opinion. From a concurrent validity perspective the risk factors included in the Minimum Data Set and Risk Assessment Framework included those with strong epidemiological evidence (immobility, existing pressure ulcer, general skin status, perfusion (including diabetes), as well as those with less consistent epidemiological evidence which were felt to be important in clinical practice (moisture, nutrition, sensory perception). Examples of expert group discussions influencing support for the inclusion of specific risk factors are detailed below.

The epidemiological evidence relating to diabetes suggesting a two fold increase in pressure ulcer development in patients with the condition, prompted much discussion and debate within the expert group. It was recognised that the impact diabetes may have on pressure ulcer risk could be influenced by the duration of the condition and how well it was controlled. However, the primary studies of the systematic review did not include this level of reporting and it was restricted to the presence of the condition only. Clinical members of the expert group felt that it was the complications of diabetes, rather than diabetes per se that were of importance: they felt that diabetes may impact the risk of pressure ulcer development due to the increased likelihood of reduced sensory perception (neuropathy), poor perfusion and abnormal anatomy and tissue property changes. These suggestions were based on expert group members' clinical or scientific knowledge of diabetes, as the primary studies of the systematic review did not discern this level of detail. It is recognised that further research is required to fully establish and understand the relationship between diabetes, reduced sensory perception, poor perfusion, abnormal anatomy and tissue property changes and pressure ulcer development.

Previous pressure ulcer was included on the basis of clinical and service user opinion and theoretical bioengineering evidence rather than by the epidemiological evidence. Conversely albumin which has strong epidemiological evidence was initially agreed for inclusion in the Minimum Data Set and Risk Assessment Framework by the expert group, but was subsequently excluded due to concerns raised by PURSUN. In these examples, where the group diverged from the epidemiological evidence the reasons were in keeping with some of those previously reported including clinical experience and patient preference (Raine *et al.* 2004). Ultimately whether the judgements of the study are correct, i.e. predictive

of pressure ulcer development, needs to be assessed in future modelling work and in the on-going development of the Risk Assessment Framework.

The outcomes detailed above also demonstrate the impact of integrating the PURSUN perspective throughout the study and to the author's knowledge is the first study to use such an approach. While others using consensus methods have incorporated patient/carer representation to their expert groups (Rycroft-Malone 2001; Jackson *et al.* 2009), this study used an alternative approach. The new approach allowed whole meetings to be dedicated to patient/carer insights with structured feedback to the expert group to ensure their views were integrated into the process. This new approach to PPI involvement in a structured consensus method may also be appropriate for other subject areas and could be used as an example of how to effectively incorporate patient/carer views into the process. As noted previously (section 4.7.5) this would also depend on the nature of the study being undertaken and the specific aim of patient/carer involvement.

While the study involved an expert group with considerable experience a weakness of the methodology relates to reliability and whether the results of this study are representative of the views of other experts in the field. This could prove especially important for uncertain areas such as friction and shear (excluded) where the expert group identified a close relationship with immobility and difficulties in measuring this risk factor in clinical practice. Raine, Sanderson and Black proposed a new approach in developing clinical guidelines which includes checking the representativeness of the groups ratings with a large similarly composed group (Raine, Sanderson and Black 2005). As the intention is to continually update the Risk Assessment Framework, further work is currently being planned to consider the risk factors that should be considered in the Minimum Data set and Risk Assessment Framework with a larger group. This will also allow new evidence to be brought forward and integrated into the work.

In addition, while the consensus study has provided us with a draft Minimum Data set and Risk Assessment Framework further development work is necessary incorporating further liaison with the expert group and PURSUN, graphic design to improve usability and pre-testing with clinical nurses to assess the acceptability, usability and clarity of the Risk Assessment Framework. This maybe particularly important for risk factors such as general skin status and its related assessment items as the expert group acknowledged difficulties associated with measuring this in clinical practice at the present time. Further work with clinical nurses is necessary

to identify the best way of assessing skin status and they may also have alternative views of when this assessment should occur.

4.23 Conclusion

Using a modified nominal group technique based on the RAND/UCLA appropriateness method, incorporating an expert group, review of the pressure ulcer evidence and the views of a PPI service user group (PURSUN) we have agreed risk factors, assessment items and have drafted a Minimum Data Set and Risk Assessment Framework. The Risk Assessment Framework comprises of 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. The Risk Assessment Framework 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 continuing development of the Risk Assessment Framework is discussed in the chapters that follow.

Chapter 5 Development of a New Pressure Ulcer Conceptual Framework

5.1 Introduction

This chapter explores the work undertaken to develop a new conceptual framework for pressure ulcer development. It builds on the consensus study (Chapter 4) which brought together the relevant fields of enquiry to clarify key risk factors for pressure ulcer development. The consensus study emphasised the need to revise the pressure ulcer conceptual framework (NPUAP/EPUAP 2009) to provide clearer linkage between the physiological, biomechanical and epidemiological evidence. This translates the physiological and biomechanical elements to characteristics which nurses can observe in their patients.

5.2 Aim

To consider the critical determinants of pressure ulcer development in order to propose a new conceptual framework. The objectives were to:

1. Review and update the biomechanical/physiological elements of the original NPUAP/ EPUAP (2009) conceptual framework.
2. Propose a theoretical causal pathway for pressure ulcer development.
3. Map risk factors identified in the consensus study to the updated conceptual framework.

5.3 Design

The expert group of the consensus study (Chapter 4) reconvened to address the aims and objectives detailed above. The facilitated meeting was audio-recorded and transcribed, allowing key themes to be identified.

5.4 Data Collection

The meeting was held in December 2011 and was planned so that members had access to the outcomes of the consensus study (Chapter 4), the systematic review (Chapter 3) and causal factor terminology prior to the face-to-face meeting. Familiarity with the 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 suggested by (Brotman *et al.* 2005).

- Risk factor – a variable with a significant statistical association with a clinical outcome.
- Independent 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 model.
- Non-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 et al suggests 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 (Brotman *et al.* 2005):

- 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.

Indirect causal factors were further categorised into key indirect causal factors (where the epidemiological/wider scientific evidence and/or clinical resonance was stronger) and other indirect causal factors. Discussions frequently incorporated consideration of pressure ulcer aetiology incorporating physiological and bioengineering research (Chapter 1, Section 1.9).

5.5 Data Analysis

The findings of the consensus study (Chapter 4) which identified the pressure ulcer risk factors considered important for summarising patient risk provided the initial structure to address the study aims. In addition, 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 provided the basis for the new proposed pressure ulcer conceptual framework and theoretical causal pathway.

5.6 Validity and Reliability

Validity and reliability issues relating to this study are linked to the preceding consensus study (Chapter 4, Section 4.7.1). Following analysis of the conceptual

framework meeting discussion the researcher (SC) drafted the new proposed pressure ulcer conceptual framework and theoretical causal pathway and circulated this to the expert group via email to gain feed-back regarding content validity. This led to minor revisions of the work.

5.7 Results

The in-depth discussions of the expert group led to amendments to the original NPUAP/EPUAP conceptual framework (2009). The original and amended version of the conceptual framework are detailed in Figure 5.1 and Figure 5.2. Most notably, it was recognised that while 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) its impact was considered to be more relevant to the susceptibility of the individual, i.e. impacting on the damage threshold and so was moved as detailed in Figure 5.2. 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 their repair capacity and this was an important consideration that was captured in the amended conceptual framework (Figure 5.1). The amended conceptual framework and its key components provided the foundation on which to link to the epidemiological evidence.

Table 5.1 shows the mapping of the direct causal factors and key indirect causal factors against the key components of the enhanced NPUAP/ EPUAP (2009) conceptual framework. Though 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. The process of mapping risk factors facilitated the proposal of a causal pathway for pressure ulcer development detailing the direct, key indirect and other potential indirect causal factors as discussed below and illustrated in the theoretical schema (Figure 5.3).

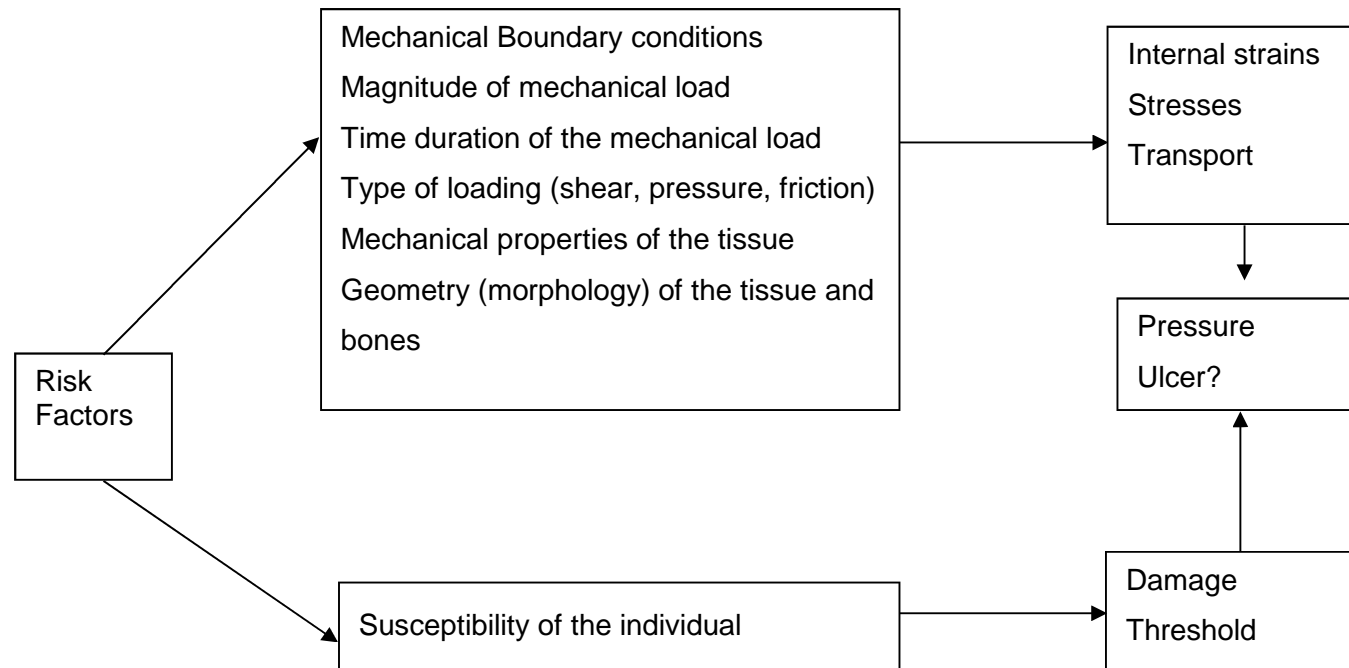


Figure 5.1 NPUAP/EPUAP (2009) Original Conceptual Framework - Factors that Influence Susceptibility

Used with permission from the National Pressure Ulcer Advisory Panel, 8th May 2014

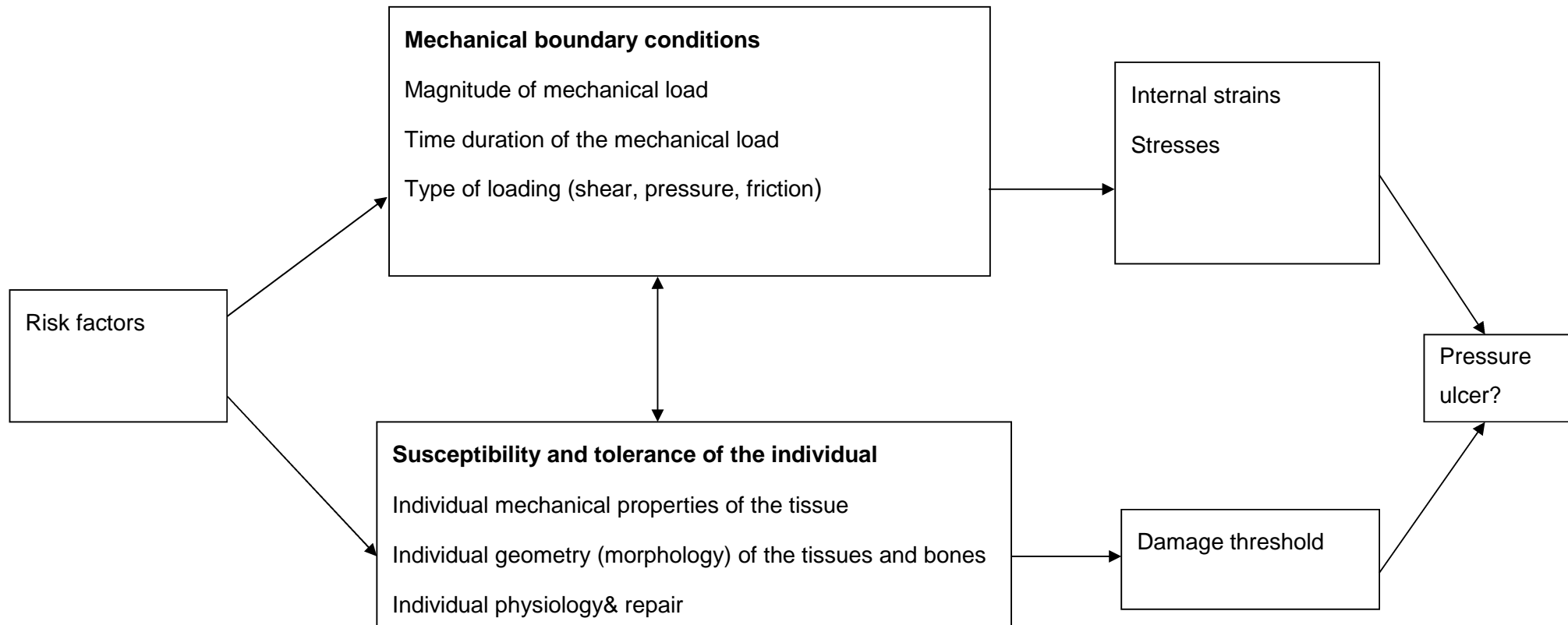


Figure 5.2 Amendment of NPUAP/EPUAP (2009) Conceptual Framework -Factors that Influence Susceptibility for Pressure Ulcer Development

Reprinted from Journal of Advanced Nursing, Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Schoonhoven, L., Bader, D.L., Gefen, A., C.W.J., O. & Nelson, E.A. A New Pressure Ulcer Conceptual Framework 2014 online, DOI:10.1111/jan.12405

Table 5.1 Mapping of Direct Causal and Key Indirect Causal Factors to the Conceptual Framework

Risk Factor	Mechanical Boundary Conditions: Type of loading (shear, pressure, friction) and magnitude & duration of mechanical load	Individual Geometry (Morphology) of the tissue & bones	Individual Mechanical Property of the Tissues	Individual Transport & Thermal Properties	Individual Physiology & Repair
Immobility	X				
Skin/PU Status		X	X	X	X
Poor Perfusion				X	X
Poor Nutrition		(x) in extreme cases	(x) in extreme cases	X	X
Moisture	X		X		
Poor Sensory Perception & Response	(x) through immobility				
Diabetes	(x) through sensory perception			(x) through perfusion	
Low Albumin				(x) through perfusion	

Reprinted from Journal of Advanced Nursing, Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Schoonhoven, L., Bader, D.L., Gefen, A., C.W.J., O. & Nelson, E.A. A New Pressure Ulcer Conceptual Framework 2014 online, DOI:10.1111/

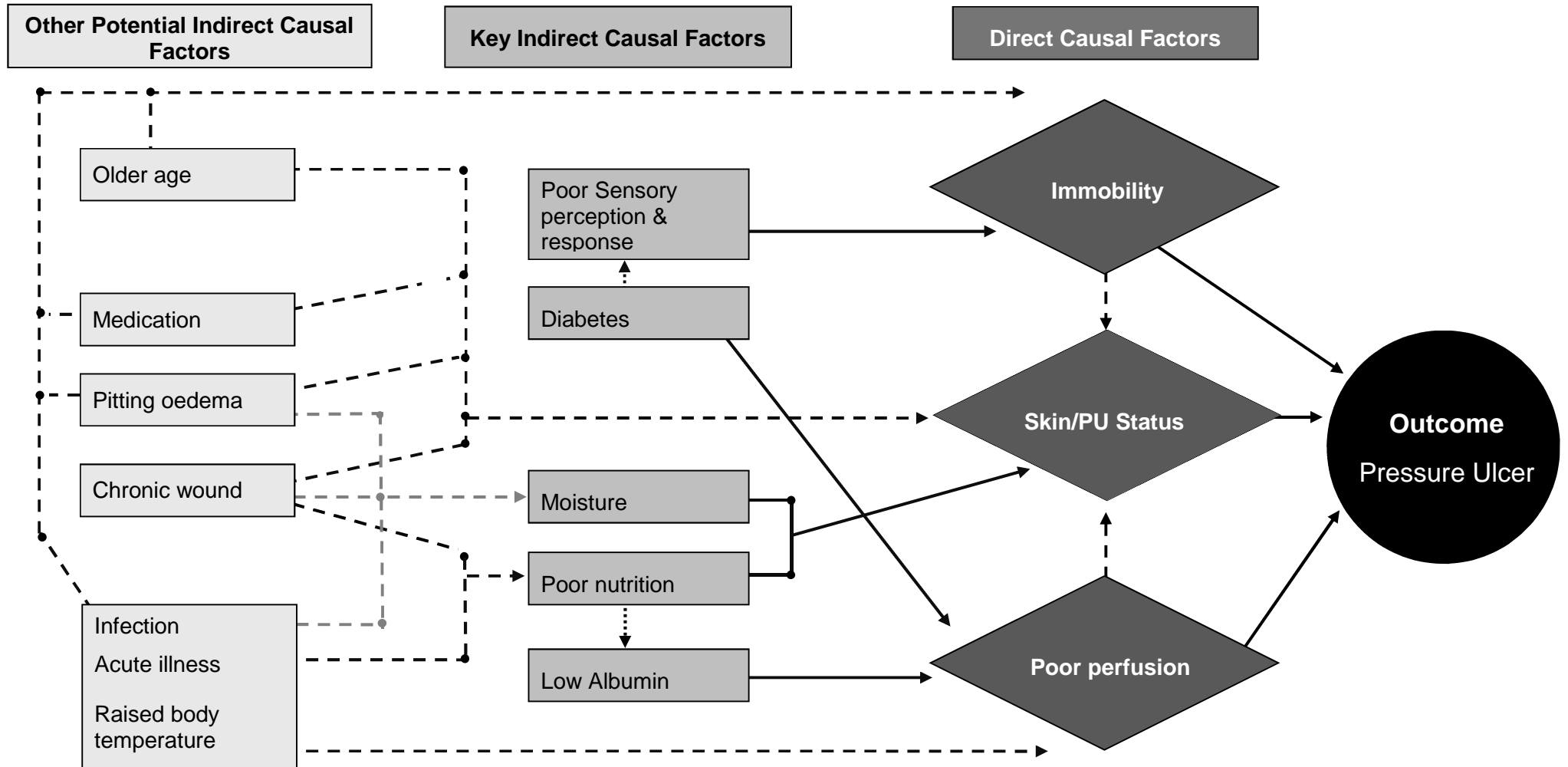


Figure 5.3 Theoretical Schema of Proposed Causal Pathway for Pressure Ulcer Development

The solid arrows show the causal relationship between the key indirect causal factors and direct causal factors and the outcome. Interrupted arrows show the causal relationship between other potential indirect causal factors and key indirect causal factors and between direct causal factors. Interrupted arrows also demonstrate interrelationships between direct causal factors and indirect causal factors

Reprinted from Journal of Advanced Nursing, Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Schoonhoven, L., Bader, D.L., Gefen, A., C.W.J., O. & Nelson, E.A. A New Pressure Ulcer Conceptual Framework 2014 online, DOI:10.1111

5.7.1 Direct Causal Factors

Three characteristics were classified as direct causal factors: immobility, skin/Pressure Ulcer status and perfusion. Immobility is a necessary condition for pressure ulcer development as through its impact on mechanical boundary conditions (Table 5.1) it directly impacts the outcome (or the likelihood of the outcome). It is therefore considered a direct causal factor (Figure 5.3). Of note is that friction and shear are not specified as a patient characteristic, rather a characteristic of the mechanical boundary condition (Table 5.1).

Identifying whether skin/pressure ulcer status (incorporating existing and previous pressure ulcer and general skin status) and poor perfusion represent direct or indirect risk factors was less straight-forward. 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 detailed above and oversimplifies the complex interplay of factors required to lead to tissue damage. There is strong epidemiological/wider scientific evidence (as detailed in chapter 1 and chapter 3) that poor perfusion and skin/pressure ulcer status reduce the patients' tolerance to pressure and increases the likelihood of pressure ulcer development. This suggests they are direct causal factors and may explain why some immobile patients develop pressure ulcers while others do not.

Further insight was gained by mapping skin/pressure ulcer status and poor perfusion to the conceptual framework and it was apparent that they were clearly implicated in the susceptibility and tolerance aspect of the framework (Table 5.1). Skin/pressure 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 element of the framework and is related to factors which impair circulation. Within the expert group it was recognised that the oxygen carrying capacity was important in maintaining healthy tissues. Other factors such as the delivery of nutrients and waste removal were also considered important, though at present it is difficult to ascertain the most crucial factors relating to perfusion. Further confirmatory research is needed to more clearly ascertain the aetiological mechanisms of importance.

5.7.2 Key Indirect Causal Factors

Moisture, sensory perception, diabetes, low albumin 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 (Figure 5.3).

5.7.3 Other Potential Causal Factors

The theoretical conceptual schema (Figure 5.3) was further developed to include other indirect causal factors to illustrate the potential relationships and impact of diverse factors which may be involved in the causal pathway. However, it is recognised that the interrelationships among potential and key indirect causal factors are complex and require further elucidation. Other indirect causal factors include those with weak or limited epidemiological/wider scientific evidence, but are thought to impact on key indirect and direct causal factors. They include age, medication, pitting oedema as well as other factors relating to general health status including infection, acute illness, raised body temperature and chronic wound.

5.7.4 New Conceptual Framework

Following consideration of the causal pathway for pressure ulcer development (Figure 5.3) and mapping of direct and key indirect causal factors for pressure ulcer development against the components of the enhanced conceptual framework (Figure 5.2), a new conceptual framework (Figure 5.4) is proposed. This enables the epidemiological evidence to be linked to the physiological and biomechanical elements of the conceptual framework. The new framework proposes the 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 including immobility, skin/Pressure Ulcer status and poor perfusion, as well as the key indirect causal factors of poor sensory perception and response, diabetes, poor nutrition, moisture and low albumin. For simplicity the risk factors are represented under the elements they are thought to predominantly affect (either mechanical boundary conditions or susceptibility and tolerance of the individual). However, the interrupted 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 (Figure 5.3) and risk factor mapping (Table 5.1). 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 someone with poor perfusion.

5.8 Discussion

Building on the work of the consensus study (Chapter 4) and the views of the expert group a new theoretical causal pathway for pressure ulcer development and a conceptual framework was developed. These bring together the epidemiological (Chapter 3), physiological and biomechanical evidence (Chapter 1), enhancing our understanding of the role of individual risk factors in pressure ulcer development. This was enabled by consideration and enhancement of the NPUAP/ EPUAP (2009) conceptual framework, mapping of risk factors to the conceptual framework and the proposal of a theoretical causal pathway for pressure ulcer development.

Agreeing the proposed elements of the new conceptual framework proved challenging as while the physiological and bioengineering research, the systematic review and the outcomes of the consensus study provide a good starting point, there are still many gaps in the evidence base. The proposal of the causal pathway for any condition/disease is a complicated process. For simplicity the pathway detailed in this paper only considers a one directional relationship between risk factors but, in reality, bi-directional relationships exist and causal factors may have multiple roles within a pathway (e.g. moisture impacts the vulnerability of the skin and may also effect the impact of immobility by increasing friction and shear).

It should be noted that the new conceptual framework does not consider varying parameters of risk factors (e.g. patients have varying levels of mobility, nutrition, moisture etc.) within the causal pathway and how these impact on pressure ulcer outcome. Furthermore, it does not explain how varying combinations of risk factors increase the likelihood of pressure ulcer development. The importance of individual risk factors may also vary in relation to body site, for example a patient with peripheral vascular disease may have reduced tolerance to pressure to their heels but not to their trunk areas. Patients may also have conditions such as contractures which may increase their risk of pressure ulcers at less commonly encountered body sites. In addition the new conceptual framework does not clearly articulate the aetiological mechanisms of importance for risk factors. For example there is still uncertainty about the specific mechanisms of importance relating to perfusion.

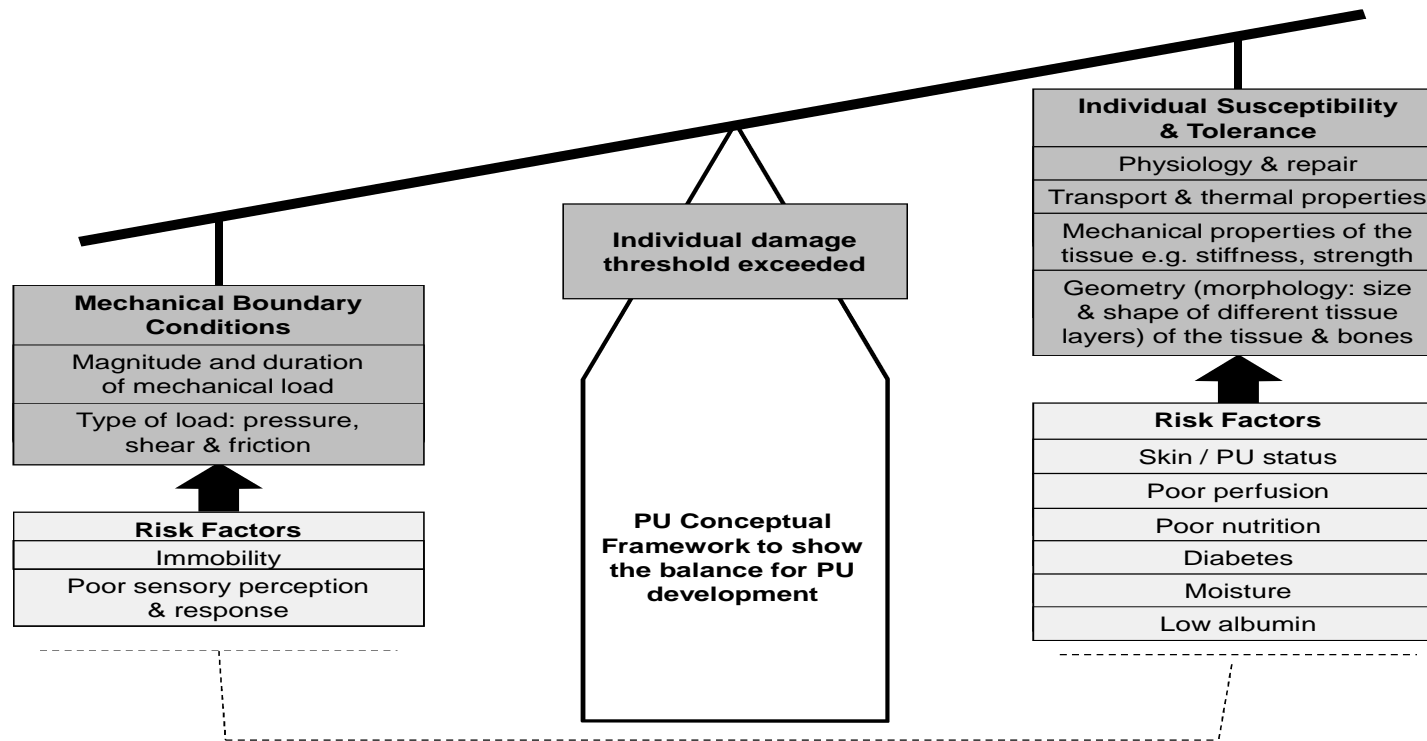


Figure 5.4 New Pressure Ulcer Conceptual Framework

Reprinted from Journal of Advanced Nursing, Coleman, S., Nixon, J., Keen, J., Wilson, L., McGinnis, E., Dealey, C., Stubbs, N., Farrin, A., Dowding, D., Schols, J.M.G.A., Cuddigan, J., Berlowitz, D., Jude, E., Vowden, P., Schoonhoven, L., Bader, D.L., Gefen, A., C.W.J., O. & Nelson, E.A. A New Pressure Ulcer Conceptual Framework 2014 online, DOI:10.1111

The development of the conceptual framework through the combination of bioengineering and epidemiological expertise and evidence also highlights that current methods available to assess the direct and indirect causal factors involved in pressure ulcer development including the mechanical boundary conditions and factors affecting tissue tolerance (geometry, mechanical properties of tissue, transport and thermal properties and physiology and repair) are very crude clinical assessments.

Limitations of the approach relate to the uncertainties associated with the primary research considered in the development of the new conceptual framework. The bioengineering research is limited due to its development in animal or tissue engineered muscle models as opposed to human subjects (Chapter 1). The evidence of the systematic review is limited by poor reporting, heterogeneity of patient populations, inconsistent inclusion of pressure ulcer domains, inconsistent measurement of risk factor variables, the use of different outcomes and lack of differentiation between pressure ulcer sites (Chapter 3). Furthermore, the primary studies of the systematic review mainly observed superficial pressure ulcers, while much of physiological and bioengineering research relates to muscle tissue and it could be argued that the associated aetiological mechanisms differ. However, there is no evidence that the key direct causal factors for superficial or deep pressure ulcers are different, rather it is the nature of surface loading that influences the type of pressure ulcer that develops (i.e. initially developing superficially or within muscle tissue) (Bouten *et al.* 2003).

Notwithstanding these limitations, the present approach facilitated consideration of a wide range of literature and the consensus study resulting in the proposal of a new pressure ulcer conceptual framework with agreement from a wide range of experts in the pressure ulcer field. The conceptual framework proposes clearer linkage between the physiological and biomechanical determinants of pressure ulcer development and patient risk factors identified through epidemiological research. This facilitates translation of the physiological and biomechanical elements to characteristics which nurses can observe in their patients. It could lead to increased understanding and has the potential to influence risk assessment guidance and practice, for example the new conceptual framework underpins the development of the pressure ulcer Risk Assessment Framework, which will influence risk assessment practice following implementation.

The proposed conceptual framework also has implications for nursing research relating to pressure ulcers. It provides an up to date account of how existing evidence has been used to develop theory and helps to identify gaps in our knowledge base. This could be used to underpin and guide future research, building on the evidence and enabling us to more clearly define the role of individual pressure ulcer risk factors conceptually and operationally.

5.9 Conclusion

The proposal of the new pressure ulcer conceptual framework incorporated consideration of physiological, biomechanical and epidemiological evidence as well as the outcomes of the consensus study and the views of an expert panel. This was enabled by consideration and enhancement of the NPUAP/ EPUAP (2009) conceptual framework, the development of a theoretical causal pathway for pressure ulcer development and mapping of risk factors to the conceptual framework. It could lead to increased understanding and improvements in risk assessment practice and underpins the pressure Ulcer Risk Assessment Framework developed as part of this PhD Thesis. The conceptual framework could also be used to underpin and guide future pressure ulcer research, to further explore the relationship between risk factors and increase our understanding of pressure ulcer development.

Chapter 6 Design and Pre-testing of the Risk Assessment Framework (incorporating risk factor Minimum Data Set)

6.1 Introduction

This chapter critically examines the next phase in the development of the Risk Assessment Framework (incorporating risk factor Minimum Data Set). It will detail the design of the Framework which involved using the key components agreed in the consensus study (Chapter 4) and incorporated in the proposed pressure ulcer conceptual framework (Chapter 5), consideration of the weighting and colour coding of risk factor items and collaboration with a graphic designer. It will also report how the draft Risk Assessment Framework was assessed by clinical nurses to improve its usability in a pre-test study. The pre-test study aims, methods and results will be described as well as a discussion of the findings.

6.2 Design of Risk Assessment Framework

The initial draft of the Risk Assessment Framework (Chapter 4, Figure 4.4) which incorporated the agreed risk factors, assessment items and the intended structure (screening and full assessment stage and decision pathways) underpinned the graphic design of the decision tool. The consensus study also agreed the need for the Risk Assessment Framework to facilitate the development of a patient specific risk profile. This was favoured over the traditional approach to Risk Assessment Instruments, where a condensed single score from different risk factors was used to determine different levels of risk and guide decision making about care interventions. It was envisaged that a patient specific risk profile would encourage the development of an individualised plan of care to address the actual risk factors present.

It was anticipated that the risk profile approach would provide enhanced support for decision making relating to the depth of the assessment required (i.e. screening and/or full more detailed assessment) and the relative importance of specific risk factors when considering the patients risk status. To reduce the temptation of condensing risk factor items into a single score and in keeping with other assessment systems within the NHS, the use of colour was considered a viable alternative to a numerical scale. The colour coding system adopted was as follows:

- Blue: 'no problem' with risk factor assessment item
- Yellow: risk factor present which *may* impact upon pressure ulcer risk
- Amber: risk factor present which puts the patient at risk and requires primary prevention
- Pink: patient has a pressure ulcer or scar from previous pressure ulcer and requires secondary prevention/treatment

The use of colour required informed judgements to be made regarding the importance of the risk factor items within the Risk Assessment Framework and their influence and weighting on the patients risk status. It was not possible to delineate this from the systematic review evidence (Chapter 3) alone. Rather, this was achieved by consideration of the overall strength of evidence which was influenced by each of the development phases of this work. For each of the risk factors agreed to be important in summarising patient risk (Chapter 4) the strength of epidemiological evidence (Chapter 3) and/or wider scientific evidence (physiological and biomechanical), its clinical resonance and its role in the pressure ulcer causal pathway i.e. whether it was considered a direct or indirect causal factor (Chapter 5) were considered. Under the leadership of the researcher (SC), these strands of evidence were discussed by the working group (sub-group of expert group) where agreement was reached regarding the weighting and colour coding of risk factors (Table 6.1).

Risk factors which had strong or good evidence and were considered direct causal factors were allocated to amber or pink (existing pressure ulcer or scarring from a previous pressure ulcer), with the exception of previous pressure ulcer. For this risk factor the epidemiological evidence was weak, though it was considered particularly important to patients and carers (PURSUN) and has clinical resonance. Additionally, from a bioengineering perspective the presence of scarring results in ongoing vulnerability to pressure at the skin site. To reflect these concerns previous pressure ulcer was allocated to yellow but the presence of scarring would escalate this to pink.

Table 6.1 Colour coding of risk factors

Risk factor agreed for inclusion in the Risk Assessment Framework	Overall strength of evidence	Type of causal factor	Risk assessment Framework Colour coding
Immobility	Strong	Direct causal factor	Amber (yellow for one category)
Skin/PU Status: Existing Pressure Ulcer	Strong	Direct causal factors	Pink
Previous Pressure Ulcer	Good		Yellow (pink if scarring present)
General skin status	Strong		Amber
Perfusion	Strong	Direct causal factor	Amber
Sensory Perception	Good	Indirect causal factor	Amber
Moisture: Skin moisture	Good	Indirect causal factors	yellow
Dual incontinence	Good		
Diabetes	Good	Indirect causal factor	Yellow
Nutrition	Good	Indirect causal factor	Yellow
Sensory Perception	Good	Indirect causal factor	Amber

Strong evidence: strong epidemiological/wider scientific evidence and clinical resonance;
Good evidence: good epidemiological/wider scientific evidence but showing some inconsistency in their statistical association with pressure ulcer development and/or good clinical resonance;

Risk factors with good evidence that were considered indirect causal factors were generally allocated to yellow, with the exception of sensory perception due to its links with diabetes. Throughout the consensus study clinical members of the expert group questioned the epidemiological evidence relating to diabetes (suggesting a two fold increase in pressure ulcer development). They did not feel it reflected what they observed in clinical practice i.e. they did not see a disproportionate number of diabetic patients with pressure ulcers when compared with the general population. They proposed that it was the complications of diabetes that were of importance and their impact on three areas including sensory perception (neuropathy), perfusion and abnormal anatomy and tissue property changes. After careful consideration of the evidence and to be consistent with the other risk factors that were affected by diabetes (i.e. perfusion and skin/Pressure Ulcer status) the working group concluded that sensory perception should be allocated to amber.

Instructions regarding the colour coding were integrated throughout the Risk Assessment Framework to support decision making. The design of the Risk Assessment Framework was led by the researcher (SC) and involved frequent liaison with the graphic designer to ensure all the agreed elements were addressed. The drafted Risk Assessment Framework was then pre-tested with clinical nurses.

6.3 Pre-test Study Aims

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 risk factor Minimum Data Set) with clinical nurses. While content validity was a key consideration of the consensus study (Chapter 4), the pre-test would confirm this with intended end users.

6.4 Methods

Cognitive pre-testing methods were used to evaluate how clinical nurses interpreted questions, response categories and instructions while using the draft Risk Assessment Framework (Collins 2003). This methodology is well established in the development of health status and patient reported outcome measures and is considered important for improving precision, confirming content validity and ensuring the instrument is understood and relevant to the target population (SAC 2002; FDA DHHS 2009; Rothman *et al.* 2009; Gorecki *et al.* 2012). The benefits of the approach were considered relevant to the development and eventual implementation of the Risk Assessment Framework.

The pre-test was conducted over three sessions and incorporated three focus groups and 12 'think out loud' interviews, which were estimated as the number required for data saturation. The study was conducted to allow analysis and adjustment to the Risk Assessment Framework to be undertaken between pre-test sessions so that three different versions of the decision tool could be pre-tested and improvements made in an iterative process.

6.4.1 Focus Groups

A focus group is a group interview which incorporates group interaction as part of the method and is useful in exploring peoples, knowledge, attitudes and experience (Kitzinger 1995). The method allows the facilitator to explore 'structured' and 'free' inquiries (Krueger 1994). It was anticipated that for this PhD study, focus groups

with clinical nurses would facilitate greater understanding of the usability of the Risk Assessment Framework, and would benefit from the proposed advantages of the method, allowing group members to “spark ideas off one another” which may lead to greater disclosure (McCull 2005).

6.4.2 Think Out Loud interviews

In addition to the focus groups, one-to-one think out loud interviews (Willis 2005) were undertaken to allow the researcher (SC) to identify specific problems with the Risk Assessment Framework that were amenable to resolution by modification. This method encourages participants to vocalise their thoughts or ‘think out loud’ while they are concurrently undertaking a task (Ericcson and Simon 1980). The interviewer may also probe the participant concurrently or retrospectively following completions of the task (Ericcson and Simon 1980). Willis ascertains that flexibility in the approach of cognitive interviewing is a beneficial feature and practitioners often mix these techniques into the same interview (Willis 2005). For this study, while participants were instructed to ‘think out loud’, verbal probing was also undertaken with less naturally vocal participants. Potential scripted probes were prepared in advance, but interviewers were also at liberty to use sponstaneous probes as relevant to the particular interview.

6.4.3 Participants

Nurses were recruited from a large acute Teaching Hopsital 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).

6.5 Ethics

This study recruited Registered Nurses and the related ethical issues were minimal, mainly relating to the time taken to attend the Risk Assessment Framework pre-test session (incorporating training and audio-taped focus groups or one-to-one think out loud interviews). There were no other forsean risks to participants. The study was approved (Appendix 11) by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC). Potential participants were given an information sheet (Appendix 12) and encouraged to ask questions about the study. Informed consent was obtained prior to participation in the study (Appendix 13). The right of potential participants to refuse without giving reasons was respected. Participants were also

free to withdraw at any time from the study without giving reasons, though this did not happen.

6.6 Data collection

The three facilitated pre-test sessions were led by the researcher (SC) with the support of several working group members (LW, EMc and DM). Each pre-test session involved 8-12 nurses from the four participating sites, who were grouped according to their job role (staff nurse, sister/charge nurse and tissue viability nurse specialist/research nurse) to facilitate openness, as heterogeneous groups can lead to inhibition in raising issues that do not seem to be shared by others (Morgan and Krueger 1993; McColl 2005). 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 (McColl 2005). The sessions were held away from the clinical area in a comfortable university setting, lasted 2.5 hours in total with refreshments available throughout and a break in the middle of the session (Kitzinger 1995). At the pre-test session, the nurses were trained in how to use the Risk Assessment Framework and then were randomly allocated to either a focus group or a one-to-one think out loud interview (Agenda, Appendix 14).

Training involved the researcher (SC) giving a short presentation and demonstration of how to use the draft Risk Assessment Framework with a simulated patient. Each nurse then completed the draft Risk Assessment Framework using a simulation of a real patient situation via written vignette case studies (Appendix 15). These were accompanied by photographs of pressure ulcers and 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 working group (clinical and academic leaders in the pressure ulcer field) and members of PURSUN UK to ensure they were realistic and clinically relevant. Nurses were encouraged to ask questions throughout the training session.

The sessions were planned to ensure four to eight nurses (Kitzinger 1995) per pre-test were assigned to the focus group and asked to complete the Risk Assessment Framework again, using three vignette case studies relevant to their area of practice prior to the focus group meeting. Nurse participants were encouraged to highlight any areas they found confusing on the Risk Assessment Framework form.

A co-facilitator assessed data completeness and listed areas where data items were not completed or 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 facilitated by (SC) and co-facilitated by (LW), and was audio recorded. The facilitator promoted group interaction and guided discussions around a topic guide (Appendix 16), which considered the usability and areas of confusion regarding the use of the Risk Assessment Framework, as well as any anticipated problems with using it in clinical practice. 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 interview. The researcher (EMc or DM) conducted the interviews around a topic guide (Appendix 17). Firstly the nurse participants were guided through the think out loud technique. Once the nurses were content with the approach, they were asked to complete the Risk Assessment Framework again using three vignette case studies appropriate to their area of practice in the presence of the researcher. 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 Framework to be identified. The interviews were audio-recorded.

6.7 Analysis

The acceptability, data completeness and usability of the Risk Assessment Framework forms were assessed using both quantitative and qualitative methods. The quantitative methods are summarised in Table 6.2.

Table 6.2 Summary of Quantitative Analysis

Test property	Definition/test	Criteria
Acceptability/ Data completeness	- The extent to which the RAF items are completed and used to allocate a risk category; quality of data is assessed by data completeness for each element of the RAF and a risk category.	-% item level data missing -% of risk categories allocated -% of items missing where a risk category has been allocated
Usability	Compliance with decision rules of the RAF	-% compliance Step 1 -% compliance progression to Step 2 - % compliance risk allocation Content analysis of think out loud interviews and focus groups

RAF: Risk Assessment Framework

From a qualitative perspective the focus group meetings and the think out loud interviews were audio-taped and transcribed. The researcher (SC) listened to the audio-tapes and read the transcripts to ensure accuracy and that they had a good overview of the focus group and one-to-one think out loud discussions. The data was then coded, which was directed by the risk factor items of Risk Assessment Framework, using a directed content-analysis approach (Hsieh and Shannon 2005). The emphasis was on identifying themes across the focus groups and think out loud interviews which 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 it reflected discussions. The report was considered by a working group (who comprised 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.

6.8 Results

The pre-test sessions were well attended by 34 nurses from acute (n=16) and community settings (n=18). Over the three pre-test sessions, 101 Risk Assessment Framework assessments were undertaken using vignette case studies by 11 tissue viability nurse/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. Tables 6.3-6.6 detail 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.

Table 6.3 Item level completion for assessments that concluded at step 1 (screening)

	Pre-test 1: N items requiring completion p/a	Pre-test 1: (TVN/RNs) Items completed	Pre-test 2: N items requiring completion p/a	Pre-test 2: (Staff Nurse) Items completed	Pre-test 2: N items requiring completion p/a	Pre-test 3: (Sisters) Items completed
Mobility	4	100% (24/24)	At least 1 of 4	100% (10/10)	At least 1 of 4	100% (8/8)
Skin/ Pressure Ulcer status	2	66.7% (8/12)	At least 1 of 4	90% (9/10)	At least 1 of 4	100% (8/8)
Decision pathway allocated	1	0% (0/6)	1	100% (10/10)	1	87.5% (7/8)
Total Item completion	-	76.2% (32/42)	-	96.7% (29/30)	-	95.8% (23/24)
Total Item completion where decision pathway allocated	-	0%	-	96.7% (29/30)	-	100% (21/21)

N number; p/a per assessment; TVN tissue viability nurse; RN research nurse; PU pressure ulcer

Table 6.4 Item level completion for assessments that included step 1(screening) and 2(full assessment)

	Pre-test 1: N items requiring completion p/a	Pre-test 1: (TVN/RNs) Items completed	Pre-test 2: N items requiring completion p/a	Pre-test 2: (Staff Nurse) Items completed	Pre-test 2: N items requiring completion p/a	Pre-test 3: (Sisters) Items completed
Mobility (1 st stage)	4	93.3% (97/104)	At least 1 of 4	96.2% (25/26)	At least 1 of 4	100% (25/25)
Skin/ Pressure Ulcer status (1 st stage)	2	98.1% (51/52)	AA	100% (3/3)	AA	100% (1/1)
Movement Matrix	1	100% (26/26)	1	100% (26/26)	1	96% (24/25)
Sensory Perception	1	96.2% (25/26)	1 of 2	100% (26/26)	1 of 2	100% (25/25)
Current DSA - listed sites	15	71.5% (279/390)	13	75.4% (255/338)	13	97.2% (316/325)
Current DSA – other sites	AA	0% (0/0)	AA	50.0% (1/2)	AA	0% (0/0)
Current PU	AA	84.2% (16/19)	AA	83.3% (20/24)	AA	80.0% (20/25)
Previous PU history	AA	75% (9/12)	AA	77.8% (7/9)	1 of 2 (if yes 3, AA)	85.3% (29/34)
Scarring	2	55.8% (29/52)	AA	100% (1/1)	AA	100% (1/1)
Perfusion	2	92.3% (48/52)	At least 1 of 3	73.1% (19/26)	At least 1 of 3	100% (25/25)
Nutrition	4	76.9% (80/104)	At least 1 of 5	100% (26/26)	At least 1 of 5	100% (25/25)
Moisture	1 (if yes 2 as applicable)	74.1% (40/54)	1 of 3	84.6% (22/26)	1 of 3	100% (25/25)
Diabetes	1	100% (26/26)	As applicable	100% (5/5)	1 of 2	100% (25/25)
Decision pathway allocated	1 of 3	53.8% (14/26)	1 of 3	96.2% (25/26)	1 of 3	100% (25/25)
Total Item completion	-	78.5% (740/943)	-	81.7% (461/564)	-	96.6% (566/586)
Total Item completion where decision pathway allocated	-	83.7% (417/498)	-	83.7% (452/540)	-	96.6% (566/586)

N number; p/a per assessment; AA as applicable; DSA detailed skin assessment; TVN tissue viability nurse; RN research nurse; PU pressure ulcer

Table 6.5 Overall total Item completion for assessments

	Pre-test 1: (TVN/RNs) Items completed	Pre-test 2: (Staff Nurse) Items completed	Pre-test 3: (Sisters) Items completed
Total item completion for assessments concluding at step1	76.2% (32/42)	96.7% (29/30)	95.8% (23/24)
Total item completion for assessments including step 1 and 2	78.5% (740/943)	81.7% (461/564)	96.6% (566/586)
Overall total item completion	78.4% (772/985)	82.5% (490/594)	96.6% (589/610)

TVN tissue viability nurse; RN research nurse

Table 6.6 Overall total Item completion for assessments with decision pathway allocated

	Pre-test 1: (TVN/RNs) Items completed	Pre-test 2: (Staff Nurse) Items completed	Pre-test 3: (Sisters) Items completed
Total item completion for assessments concluding at step1 where decision pathway allocated	0%	96.7% (29/30)	100% (21/21)
Total item completion for assessments including step 1 and 2 where decision pathway allocated	83.7% (417/498)	83.7% (452/540)	96.6% (566/586)
Overall total Item completion where decision pathway allocated	83.7% (417/498)	84.4% (481/570)	96.7% (587/607)

TVN tissue viability nurse; RN research nurse

Figure 6.1 illustrates how the levels of missing data decreased over the 3 pre-test sessions overall and where a decision pathway was allocated.



Figure 6.1 Percentage of missing data at each pre-test session

Figure 6.2 illustrates how the number of decision pathways allocated increased notably from the first to the second pre-test.

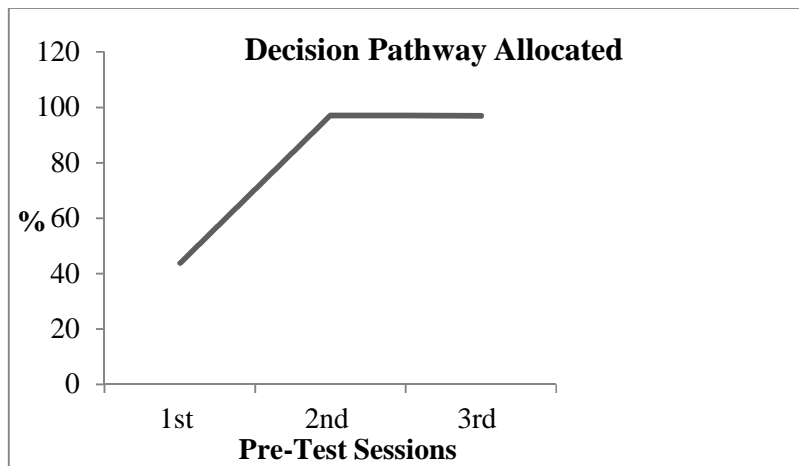


Figure 6.2 Percentage decision pathway allocated at each pre-test session

Table 6.7 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. An inappropriate decision pathway was allocated

in the first pre-test when an assessment detailed the presence of an ulcer indicating that it should have been allocated to the 'pressure ulcer Category 1 or above or scarring' pathway but was allocated to the 'at risk' pathway (see Table 6.7). 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, hence there was the possibility that a higher pathway was appropriate.

Table 6.7 Appropriate decision pathway allocation

	Pre-Test Session 1 (TVN/RNs)	Pre-Test Session 2 (Staff Nurse)	Pre-Test Session 3 (Sisters)
Appropriate pathway allocation	78.6 % (11/14)	91.4% (32/35)	90.6% (29/32)
Inappropriate pathway allocation	7.1% (1/14)		
Pathway allocated but some uncertainty of appropriateness due to missing data items	14.3% (2/14)	8.6% (3/35)	9.4% (3/32)

TVN Tissue Viability Nurse; RN research nurse

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 (Figure 6.3) and relate to three main areas, including flow and format, decision support, and wording of specific items. The changes to these main areas can be seen in the successive versions of the Risk Assessment Framework used at the pre-test sessions (Figure 6.4-6.6) for example at step 1 of the assessment. It should be acknowledged that following the step 1 changes, some nurses still completed the skin/ulcer items despite not needing to. This could be related to the use of vignette case studies in the pre-test sessions where information regarding skin/ulcer status was readily available, while in clinical practice this information may be less obvious.

Other notable changes made over the course of the pre-test sessions (Figure 6.4-6.6) related to the move from landscape to portrait orientation to improve the flow of the Framework and the development of specific items (e.g. the terminology relating to 'bedfast' and 'chairfast' of the step 1 mobility items were 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, where a positive response indicated 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.

Participants of 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 of other significant risk factors (which may be exceptions to the rule) that they should take into account when considering if the 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 other medical conditions might have on the skin, rather than the presence or absence of many different conditions.

The data completeness assessment (Table 6.3-6.6 and Figure 6.1) showed poor decision pathway allocation in the first pre-test. The corresponding focus group discussions highlighted confusion about where to indicate pathway allocation. Some nurses had attempted to indicate a pathway on the form though they were clearly unsure of where to do this. This brought to light 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. This related to the first pathway (left) being the blue 'not currently at risk pathway' the second (middle) being the amber primary prevention pathway and the third (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 amber', the boxes should be re-ordered so that the red one was first and this was undertaken for the second pre-test (Figure 6.5 and Figure 6.6).

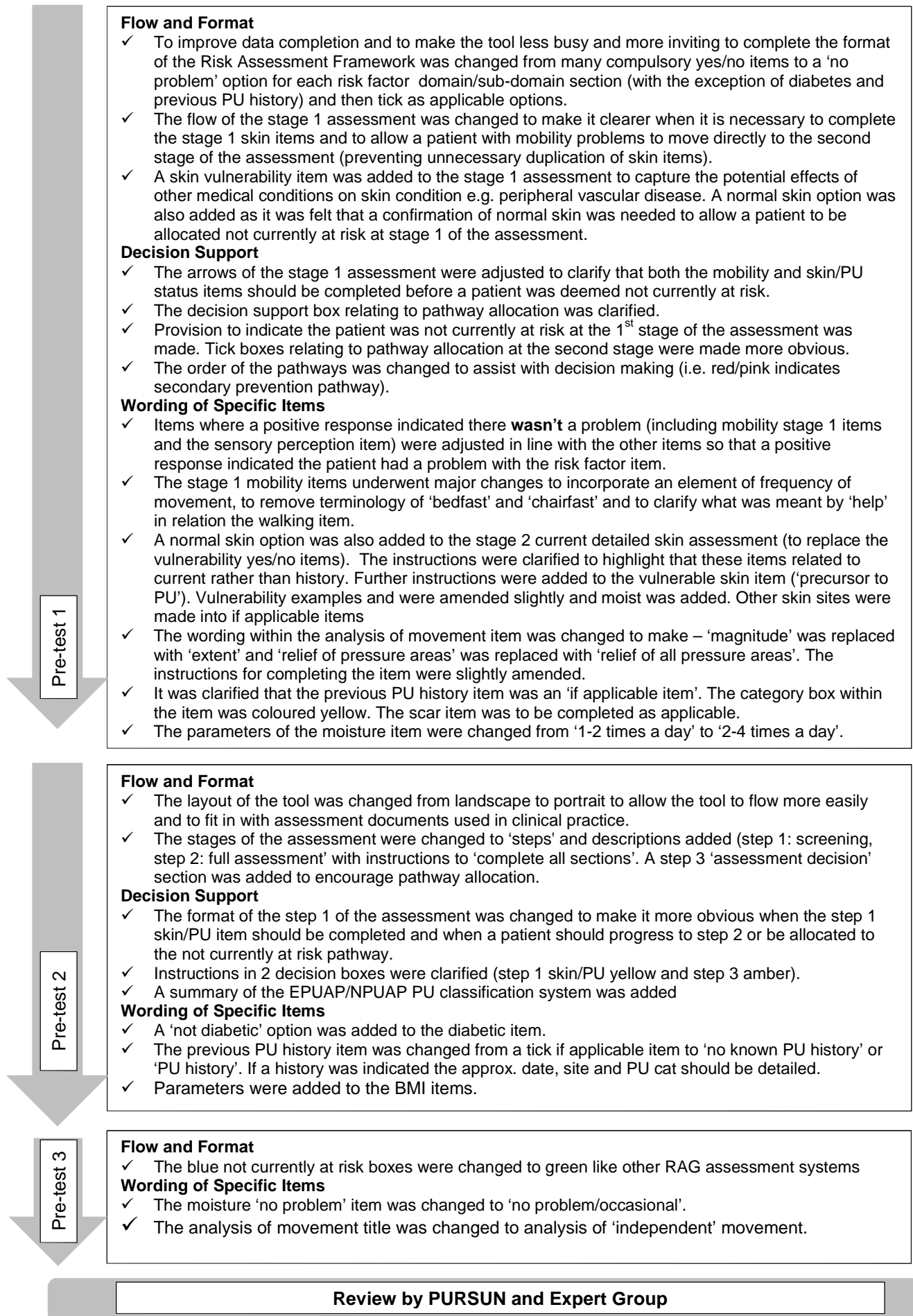


Figure 6.3 Changes to Risk Assessment Framework following each pre-test sessions

Stage 1

Mobility status	A	B
Is the patient bedfast?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is the patient chairfast?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does the patient walk without help?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
Does the patient change position?	No <input type="checkbox"/>	Yes <input type="checkbox"/>

If all answers are in column B then the patient is not currently at risk

- Advise patient of PU risk factors
- Re-assess if patients condition changes and at locally specified times
- Re-assess if you anticipate increased risk due to:
 - surgery (during surgery and post-operatively)
 - investigations e.g. x-ray
 - treatments e.g. epidurals or sedation
 - other reasons

If any answers are in column A then the patient may be at risk. Proceed to stage 2.

Stage 2

Complete ALL sections

Analysis of movement

Tick the applicable category. Where the two axes meet indicates risk.

Frequency of position changes	Doesn't move	Magnitude of independent movement Relief of pressure areas		
		Doesn't move	Slight position changes	Major position changes
Doesn't move	At risk <input type="checkbox"/>	N/A	N/A	
Moves occasionally	N/A	At risk <input type="checkbox"/>	At risk <input type="checkbox"/>	
Moves frequently	N/A	At risk <input type="checkbox"/>	Potentially at risk <input type="checkbox"/>	

Sensory perception

Does the patient feel and respond appropriately to discomfort from pressure? Y N

Detailed Skin Assessment

Skin site	Vulnerable skin Redness, dryness, paper thin		PU category N/PUA/E/PUAP
	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Sacrum	Y <input type="checkbox"/>	N <input type="checkbox"/>	
L Buttock	Y <input type="checkbox"/>	N <input type="checkbox"/>	
R Buttock	Y <input type="checkbox"/>	N <input type="checkbox"/>	
L Ischial	Y <input type="checkbox"/>	N <input type="checkbox"/>	
R Ischial	Y <input type="checkbox"/>	N <input type="checkbox"/>	
L Hip	Y <input type="checkbox"/>	N <input type="checkbox"/>	

Skin site	Vulnerable skin Redness, dryness, paper thin		PU category N/PUA/E/PUAP
	Y <input type="checkbox"/>	N <input type="checkbox"/>	
R Hip	Y <input type="checkbox"/>	N <input type="checkbox"/>	
L Heel	Y <input type="checkbox"/>	N <input type="checkbox"/>	
R Heel	Y <input type="checkbox"/>	N <input type="checkbox"/>	
L Ankle	Y <input type="checkbox"/>	N <input type="checkbox"/>	
R Ankle	Y <input type="checkbox"/>	N <input type="checkbox"/>	
L Elbow	Y <input type="checkbox"/>	N <input type="checkbox"/>	

Skin site	Vulnerable skin Redness, dryness, paper thin		PU category N/PUA/E/PUAP
	Y <input type="checkbox"/>	N <input type="checkbox"/>	
R Elbow	Y <input type="checkbox"/>	N <input type="checkbox"/>	
Other	Y <input type="checkbox"/>	N <input type="checkbox"/>	

Specify: _____

Other: Y N

Specify: _____

PU history

Site:	PU cat N/PUA/E/PUAP	Scarring	
		Y <input type="checkbox"/>	N <input type="checkbox"/>
Site:		Y <input type="checkbox"/>	N <input type="checkbox"/>
Site:		Y <input type="checkbox"/>	N <input type="checkbox"/>

Perfusion

Conditions affecting central circulation eg. shock, heart failure, hypotension	Y <input type="checkbox"/>	N <input type="checkbox"/>
Conditions affecting peripheral circulation eg. peripheral vascular/arterial disease	Y <input type="checkbox"/>	N <input type="checkbox"/>

Nutrition

Unplanned weight loss	Y <input type="checkbox"/>	N <input type="checkbox"/>
Poor nutritional intake	Y <input type="checkbox"/>	N <input type="checkbox"/>
Low BMI	Y <input type="checkbox"/>	N <input type="checkbox"/>
High BMI	Y <input type="checkbox"/>	N <input type="checkbox"/>

Diabetes

Is the patient diabetic? Y N

Moisture

Moisture due to perspiration, urine, faeces or exudate Y N

If Yes please give the frequency below

Frequent (1 - 2 times a day)	Y <input type="checkbox"/>	N <input type="checkbox"/>
Constant	Y <input type="checkbox"/>	N <input type="checkbox"/>

If ALL yellow boxes are ticked, the nurse must consider the risk profile (risk factors present) to decide whether the patient is at risk or not currently at risk.

If ANY orange boxes are ticked, the patient is at risk.

If ANY pink boxes are ticked/completed, the patient has an existing pressure ulcer or pressure ulcer scarring.

Tick as appropriate (one only)

No pressure ulcer not currently at risk	No pressure ulcer but at risk	PU Category 1 or more Scarring
--	--------------------------------------	---------------------------------------

No pressure ulcer not currently at risk

- Advise patient of PU risk factors
- Re-assess if patients condition changes and at locally specified times
- Re-assess if you anticipate increased risk due to:
 - surgery (during surgery and post-operatively)
 - investigations e.g. x-ray
 - treatments e.g. epidurals or sedation
 - other reasons

No pressure ulcer but at risk

Primary Prevention Interventions

- Communication of 'primary prevention' pathway risk profile and interventions with patient and carers
- Support surface allocation (beds, mattress and seating) considering promotion of mobility and minimisation of friction and shear
- Skin evaluation
- Repositioning schedule
- Patient Specific elements of care e.g. nutrition and moisture

PU Category 1 or more Scarring

Secondary Prevention and Treatment Interventions

- Communication of 'secondary prevention/treatment' pathway, risk profile and interventions in MDT and with patient and carers
- Support surface allocation (beds, mattress and seating) considering promotion of mobility and minimisation of friction and shear
- Skin evaluation
- Repositioning schedule and pressure relief of affected PU site
- Pain assessment and interventions
- PU woundcare
- Patient Specific elements of care e.g. nutrition and moisture
- Consider referral to specialist TVN team

Figure 6.4 Pre-Test 1 Risk Assessment Framework (Draft)

Copyright © Clinical Trials Research Unit, University of Leeds and Leeds Teaching Hospitals Trust, 2013 (do not use without permission) Colour Key: Blue: - 'no problem'; Yellow- risk factor present which may impact upon pressure ulcer risk; Amber- risk factor present which puts the patient at risk; Pink- patient has a pressure ulcer or scar from previous pressure ulcer

Stage 1

Mobility status - tick all applicable

Walks independently with or without walking aids	<input type="checkbox"/>
Needs the help of another person to walk	<input type="checkbox"/>
Spends all or the majority of time in bed or chair	<input type="checkbox"/>
Remains in the same position for long periods	<input type="checkbox"/>

Skincare status - tick as applicable

Normal skin	<input type="checkbox"/>
Current PU category 1 or more?	<input type="checkbox"/>
Reported history of previous PU?	<input type="checkbox"/>
Vulnerable skin e.g. redness, dryness, paper thin, moist	<input type="checkbox"/>

Perfusion - tick as applicable

No problem	<input type="checkbox"/>
Conditions affecting central circulation eg. shock, heart failure, hypotension	<input type="checkbox"/>
Conditions affecting peripheral circulation eg. peripheral vascular/arterial disease	<input type="checkbox"/>

Diabetes - tick if applicable

Diabetic	<input type="checkbox"/>
----------	--------------------------

Nutrition - tick as applicable

No problem	<input type="checkbox"/>
Unplanned weight loss	<input type="checkbox"/>
Poor nutritional intake	<input type="checkbox"/>
Low BMI	<input type="checkbox"/>
High BMI	<input type="checkbox"/>

Moisture due to perspiration, urine, faeces or exudate - tick as applicable

No problem	<input type="checkbox"/>
Frequent (2-4 times a day)	<input type="checkbox"/>
Constant	<input type="checkbox"/>

Previous PU history - tick if applicable and complete below

Approx date	Site	PU cat NPUAP/EPUAP	Scar (if applicable)
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>

Analysis of movement

Tick the applicable box (where frequency and extent categories meet)		Extent of independent movement Relief of all pressure areas		
		Doesn't move	Slight position changes	Major position changes
Frequency of position changes	Doesn't move	<input type="checkbox"/>	N/A	N/A
	Moves occasionally	N/A	<input type="checkbox"/>	<input type="checkbox"/>
	Moves frequently	N/A	<input type="checkbox"/>	<input type="checkbox"/>

Sensory perception - tick as applicable

No problem	<input type="checkbox"/>
Conditions affecting the patients ability to feel and respond appropriately to discomfort from pressure.	<input type="checkbox"/>

Current Detailed Skin Assessment - tick applicable column for each skin site. Where there is a current PU, record the category.

Skin site	Normal skin			Vulnerable skin (precursor to PU eg. red, dry, moist, paper thin)			PU category (NPUAP/EPUAP)		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - detail below if applicable									

Stage 2

Consider ALL sections

PU Category 1 or more or scarring from previous pressure ulcers

No pressure ulcer but at risk

No pressure ulcer not currently at risk

Perfusion - tick as applicable

No problem	<input type="checkbox"/>
Conditions affecting central circulation eg. shock, heart failure, hypotension	<input type="checkbox"/>
Conditions affecting peripheral circulation eg. peripheral vascular/arterial disease	<input type="checkbox"/>

Diabetes - tick if applicable

Diabetic	<input type="checkbox"/>
----------	--------------------------

Nutrition - tick as applicable

No problem	<input type="checkbox"/>
Unplanned weight loss	<input type="checkbox"/>
Poor nutritional intake	<input type="checkbox"/>
Low BMI	<input type="checkbox"/>
High BMI	<input type="checkbox"/>

Moisture due to perspiration, urine, faeces or exudate - tick as applicable

No problem	<input type="checkbox"/>
Frequent (2-4 times a day)	<input type="checkbox"/>
Constant	<input type="checkbox"/>

Previous PU history - tick if applicable and complete below

Approx date	Site	PU cat NPUAP/EPUAP	Scar (if applicable)
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>

Analysis of movement

Tick the applicable box (where frequency and extent categories meet)		Extent of independent movement Relief of all pressure areas		
		Doesn't move	Slight position changes	Major position changes
Frequency of position changes	Doesn't move	<input type="checkbox"/>	N/A	N/A
	Moves occasionally	N/A	<input type="checkbox"/>	<input type="checkbox"/>
	Moves frequently	N/A	<input type="checkbox"/>	<input type="checkbox"/>

Sensory perception - tick as applicable

No problem	<input type="checkbox"/>
Conditions affecting the patients ability to feel and respond appropriately to discomfort from pressure.	<input type="checkbox"/>

Current Detailed Skin Assessment - tick applicable column for each skin site. Where there is a current PU, record the category.

Skin site	Normal skin			Vulnerable skin (precursor to PU eg. red, dry, moist, paper thin)			PU category (NPUAP/EPUAP)		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - detail below if applicable									

Decision Logic:

- If ANY pink boxes are ticked/completed, the patient has an existing pressure ulcer or scarring from previous pressure ulcer.
- If ANY orange boxes are ticked, the patient is at risk.
- If only yellow and blue boxes are ticked, the nurse must consider the risk profile (risk factors present) to decide whether the patient is at risk or not currently at risk.

Outcomes:

- PU Category 1 or more or scarring from previous pressure ulcers:** Secondary prevention and treatment pathway.
- No pressure ulcer but at risk:** Primary prevention pathway.
- No pressure ulcer not currently at risk:** Not currently at risk pathway.

Figure 6.5 Pre-Test 2 Risk Assessment Framework (Draft)

Copyright © Clinical Trials Research Unit, University of Leeds and Leeds Teaching Hospitals Trust, 2013 (do not use without permission) Colour Key: Blue: - 'no problem'; Yellow- risk factor present which may impact upon pressure ulcer risk; Amber- risk factor present which puts the patient at risk; Pink- patient has a pressure ulcer or scar from previous pressure ulcer

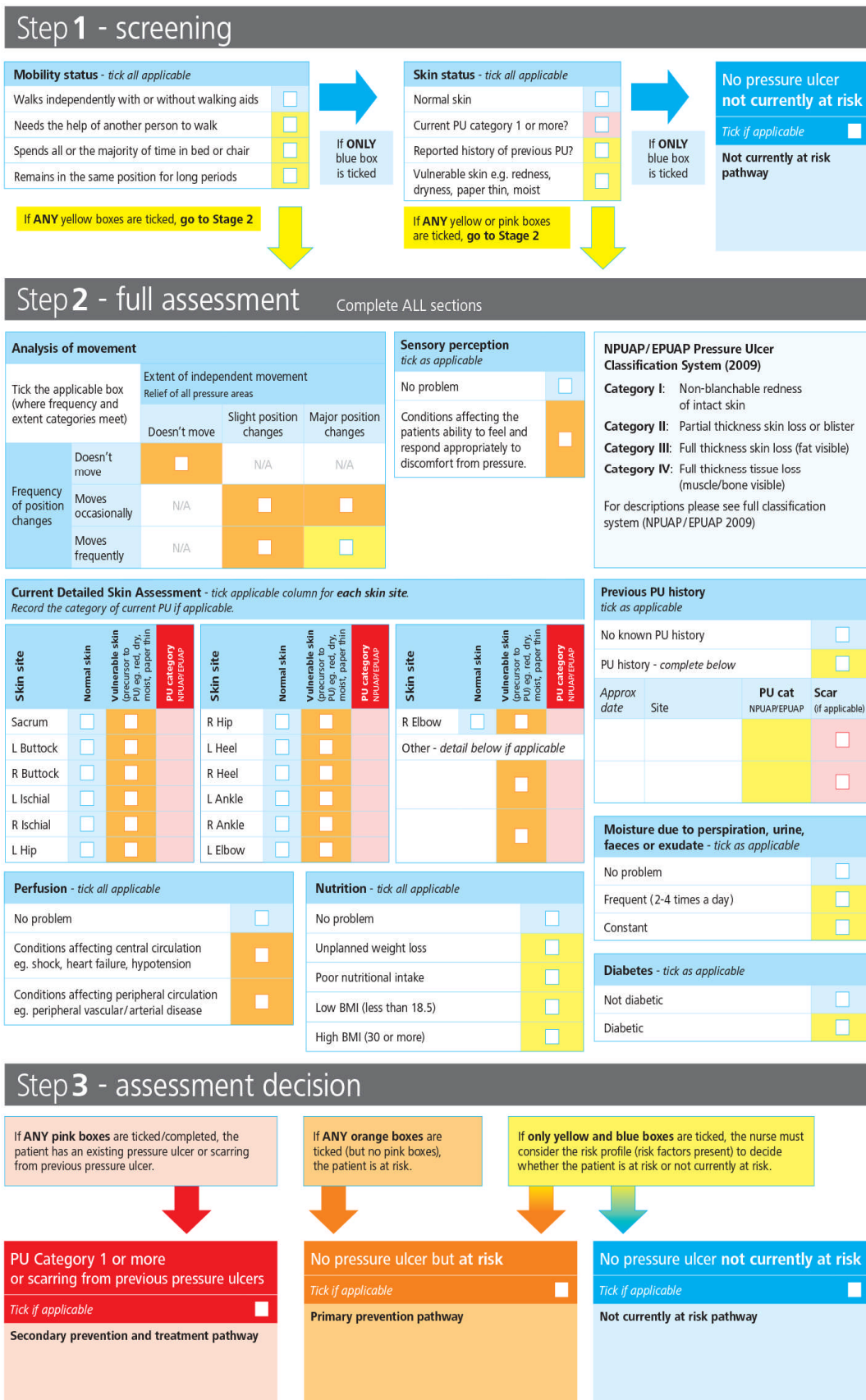


Figure 6.6 Pre-Test 3 Risk Assessment Framework (Draft)

Copyright © Clinical Trials Research Unit, University of Leeds and Leeds Teaching Hospitals Trust, 2013 (do not use without permission). Colour Key: Blue: - 'no problem'; Yellow- risk factor present which may impact upon pressure ulcer risk; Amber- risk factor present which puts the patient at risk; Pink- patient has a pressure ulcer or scar from previous pressure ulcer

6.9 Review by PURSUN and Expert Group

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. While PURSUN felt that the Risk Assessment Framework was clear and understandable, they raised concern about the wording of the sensory perception item relating to the 'ability to feel and respond' aspect of the item. The group agreed that the patient might only be able to fulfil one of these requirements which should be considered a problem, but the wording suggested that it would only be a problem 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 re-considered at the subsequent expert group meeting and amendments being made. Preliminary Risk Assessment Framework

6.10 Preliminary Risk Assessment Framework

The pre-test facilitated the development of the preliminary Risk Assessment Framework (Figure 6.7) which incorporates 9 risk factors (mobility, existing pressure ulcer, previous pressure ulcer, vulnerable skin, sensory perception, perfusion, diabetes, nutrition and moisture) and related assessment items. It also informed the development of a user guide (Appendix 18) which provides information on how to use the Risk Assessment Framework and how to interpret the included assessment items. At Step 1 of the Risk Assessment Framework there are four mobility options with 'tick all applicable' instructions. If only the blue coded criteria '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 (Figure 6.7).

The Step 1 Skin status also has 4 options with 'tick all applicable' instructions. If only the blue coded 'normal skin' is ticked the instructions are to allocate the patient to the Green assessment decision - 'No pressure ulcer not currently at risk' pathway. If any other skin status criteria are ticked (coded yellow and pink), the instructions are to progress to Step 2 full assessment (Figure 6.7).

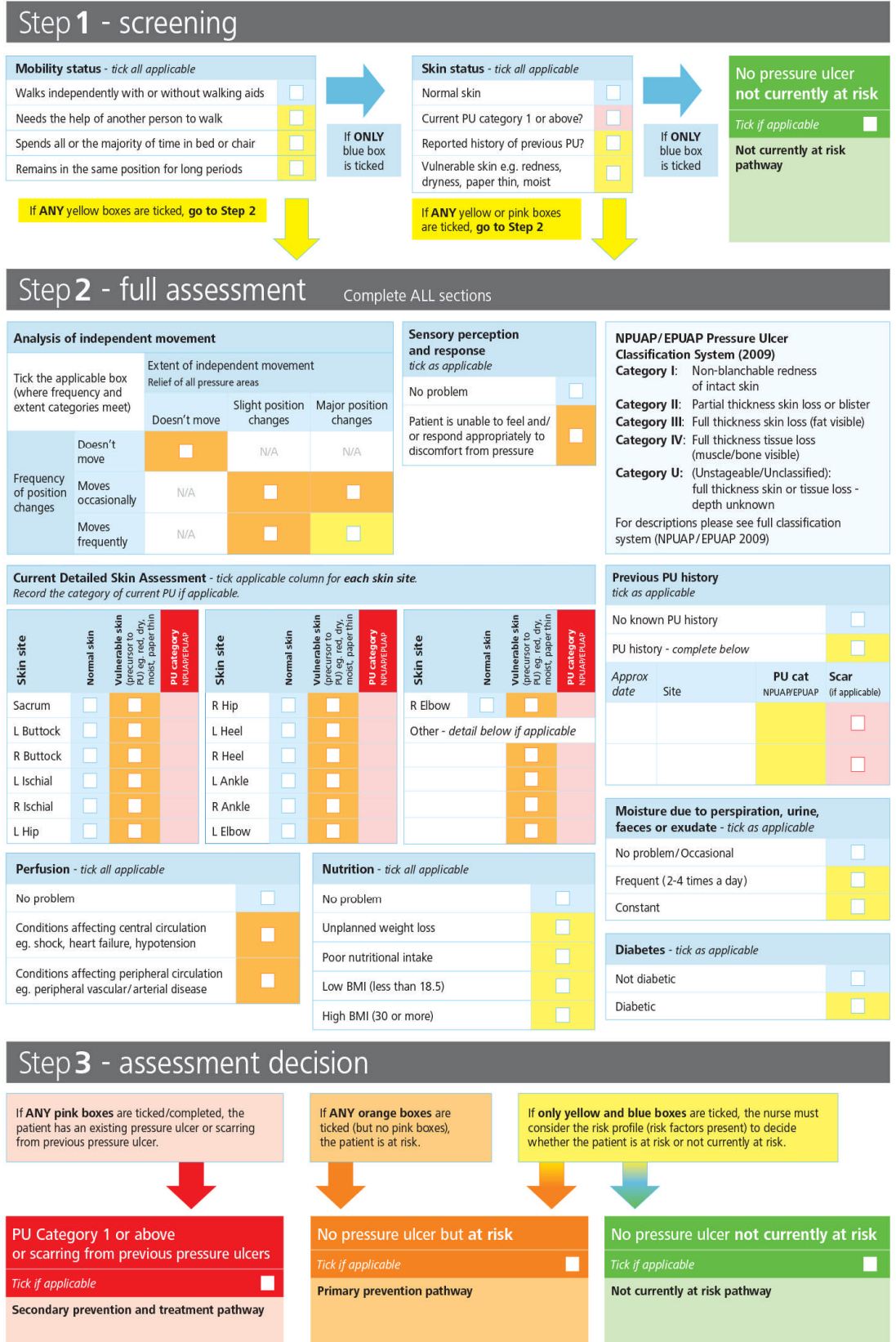
Step 2 includes assessment of the following:

- Analysis of independent movement: five options, including four coded amber (with varying limitations to frequency and extent of independent movement) and one coded yellow (making major position changes frequently).
- Detailed skin assessment for 13 skin sites (with the option for 'other' skin sites): with three options for each including: 'normal skin' coded blue; 'vulnerable skin' coded amber and; pressure ulcer category (1) coded pink.
- Previous 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 pink
- Sensory perception: two options, including: 'no problem' coded blue and; 'patient is unable to feel and/or respond to discomfort from pressure' coded amber.
- Perfusion: three options including 'no problem' coded blue and two options coded amber including: 'conditions affecting central circulation e.g. shock, heart failure, hypotension' and; 'conditions affecting peripheral circulation e.g. peripheral vascular/arterial disease'.
- Nutrition: five options including: 'no problem' coded blue and four options coded yellow including: '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 and incorporates support for decision making as outlined in Table 6.8.

Table 6.8 Step 3 Assessment decision instructions

Colour code	Assessment	Assessment decision
Any Pink	Pressure ulcer of Category 1 or above or scarring from previous pressure ulcer	RED: Secondary prevention and treatment pathway
Any Amber (but no pink)	No pressure ulcer but at risk	AMBER Primary prevention pathway
Only Yellow and blue	Nurse to consider risk factors present and decide	AMBER Primary prevention pathway OR GREEN Not currently at risk pathway



Analysis of independent movement

Tick the applicable box (where frequency and extent categories meet)		Extent of independent movement Relief of all pressure areas		
		Doesn't move	Slight position changes	Major position changes
Frequency of position changes	Doesn't move	<input type="checkbox"/>	N/A	N/A
	Moves occasionally	N/A	<input type="checkbox"/>	<input type="checkbox"/>
	Moves frequently	N/A	<input type="checkbox"/>	<input type="checkbox"/>

Sensory perception and response - tick as applicable

No problem	<input type="checkbox"/>
Patient is unable to feel and/or respond appropriately to discomfort from pressure	<input type="checkbox"/>

NPUAP/EPUAP Pressure Ulcer Classification System (2009)

Category I: Non-blanchable redness of intact skin

Category II: Partial thickness skin loss or blister

Category III: Full thickness skin loss (fat visible)

Category IV: Full thickness tissue loss (muscle/bone visible)

Category U: (Unstageable/Unclassified): full thickness skin or tissue loss - depth unknown

For descriptions please see full classification system (NPUAP/EPUAP 2009)

Current Detailed Skin Assessment - tick applicable column for each skin site. Record the category of current PU if applicable.

Skin site	Current PU Category			Skin site	Current PU Category			Skin site	Current PU Category		
	Normal skin	Vulnerable skin (precursor to PU) eg. red, dry, moist, paper thin	PU category NPUAP/EPUAP		Normal skin	Vulnerable skin (precursor to PU) eg. red, dry, moist, paper thin	PU category NPUAP/EPUAP		Normal skin	Vulnerable skin (precursor to PU) eg. red, dry, moist, paper thin	PU category NPUAP/EPUAP
Sacrum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other - detail below if applicable			
R Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
L Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
R Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
L Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

Previous PU history - tick as applicable

No known PU history	<input type="checkbox"/>
PU history - complete below	<input type="checkbox"/>

Approx date	Site	PU cat NPUAP/EPUAP	Scar (if applicable)
			<input type="checkbox"/>
			<input type="checkbox"/>

Perfusion - tick all applicable

No problem	<input type="checkbox"/>
Conditions affecting central circulation eg. shock, heart failure, hypotension	<input type="checkbox"/>
Conditions affecting peripheral circulation eg. peripheral vascular/arterial disease	<input type="checkbox"/>

Nutrition - tick all applicable

No problem	<input type="checkbox"/>
Unplanned weight loss	<input type="checkbox"/>
Poor nutritional intake	<input type="checkbox"/>
Low BMI (less than 18.5)	<input type="checkbox"/>
High BMI (30 or more)	<input type="checkbox"/>

Moisture due to perspiration, urine, faeces or exudate - tick as applicable

No problem/Occasional	<input type="checkbox"/>
Frequent (2-4 times a day)	<input type="checkbox"/>
Constant	<input type="checkbox"/>

Diabetes - tick as applicable

Not diabetic	<input type="checkbox"/>
Diabetic	<input type="checkbox"/>

If ANY pink boxes are ticked/completed, the patient has an existing pressure ulcer or scarring from previous pressure ulcer.

↓

If ANY orange boxes are ticked (but no pink boxes), the patient is at risk.

↓

If only yellow and blue boxes are ticked, the nurse must consider the risk profile (risk factors present) to decide whether the patient is at risk or not currently at risk.

↓

PU Category 1 or above or scarring from previous pressure ulcers

Tick if applicable

Secondary prevention and treatment pathway

No pressure ulcer but at risk

Tick if applicable

Primary prevention pathway

No pressure ulcer not currently at risk

Tick if applicable

Not currently at risk pathway

Figure 6.7 Preliminary Risk Assessment Framework for Clinical Evaluation

Copyright © Clinical trials Research Unit, University of Leeds and Leeds Teaching Hospitals Trust, 2013 (do not use without permission). Colour Key: Blue- 'no problem'; Yellow- risk factor present which may impact upon pressure ulcer risk; Amber- risk factor present which puts the patient at risk; Pink- patient has a pressure ulcer or scar from previous pressure ulcer

6.11 Discussion

Designing the Risk Assessment Framework was facilitated by the results of the consensus study and conducted in liaison with a graphic designer. Further consideration of the colour coding and weighting of risk factors was also necessary when designing the Framework. Decisions about risk factor weighting were facilitated by consideration of each of the developmental phases of this work. This was particularly important for risk factors with less robust evidence. Further statistical modelling work will be needed to assess whether the allocated weighting for each risk factor is appropriate and this may lead to amendments of the Risk Assessment Framework. The design process led to the first graphic designed draft of the Risk Assessment Framework and was subject to the pre-test study.

This is the first study to incorporate pre-testing as a key methodological component in the development of a pressure ulcer Risk Assessment Instrument, drawing on methodologies used in the development of other health measurement Instruments and patient reported outcome measures (SAC 2002; Streiner and Norman 2008; FDA DHHS 2009; Rothman *et al.* 2009; Gorecki *et al.* 2012). The approach worked well and was relevant to the development of the Risk Assessment Framework as it allowed areas of confusion to be identified and improvements to be made to enhance the usability and acceptability of the Risk Assessment Framework. It also allowed confirmation of content validity with clinical nurses, the intended end users of the Framework.

It could be argued that undertaking a pre-test using vignette case studies, is no substitute for assessing the Risk Assessment Framework in clinical practice. A limitation of the approach relates to it being an artificial situation and it is acknowledged that participants may have responded differently in a real life situation (Lanza 1990). However, the need to assess and improve the acceptability of the Risk Assessment Framework with clinical nurses was considered a robust and logical step to ensure content validity and usability, prior to evaluation in clinical practice with real patients. In addition, the vignettes were co-developed by the project lead, clinical and academic leaders in the pressure ulcer field and patients and carers (members of PURSUN UK) to ensure they were realistic, clinically relevant and to give an indication of external validity (Flaskerud 1979). The use of vignettes has been used previously by social scientists in various fields (Flaskerud 1979) and in dental, medical and nursing education (Littlefield *et al.* 2003; Dillon *et al.* 2004; Goodstone *et al.* 2013) and to establish the validity of pressure ulcer Risk Assessment Instruments (Gould *et al.* 2002; Gould *et al.* 2004). In keeping with

those who have used vignettes previously, the present PhD study, benefitted from the approach as it allowed exploration of participants knowledge, attitudes and how they might respond to a simulated event (Lanza 1990; Gould 1996).

The use of homogenous groups of nurses in similar roles, prevented hierarchical issues impeding group member involvement in the sessions and was felt to facilitate greater disclosure (Morgan and Krueger 1993; McColl 2005). The order of the pre-test sessions (in terms of the job role of the nurses involved) was carefully considered during the planning stages. This was to ensure usability issues were identified as quickly as possible, so that changes could be made to the draft Risk Assessment Framework and pre-tested in the subsequent session. The Tissue Viability Nurses pre-test session was conducted first as it was anticipated that as specialist nurses in the pressure ulcer field, they were best placed to identify any subject specific and key usability issues which could be addressed in subsequent versions. Additionally, the third and last pre-test session deliberately involved Sister/charge Nurses so that Risk Assessment Framework (incorporating changes that were made in response to pre-test 1 and 2) could be considered by senior nurses responsible for patient care. The chosen order (of the nurses job role) worked well as demonstrated by the decreasing number of changes made to the Risk Assessment Framework (Figure 6.3) which is also indicative that saturation had been reached. However, there remains ambiguity as to whether this related to the order of the nurses undertaking the pre-test or the general process i.e. similar results may have been obtained if a different order had been used.

The focus groups and think out loud interviews were undertaken in accordance with principles of good practice, held in a pleasant environment and were carefully planned to encourage disclosure amongst participants which would not have been possible in a busy clinical area. In addition, topic guides were used by trained facilitators, group numbers were congruent to facilitation and participants were fully briefed and had opportunities to ask questions prior to the actual interview/focus group. The use of both focus groups and think out loud interviews is unusual for evaluation purposes, but this is mainly due to differences in backgrounds and cultures of researchers which use the techniques (Willis 2005). The use of both techniques in the context of developing the Risk Assessment Framework was advantageous as while there was some overlap between the groups in terms of the nature of the issues raised (i.e. both groups identified issues relating to specific usability and wider application), they also worked in a complimentary manner. The think out loud interviews most consistently highlighted specific usability issues (e.g. relating to specific items) while the focus groups most consistently identified issues relating to the wider application/implementation of the Framework in clinical practice

(Willis 2005). This ensured that all aspects of usability were considered and led to key changes to the Framework related to three main areas including the flow and format, decision support, and the wording of specific items. This led to the development of the preliminary Risk Assessment Framework which requires further clinical evaluation to assess its reliability and validity.

6.12 Conclusion

The design of the Risk Assessment Framework was underpinned by the consensus study, consideration of the weighting of risk factor items and with the support of a graphic designer. This was then subject to pre-testing with clinical nurses to assess and improve its usability. The pre-test incorporated clinical nurses being trained in the use of the Risk Assessment Framework and participating in focus groups or think out loud interviews. The analysis facilitated changes to the Risk Assessment Framework relating to three main areas including the flow and format, decision support, and the wording of specific items. This is the first study to incorporate pre-testing with clinical nurses in the development of a Risk Assessment Instrument and allowed important usability issues to be identified and addressed and content validity to be confirmed leading to the development of a preliminary Risk Assessment Framework in readiness for clinical evaluation.

Chapter 7 General Discussion

7.1 Introduction

Due to the noted limitations of existing pressure ulcer Risk Assessment Instruments, the need for a transparent and consistent approach to assessment in clinical practice and increasing evidence relating to pressure ulcer risk factors, this PhD thesis aimed to describe the development of a new decision tool, the Risk Assessment Framework (with underpinning Pressure Ulcer Minimum Data Set) for use with adult populations. The overall methodological approach drew on research from other fields and comprised four distinct phases including a systematic review of pressure ulcer risk factors (Chapter 3), consensus study (Chapter 4), conceptual framework development (Chapter 5) and design and pre-testing (Chapter 6).

A detailed account of each phase of the PhD including research aims, methodological development, results and discussions are detailed in the previous chapters. Therefore this final chapter will summarise the key findings of this PhD and discuss the overall methodological approach, its limitations and highlight areas of methodological development and limitations. It will go on to discuss the implications of this PhD for clinical practice and research and plans for the ongoing validation of the Risk Assessment Framework.

7.2 Summary of Findings

7.2.1 Phase 1, Pressure Ulcer Risk Factor Systematic Review

The first study, the systematic review of pressure ulcer risk factors provided the foundation of this PhD. The review comprised 54 eligible studies and identified a large number of potential risk factors (15 domains, 46 sub-domains including over 250 named variables) and lack of comparable data fields for measurement of the same constructs and key risk factors not being routinely recorded in all studies (chapter 3). Due to these limitations meta-analysis was not possible and a narrative synthesis was undertaken. The review highlights the advantages of considering numerous studies (rather than single studies) to provide a more reliable approach to identifying risk factors which increases pressure ulcer probability.

The narrative synthesis of the review found that the most consistently emerging risk factor domains in multivariable analysis were immobility (mobility/activity) and perfusion (including diabetes). In addition skin/ pressure ulcer status particularly relating to stage/grade 1, emerged as a major risk variable. Other important but less consistently emerging risk factor domains included nutrition, moisture, age, haematological measures, general health status, sensory perception and mental status. A small number of studies suggest a relationship between body temperature and immunity and pressure ulcer development and these factors require further research. The evidence regarding race and gender was equivocal. While immobility assessment is included in existing pressure ulcer Risk Assessment Instruments, the inclusion of skin/Pressure Ulcer status and perfusion (including diabetes) is not universal.

The systematic review highlighted the need to re-consider which risk factors should be considered in pressure ulcer risk assessment, how these should be assessed and the overall assessment process. In addition, a key recommendation of the review was the development of a risk factor Minimum Data Set, to encourage the use of consistent risk factors across pressure ulcer studies, facilitating large scale multivariable analysis, meta-analysis and case mix adjustment (Berlowitz et al. 2001). It was also proposed that to enable routine recording in practice, the Minimum Data Set would be incorporated into the Risk Assessment Framework. The review provided the basis for the proposal of a new conceptual framework of pressure ulcer development 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.

7.2.2 Phase 2, Consensus Study

The consensus study used a modified nominal group technique based on the RAND/UCLA appropriateness method. This incorporated an international expert group, review of the pressure ulcer evidence including the systematic review (chapter 3) and wider scientific evidence and its relevance to clinical practice. The consensus study incorporated facilitated face-to face interaction of the expert group and the use of questionnaires before and after the meetings to quantify the level of support for the inclusion of risk factors and assessment items in the Minimum Data Set and Risk Assessment Framework. In addition the views of a PPI service user group (PURSUN) were sought, particularly relating to the acceptability of collecting risk factor and assessment items information on a routine basis. Their views were

incorporated into each cycle of the consensus process ensuring that service user views were considered when deciding the risk factors and assessment items to be included in the Risk Assessment Framework (incorporating the Minimum Data Set).

The consensus study facilitated the structured and transparent consideration of the initial 15 risk factor domains and 46 sub-domains of the systematic review (chapter 3). This led to the agreement that nine risk factors (immobility, existing pressure ulcer, previous pressure ulcer, general skin status, perfusion, sensory perception, nutrition, moisture and diabetes) and their assessment items should be included in the Risk Assessment Framework (incorporating the Minimum Data Set). This allowed an initial draft of the framework to be made.

7.2.3 Phase 3, Conceptual Framework

Building on the phase 2 consensus study further consideration was given to the proposal of the new pressure ulcer conceptual framework and theoretical causal pathway (Chapter 5). This incorporated consideration of physiological, biomechanical (Chapter 1, Section 1.9) and epidemiological evidence (Chapter 3) as well as the outcomes of the consensus study and the views of an expert panel. The theoretical causal pathway was developed with consideration of causal factor terminology (Brotman *et al.* 2005) and it was agreed that immobility, skin/pressure ulcer status and perfusion were direct causal factors (directly impacts the outcome, or the likelihood of the outcome); poor sensory perception and response, diabetes, moisture, poor nutrition and low albumin were key indirect factors (impacts the outcome, or affects its likelihood of occurrence by changing a direct causal factor); and older age, medication, pitting oedema, chronic wound, infection, increased temperature and acute illness were other potential indirect factors.

The development of the new conceptual framework was also enabled by consideration and enhancement of the NPUAP/ EPUAP (2009) conceptual framework, the theoretical causal pathway for pressure ulcer development and mapping of risk factors to the conceptual framework. The new proposed pressure ulcer conceptual framework incorporates key physiological and biomechanical components and their impact on internal strains, stresses and damage. The direct and key indirect factors suggested in a theoretical causal pathway are mapped to the physiological and biomechanical components of the framework. The new proposed conceptual framework provides the basis for understanding the critical determinants of pressure ulcer development.

7.2.4 Phase 4, Design and Pre-testing of the Risk Assessment Framework

The design of the Risk Assessment Framework was underpinned by the consensus study, consideration of the weighting of risk factor items and the support of a graphic designer. To increase support for decision making and encourage nurses to plan the patients care in response to their individual risk profile (rather than a numerical score), the use of colour was adopted. To do this the importance of included risk factor items and their impact on the patients risk status was considered. This was achieved by consideration of the overall strength of evidence, which was influenced by each of the development phases of this work leading to a colour system to indicate risk factor weighting. Instructions regarding the colour coding were integrated in the Risk Assessment Framework to support decision making and the physical development of the Framework involved frequent liaison with the graphic designer.

The graphically designed draft Risk Assessment Framework was then subject to pre-testing with clinical nurses to assess and improve its usability. The pre-test was undertaken over 3 sessions incorporating, training, focus groups and think out loud interviews. Changes to Risk Assessment Framework were made after each session, allowing enhancement and further pre-testing at the subsequent session. The key changes made over the course of the pre-test related to the format and flow, decision support and the wording of specific items. This led to the development of a preliminary Risk Assessment Framework in readiness for clinical evaluation.

7.3 The Preliminary Risk Assessment Framework

The preliminary Risk Assessment Framework incorporates 3 steps to the assessment, 9 risk factors and related assessment items, the use of colour to weight the importance of risk factors and integrates support for decision making throughout (Chapter 6, section 6.2). It has been developed for use with adult populations in clinical practice. Step 1 of the Risk Assessment Framework, comprises screening which is intended for all adult patients and incorporates mobility status and skin status assessment items and allows those who are clearly not at risk to be identified, preventing the need for a full assessment. Step 2, the full assessment is intended for patients at potential/actual risk (identified by step1) and incorporates assessment items relating to immobility, sensory perception, current skin status, previous pressure ulcer, perfusion, nutrition, moisture and diabetes.

Step 3, the assessment decision involves the nurse considering the individual risk profile of the patient and with support for decision making integrated into the Risk Assessment Framework, allocating the patient to the secondary prevention and treatment pathway (for those with an existing pressure ulcer or with scarring from a previous pressure ulcer), the primary prevention pathway (for those at risk of a pressure ulcer) or the not currently at risk pathway.

The development of the Risk Assessment Framework incorporated rigorous development methods to ensure the fundamental properties of content validity and acceptability and usability were met. Content validity is important in ensuring the decision tool adequately represents the domain it is supposed to measure and in this context is underpinned by empirical evidence of a systematic review, conceptual framework development and a consensus study incorporating the views of experts in the pressure ulcer field as well as service users. This methodological approach identified the importance of skin/ pressure ulcer status and poor perfusion as primary risk factors, which are not universally incorporated in existing instruments. Their inclusion in the new decision tool facilitates the nurse to consider them in her assessment and subsequent care planning. Content validity of the new decision tool was confirmed in a pre-test with its intended end users, clinical nurses. The pre-test also allowed areas of confusion to be identified and improvements to be made to the decision tool to enhance the usability and acceptability of the Risk Assessment Framework.

Of note is that the Risk Assessment Framework requires nurses' to assess the presence of most risk factors in a subjective manner, as at present there are no objective measures routinely available in clinical practice to achieve this. A user guide (Appendix 18) was developed following the pre-test to provide information on how to use the Risk Assessment Framework and how to interpret the included assessment items. This will help to standardise the assessment, though it is recognised that clinical judgement has a key role in the assessment process. Some risk factors require more clinical judgement than others for example, diabetes is not reliant on clinical judgement, rather the presence of the condition and this information could be obtained from the patient or clinical record.

Other risk factors rely more heavily on clinical judgement for example, the analysis of independent movement item. This incorporates consideration of the extent and frequency of independent movement. While the user guide (Appendix 18) provides some clarity on how the item should be interpreted (i.e. a slight position change

would involve the patient shifting their position a little when in bed or chair which may result in some, but not complete pressure relief while a major position change would result in complete pressure relief), the nurse would need to use her clinical judgment, informed by observation of the patient, history taking and clinical records to decide whether the patient's extent of movement was slight or major and the frequency of movement which would influence the category the patient falls into. Essentially the nurse is judging the extent to which the patient is able to independently relieve their pressure areas. This item is based on pressure ulcer aetiology and the importance of intensity and duration of pressure in ulcer development (Linder-Ganz *et al.* 2006; Stekelenburg *et al.* 2007). While these factors are key to pressure ulcer development, it is still difficult to determine the relative contribution of these two parameters and they are influenced by the patient's susceptibility and tolerance to pressure, which in turn are affected by the presence of risk factors. While the analysis of independent movement gives an indication of the intensity and duration of pressure, the ongoing skin assessment, allows the impact of this to be established.

The nurse's clinical judgement is also important when considering the pathway the patient should be allocated to and this is particularly relevant where the patient has a mixture of blue 'no problem' and yellow 'risk factor present which *may* impact upon pressure ulcer risk' items. In this situation the nurse must consider the risk profile of the patient and use their clinical judgement to determine whether the patient is 'at risk' or 'not currently at risk'. This would be influenced by the number of yellow boxes ticked i.e. increased numbers of yellow boxes ticked may lead the nurse to consider the patient to be 'at risk'. It would also be influenced by knowledge of the patient's individual circumstance. For example, a patient may only have the presence of unplanned weight loss, but may be terminally ill and nearing the end of life where the general trajectory of dependence will increase and the nurse may therefore consider the patient to be 'at risk'. Alternatively a diabetic patient who has undergone acute surgery but is recovering well and the general trajectory is increasing independence, may be considered 'not currently at risk'. These examples demonstrate that clinical judgement has a key role in the use of the Risk Assessment Framework, as it allows wider knowledge of the patient to be considered when deciding appropriate pathway allocation and provides a safety net for identifying 'at risk' and 'not currently at risk' patients.

7.3.1 Main Differences Between the Preliminary Risk Assessment Framework and Other Widely Used Pressure Ulcer Risk Assessment Instruments

The Risk Assessment Framework marks a new approach to the assessment of pressure ulcer risk. It moves away from the traditional approach used in Risk Assessment Instruments where the total scores from numerical scales are used to underpin care provision, to a decision tool which encourages a more thoughtful approach to the assessment process.

This empirically derived decision tool differs to existing Risk Assessment Instruments in a number of ways. Firstly, the Risk Assessment Framework incorporates a two stage assessment process with support for decision making regarding the depth of assessment required. This facilitates more appropriate use of nursing time as it allows patients' who are clearly not at risk to be screened out with only those who are potentially 'at risk' (as identified at screening stage) undergoing full detailed risk assessment. The new Risk Assessment Framework assists nurses to identify the presence of risk factors and identify the patient's individual risk profile. This provides more meaningful information than that obtained from the total scores of existing instruments, as it facilitates individualised care planning to address the patient's specific needs.

The use of colour makes a distinction between primary risk factors and those with weaker evidence i.e. yellow risk factors. This supports clinical decision making to facilitate appropriate pathway allocation and the discrimination of those with existing pressure ulcers who should be allocated to the secondary prevention/treatment pathway, those 'at risk' of developing pressure ulcers who should be allocated to the primary prevention pathway and those not at risk who should be allocated to the 'not currently at risk' pathway. Unlike existing Risk Assessment Instruments, this ensures the presence of an existing pressure ulcer is taken into account within the assessment and decision making process and aims to facilitate the escalation of care interventions to prevent deterioration of an existing pressure ulcer, promote healing and prevent additional pressure ulcer development. The Risk Assessment Framework also incorporates a risk factor Minimum Data Set which can be used at an organisational level for case-mix adjustment and to facilitate large multivariable modelling, which will enhance our understanding of pressure ulcer risk factors in the future.

Finally there is a subtle but important shift in focus in the new decision tool when compared with existing Risk Assessment Instruments. The literature relating to

existing Risk Assessment Instruments has concentrated on predictive validity and this has led to a lack of clarity of the aims of existing instruments and how they should be evaluated. The intention of the new decision tool is not to predict pressure ulcer development, but to identify pressure ulcer risk or presence so that appropriate primary prevention or secondary prevention/treatment interventions can be put in place. Being very clear about this at the outset sends a clear message to nurses of the need to take action in response to the patient's risk profile and assessment outcome. It also has the potential to divert future researchers away from undertaking inappropriate predictive validity evaluations to focussing on the impact the decision tool has on care processes and patient and pressure ulcer outcomes.

In summary the main differences between preliminary Risk Assessment Framework and other widely used Risk Assessment Instruments are as follows:

- Content based on empirical evidence including systematic review, consensus study, conceptual framework and pre-test study
- Aims to identify pressure ulcer risk or presence rather than predict pressure ulcer development
- Integration of skin / pressure ulcer status and poor perfusion
- Incorporation of a screening stage for all patients and a full assessment stage for those at potential/actual risk or with an existing pressure ulcer allowing those who are obviously 'not at risk' to be quickly identified.
- Enhanced support for decision making with regard to the depth of the assessment required (i.e. screening and/or full more detailed assessment) and the relative importance of specific risk factors when considering the patients risk status.
- Consideration of the patients individual risk profile (i.e. risk factors present), rather than a condensed score to provide a 'framework' for care (i.e. underpin appropriate care planning and the instigation of preventative/management interventions).
- The use of colour to weight the importance of risk factors and aid decision making.
- Clear distinction between primary and secondary prevention.
- Incorporation of a risk factor Minimum Data Set within the actual assessment items to facilitate multivariable modelling.

7.4 Methodological development

The overall approach used in the development of the Risk Assessment Framework incorporating a systematic review, consensus methods and pre-testing has, to the author's knowledge, never been undertaken previously for pressure ulcer Risk Assessment Instrument development. Most other instruments were developed on the basis of clinical/expert opinion (Andersen *et al.* 1982; Norton, McClaren and Exton-Smith 1962), literature review and/or pressure ulcer surveys (Abruzzese 1985; Waterlow 1985; Bergstrom *et al.* 1987), existing instruments (Gosnell 1973; Pritchard 1986; Cubbin and Jackson 1991; Song and Choi 1991; Lindgren *et al.* 2002), with only a few recent studies with serious methodological limitations considering multivariable analyses (Perneger *et al.* 2002; Suriadi *et al.* 2006; Page, Barker and Kamar 2011). Consequently the content of these Instruments is variable (chapter 2, section 2.4.1.1) raising questions about their overall validity.

The methodology described in this thesis provides a much more robust approach to identifying the content of the Risk Assessment Framework, as it considers the evidence of the systematic review (incorporating 54 primary studies including multivariable analyses and 34,449 patients) and the views of an international expert group, patients and carers and clinical nurses. The approach drew on methodologies from other fields including patient health status and quality of life instruments and patient reported outcome measures (SAC 2002; FDA DHHS 2009) and was influenced by the development and validation of clinical prediction models (Steyerberg 2010). The similarities and differences of developing and validating a pressure ulcer Risk Assessment Framework, when compared with instruments for these other fields of enquiry were carefully considered in the development of methodological approach of this PhD.

Systematic reviews of Risk Assessment Instruments have been undertaken previously, (Cullum *et al.* 1995; McGough 1999; Pancorbo-Hidalgo *et al.* 2006; Moore and Cowman 2010; Moore and Cowman 2014; NICE 2014). However, while of relevance to this PhD they focus on sensitivity, specificity and clinical effectiveness of the instrument overall, rather than considering the predictive ability of their risk factor components. The systematic review undertaken as part of this PhD is the first to consider risk factors predictive of pressure ulcer development and allowed objective deliberation of a much wider range of risk factor variables. The review was considered a necessary step to ensure all important risk factors were

considered in order to develop a clear conceptual basis and facilitate content validity for the Minimum Data Set and Risk Assessment Framework.

The methodology for the quality appraisal and classification of the primary studies of the systematic review were developed in the absence of published guidance for risk factor research. It incorporated a two stage assessment process, the first of which was nestled into study eligibility criteria to ensure a minimum standard for the quality of included studies (including design specific aspects of quality). This provided an efficient means of screening out studies with bias that was considered unacceptable and meant that the second stage, detailed quality appraisal could focus on risk factor measurement allowing a consistent approach to the overall assessment of study quality to be achieved. As with other quality appraisal systems (GRADE Working Group 2004; Guyatt *et al.* 2008; Cochrane 2009) the detailed quality appraisal of this study provided information on the criteria and key domain for each study (Table 3.4). In addition, each study was classified to provide an overall summary of study quality to facilitate the development of the evidence tables. The evidence tables worked well and provided a transparent approach to identifying the strength of evidence for each risk factor and facilitated the interpretation of the results.

The results of the review identified several important pressure ulcer risk factors which emerged strongly in multivariable modelling, but which are not included in most existing Risk Assessment Instruments (poor perfusion and skin/ pressure ulcer status). This suggests there was merit in considering a wide range of risk factors which could have important implications for the predictive ability of the Risk Assessment Framework. The systematic review makes an important and unique contribution to the evidence base of the pressure ulcer field and can be used to underpin future studies and clinical guideline development.

The consensus study was also considered an important phase in the development of the Minimum Data Set and Risk Assessment Framework, as unfortunately, a direct risk factor item pool could not be identified from the systematic review (Steyerberg 2010). An alternative option might have been for the author alone to decide the risk factors and assessment items of the Minimum Data Set and Risk Assessment Framework. However, the benefit of using a group rather than being reliant on one person is that it is supported by a wider range of knowledge and experience. This should promote consideration of a wider range of options (Murphy *et al.* 1998) which may lead to greater validity and reliability of the judgements

made (Raine, Sanderson and Black 2005). Another approach might have been to incorporate group decision making in a less structured way. However, the structured approach used in this PhD thesis provided a transparent means of synthesising individual views, allowed greater insight to the reasons for divergent opinion and encouraged the involvement of all participants, rather than the dominance of a few (Raine, Sanderson and Black 2005). The approach worked well and allowed a large number of potential risk factors and assessment items to be considered and focussed down to a clinically manageable number of items considered important for summarising patient risk.

The decision to use an international expert group in the consensus study was considered important for two reasons. Firstly the pressure ulcer field is a relatively small one and specialised expertise relating to certain aspects, particularly biomechanics and epidemiology is only available internationally. Secondly, the benefits of engaging key opinion leaders and recognised experts in the field could increase credibility for end users of the Minimum data Set and Risk Assessment Framework (Fink *et al.* 1984; Vakil 2011).

The involvement of PURSUN has been instrumental throughout the development of the Risk Assessment Framework, incorporating the consensus study, the development of vignette case studies for the pre-test and final review of the preliminary decision tool. It is the first pressure ulcer Risk Assessment Instrument to incorporate the patient/carer perspective throughout its development and it is anticipated that this will ensure the acceptability of the assessment items to patients in practice. It was doubtful that the representation of 1 or 2 patient/carers on the expert group as used in previous consensus studies (Rycroft-Malone 2001; Jackson *et al.* 2009) would have generated the depth of discussion encountered in the separate PURSUN meetings used in the PhD. Here we were able to draw on their personal experience to explore the acceptability of pressure ulcer assessment items, rather than in the consideration of complicated literature and this approach is in keeping with other PPI priority exercises (Buckley *et al.* 2010; Hutchings *et al.* 2012). An important aspect of the methodology used in the consensus study of the PhD was ensuring that PURSUN insights were considered by the expert group when they made individual judgements about item inclusion. This was facilitated by verbal feedback at the expert group meetings and integration of the PURSUN perspective in questionnaires. Indeed, it was apparent from some of the outcomes of the study that the PURSUN perspective influenced the decision making of the expert group (particularly relating to the exclusion of albumin and inclusion of previous pressure ulcer in the Minimum Data Set and Risk Assessment

Framework). This is a new approach to PPI in consensus studies and may be appropriate for future studies in other areas.

The pre-test provided a structured approach to assess and improve the usability and confirm content of the Risk Assessment Framework with the intended key users, clinical nurses. This was particularly important given the increased support for decision making and instructions that were integrated in the Risk Assessment Framework. Their insight led to the identification of areas of confusion and subsequent changes to the Framework. Ultimately this allowed improved usability in preparation for its onward validation in clinical practice. This is was an important stage of the Risk Assessment Frameworks development and is the first study to use such an approach in the development of a pressure ulcer Risk Assessment Instrument. The involvement of clinical nurses has only been reported briefly in the development literature of other instruments (Abruzzese 1985; Waterlow 1985; Pritchard 1986; Cubbin and Jackson 1991). The pre-test also provides an example of how the use of both focus groups and think out loud interviews can work in a complementary manner as suggested previously (Willis 2005). In addition, while the use of vignette case studies has been used previously for the validation of existing instruments (Gould *et al.* 2002; Gould *et al.* 2004), it has not been used as part of the development process for pressure ulcer Risk Assessment Instruments. The involvement of patients/carers (via PURSUN) in the development of the vignette case studies made them more realistic and this approach could be used in other areas of research.

Overall the methodological approach of this PhD, which comprised 4 distinct work packages and drew on guidance from the development and validation of health measurement instruments in other fields (SAC 2002; FDA DHHS 2009; Steyerberg 2010) provided a logical and rigorous means of developing the Risk Assessment Framework. However, there were some limitations and these are discussed below.

7.5 Methodological Limitations

A fundamental component of this PhD was to identify the content for the Risk Assessment Framework. Ideally this would have incorporated a methodological approach used in the development and validation of clinical prediction models where multivariable modelling is used to identify the content items for a risk instrument, with subsequent model testing on a 'new' prospective target population

(Steyerberg 2010). This would have also allowed a robust method for weighting risk factors. However, this was not possible due to specific limitations in the literature including inadequate sample sizes and inconsistent inclusion of risk factors in multivariable modelling, compounded by the large number of associated descriptor variables in risk factor studies. To address these limitations and make large scale multivariable modelling a possibility in the future, an alternative approach was undertaken, whereby the content of a risk factor Minimum Data Set was identified and integrated into the new Risk Assessment. In the future, the Minimum Data Set can serve as the core risk factor variables to be considered in future studies allowing meta-analysis. The approach taken made use of the best available epidemiological and scientific evidence as well as the views of experts in the field and patients and carers to identify the risk factors that should be included in the Risk Assessment Framework and their relative weighting. Despite this further large-scale multivariable modelling is necessary for refinement of the Framework which could lead to changes to the weighting of specific risk factors. It could also lead to the exclusion of some risk factors currently incorporated in the Risk Assessment Framework.

There are also methodological limitations associated the component studies of this PhD which have potential implications to the validity of the Minimum Data Set and Risk Assessment Framework. The systematic review highlighted methodological challenges associated with the conduct and interpretation of risk factor systematic reviews. The challenges included the absence of clear guidance or recommendations for the quality appraisal and classification of risk factor studies and the poor quality of primary research undertaken in the field (Chapter 3). These challenges necessitated the development of a study specific quality appraisal process of the primary studies of the review to ensure any weaknesses were considered in the analysis and interpretation of the results. It is recognised that further work should be undertaken with methodological experts to reach consensus on the most important criteria required to assess the quality of exploratory risk factor studies to develop and validate a tool specifically for this.

The approach for quality appraisal that was developed for this study allowed studies to be classified into high, moderate, low or very low quality studies. However the classification of studies was not specified prior to the quality assessment, rather it was developed following appraisal of all criteria. Though this could be viewed as a limitation, the approach was necessitated by the lack of published guidance and the need to fully consider the strengths and weaknesses of research in the pressure

ulcer field. It is also recognised that the classification system was limited as it did not cover all potential combinations of compliance with the four key domains (i.e. whether they met - yes, no, partial, uncertain). Where there was uncertainty regarding compliance with each domain a logical approach to study derivation was adopted (see section 3.8), though it is recognised that this should be developed further in future work, to accommodate all potential outcomes in the classification of study quality.

While the consensus methods used in this PhD were developed and conducted in as rigorous manner as possible it is important to acknowledge inherent limitations in the approach. Consensus methods provide a structured process with consideration of relevant information to facilitate valid decision making. However there is always the risk that the method will capture 'collective ignorance' rather than wisdom (Murphy *et al.* 1998). Indeed, establishing the validity of the decisions made at the time of conducting the study is problematic in consensus methods. Ultimately this will need to be established in the on-going validation of the Risk Assessment Framework. The reliability of the judgements made and whether they are representative of other experts in the field is also another elements that will be considered in the ongoing validation of the decision tool (Raine, Sanderson and Black 2005). In addition, while the consensus method was useful for identifying the risk factors important for summarising patient risk and for identifying the key principles of the assessment items, the method was inappropriate for considering the specific wording of items. This is due to the large volume of work required (i.e. re-rating of questionnaires) to reach consensus on small changes to wording.

Another consideration for others who might use the method is the time consuming nature involved in the preparation and planning of the study, including the development of evidence based materials, questionnaires and the planning and co-ordination of expert group/service user meetings. While these are fundamental to ensuring as rigorous approach as possible, they also involve a large amount of work which needs to be achieved in a timely manner. This has the potential to create undue burden on the researcher and it is therefore important that a team approach is adopted to lessen the load on individuals. The support of the working group and the small team of facilitators was funded and certainly valued by the researcher in the undertaking this study. Adequate funding should certainly be considered by others who might use the method. Cost has been raised previously (Raine, Sanderson and Black 2005; Vakil 2011) as a potential barrier for face-to-

face group processes and this could be particularly evident when involving international group member in the process. Fortunately, for the consensus study of this PhD, additional funding was secured to meet the travel and subsistence costs of the international expert group and the benefits of involving international leading experts was considered to outweigh the cost.

While the pre-test provided a structured approach to assess and improve the usability of the Risk Assessment Framework it could be argued that a pre-test is an artificial situation and that participants may respond differently in a real life situation (Lanza 1990; Gould 1996). However, while acknowledging these suggestions the pre-test was considered a logical step to ensure content validity and usability, prior to evaluation in clinical practice with real patients. It worked well to prepare the Risk Assessment Framework for ongoing validation in clinical practice.

7.6 Future Validation of the Risk Assessment Framework

The next stage of the development process for the Risk Assessment Framework involves evaluation of the reliability and validity of the decision tool. Evaluation of reliability (inter-rater and test re-test) will establish the consistency and stability of the instrument (Streiner and Norman 2008). This property is important for the clinical decision tool, as poor reliability could lead to a lack of confidence in the assessment outcomes and inconsistent care planning which may not address the patient's needs. This would raise questions about the usefulness of the instrument to support appropriate decision making in clinical practice and therefore hamper its implementation. The acceptability and usability of the Risk Assessment Framework also needs to be considered in clinical practice to ensure it is interpreted as intended and to facilitate the long-term implementation of the decision tool.

Another psychometric property which is relevant to the decision tool is construct validity incorporating convergent, discriminant and known groups validity. These are important in facilitating greater understanding of the instrument by demonstrating evidence of logical relationships among items, domains and concepts that should exist with measures of related concepts or scores (FDA DHHS 2009). This is particularly relevant for the risk factor items within the decision tool which can be compared with items from existing Risk Assessment Instruments to establish logical relationships. Another relevant property that has not been considered in existing Risk Assessment Instruments and is relevant to the Risk Assessment Framework is its responsiveness to detect clinically significant changes. This is important as changes in the patient's condition may require an escalation or reduction in care

interventions and has implications for patient care and the appropriate use of scarce resources.

A property which has been extensively used in the evaluation of existing Risk Assessment Instrument is predictive validity. The appropriateness of this has been challenged (Deeks 1996; Defloor and Grypdonck 2004) and the limitations discussed (see sections 2.4.7, 2.4.9, 2.7.1 and 7.31). Reflecting on this, predictive validity is not an appropriate property to evaluate the Risk Assessment Framework, rather the impact of using the decision tool on processes of care and their effectiveness in reducing pressure ulcer incidence would provide more appropriate evaluation.

It is envisaged that future electronic records in the NHS will facilitate large-scale multivariable modelling allowing further refinement of the Framework. Another area of development for the Risk Assessment Framework is the adaptation of a lay person version. This was suggested to be an important consideration by PURSUN to enable patients and carers to undertake self-assessment. The Risk Assessment Framework may also be adapted and validated for paediatric populations. Further adaptations for specialist environments such as the operating theatre and ambulance services may also be considered.

7.7 Implications of the PhD for Clinical Practice

The Risk Assessment Framework is a decision tool that provides a new approach to pressure ulcer risk assessment for adult populations in clinical practice. It is underpinned by enhanced support for clinical decision making and an up to date evidence base and the views of experts, clinicians and patients and carers and has enhanced content validity when compared with other Risk Assessment Instruments. The Risk Assessment Framework encourages a more holistic approach for care planning as risk assessment encourages consideration of the individual patient's risk profile, rather than a numerical score as used in traditional Risk Assessment Instruments. Furthermore the increased weighting of key risk factors, i.e. those most predictive of pressure ulcer development is taken into account in the decision making guidance of the Risk Assessment Framework. These factors could lead to the instigation of more appropriate preventative interventions, individualised care planning with the potential for improved care and pressure ulcer outcomes.

The use of the Risk Assessment Framework could be integrated into existing pressure ulcer prevention policies and initiatives (section 1.11.5) such as the SKIN Bundle (Whitlock 2011), though these would need to be further developed to ensure that important risk factors identified by this PhD and not currently considered (i.e. perfusion, sensory perception) are integrated into the approach. Alternatively the Risk Assessment Framework could provide the basis for the development of new pressure ulcer prevention initiatives where intervention guidance and care plans could be developed to assist in identifying potential interventions for primary and secondary/treatment pathways.

The Risk Assessment Framework was developed in recognition of the complexity of modern healthcare provision and the need for a quick and easy to use framework for care. The incorporation of the screening stage and support for decision making allows those who are obviously 'not at risk' to be quickly identified and prevents the need for a more time consuming full risk assessment. This allows nursing time to be used more efficiently and prevents their attention being unnecessarily diverted away from other priorities.

The incorporation of skin/pressure ulcer status actually within the Risk Assessment Framework ensures this important risk factor is integral to the assessment process. It also allows a distinction to be made between primary prevention for those at risk (without an existing pressure ulcer) and secondary prevention and treatment for those with an existing pressure ulcer (or scarring from a previous pressure ulcer). This is important in clinical practice since both groups of patients need a framework for care. Furthermore, the distinction between the groups limits the possibility of nurses disregarding the presence of an existing ulcer in their decision making and failing to escalate care intervention to prevent the progression to a more severe pressure ulcer (Pinkney *et al.* 2014). The inclusion of perfusion within the Risk Assessment Framework will raise awareness of this important risk factor and ensure it is considered in the assessment of pressure ulcer risk. This has the potential to lead to the instigation of more appropriate care provision and improved pressure ulcer and patient outcomes. It is noteworthy that few existing Risk Assessment Instruments incorporate this important risk factor despite their being strong evidence of its importance.

The new conceptual framework and theoretical causal pathway together propose clearer linkage between the physiological and biomechanical determinants of

pressure ulcer development and patient risk factors. They provide a framework for understanding the critical determinants of pressure ulcer development and facilitate the translation of physiological and biomechanical elements to characteristics which nurses can observe in their patients. The new conceptual framework could be used as an educational aid for student and qualified nurses to help raise awareness of this important health care issue. The new conceptual framework has been included (with permission) in the updated NPUAP/EPUAP international guidelines which will be published later in 2014.

Another important component of relevance to clinical practice is the integration of the Minimum Data Set within the Risk Assessment Framework. At a local level this could facilitate case mix adjustment and allow care organisations to plan their resources effectively particularly relating to equipment (bedframes, mattresses, seating and cushions etc.) and treatment (equipment and wound care) provision, as well as staffing ratios, specialist services and staff training in response to their patient populations needs. It also has the potential to be used in the review of care standards. In a wider sense Minimum Data Set information from health care organisations could be used centrally to undertake large scale multivariable analysis which could lead to refinement of the Risk Assessment Framework making a more useful decision tool for clinical practice.

7.8 Implications of the PhD for Research

The new conceptual framework and theoretical causal pathway also have implications for research. They provide an up to date account of how existing evidence can be used to develop theory and help to identify gaps in our knowledge base. Particularly, the causal pathway provides a hierarchy of risk factors which could be used in setting research priorities. These could be used to underpin and guide future research, building on the evidence and enable us to more clearly define the role of individual pressure ulcer risk factors conceptually and operationally.

An overall limitation of pressure ulcer prevention is the remaining limited means of patient assessment in clinical practice, which is based primarily on observation of risk factors (e.g. visual skin assessment) or the presence of predisposing conditions (e.g. factors which affect perfusion). The new conceptual framework facilitates the translation of epidemiological evidence to its biomechanical components and it is hoped that this linkage will increase the wider scientific community and industry's understanding of how clinicians currently identify pressure ulcer risk in practice.

This could influence the development of more objective and improved assessment techniques with greater precision, allowing the key biomechanical mechanism of importance to be measured and interpreted in routine practice.

At the present time an objective measure to identify overall pressure ulcer risk which could replace clinical risk assessment is unrealistic. This type of development work is in its infancy and is confined to considering the assessment of biomechanical elements which link to pressure ulcer risk factors. In the future biomechanical measurements could be considered and integrated into the Risk Assessment Framework to improve its validity and usefulness in supporting clinical decision making for nurses in practice. An example of where this would be most useful relates to finding a more objective means of measuring skin vulnerability which is difficult to assess in clinical practice, particularly relating to patients with darker skin tones. Recent guidance still advocates the use of finger palpation, visual skin assessment and consideration of patient reported pain or discomfort (NICE 2014) and relies on the nurse's skill and experience of undertaking the assessment. Preliminary work has been undertaken to measure sub-epidermal moisture by use of a hand-held dermal phase meter as a means of predicting future pressure ulcer development (Bates-Jensen, McCreath and Pongquan 2009). While this work requires further development and testing, it is a device such as this that has the potential to provide a more objective measure of skin vulnerability and inform this element of the Risk Assessment Framework to support clinical decision making. Another example relates to the need to more fully understanding the physiological mechanisms of importance relating to poor perfusion and develop more objective measures of these that can inform the relevant sections of the Risk Assessment Framework.

In terms of the implications of this thesis to epidemiological studies, the use of the Minimum Data Set will ensure the core risk factor variables considered to be most predictive of pressure ulcer risk are included, facilitating future meta-analysis allowing more fruitful analysis and interpretation of results. The core Minimum Data Set and the theoretical causal pathway should provide the foundation for the exploration of other potential important risk factors or in clarifying the specific aspects of importance in established risk factors. It is also hoped that the new approach of the Risk Assessment Framework as a decision tool will steer future researchers away from evaluating its predictive validity, to more appropriately considering the effect of using the decision tool on care processes and patient and

pressure ulcer outcomes, as this has more scope to impact and improve clinical practice.

7.9 Conclusion

The aim of this PhD was to develop a pressure ulcer Risk Assessment Framework underpinned by a Minimum Data Set, and incorporated a 4 phase approach. The systematic review identified 3 primary risk factor domains, mobility/activity, skin/pressure ulcer status and perfusion (including diabetes) and other risk factors which emerged less consistently. The review highlighted the lack of comparable data fields which limited interpretation, prevented meta-analysis and highlighted the need for a risk factor Minimum Data Set. This was addressed in the consensus study which facilitated the agreement of risk factors and assessment items of the Minimum Data Set establishing content validity and allowing the development of a draft Risk Assessment Framework. It also facilitated the development of the new pressure ulcer conceptual framework and theoretical causal pathway. The design and pre-testing of the Risk Assessment Framework confirmed content validity and led to improved usability.

The work of this PhD makes an important contribution to the pressure ulcer field, drawing on wider instrument development methodologies. The incorporation of the systematic review of pressure ulcer risk factors to underpin Risk Assessment Framework development is the first to be undertaken in the field. This allowed further consideration of the conceptual framework and clearer linkage of epidemiological and biomechanical/physiological evidence, leading to the development of the first pressure ulcer theoretical causal pathway. The structured inclusion of service users (PURSUN) and clinical nurses in the development of the Risk Assessment Framework provides another example of the innovative approach adopted throughout this research. Methodological development is also evident throughout each phase of the PhD, which is important for the pressure ulcer field but may also have wider application to other health related instrument development.

The resulting decision tool, the Risk Assessment Framework incorporates the Minimum Data Set and a 2 stage assessment process including a screening stage which considers mobility and pressure ulcer and skin status and a full assessment stage which considers immobility, pressure ulcer and skin status, perfusion, diabetes, skin moisture, sensory perception and nutrition. The Risk Assessment Framework also includes primary prevention and secondary prevention/treatment

pathways and support for decision making and pathway allocation. It provides a fresh approach to pressure ulcer risk assessment in clinical practice which encourages individualised care planning in response patient need and offers enhanced support for clinical decision making throughout the assessment process. The Risk Assessment Framework now requires further clinical evaluation and validation to assess the reliability, convergent, discriminant and known group validity and clinical usability of the decision tool. In the longer-term evaluation of impact of using the decision tool on processes of care and its effectiveness in reducing pressure ulcer incidence should be established.

References

- ABRUZZESE, R. S. 1985. *Early assessment and prevention of pressure sores. In Lee B Y (Ed). In Chronic ulcers of the skin* New York: McGraw-Hill.
- AHCPR. 1992. Pressure ulcers in adults: prediction and prevention. Quick reference guide for clinicians. *US Department of Health and Human Services, Rockville.*
- ALFIREVIC, Z., F. MUJEZINOVIC and K. SUNDBERG. 2009. Amniocentesis and chorionic villus sampling for prenatal diagnosis (Review).
- ALLMAN, R. M., P. S. GOODE, M. M. PATRICK, N. BURST and A. A. BARTOLUCCI. 1995. Pressure ulcer risk factors among hospitalized patients with activity limitation. *JAMA*, **273**(11), pp.865-70.
- ALTMAN, D. 2009. Prognostic models: a methodological framework and review of models for breast cancer. *Cancer Invest*, **27**, pp.235 - 243.
- ALTMAN, D. and J. BLAND. 1997. Statistics Notes: Units of analysis. *BMJ*, **314**(7098), p1874.
- ALTMAN, D., B. LAUSEN, W. SAUERBREI and M. SCHUMACHER. 1994. Dangers of using "optimal" cutpoints in the evaluation of prognostic factors. *J Natl Cancer Inst*, **86**, pp.829 - 835.
- ALTMAN, D. G. 2001. Systematic reviews in health care: systematic reviews of evaluations of prognostic variables. *BMJ*, **323**(7306), pp.224-8.
- ANDERSEN, K. E., O. JENSEN, S. A. KVORNING and E. BACH. 1982. Prevention of pressure sores by identifying patients at risk. *British Medical Journal Clinical Research Ed.*, **284**(6326), pp.1370-1.
- BADER, D. L., R. L. BARNHILL and T. J. RYAN. 1986. Effect of externally applied skin surface forces on tissue vasculature. *Archives of Physical Medicine & Rehabilitation*, **67**(11), pp.807-11.
- BAHARESTANI, M. M., J. M. BLACK, K. CARVILLE, M. CLARK, J. E. CUDDIGAN, C. DEALEY, T. DEFLOOR, K. G. HARDING, N. A. LAHMANN, M. J. LUBBERS, C. H. LYDER, T. OHURA, H. L. ORSTED, S. I. REGER, M. ROMANELLI and H. SANADA. 2009. Dilemmas in measuring and using pressure ulcer prevalence and incidence: an international consensus. *International Wound Journal*, **6**(2), pp.97-104.
- BALDELLI, P. and M. PACIELLA. 2008. Creation and implementation of a pressure ulcer prevention bundle improves patient outcomes. *Am J Med Qual*, **23**(2), pp.136-42.
- BALDWIN, K. M. and S. M. ZIEGLER. 1998. Pressure ulcer risk following critical traumatic injury. *Adv Wound Care*, **11**(4), pp.168-73.
- BALZER, K., S. KOPKE, D. LUHMANN, B. HAASTERT, J. KOTTNER and G. MEYER. 2013. Designing trials for pressure ulcer risk assessment research: methodological challenges. *International Journal of Nursing Studies*, **50**(8), pp.1136-50.
- BALZER, K., C. POHL, T. DASSEN and R. HALFENS. 2007. The Norton, Waterlow, Braden, and Care Dependency Scales: comparing their validity when identifying patients' pressure sore risk. *Journal of Wound, Ostomy, & Continence Nursing*, **34**(4), pp.389-98.

- BARTON, A. A. and M. BARTON. 1981. The management and prevention of pressure sores. Londnn: Faber, pp.26-28.
- BATES-JENSEN, B. M., H. E. MCCREATH, A. KONO, N. C. APELES and C. ALESSI. 2007. Subepidermal moisture predicts erythema and stage 1 pressure ulcers in nursing home residents: a pilot study. *J Am Geriatr Soc*, **55**(8), pp.1199-205.
- BATES-JENSEN, B. M., H. E. MCCREATH and V. PONGQUAN. 2009. Subepidermal moisture is associated with early pressure ulcer damage in nursing home residents with dark skin tones: pilot findings. *J Wound Ostomy Continence Nurs*, **36**(3), pp.277-84.
- BAUMGARTEN, M., D. MARGOLIS, C. VAN DOORN, A. L. GRUBER-BALDINI, J. R. HEBEL, S. ZIMMERMAN and J. MAGAZINER. 2004. Black/White differences in pressure ulcer incidence in nursing home residents. *J Am Geriatr Soc*, **52**(8), pp.1293-8.
- BEECKMAN, D., C. MATHEI, A. VAN LANCKER, S. VAN HOUDT, G. VANWALLEGHEM, L. GRYSOON, H. HEYMAN, C. THYSE, A. TOPPETS, S. STORDEUR and K. VAN DEN HEEDE. 2012. *Good Clinical Practice: A National Guideline for the Prevention of Pressure Ulcers KCE Report 193C*
- BEECKMAN, D., S. WOODWARD, K. RAJPAUL and K. VANDERWEE. 2011. Clinical challenges of preventing incontinence-associated dermatitis. *British Journal of Nursing*, **20**(13), pp.784-6,788,790.
- BEGG, C., M. CHO, S. EASTWOOD, R. HORTON, D. MOHER, I. OLKIN, R. PITKIN, D. RENNIE, K. F. SCHULZ, D. SIMEL and D. F. STROUP. 1996. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA*, **276**(8), pp.637-9.
- BEKKER, H. L., J. HEWISON and J. G. THORNTON. 2003. Understanding why decision aids work: linking process with outcome. *Patient Education and Counseling*, **50**(3), pp.323-329.
- BENNETT, G., C. DEALEY and J. POSNETT. 2004. The cost of pressure ulcers in the UK. *Age Ageing*, **33**(3), pp.230-5.
- BENOIT, R. and L. MION. 2012. Risk factors for pressure ulcer development in critically ill patients: a conceptual model to guide research. *Research in Nursing & Health*, **35**(4), pp.340-62.
- BERGQUIST, S. and R. FRANTZ. 1999. Pressure ulcers in community-based older adults receiving home health care. Prevalence, incidence, and associated risk factors. *Adv Wound Care*, **12**(7), pp.339-51.
- BERGSTROM, N. and B. BRADEN. 1992. A prospective study of pressure sore risk among institutionalized elderly. *J Am Geriatr Soc*, **40**(8), pp.747-58.
- BERGSTROM, N., B. BRADEN, M. KEMP, M. CHAMPAGNE and E. RUBY. 1996. Multi-site study of incidence of pressure ulcers and the relationship between risk level, demographic characteristics, diagnoses, and prescription of preventive interventions. *J Am Geriatr Soc*, **44**(1), pp.22-30.
- BERGSTROM, N., B. J. BRADEN, A. LAGUZZA and V. HOLMAN. 1987. The Braden Scale for Predicting Pressure Sore Risk. *Nursing Research*, **36**(4), pp.205-10.

- BERGSTROM, N., S. D. HORN, M. P. RAPP, A. STERN, R. BARRETT and M. WATKISS. 2013. Turning for Ulcer Reduction: A Multisite Randomized Clinical Trial in Nursing Homes. *Journal of the American Geriatrics Society*, **61**(10), pp.1705-1713.
- BERLOWITZ, D., C. VANDEUSEN LUKAS, V. PARKER, A. NIEDERHAUSER, J. SILVER, C. LOGAN and E. AYELLO. 2011. Preventing Pressure Ulcers in hospitals: A toolkit for improving quality of care. [online]. [Accessed 15/10/2012]. Available from: <http://www.ahrq.gov/research/ltc/pressureulcertoolkit/putool1.htm>.
- BERLOWITZ, D. R. and S. V. WILKING. 1989. Risk factors for pressure sores. A comparison of cross-sectional and cohort-derived data. *J Am Geriatr Soc*, **37**(11), pp.1043-50.
- BERNSTEIN, S. J., P. LAZARO, K. FITCH, M. D. AGUILAR, H. RIGTER and J. P. KAHAN. 2002. Appropriateness of coronary revascularization for patients with chronic stable angina or following an acute myocardial infarction: multinational versus Dutch criteria. *International Journal for Quality in Health Care*, **14**(2), pp.103-9.
- BLACK, N. 2006. Consensus development methods. In: C. POPE and N. MAYS, eds. *Qualitative research in health care*. 3rd ed. Channai: Blackwell publishing.
- BOSTROM, J., J. MECHANIC, N. LAZAR, S. MICHELSON, L. GRANT and L. NOMURA. 1996. Preventing skin breakdown: nursing practices, costs, and outcomes. *Appl Nurs Res*, **9**(4), pp.184-8.
- BOULT, M., K. FITZPATRICK, M. BARNES, G. MADDERN and R. FITRIDGE. 2011. Developing tools to predict outcomes following cardiovascular surgery. *ANZ J Surg*, **81**(11), pp.768-73.
- BOURDEL-MARCHASSON, I., M. BARATEAU, V. RONDEAU, L. DEQUAE-MERCHADOU, N. SALLES-MONTAUDON, J. P. EMERIAU, G. MANCIET and J. F. DARTIGUES. 2000. A multi-center trial of the effects of oral nutritional supplementation in critically ill older inpatients. GAGE Group. Groupe Aquitain Geriatrique d'Evaluation. *Nutrition*, **16**(1), pp.1-5.
- BOUTEN, C. V., C. W. OOMENS, F. P. BAAIJENS and D. L. BADER. 2003. The etiology of pressure ulcers: skin deep or muscle bound? *Archives of Physical Medicine & Rehabilitation*, **84**(4), pp.616-9.
- BOWLING. 2009. *Research Methods in Health: Investigating Health and Health Services*. New York: Open University Press, McGraw Hill.
- BOYLE, M. and M. GREEN. 2001. Pressure sores in intensive care: defining their incidence and associated factors and assessing the utility of two pressure sore risk assessment tools. *Aust Crit Care*, **14**(1), pp.24-30.
- BRADEN, B. and N. BERGSTROM. 1987. A Conceptual Schema for the Study of the Etiology of Pressure Sores. *Rehabilitation Nursing*, **12**(1), pp.8-16.
- BRANDEIS, G. H., W. L. OOI, M. HOSSAIN, J. N. MORRIS and L. A. LIPSITZ. 1994. A longitudinal study of risk factors associated with the formation of pressure ulcers in nursing homes. *J Am Geriatr Soc*, **42**(4), pp.388-93.
- BRIDEL, J. 1993. The epidemiology of pressure sores. *Nurs Stand*, **7**(42), pp.25-30.
- BRIDEL, J. 1994. Risk assessment. *Journal of Tissue Viability*, **4**(3), pp.84-85.

- BRIGGS, M., M. COLLINSON, L. WILSON, C. RIVERS, E. MCGINNIS, C. DEALEY, J. BROWN, S. COLEMAN, N. STUBBS, R. STEVENSON, E. A. NELSON and J. NIXON. 2013. The prevalence of pain at pressure areas and pressure ulcers in hospitalised patients <http://www.biomedcentral.com/1472-6955/12/19>. *BMC Nurs*, **12**(1), p19.
- BROTMAN, D. J., E. WALKER, M. S. LAUER and R. G. O'BRIEN. 2005. In search of fewer independent risk factors. *Archives of Internal Medicine*, **165**(2), pp.138-45.
- BRYANT, M., L. ASHTON, J. BROWN, S. JEBB, J. WRIGHT, K. ROBERTS and J. NIXON. In pres. Systematic review to identify and appraise outcome measures used to evaluate childhood obesity treatment interventions: evidence of purpose, application, validity, reliability and sensitivity. *HTA Monograph*.
- BUCKLEY, B. S., A. M. GRANT, D. G. TINCELLO, A. S. WAGG and L. FIRKINS. 2010. Prioritizing research: Patients, carers, and clinicians working together to identify and prioritize important clinical uncertainties in urinary incontinence. *Neurourology & Urodynamics*, **29**(5), pp.708-14.
- BUETOW, S. A. and G. D. COSTER. 2000. New Zealand and United Kingdom experiences with the RAND modified Delphi approach to producing angina and heart failure criteria for quality assessment in general practice. *Quality in Health Care*, **9**(4), pp.222-31.
- CANO, S. J. and J. C. HOBART. 2011. The problem with health measurement. *Patient preference and adherence*, **5**, p279.
- CARPENTER, J., A. HUTCHINGS, R. RAINE, C. SANDERSON, J. CARPENTER, A. HUTCHINGS, R. RAINE and C. SANDERSON. 2007. An experimental study of the influence of individual participant characteristics on formal consensus development. *International Journal of Technology Assessment in Health Care*, **23**(1), pp.108-15.
- CELEN, K. K., A. STEKELENBURG, S. LOERAKKER, G. J. STRIJKERS, D. L. BADER, K. NICOLAY, F. P. T. BAAIJENS and C. W. J. OOMENS. 2008. Compression-induced damage and internal tissue strains are related. *Journal of Biomechanics*, **41**(16), pp.3399-404.
- CHAN, E. Y., S. L. TAN, C. K. LEE and J. Y. LEE. 2005. Prevalence, incidence and predictors of pressure ulcers in a tertiary hospital in Singapore. *J Wound Care*, **14**(8), pp.383-4, 386-8.
- CLARK, M., M. ROMANELLI, V. K. RANGANATHAN, J. BLACK and C. DEALEY. eds. 2010. *Microclimate in context in International Review. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A consensus document* London: Wounds International.
- COBB, G., A., L. YODER, H. and J. WARREN, B. 1997. *Pressure ulcers: Patient Outcomes on a KinAir Bed or EHOB Waffle Mattress. TriService Nursing Research Programme (TSNRP)*, 30.
- COCHRANE. 2009. *Cochrane Library Retrieved from <http://www.cochranelibrary.com/view/0/index.html>*.
- COLLINS, D. 2003. Pretesting survey instruments: an overview of cognitive methods. *Qual Life Res*, **12**(3), pp.229-38.
- COMPTON, F., F. HOFFMANN, T. HORTIG, M. STRAUSS, J. FREY, W. ZIDEK and J. H. SCHAFFER. 2008. Pressure ulcer predictors in ICU

- patients: nursing skin assessment versus objective parameters. *J Wound Care*, **17**(10), pp.417-20, 422-4.
- COURTNEY, B. A., J. B. RUPPMAN and H. M. COOPER. 2006. Save our skin: initiative cuts pressure ulcer incidence in half. *Nurs Manage*, **37**(4), pp.36, 38, 40 passim.
- CRD. 2009. Systematic Reviews: Centre for reviews and Disseminations Guidance for Undertaking Reviews in Health Care. retrieved from http://www.york.ac.uk/inst/crd/index_guidance.htm. [online].
- CUBBIN, B. and C. JACKSON. 1991. Trial of a pressure area risk calculator for intensive therapy patients. *Intensive Care Nursing*, **7**(1), pp.40-4.
- CULLUM, N., J. DEEKS, A. FLETCHER, H. MOUNEIMNE, T. SHELDON, F. SONG and A. LONG. 1995. *The Prevention and Treatment of Pressure Sores: how useful are the measures for scoring people's risk of developing a pressure sore?* 2 (1). Effective Health Care Bulletin
- CULLUM, N., E. A. NELSON, K. FLEMMING and T. SHELDON. 2001. *Systematic Reviews of Wound Care Management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy.* 5 (9). Health Technology Assessment
- DALKEY, N. and O. HELMER. 1963. An experimental application of the delphi method to the use of experts. *Management Science*, **9**(3), pp.458-467.
- DE LAAT, E. H., P. PICKKERS, L. SCHOONHOVEN, A. L. VERBEEK, T. FEUTH and T. VAN ACHTERBERG. 2007. Guideline implementation results in a decrease of pressure ulcer incidence in critically ill patients. *Critical Care Medicine*, **35**(3), pp.815-20.
- DEALEY, C. 1991. The size of the pressure-sore problem in a teaching hospital. *Journal of Advanced Nursing*, **16**(6), pp.663-670.
- DEALEY, C. 2005. *The care of wounds: A guide for nurses.* 3rd ed. Oxford: Blackwell Publishing Ltd.
- DEALEY, C., J. POSNETT and A. WALKER. 2012. The cost of pressure ulcers in the United Kingdom. *Journal of Wound Care*, **21**(6), pp.261-6.
- DEEKS, J. J. 1996. Pressure sore prevention: using and evaluating risk assessment tools. *Br J Nurs*, **5**(5), pp.313-4, 316-20.
- DEFLOOR, T. 1999. The risk of pressure sores: a conceptual scheme. *Journal of Clinical Nursing*, **8**(2), pp.206-16.
- DEFLOOR, T., D. D. BACQUER and M. H. F. GRYPDONCK. 2005. The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. *International Journal of Nursing Studies*, **42**(1), pp.37-46.
- DEFLOOR, T. and M. F. GRYPDONCK. 2004. Validation of pressure ulcer risk assessment scales: a critique. *Journal of Advanced Nursing*, **48**(6), pp.613-21.
- DEFLOOR, T. and M. F. GRYPDONCK. 2005. Pressure ulcers: validation of two risk assessment scales. *J Clin Nurs*, **14**(3), pp.373-82.
- DELMI, M., C. H. RAPIN, J. M. BENGEOA, J. P. BONJOUR, H. VASEY and P. D. DELMAS. 1990. Dietary supplementation in elderly patients with fractured neck of the femur. *The Lancet*, **335**(8696), pp.1013-1016.

- DENNIS, M. S., S. C. LEWIS and C. WARLOW. 2005. Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicentre randomised controlled trial. *Lancet*, **365**(9461), pp.755-63.
- DEPARTMENT FOR EDUCATION AND SKILLS. 2006. *Safeguarding Vulnerable Groups Bill* Department for Education and Skills London: The Stationary Office.
- DEPARTMENT OF HEALTH (DH). 2000. *No Secrets: Guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse* London.
- DH. 2001a. *Essence of Care: Patient Focused Benchmarking for Health Care Professionals*. London: The Stationary Office.
- DH. 2001b. *National Service Framework for Older People*. . London: The Stationary Office.
- DH. 2008. *Using the Commissioning for quality and Innovation (CQUIN) Payment Framework for the NHS England*. . London.
- DH. 2009a. *NHS 2010-2015, Good to Great, Preventative People Centred, Productive*. . London: The stationary Office.
- DH. 2010. *Clinical Governance and Adult Safeguarding*. . London.
- DH. 2012. *Delivering the NHS Safety Thermometer CQUIN 2012/13; A Preliminary Guide to Delivering 'Harm Free' Care*. London: Department of Health.
- DH, I. F. I. A. I. 2009b. *High Impact Actions for Nursing and Midwifery*. London.
- DILLON, G. F., J. R. BOULET, R. E. HAWKINS and D. B. SWANSON. 2004. Simulations in the United States Medical Licensing Examination (USMLE). *Quality & Safety in Health Care*, **13 Suppl 1**, pp.i41-5.
- DINSDALE, S. M. 1974. Decubitus ulcers: role of pressure and friction in causation. *Arch Phys Med Rehabil*, **55**(4), pp.147-52.
- DONNELLY, J. 2006. *A randomised controlled trial Comparing the Heelift suspension boot with standard care in the prevention of pressure ulcers on the heels of older people with fractured hips*. thesis, Univeristy of Belfast.
- DOUGHTY, D. 2012. Differential assessment of trunk wounds: pressure ulceration versus incontinence associated dermatitis versus intertriginous dermatitis. *Ostomy Wound Management*, **58**(4), pp.20-2.
- EGGER, M., G. D. SMITH and K. O'ROURKE. 2001. Rationale, potentials, and promise of systematic reviews. *In: M. EGGER, G. D. SMITH and D. G. ALTMAN, eds. Systematic Reviews in Health Care: Meta-analysis in context*. London: BMJ Publishing Group, pp.3-19.
- EGGER, M., G. D. SMITH and M. SCHNEIDER. 2001. Systematic Reviews of Observational Studies. *In: M. EGGER, G. D. SMITH and D. G. ALTMAN, eds. Systematic Reviews in Health Care: Meta-analysis in context*. London: BMJ Publishing Group, pp.211-227.
- EK, A. C. 1987. Prediction of pressure sore development. *Scand J Caring Sci*, **1**(2), pp.77-84.
- EK, A. C., M. UNOSSON, J. LARSSON, H. VON SCHENCK and P. BJURULF. 1991. The development and healing of pressure sores related to the nutritional state. *Clin Nutr*, **10**(5), pp.245-50.

- ELLIOTT, R., S. MCKINLEY and V. FOX. 2008. Quality improvement program to reduce the prevalence of pressure ulcers in an intensive care unit. *American Journal of Critical Care*, **17**(4), pp.328-34; quiz 335; discussion 336-7.
- EPUAP. 1999. *Pressure Ulcer Treatment Guidelines*. Oxford: European Pressure Ulcer Advisory Panel.
- ERICSSON, K. and H. SIMON. 1980. Verbal Reports as Data. *Psychological review*, **87**(3), pp.215-251.
- EXTON-SMITH, A. N. and R. W. SHERWIN. 1961. The prevention of pressure sores. Significance of spontaneous bodily movements. *Lancet*, **2**(7212), pp.1124-6.
- FDA DHHS. 2009. Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (accessed March 2014)
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf>.
- FEUCHTINGER, J., R. DE BIE, T. DASSEN and R. HALFENS. 2006. A 4-cm thermoactive viscoelastic foam pad on the operating room table to prevent pressure ulcer during cardiac surgery. *J Clin Nurs*, **15**(2), pp.162-7.
- FIFE, C., G. OTTO, E. G. CAPSUTO, K. BRANDT, K. LYSSY, K. MURPHY and C. SHORT. 2001. Incidence of pressure ulcers in a neurologic intensive care unit. *Crit Care Med*, **29**(2), pp.283-90.
- FINK, A., J. KOSECOFF, M. CHASSIN and R. H. BROOK. 1984. Consensus methods: characteristics and guidelines for use. *American Journal of Public Health*, **74**(9), pp.979-83.
- FITCH, K., S. BERNSTEIN, J. , M. AGUILAR, S. , B. BURNAND, J. LACALLE, R. , P. LAZARO, V. LOO M, H. , J. MCDONNELL, J. VADER and J. KHAN, P. 2001. *The RAND/UCLA Appropriateness Method User's Manual*. Santa Monica CA: RAND Corporation.
- FLASKERUD, J. H. 1979. Use of vignettes to elicit responses toward broad concepts. *Nursing Research*, **28**(4), pp.210-2.
- FLETCHER, R., S. FLETCHER and G. FLETCHER. 2014. *Clinical Epidemiology: The Essentials fifth edition*. Philadelphia: Lippincott Williams and Wilkins.
- FLETCHER, R. H., S. W. FLETCHER and G. S. FLETCHER. 2005. *Clinical Epidemiology: the essentials*. 5 ed. Lippincott Williams and Wilkins.
- FOSSUM, M., O. SODERHAMN, C. CLIFFORDSON and U. SODERHAMN. 2012. Translation and testing of the Risk Assessment Pressure Ulcer Sore scale used among residents in Norwegian nursing homes. *BMJ Open*, **2**(5).
- FOX, C. 2002. Living with a pressure ulcer: a descriptive study of patients' experiences. *British Journal of Community Nursing*, **7**(6 Suppl), pp.10, 12, 14, 16.
- GALLAGHER, M., T. HARES, J. SPENCER, C. BRADSHAW and I. WEBB. 1993. The nominal group technique: a research tool for general practice? *Fam Pract*, **10**(1), pp.76-81.
- GAWLITTA, D., C. W. OOMENS, D. L. BADER, F. P. BAAIJENS and C. V. BOUTEN. 2007. Temporal differences in the influence of ischemic factors and deformation on the metabolism of engineered skeletal muscle. *J Appl Physiol*, **103**(2), pp.464-73.

- GEFEN, A., B. VAN NIEROP, D. L. BADER and C. W. OOMENS. 2008. Strain-time cell-death threshold for skeletal muscle in a tissue-engineered model system for deep tissue injury. *Journal of Biomechanics*, **41**(9), pp.2003-12.
- GIBBONS, W., H. T. SHANKS, P. KLEINHELTER and P. JONES. 2006. Eliminating facility-acquired pressure ulcers at Ascension Health. *Joint Commission Journal on Quality & Patient Safety*, **32**(9), pp.488-96.
- GOODRIDGE, D. M., J. A. SLOAN, Y. M. LEDOYEN, J. A. MCKENZIE, W. E. KNIGHT and M. GAYARI. 1998. Risk-assessment scores, prevention strategies, and the incidence of pressure ulcers among the elderly in four Canadian health-care facilities. *Can J Nurs Res*, **30**(2), pp.23-44.
- GOODSTONE, L., M. S. GOODSTONE, K. CINO, C. A. GLASER, K. KUPFERMAN and T. DEMBER-NEAL. 2013. Effect of simulation on the development of critical thinking in associate degree nursing students. *Nursing Education Perspectives*, **34**(3), pp.159-62.
- GORECKI, C. 2011. The development and validation of a patient-reported outcome measure of health-related quality of life for patients with pressure ulcers: PUQOL Project. *PhD Thesis, University of Leeds*.
- GORECKI, C., J. M. BROWN, S. CANO, D. L. LAMPING, M. BRIGGS, S. COLEMAN, C. DEALEY, E. MCGINNIS, A. E. NELSON, N. STUBBS, L. WILSON and J. NIXON. 2013. Development and validation of a new patient-reported outcome measure for patients with pressure ulcers: the PU-QOL instrument. *Health & Quality of Life Outcomes*, **11**, p95.
- GORECKI, C., J. M. BROWN, E. A. NELSON, M. BRIGGS, L. SCHOONHOVEN, C. DEALEY, T. DEFLOOR, J. NIXON and G. EUROPEAN QUALITY OF LIFE PRESSURE ULCER PROJECT. 2009. Impact of pressure ulcers on quality of life in older patients: a systematic review. *Journal of the American Geriatrics Society*, **57**(7), pp.1175-83.
- GORECKI, C., D. L. LAMPING, J. NIXON, J. M. BROWN and S. CANO. 2012. Applying mixed methods to pretest the Pressure Ulcer Quality of Life (PU-QOL) instrument. *Quality of Life Research*, **21**(3), pp.441-451.
- GOSNELL, D. J. 1973. An assessment tool to identify pressure sores. *Nursing Research*, **22**(1), pp.55-9.
- GOSNELL, D. J. 1989. Pressure sore risk assessment: a critique. Part I. The Gosnell scale. *Decubitus*, **2**(3), pp.32-8.
- GOULD, D. 1996. Using vignettes to collect data for nursing research studies: how valid are the findings? *Journal of Clinical Nursing*, **5**(4), pp.207-12.
- GOULD, D., L. GOLDSTONE, J. GAMMON, D. KELLY and A. MAIDWELL. 2002. Establishing the validity of pressure ulcer risk assessment scales: a novel approach using illustrated patient scenarios. *International Journal of Nursing Studies*, **39**(2), pp.215-28.
- GOULD, D., L. GOLDSTONE, D. KELLY and J. GAMMON. 2004. Examining the validity of pressure ulcer risk assessment scales: a replication study. *International Journal of Nursing Studies*, **41**(3), pp.331-9.

- GRADE WORKING GROUP. 2004. Grading quality of evidence and strength of recommendations. *BMJ*, **328**(7454), p1490.
- GRAY-SIRACUSA, K. and L. SCHRIER. 2011. Use of an intervention bundle to eliminate pressure ulcers in critical care. *Journal of Nursing Care Quality*, **26**(3), pp.216-25.
- GREENHALGH, J., A. F. LONG, A. J. BRETTLE and M. J. GRANT. 1998. Reviewing and selecting outcome measures for use in routine practice. *Journal of Evaluation in Clinical Practice*, **4**(4), pp.339-50.
- GUNNINGBERG, L., C. LINDHOLM, M. CARLSSON and P. O. SJODEN. 2001. Reduced incidence of pressure ulcers in patients with hip fractures: a 2-year follow-up of quality indicators. *International Journal for Quality in Health Care*, **13**(5), pp.399-407.
- GURWITZ, J. H., N. F. COL and J. AVORN. 1992. The exclusion of the elderly and women from clinical trials in acute myocardial infarction. *JAMA*, **268**(11), pp.1417-22.
- GUYATT, G. H., A. D. OXMAN, R. KUNZ, G. E. VIST, Y. FALCK-YTTER and H. J. SCHÜNEMANN. 2008. What is "quality of evidence" and why is it important to clinicians? *BMJ*, **336**(7651), pp.995-998.
- HALBERT, R. J., R. A. FIGLIN, M. B. ATKINS, M. BERNAL, T. E. HUTSON, R. G. UZZO, R. M. BUKOWSKI, K. D. KHAN, C. G. WOOD and R. W. DUBOIS. 2006. Treatment of patients with metastatic renal cell cancer: a RAND Appropriateness Panel. *Cancer*, **107**(10), pp.2375-83.
- HALFENS, R. J., T. VAN ACHTERBERG and R. M. BAL. 2000. Validity and reliability of the braden scale and the influence of other risk factors: a multi-centre prospective study. *Int J Nurs Stud*, **37**(4), pp.313-9.
- HAPI. Accessed Oct 2014. <http://www.ebscohost.com/academic/health-and-psychosocial-instruments-hapi>
- HARRELL, F. E., JR., K. L. LEE, D. B. MATCHAR and T. A. REICHERT. 1985. Regression models for prognostic prediction: advantages, problems, and suggested solutions. *Cancer Treat Rep*, **69**(10), pp.1071-77.
- HARTGRINK, H. H., J. WILLE, P. KÖNIG, J. HERMANS and P. J. BRESLAU. 1998. Pressure sores and tube feeding in patients with a fracture of the hip: a randomized clinical trial. *Clinical Nutrition*, **17**(6), pp.287-292.
- HASSON, F., S. KEENEY and H. MCKENNA. 2000. Research guidelines for the Delphi survey technique. *Journal of Advanced Nursing*, **32**(4), pp.1008-15.
- HATANAKA, N., Y. YAMAMOTO, K. ICHIHARA, S. MASTUO, Y. NAKAMURA, M. WATANABE and Y. IWATANI. 2008. A new predictive indicator for development of pressure ulcers in bedridden patients based on common laboratory tests results. *J Clin Pathol*, **61**(4), pp.514-8.
- HAYDEN, J. A., P. CÔTÉ and C. BOMBARDIER. 2006. Evaluation of the Quality of Prognosis Studies in Systematic Reviews. *Annals of Internal Medicine*, **144**(6), pp.427-437.
- HISER, B., J. ROCHETTE, S. PHILBIN, N. LOWERHOUSE, C. TERBURGH and C. PIETSCH. 2006. Implementing a pressure ulcer prevention program and enhancing the role of the CWOCN: impact on outcomes. *Ostomy Wound Manage*, **52**(2), pp.48-59.

- HOPKINS, A., C. DEALEY, S. BALE, T. DEFLOOR and F. WORBOYS. 2006. Patient stories of living with a pressure ulcer. *Journal of Advanced Nursing*, **56**(4), pp.345-53.
- HOUWING, R. H., M. ROZENDAAL, W. WOUTERS-WESSELING, J. W. BEULENS, E. BUSKENS and J. R. HAALBOOM. 2003. A randomised, double-blind assessment of the effect of nutritional supplementation on the prevention of pressure ulcers in hip-fracture patients. *Clin Nutr*, **22**(4), pp.401-5.
- HSCIC, H. A. S. C. I. C. 2013. NHS Safety Thermometer. [online]. [Accessed 14/10/2013].
- HSIEH, H. F. and S. E. SHANNON. 2005. Three approaches to qualitative content analysis. *Qualitative Health Research*, **15**(9), pp.1277-88.
- HUTCHINGS, A. and R. RAINE. 2006. A systematic review of factors affecting the judgments produced by formal consensus development methods in health care. *Journal of Health Services & Research Policy*, **11**(3), pp.172-9.
- HUTCHINGS, A., R. RAINE, C. SANDERSON and N. BLACK. 2005. An experimental study of determinants of the extent of disagreement within clinical guideline development groups. *Qual Saf Health Care*, **14**(4), pp.240-5.
- HUTCHINGS, A., R. RAINE, C. SANDERSON, N. BLACK, A. HUTCHINGS, R. RAINE, C. SANDERSON and N. BLACK. 2006. A comparison of formal consensus methods used for developing clinical guidelines. *Journal of Health Services & Research Policy*, **11**(4), pp.218-24.
- HUTCHINGS, H., F. RAPPORT, S. WRIGHT, M. DOEL and A. JONES. 2012. Obtaining consensus about patient-centred professionalism in community nursing: nominal group work activity with professionals and the public. *Journal of Advanced Nursing*, **68**(11), pp.2429-2442.
- ICH EXPERT WORKING GROUP. 1998. ICH Harmonised Tripartite Guideline Statistical Principles for Clinical Trials E9. [online]. **Current Step 4 version** section 5.1.
- INMAN, K. J., K. DYMOCK, N. FYSH, B. ROBBINS, F. S. RUTLEDGE and W. J. SIBBALD. 1999. Pressure ulcer prevention: a randomized controlled trial of 2 risk-directed strategies for patient surface assignment. *Adv Wound Care*, **12**(2), pp.72-80.
- JACKSON, A., D. M. HETTINGA, J. MEAD and C. MERCER. 2009. Using consensus methods in developing clinical guidelines for exercise in managing persistent low back pain. *Physiotherapy*, **95**(4), pp.302-11.
- JONES, J. and D. HUNTER. 1995. Consensus methods for medical and health services research. *BMJ*, **311**(7001), pp.376-80.
- JONES, K. R. 2010. Rating the level, quality, and strength of the research evidence. *J Nurs Care Qual*, **25**(4), pp.304-12.
- JUNI, P., D. G. ALTMAN and M. EGGER. 2001. Assessing the quality of randomised controlled trials. In: M. EGGER, G. D. SMITH and D. G. ALTMAN, eds. *Systematic Reviews in Health Care: Meta-analysis in context*. London: BMJ Publishing Group, pp.87-108.
- KADAM, U. T., K. JORDAN, P. R. CROFT, U. T. KADAM, K. JORDAN and P. R. CROFT. 2006. A comparison of two consensus methods for classifying morbidities in a single professional group showed the same outcomes. *Journal of Clinical Epidemiology*, **59**(11), pp.1169-73.

- KALTENTHALER, E., M. D. WHITFIELD, S. J. WALTERS, R. L. AKEHURST and S. PAISLEY. 2001. UK, USA and Canada: how do their pressure ulcer prevalence and incidence data compare? *Journal of Wound Care*, **10**(1), pp.530-5.
- KAPLAN, R., J. BUSH and C. BERRY. 1976. Health status: types of validity and the index of well-being. *Health Services Research*, **11**, pp.478-507.
- KEENEY, S., F. HASSON and H. P. MCKENNA. 2001. A critical review of the Delphi technique as a research methodology for nursing. *International Journal of Nursing Studies*, **38**(2), pp.195-200.
- KEMP, M. G., D. KOPANKE, L. TORDECILLA, L. FOGG, S. SHOTT, V. MATTHIESEN and B. JOHNSON. 1993. The role of support surfaces and patient attributes in preventing pressure ulcers in elderly patients. *Res Nurs Health*, **16**(2), pp.89-96.
- KERLINGER, F. 1973. Foundations of behavioural research. *Holt, Rinehart and Winston. New York*.
- KIM, E. K., S. M. LEE, E. LEE and M. R. EOM. 2005. Comparison of the predictive validity among pressure ulcer risk assessment scales for surgical patients. *Australian Journal of Advanced Nursing*, **26**(4), pp.87-94.
- KIRSHNER, B. and G. GUYATT. 1985. A methodological framework for assessing health indices. *Journal of Chronic Diseases*, **38**(1), pp.27-36.
- KITZINGER, J. 1995. Qualitative research. Introducing focus groups. *BMJ*, **311**(7000), pp.299-302.
- KNOX, D. M., T. M. ANDERSON and P. S. ANDERSON. 1994. Effects of different turn intervals on skin of healthy older adults. *Advances in Wound Care*, **7**(1), pp.48-52, 54-6.
- KOSIAK, M. 1961. Etiology of decubitus ulcers. *Archives of Physical Medicine & Rehabilitation*, **42**, pp.19-29.
- KOTTNER, J. and K. BALZER. 2010. Do Pressure Ulcer risk Assessment Scales Improve Clinical Practice. *Journal of Multidisciplinary Healthcare*, **3**, pp.103-111.
- KOTTNER, J. and T. DASSEN. 2008a. Interpreting interrater reliability coefficients of the Braden scale: A discussion paper. *International journal of nursing studies*, **45**(8), pp.1238-1246.
- KOTTNER, J. and T. DASSEN. 2008b. An interrater reliability study of the Braden scale in two nursing homes. *Int J Nurs Stud*, **45**(10), pp.1501-11.
- KOTTNER, J. and T. DASSEN. 2010. Pressure ulcer risk assessment in critical care: interrater reliability and validity studies of the Braden and Waterlow scales and subjective ratings in two intensive care units. *International Journal of Nursing Studies*, **47**(6), pp.671-7.
- KOTTNER, J., R. HALFENS and T. DASSEN. 2009. An interrater reliability study of the assessment of pressure ulcer risk using the Braden scale and the classification of pressure ulcers in a home care setting. *International journal of nursing studies*, **46**(10), pp.1307-1312.
- KOTTNER, J., D. WILBORN, T. DASSEN and N. LAHMANN. 2009. The trend of pressure ulcer prevalence rates in German hospitals: results of seven cross-sectional studies. *Journal of Tissue Viability*, **18**(2), pp.36-46.

- KROGER, E., A. TOURIGNY, D. MORIN, L. COTE, M. J. KERGOAT, P. LEBEL, L. ROBICHAUD, S. IMBEAULT, S. PROULX and Z. BENOUNISSA. 2007. Selecting process quality indicators for the integrated care of vulnerable older adults affected by cognitive impairment or dementia. *BMC Health Services Research*, **7**, p195.
- KRUEGER, R. A. 1994. Focus Groups: a practical guide for applied research (2nd ed). Sage, Thousand Oaks, USA.
- KWONG, E., S. PANG, T. WONG, J. HO, X. SHAO-LING and T. LI-JUN. 2005. Predicting pressure ulcer risk with the modified Braden, Braden, and Norton scales in acute care hospitals in Mainland China. *Applied Nursing Research*, **18**(2), pp.122-8.
- LANGER, G., G. SCHLOEMER, A. KNERR, O. KUSS and J. BEHRENS. 2003. Nutritional interventions for preventing and treating pressure ulcers. *Cochrane Database Syst Rev*, (4), pCD003216.
- LANZA, M. L. 1990. A methodological approach to enhance external validity in simulation based research. *Issues in Mental Health Nursing*, **11**(4), pp.407-22.
- LIANG, M. H., M. G. LARSON, K. E. CULLEN and J. A. SCHWARTZ. 1985. Comparative measurement efficiency and sensitivity of five health status instruments for arthritis research. *Arthritis & Rheumatism*, **28**(5), pp.542-547.
- LINDER-GANZ, E., S. ENGELBERG, M. SCHEINOWITZ and A. GEFEN. 2006. Pressure-time cell death threshold for albino rat skeletal muscles as related to pressure sore biomechanics. *Journal of Biomechanics*, **39**(14), pp.2725-32.
- LINDER-GANZ, E. and A. GEFEN. 2007. The effects of pressure and shear on capillary closure in the microstructure of skeletal muscles. *Annals of Biomedical Engineering*, **35**(12), pp.2095-107.
- LINDGREN, M., M. UNOSSON, M. FREDRIKSON and A. C. EK. 2004. Immobility--a major risk factor for development of pressure ulcers among adult hospitalized patients: a prospective study. *Scand J Caring Sci*, **18**(1), pp.57-64.
- LINDGREN, M., M. UNOSSON, A. M. KRANTZ and A. C. EK. 2002. A risk assessment scale for the prediction of pressure sore development: reliability and validity. *Journal of Advanced Nursing*, **38**(2), pp.190-9.
- LITTLEFIELD, J. H., E. L. DEMPS, K. KEISER, L. CHATTERJEE, C. H. YUAN and K. M. HARGREAVES. 2003. A multimedia patient simulation for teaching and assessing endodontic diagnosis. *Journal of Dental Education*, **67**(6), pp.669-77.
- LIU, J., J. WYATT and D. ALTMAN. 2006. Decision tools in health care: focus on the problem, not the solution. *BMC Medical Informatics and Decision Making*, **6**(1), pp.1-7.
- LOERAKKER, S. 2011. *The relative contributions of muscle deformation and ischemia to pressure ulcer development*. PhD thesis, Eindhoven University.
- LOERAKKER, S., A. STEKELENBURG, G. J. STRIJKERS, J. J. RIJPKEMA, F. P. BAAIJENS, D. L. BADER, K. NICOLAY and C. W. OOMENS. 2010. Temporal effects of mechanical loading on deformation-induced damage in skeletal muscle tissue. *Ann Biomed Eng*, **38**(8), pp.2577-87.

- LYMAN, V. 2009. Successful heel pressure ulcer prevention program in a long-term care setting. *Journal of Wound, Ostomy, & Continence Nursing*, **36**(6), pp.616-21.
- MAK, K. and C. K. KUM. 2005. How to appraise a prognostic study. *World J Surg*, **29**(5), pp.567-9.
- MALLETT, S., P. ROYSTON, S. DUTTON, R. WATERS and D. ALTMAN. 2010. Reporting methods in studies developing prognostic models in cancer: a review. *BMC Medicine*, **8**(1), p20.
- MALTONI, M., A. CARACENI, C. BRUNELLI, B. BROECKAERT, N. CHRISTAKIS, S. EYCHMUELLER, P. GLARE, M. NABAL, A. VIGANO, P. LARKIN, F. DE CONNO, G. HANKS and S. KAASA. 2005. Prognostic factors in advanced cancer patients: evidence-based clinical recommendations-a study by the Steering Committee of the European Association for Palliative Care. *Journal of Clinical Oncology*, **23**(25), pp.6240-8.
- MANN, C. J. 2003. Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emergency Medicine Journal*, **20**(1), pp.54-60.
- MARCHETTE, L., I. ARNELL and E. REDICK. 1991. Skin ulcers of elderly surgical patients in critical care units. *Dimens Crit Care Nurs*, **10**(6), pp.321-9.
- MARRIE, R. A., J. B. ROSS and K. ROCKWOOD. 2003. Pressure Ulcers: Prevalence, Staging, and Assessment of Risk. *Geriatrics Today: Journal of the Canadian Geriatrics Society*, **6**(3), pp.134-140.
- MCCOLL, E. 2005. *Developing questionnaires. In Assessing quality of life in clinical trials* 2nd ed. New York: Oxford University Press.
- MCDONALD, H., C. CHARLES and A. GAFNI. 2011. Assessing the conceptual clarity and evidence base of quality criteria/standards developed for evaluating decision aids. *Health Expectations*, **17**(2), pp.232-43.
- MCDONNELL, J., H. J. STOEVELAAR, J. L. H. RUUD BOSCH and J. P. KAHAN. 2001. The appropriateness of treatment of benign prostatic hyperplasia: a comparison of Dutch and multinational criteria. *Health Policy*, **57**(1), pp.45-56.
- MCDOWELL, I. 2006. *Measuring Health: A Guide to Rating Scales and Questionnaires*. 3rd ed. Oxford University Press, New York.
- MCGOUGH, A. 1999. A systematic review of the effectiveness of risk assessment scales used in the prevention and management of pressure sores. *University of York MSc Dissertation*.
- MCHORNEY, C. A., J. E. WARE, JR., J. F. LU and C. D. SHERBOURNE. 1994. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Medical Care*, **32**(1), pp.40-66.
- MCINERNEY, J. A. 2008. Reducing hospital-acquired pressure ulcer prevalence through a focused prevention program. *Adv Skin Wound Care*, **21**(2), pp.75-8.
- MCINNES, E., A. JAMMALI-BLASI, S. E. BELL-SYER, J. C. DUMVILLE and N. CULLUM. 2011. Support surfaces for pressure ulcer prevention. *Cochrane Database of Systematic Reviews*, (4), pCD001735.

- MCKENNA, H. P. 1994. The Delphi technique: a worthwhile research approach for nursing? *Journal of Advanced Nursing*, **19**(6), pp.1221-5.
- MERTENS, E. I., R. J. G. HALFENS, E. DIETZ, R. SCHEUFELE and T. DASSEN. 2008. Pressure ulcer risk screening in hospitals and nursing homes with a general nursing assessment tool: Evaluation of the care dependency scale. *Journal of Evaluation in Clinical Practice*, **14**(6), pp.1018-1025.
- MILLER, G. E. and J. SEALE. 1981. Lymphatic clearance during compressive loading. *Lymphology*, **14**(4), pp.161-6.
- MOHER, D., D. J. COOK, S. EASTWOOD, I. OLKIN, D. RENNIE and D. F. STROUP. 1999. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of Reporting of Meta-analyses. *Lancet*, **354**(9193), pp.1896-900.
- MOHER, D., A. R. JADAD, G. NICHOL, M. PENMAN, P. TUGWELL and S. WALSH. 1995. Assessing the quality of randomized controlled trials: an annotated bibliography of scales and checklists. *Controlled Clinical Trials*, **16**(1), pp.62-73.
- MOHER, D., A. LIBERATI, J. TETZLAFF, D. G. ALTMAN and P. GROUP. 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ*, **339**, pb2535.
- MOHER, D., K. F. SCHULZ, D. ALTMAN and C. GROUP. 2001. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA*, **285**(15), pp.1987-91.
- MOONS, K., P. ROYSTON, Y. VERGOUWE, D. GROBBEE and D. ALTMAN. 2009. Prognosis and prognostic research: what, why, and how? *BMJ*, **338**, pb375.
- MOORE, Z. 2009. The effect of repositioning 3 hourly at night, using the 30 degree tilt, on the incidence of pressure ulcers, in older persons at risk of pressure ulcer development hospitalised in long-term care settings. *PD Theses, Royal college of Surgeons in Ireland*.
- MOORE, Z. and S. COWMAN. 2010. Risk Assessment Tools for the Prevention of Pressure Ulcers. *Cochrane Database of Systematic Reviews*, (12).
- MOORE, Z. and S. COWMAN. 2014. Risk Assessment Tools for the Prevention of Pressure Ulcers. *Cochrane Database of Systematic Reviews*, (2).
- MORGAN, D. L. and R. A. KRUEGER. 1993. When to use focus groups and why. In *Successful focus groups: Advancing the state of the art* (Morgan D ed) Sage, London pp3-19.
- MURPHY, M. K., N. A. BLACK, D. L. LAMPING, C. M. MCKEE, C. F. SANDERSON, J. ASKHAM and T. MARTEAU. 1998. Consensus development methods, and their use in clinical guideline development. *Health Technol Assess*, **2**(3), pp.i-iv, 1-88.
- NAIR, R., R. AGGARWAL and D. KHANNA. 2011. Methods of Formal Consensus in Classification/Diagnostic Criteria and Guideline Development. *Seminars in Arthritis and Rheumatism*, **41**(2), pp.95-105.
- NANDA, K., D. C. MCCRORY, E. R. MYERS, L. A. BASTIAN, V. HASSELBLAD, J. D. HICKEY and D. B. MATCHAR. 2000. Accuracy

- of the Papanicolaou Test in Screening for and Follow-up of Cervical Cytologic Abnormalities A Systematic Review. *Annals of Internal Medicine*, **132**(10), pp.810-819.
- NELSON, W. L., P. K. HAN, A. FAGERLIN, M. STEFANEK and P. A. UBEL. 2007. Rethinking the objectives of decision aids: a call for conceptual clarity. *Med Decis Making*, **27**(5), pp.609-18.
- NEUMAN, H. B., M. E. CHARLSON and L. K. TEMPLE. 2007. Is there a role for decision aids in cancer-related decisions? *Crit Rev Oncol Hematol*, **62**(3), pp.240-50.
- NICE. 2003. *CG7 Pressure Relieving Devices*. London: National Institute of Clinical Excellence.
- NICE. 2005. *CG29 The Prevention and Treatment of Pressure Ulcers*. London: NICE.
- NICE. 2014. Pressure ulcer prevention: the prevention and management of pressure ulcers in primary and secondary care, Clinical Guideline 179, Methods, evidence and recommendations. *National Clinical Guideline Centre*.
- NIJS, N., A. TOPPETS, T. DEFLOOR, K. BERNAERTS, K. MILISEN and G. VAN DEN BERGHE. 2009. Incidence and risk factors for pressure ulcers in the intensive care unit. *J Clin Nurs*, **18**(9), pp.1258-66.
- NIXON, J., G. CRANNY and S. BOND. 2007. Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: a cohort study. *International Journal of Nursing Studies*, **44**(5), pp.655-63.
- NIXON, J., G. CRANNY, C. IGLESIAS, E. A. NELSON, K. HAWKINS, A. PHILLIPS, D. TORGERSON, S. MASON and N. CULLUM. 2006a. Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) *BMJ*, **332**(7555), pp.1413-1416.
- NIXON, J. and A. MCGOUGH. eds. 2001. *Principles of patient assessment: screening for pressure ulcers and potential risk in: Morison, M (Ed). The prevention and treatment of pressure ulcers*. 1 ed. Edinburgh: Mosby.
- NIXON, J., E. A. NELSON, G. CRANNY, C. P. IGLESIAS, K. HAWKINS, N. A. CULLUM, A. PHILLIPS, K. SPILSBURY, D. J. TORGERSON, S. MASON and P. T. GROUP. 2006b. Pressure relieving support surfaces: a randomised evaluation. *Health Technology Assessment*, **10**(22), pp.iii-iv, ix-x, 1-163.
- NIXON, J., E. A. NELSON, C. RUTHERFORD, S. COLEMAN, D. MUIR, J. KEEN, C. MCCABE, C. DEALEY, M. BRIGGS, S. BROWN, M. COLLINSON, C. HULME, D. MEADS, E. MCGINNIS, M. PATTERSON, C. CZOSKI-MURRAY, L. PINKNEY, I. SMITH, R. STEVENSON, N. STUBBS, L. WILSON and J. BROWN. Submitted. Pressure UlceR Programme Of ReSEarch *Programme Grants for Applied Research*
- NORTON, D., R. MCCLAREN and A. N. EXTON-SMITH. 1962. *An investigation of geriatric nursing problems in hospital*. London: Churchill Livingstone.

- NPUAP/EPUAP. 2009. *Prevention and treatment of pressure ulcers:clinical practice guideline*. Washington DC: National Pressure Ulcer Advisory Panel
- NUNNALLY, J. 1967. *Psychometric theory*. McGraw-Hill, New York.
- NUNNALLY, J. 1970. *Introduction to Psychological Measurement*. **McGraw Hill Book Company, Japan**.
- OKUWA, M., H. SANADA, J. SUGAMA, M. INAGAKI, C. KONYA, A. KITAGAWA and K. TABATA. 2006. A prospective cohort study of lower-extremity pressure ulcer risk among bedfast older adults. *Adv Skin Wound Care*, **19**(7), pp.391-7.
- OLSON, B., D. LANGEMO, C. BURD, D. HANSON, S. HUNTER and T. CATHCART-SILBERBERG. 1996. Pressure ulcer incidence in an acute care setting. *J Wound Ostomy Continence Nurs*, **23**(1), pp.15-22.
- OMOLAYO, T., K. BROWN, M. P. RAPP, J. LI, R. BARRETT, S. HORN and N. BERGSTROM. 2013. Construct validity of the moisture subscale of the Braden Scale for Predicting Pressure Sore Risk. *Advances in Skin & Wound Care*, **26**(3), pp.122-7.
- OOI, W. L., J. N. MORRIS, G. H. BRANDEIS, M. HOSSAIN and L. A. LIPSITZ. 1999. Nursing home characteristics and the development of pressure sores and disruptive behaviour. *Age Ageing*, **28**(1), pp.45-52.
- OOMENS, C. W., S. LOERAKKER and D. L. BADER. 2010. The importance of internal strain as opposed to interface pressure in the prevention of pressure related deep tissue injury. *J Tissue Viability*, **19**(2), pp.35-42.
- ORSTED, H. L., S. ROSENTHAL and M. G. WOODBURY. 2009. Pressure ulcer awareness and prevention program: a quality improvement program through the Canadian Association of Wound Care. *Journal of Wound, Ostomy, & Continence Nursing*, **36**(2), pp.178-83.
- OXFORD and DICTIONARY. Accessed October 2014.
<http://www.oxforddictionaries.com/definition/english/framework>.
- PAGE, K. N., A. L. BARKER and J. KAMAR. 2011. Development and validation of a pressure ulcer risk assessment tool for acute hospital patients. *Wound Repair Regen*, **19**(1), pp.31-7.
- PANCORBO-HIDALGO, P. L., F. P. GARCIA-FERNANDEZ, I. M. LOPEZ-MEDINA and C. ALVAREZ-NIETO. 2006. Risk assessment scales for pressure ulcer prevention: a systematic review. *Journal of Advanced Nursing*, **54**(1), pp.94-110.
- PANCORBO HIDALGO, P. L. and F. P. GARCIA FERNANDEZ. 2001. Risk factors for the development of pressure ulcers among hospitalized elderly patients. *Gerokomos*, **12**(4), pp.175-184.
- PANG, S. M. and T. K. WONG. 1998. Predicting pressure sore risk with the Norton, Braden, and Waterlow scales in a Hong Kong rehabilitation hospital. *Nursing Research*, **47**(3), pp.147-53.
- PAPANIKOLAOU, P., P. LYNE and D. ANTHONY. 2007. Risk assessment scales for pressure ulcers: a methodological review. *International Journal of Nursing Studies*, **44**(2), pp.285-96.
- PEDUZZI, P., J. CONCATO, A. R. FEINSTEIN and T. R. HOLFORD. 1995. Importance of events per independent variable in proportional hazards regression analysis. II. Accuracy and precision of regression estimates. *J Clin Epidemiol*, **48**(12), pp.1503-10.

- PEIRCE, S. M., T. C. SKALAK and G. T. RODEHEAVER. 2000. Ischemia-reperfusion injury in chronic pressure ulcer formation: a skin model in the rat. *Wound Repair Regen*, **8**(1), pp.68-76.
- PERNEGER, T. V., A. C. RAE, J. M. GASPOZ, F. BORST, O. VITEK and C. HELIOT. 2002. Screening for pressure ulcer risk in an acute care hospital: development of a brief bedside scale. *Journal of Clinical Epidemiology*, **55**(5), pp.498-504.
- PIEPER, B. E. W. T. N. P. U. A. P. N. 2012. *Pressure Ulcers: Prevalence, Incidence, and Implications for the Future*. Washinton DC: NPUAP.
- PINKNEY, L., J. NIXON, L. WILSON, S. COLEMAN, E. MCGINNIS, N. STUBBS, C. DEALEY, A. NELSON, M. PATTERSON and J. KEEN. 2014. Why do patients develop severe pressure ulcers? A retrospective case study, <http://bmjopen.bmj.com/content/4/1/e004303.full.pdf> *BMJ Open*, **4**(1).
- POWERS, G. C., T. ZENTNER, F. NELSON and N. BERGSTROM. 2004. Validation of the mobility subscale of the Braden Scale for predicting pressure sore risk. *Nursing Research*, **53**(5), pp.340-6.
- PRITCHARD, V. 1986. Pressure sores. Calculating the risk. *Nursing Times*, **82**(8), pp.59-61.
- RADEMAKERS, L. M. F., T. VAINAS, S. W. A. M. VAN ZUTPHEN, P. R. G. BRINK and S. H. VAN HELDEN. 2007. Pressure ulcers and prolonged hospital stay in hip fracture patients affected by time-to-surgery. *European Journal of Trauma and Emergency Surgery*, **33**(3), pp.238-244.
- RAINE, R., C. SANDERSON and N. BLACK. 2005. Developing clinical guidelines: a challenge to current methods. *BMJ*, **331**(7517), pp.631-3.
- RAINE, R., C. SANDERSON, A. HUTCHINGS, S. CARTER, K. LARKIN, N. BLACK, R. RAINE, C. SANDERSON, A. HUTCHINGS, S. CARTER, K. LARKIN and N. BLACK. 2004. An experimental study of determinants of group judgments in clinical guideline development.[see comment]. *Lancet*, **364**(9432), pp.429-37.
- RANDELL, R., N. MITCHELL, D. DOWDING, N. CULLUM and C. THOMPSON. 2007. Effects of computerized decision support systems on nursing performance and patient outcomes: a systematic review. *Journal of Health Services Research & Policy*, **12**(4), pp.242-251.
- REDDY, N. P., G. V. B. COCHRAN and T. A. KROUSKOP. 1981. Interstitial fluid flow as a factor in decubitus ulcer formation. *Journal of Biomechanics*, **14**(12), pp.879-881.
- REED, R. L., K. HEPBURN, R. ADELSON, B. CENTER and P. MCKNIGHT. 2003. Low serum albumin levels, confusion, and fecal incontinence: are these risk factors for pressure ulcers in mobility-impaired hospitalized adults? *Gerontology*, **49**(4), pp.255-9.
- REGER, S. I., V. K. RANGANATHAN, H. L. ORSTED, T. OHURA and A. GEFEN. 2010. *Shear and Friction in Context in International Review. Pressure ulcer prevention: pressure, shear, friction and microclimate in context. A consensus document* [online]. London: Wounds International.
- RESWICK, J. and J. ROGERS. eds. 1976. *Bedsore Biomechanics*. London: Macmillan Pres.

- RICHARDSON, F. M. 1972. Peer review of medical care. *Medical Care*, **10**(1), pp.29-39.
- RILEY, R. D., W. SAUERBREI and D. G. ALTMAN. 2009. Prognostic markers in cancer: the evaluation of evidence from single studies to meta-analysis, and beyond. *Br J Cancer*, **100**(8), pp.1219-29.
- ROLLS, K. D. and D. ELLIOTT. 2008. Using consensus methods to develop clinical practice guidelines for intensive care: the intensive care collaborative project.[see comment]. *Australian Critical Care*, **21**(4), pp.200-15.
- ROSE, P., R. COHEN and R. AMSEL. 2006. Development of a scale to measure the risk of skin breakdown in critically ill patients. *American Journal of Critical Care*, **15**(3), pp.337-341.
- ROTHMAN, M., L. BURKE, P. ERICKSON, N. K. LEIDY, D. L. PATRICK and C. D. PETRIE. 2009. Use of existing patient-reported outcome (PRO) instruments and their modification: the ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report. *Value in Health*, **12**(8), pp.1075-83.
- ROYSTON, P., D. ALTMAN and W. SAUERBREI. 2006. Dichotomizing continuous predictors in multiple regression: a bad idea. *Stat Med*, **25**, pp.127 - 141.
- RYCROFT-MALONE, J. 2001. Formal consensus: the development of a national clinical guideline. *Qual Health Care*, **10**(4), pp.238-44.
- SAC. 2002. Assessing health status and quality-of-life instruments: Attributes and review criteria. *Quality of life research*, **11**, pp.193-205.
- SACKMAN, H. 1974. *Delphi assessment: expert opinion, forecasting and group process* [online]. Santa Monica: RAND.
- SALEH, M., D. ANTHONY and S. PARBOTEEAH. 2009. The impact of pressure ulcer risk assessment on patient outcomes among hospitalised patients. *Journal of Clinical Nursing*, **18**(13), pp.1923-9.
- SALZBERG, C. A., D. W. BYRNE, R. KABIR, P. VAN NIEWERBURGH and C. G. CAYTEN. 1999. Predicting pressure ulcers during initial hospitalization for acute spinal cord injury. *Wounds: A Compendium of Clinical Research and Practice* **11**(2), pp.45-57.
- SANDERSON, S., I. D. TATT and J. P. HIGGINS. 2007. Tools for assessing quality and susceptibility to bias in observational studies in epidemiology: a systematic review and annotated bibliography. *Int J Epidemiol*, **36**(3), pp.666-76.
- SAYAR, S., S. TURGUT, H. DOGAN, A. EKICI, S. YURTSEVER, F. DEMIRKAN, N. DORUK and B. TASDELEN. 2009. Incidence of pressure ulcers in intensive care unit patients at risk according to the Waterlow scale and factors influencing the development of pressure ulcers. *J Clin Nurs*, **18**(5), pp.765-74.
- SCHNELLE, J. F., G. M. ADAMSON, P. A. CRUISE, N. AL-SAMARRAI, F. C. SARBAUGH, G. UMAN and J. G. OUSLANDER. 1997. Skin disorders and moisture in incontinent nursing home residents: intervention implications. *J Am Geriatr Soc*, **45**(10), pp.1182-8.
- SCHOONHOVEN, L., M. T. BOUSEMA and E. BUSKENS. 2007. The prevalence and incidence of pressure ulcers in hospitalised patients in The Netherlands: A prospective inception cohort study. *International Journal of Nursing Studies*, **44**(6), pp.927-935.

- SCHOONHOVEN, L., T. DEFLOOR, I. VAN DER TWEEL, E. BUSKENS and M. H. GRYPDONCK. 2002. Risk indicators for pressure ulcers during surgery. *Appl Nurs Res*, **15**(3), pp.163-73.
- SCHULTZ, A., M. BIEN, K. DUMOND, K. BROWN and A. MYERS. 1999. Etiology and incidence of pressure ulcers in surgical patients. *AORN J*, **70**(3), pp.434, 437-40, 443-9.
- SCHULZ, K. F., D. G. ALTMAN, D. MOHER and C. GROUP. 2010. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*, **340**, pp.698-702.
- SCHUURMAN, J.-P., L. SCHOONHOVEN, T. DEFLOOR, I. VAN ENGELSHOVEN, B. VAN RAMSHORST and E. BUSKENS. 2009. Economic evaluation of pressure ulcer care: a cost minimization analysis of preventive strategies. *Nursing Economics*, **27**(6), pp.390-400.
- SCOTT, E. A. and N. BLACK. 1991. Appropriateness of cholecystectomy in the United Kingdom--a consensus panel approach. *Gut*, **32**(9), pp.1066-70.
- SERPA, L. F. and V. L. C. G. SANTOS. 2007. Assessment of the nutritional risk for pressure ulcer development through Braden scale. 39th Annual Wound, Ostomy and Continence Nurses Annual conference *In: Journal of WOCN*, pp.S4-S6.
- SEVERENS, J. L., J. M. HABRAKEN, S. DUIVENVOORDEN and C. M. A. FREDERIKS. 2002. The cost of illness of pressure ulcers in The Netherlands. *Advances in Skin & Wound Care*, **15**(2), pp.72-7.
- SHEA, J. D. 1975. Pressure sores: classification and management. *Clin Orthop Relat Res*, (112), pp.89-100.
- SHIFFMAN, R. N., P. SHEKELLE, J. M. OVERHAGE, J. SLUTSKY, J. GRIMSHAW and A. M. DESHPANDE. 2003. Standardized reporting of clinical practice guidelines: a proposal from the Conference on Guideline Standardization. *Annals of Internal Medicine*, **139**(6), pp.493-8.
- SIMON, R. and D. ALTMAN. 1994. Statistical aspects of prognostic factor studies in oncology. *Br J Cancer*, **69**, pp.979 - 985.
- SMITH, A. M. and J. A. MALONE. 1990. Preventing Pressure Ulcers in Institutionalized Elders: Assessing The Effects of Small, Unscheduled Shifts in Body Position. *Advances in Skin & Wound Care*, **3**(4), pp.20-25.
- SONG, M. and K. S. CHOI. 1991. [Factors predicting development of decubitus ulcers among patients admitted for neurological problems]. *Kanho Hakhoe Chi [Journal of Nurses Academic Society]*, **21**(1), pp.16-26.
- STEKELENBURG, A., G. J. STRIJKERS, H. PARUSEL, D. L. BADER, K. NICOLAY and C. W. OOMENS. 2007. Role of ischemia and deformation in the onset of compression-induced deep tissue injury: MRI-based studies in a rat model. *J Appl Physiol*, **102**(5), pp.2002-11.
- STEVENS, S. S. 1946. *On the theory of scales of measurement*. Bobbs-Merrill, College Division.
- STEYERBERG, E., W. 2010. *Clinical Prediction Models: A Practical Approach to Development, Validation, and Updating*. New York, USA: Springer.

- STIELL, I. G. and G. A. WELLS. 1999. Methodologic standards for the development of clinical decision rules in emergency medicine. *Ann Emerg Med*, **33**(4), pp.437-47.
- STIGGELBOUT, A. M. and D. R. TIMMERMANS. 2010. Revisiting decision aids: about definitions and classifications. *Med Decis Making*, **30**(6), pp.696-8.
- STORDEUR, S., S. LAURENT and W. D'HOORE. 1998. The importance of repeated risk assessment for pressure sores in cardiovascular surgery. *J Cardiovasc Surg (Torino)*, **39**(3), pp.343-9.
- STREINER, D. and G. NORMAN. 2008. Health Measurement Scales: a practical guide to their development and use. 4th ed. *Oxford University Press, New York*.
- SURIADI, H. SANADA, J. SUGAMA, A. KITAGAWA, B. THIGPEN, S. KINOSITA and S. MURAYAMA. 2007. Risk factors in the development of pressure ulcers in an intensive care unit in Pontianak, Indonesia. *Int Wound J*, **4**(3), pp.208-15.
- SURIADI, H. SANADA, J. SUGAMA, B. THIGPEN, A. KITAGAWA, S. KINOSITA and S. MURAYAMA. 2006. A new instrument for predicting pressure ulcer risk in an intensive care unit. *Journal of Tissue Viability*, **16**(3), pp.21-6.
- SURIADI, H. SANADA, J. SUGAMA, B. THIGPEN and M. SUBUH. 2008. Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit. *Nurs Crit Care*, **13**(1), pp.34-43.
- TANNEN, A., K. BALZER, J. KOTTNER, T. DASSEN, R. HALFENS and E. MERTENS. 2010. Diagnostic accuracy of two pressure ulcer risk scales and a generic nursing assessment tool. A psychometric comparison. *Journal of Clinical Nursing*, **19**(11-12), pp.1510-8.
- THE MENTAL CAPACITY ACT. 2005. *The Mental Capacity Act UK: The Stationery Office Limited*.
- TIPPET, A. W. 2009. Reducing the incidence of pressure ulcers in nursing home residents: a prospective 6-year evaluation. *Ostomy Wound Management*, **55**(11), pp.52-8.
- TO, T., A. GUTTMANN, M. D. LOUGHEED, A. S. GERSHON, S. D. DELL, M. B. STANBROOK, C. WANG, S. MCLIMONT, J. VASILEVSKA-RISTOVSKA, E. J. CRIGHTON and D. N. FISMAN. 2010. Evidence-based performance indicators of primary care for asthma: a modified RAND Appropriateness Method. *Int J Qual Health Care*, **22**(6), pp.476-85.
- TORRANCE, C. 1983. *Pressure sores: aetiology, treatment and prevention*. London: Croom Helm.
- TOURTOUAL, D. M., L. A. RIESENBERG, C. J. KORUTZ, A. H. SEMO, A. ASEF, K. TALATI and R. D. GILL. 1997. Predictors of hospital acquired heel pressure ulcers. *Ostomy Wound Manage*, **43**(9), pp.24-8, 30, 32-4 passim.
- TSUJI, S., S. ICHIOKA, N. SEKIYA and T. NAKATSUKA. 2005. Analysis of ischemia-reperfusion injury in a microcirculatory model of pressure ulcers. *Wound Repair & Regeneration*, **13**(2), pp.209-15.
- UNAL, S., S. OZMEN, Y. DEMIR, R. YAVUZER, O. LATIFOGLU, K. ATABAY and M. OGUZ. 2001. The effect of gradually increased blood flow on ischemia-reperfusion injury.[Erratum appears in Ann

- Plast Surg 2002 Feb;48(2):153]. *Annals of Plastic Surgery*, **47**(4), pp.412-6.
- VAKIL, N. 2011. Editorial: consensus guidelines: method or madness? *American Journal of Gastroenterology*, **106**(2), pp.225-7; quiz 228.
- VAN DE VEN, A. and A. L. DELBECQ. 1971. Nominal versus Interacting Group Processes for Committee Decision-Making Effectiveness. *The Academy of Management Journal*, **14**(2), pp.203-212.
- VAN DE VEN, A. H. and A. L. DELBECQ. 1972. The nominal group as a research instrument for exploratory health studies. *American Journal of Public Health*, **62**(3), pp.337-42.
- VAN NIEUWENHOVEN, C. A., C. VANDENBROUCKE-GRAULS, F. H. VAN TIEL, H. C. JOORE, R. J. VAN SCHIJNDEL, I. VAN DER TWEEL, G. RAMSAY and M. J. BONTEN. 2006. Feasibility and effects of the semirecumbent position to prevent ventilator-associated pneumonia: a randomized study. *Crit Care Med*, **34**(2), pp.396-402.
- VANDERWEE, K., M. GRYPDONCK, D. DE BACQUER and T. DEFLOOR. 2009. The identification of older nursing home residents vulnerable for deterioration of grade 1 pressure ulcers. *J Clin Nurs*, **18**(21), pp.3050-8.
- VANDERWEE, K., M. H. F. GRYPDONCK, D. DE BACQUER and T. DEFLOOR. 2007. Effectiveness of turning with unequal time intervals on the incidence of pressure ulcer lesions. *Journal of Advanced Nursing*, **57**(1), pp.59-68.
- VON ELM, E., D. G. ALTMAN, M. EGGER, S. J. POCOCK, P. C. GOTZSCHE, J. P. VANDENBROUCKE and S. INITIATIVE. 2007. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies *Lancet*, **370**(9596), pp.1453-7.
- VOWDEN, K. R. and P. VOWDEN. 2009. The prevalence, management, equipment provision and outcome for patients with pressure ulceration identified in a wound care survey within one English health care district. *Journal of Tissue Viability*, **18**(1), pp.20-6.
- WARE JR, J. E., R. H. BROOK, A. R. DAVIES and K. N. LOHR. 1981. Choosing measures of health status for individuals in general populations. *American Journal of Public Health*, **71**(6), pp.620-625.
- WASHINGTON, D. L., S. J. BERNSTEIN, J. P. KAHAN, L. L. LEAPE, C. J. KAMBERG and P. G. SHEKELLE. 2003. Reliability of clinical guideline development using mail-only versus in-person expert panels. *Med Care*, **41**(12), pp.1374-81.
- WATERLOW, J. 1985. Pressure sores: a risk assessment card. *Nursing Times*, **81**(48), pp.49-55.
- WATTS, D., E. ABRAHAMS, C. MACMILLAN, J. SANAT, R. SILVER, S. VANGORDER, M. WALLER and D. YORK. 1998. Insult after injury: pressure ulcers in trauma patients. *Orthop Nurs*, **17**(4), pp.84-91.
- WEBSTER, J., K. COLEMAN, A. MUDGE, L. MARQUART, G. GARDNER, M. STANKIEWICZ, J. KIRBY, C. VELLACOTT, M. HORTON-BRESHEARS and A. MCCLYMONT. 2011. Pressure ulcers: effectiveness of risk-assessment tools. A randomised controlled trial (the ULCER trial). *BMJ Quality & Safety*, **20**(4), pp.297-306.

- WEBSTER, J., N. GAVIN, C. NICHOLAS, K. COLEMAN and G. GARDNER. 2010. Validity of the Waterlow scale and risk of pressure injury in acute care. *Br J Nurs*, **19**(6), pp.S14, S16, S18 passim.
- WHITLOCK, J. 2011. Using the skin bundle to prevent pressure ulcers. *Nursing Times*, **107**(35).
- WILLIAMS, P. L. and C. WEBB. 1994. The Delphi technique: a methodological discussion. *Journal of Advanced Nursing*, **19**(1), pp.180-6.
- WILLIS, G., B. 2005. *Cognitive interviewing: a tool for improving questionnaire design*. Thousand Oaks, California: Sage Publications.
- YEPES, D., F. MOLINA, W. LEON and E. PEREZ. 2009. Incidence and risk factors associated with the presence of pressure ulcers in critically ill patients. *Med Intensiva*, **33**(6), pp.276-81.
- YOUNG, T. 2004. The 30° tilt position vs the 90° lateral and supine positions in reducing the incidence of non-blanching erythema in a hospital inpatient population: a randomised controlled trial. *Journal of Tissue Viability*, **14**(3), pp.88-96.

Appendices

Appendix 1 Norton Scale

Norton Scale for Assessing Risk of Pressure Ulcers

	Physical Condition	Mental Condition	Activity	Mobility	Incontinent	Total Score
	Good 4 Fair 3 Poor 2 Very bad 1	Alert 4 Apathetic 3 Confused 2 Stupor 1	Ambulant 4 Walk/help 3 Chair-bound 2 Bed 1	Full 4 Slightly Limited 3 Very Limited 2 Immobile 1	Not Occasional 3 Usually/urine 2 Doubly 1	
Name/Date						

The Norton Scale uses five criteria to assess patients' risk for pressure ulcers. Scores of 14 or less indicate liability to ulcers; scores of <12 indicate very high risk.

Norton, D., McLaren, R. & Exton-Smith, A. N. (1962). An investigation of geriatric nursing problems in hospital. London: National Corporation for the Care of Old People (now Centre for Policy on Ageing).

Appendix 2 Waterlow Score

WATERLOW PRESSURE ULCER PREVENTION/TREATMENT POLICY									
RING SCORES IN TABLE, ADD TOTAL. MORE THAN 1 SCORE/CATEGORY CAN BE USED									
BUILD/WEIGHT FOR HEIGHT	◆	SKIN TYPE VISUAL RISK AREAS	◆	SEX AGE	◆	MALNUTRITION SCREENING TOOL (MST) (Nutrition Vol.15, No.6 1999 - Australia)			
AVERAGE BMI = 20-24.9	0	HEALTHY	0	MALE	1	A - HAS PATIENT LOST WEIGHT RECENTLY		B - WEIGHT LOSS SCORE	
ABOVE AVERAGE BMI = 25-29.9	1	TISSUE PAPER DRY	1	FEMALE	2	YES	- GO TO B	0.5 - 5kg	= 1
OBESE BMI > 30	2	OEDEMATOUS	1	14 - 49	1	NO	- GO TO C	5 - 10kg	= 2
BELOW AVERAGE BMI < 20	3	CLAMMY, PYREXIA	1	50 - 64	2	UNSURE	- GO TO C AND SCORE 2	10 - 15kg	= 3
BMI = W(Kg)/Ht (m) ²		DISCOLOURED	2	65 - 74	3	C - PATIENT EATING POORLY OR LACK OF APPETITE		NUTRITION SCORE	
		GRADE 1	2	75 - 80	4	'NO' = 0; 'YES' SCORE = 1		if > 2 refer for nutrition assessment / intervention	
		BROKEN/SPOTS	3	81 +	5				
		GRADE 2-4	3						
CONTINENCE	◆	MOBILITY	◆	SPECIAL RISKS					
COMPLETE/ CATHETERISED	0	FULLY	0	TISSUE MALNUTRITION	◆	NEUROLOGICAL DEFICIT			◆
URINE INCONT.	1	RESTLESS/FIDGETY	1	TERMINAL CACHEXIA	8	DIABETES, MS, CVA			4-6
FAECAL INCONT.	2	APATHETIC	2	MULTIPLE ORGAN FAILURE	8	MOTOR/SENSORY			4-6
URINARY + FAECAL INCONTINENCE	3	RESTRICTED	3	SINGLE ORGAN FAILURE (RESP, RENAL, CARDIAC,)	5	PARAPLEGIA (MAX OF 6)			4-6
		BEDBOUND e.g. TRACTION	4	PERIPHERAL VASCULAR DISEASE	5	MAJOR SURGERY or TRAUMA			
		CHAIRBOUND e.g. WHEELCHAIR	5	ANAEMIA (Hb < 8)	2	ORTHOPAEDIC/SPINAL			5
				SMOKING	1	ON TABLE > 2 HR#			5
						ON TABLE > 6 HR#			8
						MEDICATION - CYTOTOXICS, LONG TERM/HIGH DOSE STEROIDS, ANTI-INFLAMMATORY MAX OF 4			
						# Scores can be discounted after 48 hours provided patient is recovering normally			
SCORE									
10+ AT RISK									
15+ HIGH RISK									
20+ VERY HIGH RISK									

© J Waterlow 1985 Revised 2005*

Obtainable from the Nook, Stoke Road, Henlade TAUNTON TA3 5LX

* The 2005 revision incorporates the research undertaken by Queensland Health.

www.judy-waterlow.co.uk

Reprinted with permission 11th May 2014

Appendix 3 Braden Scale

BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

Patient's Name _____		Evaluator's Name _____		Date of Assessment _____					
SENSORY PERCEPTION ability to respond meaningfully to pressure-related discomfort	1. Completely Limited Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation. OR limited ability to feel pain over most of body	2. Very Limited Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over 1/2 of body.	3. Slightly Limited Responds to verbal commands, but cannot always communicate discomfort or the need to be turned. OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	4. No Impairment Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.					
MOISTURE degree to which skin is exposed to moisture	1. Constantly Moist Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	2. Very Moist Skin is often, but not always moist. Linen must be changed at least once a shift.	3. Occasionally Moist: Skin is occasionally moist, requiring an extra linen change approximately once a day.	4. Rarely Moist Skin is usually dry, linen only requires changing at routine intervals.					
ACTIVITY degree of physical activity	1. Bedfast Confined to bed.	2. Chairfast Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	3. Walks Occasionally Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	4. Walks Frequently Walks outside room at least twice a day and inside room at least once every two hours during waking hours					
MOBILITY ability to change and control body position	1. Completely Immobile Does not make even slight changes in body or extremity position without assistance	2. Very Limited Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	3. Slightly Limited Makes frequent though slight changes in body or extremity position independently.	4. No Limitation Makes major and frequent changes in position without assistance.					
NUTRITION <u>usual</u> food intake pattern	1. Very Poor Never eats a complete meal. Rarely eats more than 1/2 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	2. Probably Inadequate Rarely eats a complete meal and generally eats only about 1/2 of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding	3. Adequate Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	4. Excellent Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.					
FRICTION & SHEAR	1. Problem Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction	2. Potential Problem Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	3. No Apparent Problem Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.						
© Copyright Barbara Braden and Nancy Bergstrom, 1988 All rights reserved					Total Score				

Reprinted with permission 17th June 2014

Appendix 4 Pressure Ulcer Risk Assessment Scale Validity Search

Four electronic databases were searched through OVID web gateway including AMED, MEDLINE, EMBASE and CINAHL from their inception, using the search template detailed below. The search plan included pressure ulcer search terms ²⁴

1. decubitus.sh.
2. skin ulcer.sh,tw.
3. exp decubitus ulcer/
4. decubitus ulcer\$.tw.
5. pressure ulcer\$.tw.
6. pressure damage\$.tw.
7. pressure sore\$.tw.
8. bed sore\$.tw.
9. or/1-8
- 10 risk assessment
11. scale
- 12 tool
- 13 score
14. instrument
15. or/11-14
16. content validity
17. construct validity
18. convergent validity
19. known group\$
20. discriminant validity
21. responsiveness
22. or/16-22
23. 9 and 15 and 22

Appendix 5 PRISMA Checklist

Section/topic	#	Checklist item For Section 5.3 Systematic Review of PU Risk Factors	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	√
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	n/a
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	√
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	√
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	x
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	√
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	√
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	√

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	√
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	√
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	n/a
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	√
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	√
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n/a
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	√
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	√
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	√
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	√
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	√
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	√

Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	√
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	√
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	√
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	n/a

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Appendix 6 Systematic Review Search Strategy

Four electronic databases were searched through OVID web gateway including AMED, MEDLINE, EMBASE and CINAHL from their inception, using the search template detailed below. The search plan included pressure ulcer search terms²⁴ and OVID maximum sensitivity filters for Prognosis and Aetiology or Harm²⁵.

1. decubitus.sh.
2. skin ulcer.sh,tw.
3. exp decubitus ulcer/
4. decubitus ulcer\$.tw.
5. pressure ulcer\$.tw.
6. pressure damage\$.tw.
7. pressure sore\$.tw.
8. bed sore\$.tw.
9. or/1-8
10. exp cohort-studies/
11. exp risk/
12. (odds and ratio\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
13. (relative and risk\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
14. (case and control\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15. or/10-14
16. incidence.tw.
17. exp mortality/
18. Follow-Up Studies/
19. prognos\$.tw.
20. predict\$.tw.
21. course.tw.
22. Survival Analysis/
23. or/16-22
24. 9 and 15
25. 9 and 23
26. 24 or 25
27. case report.sh.
28. historical article.pt.
29. review of reported cases.pt.
30. review, multicase.pt.
31. letter.pt.
32. comment.pt.
33. editorial.pt.
34. or/27-33
35. 26 not 34
36. limit 35 to humans

The first 200 retrieved abstracts were screened and key words from non-relevant papers identified and used to further refine the search (i.e. increase specificity).

37. leg ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
38. varicose ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
39. pilonidal.tw.

40. surgical flaps.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
41. skin transplantation\$.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
42. burn\$.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
43. gunshot.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
44. corneal ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
45. exp dentistry/
46. peptic ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
47. duodenal ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
48. stomach ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
49. fistula\$.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
50. bite.tw.
51. or/37-50
52. 36 not 51

Hand Search

- Proceedings of the 1st European Conference on Advances in Wound Management, September 1991, Cardiff, UK
- Proceedings of the 2nd European Conference on Advances in Wound Management, October 1992, Harrogate, UK
- Proceedings of the 3rd European Conference on Advances in Wound Management, October 1993, Harrogate, UK
- Proceedings of the 4th European Conference on Advances in Wound Management, September 1994, Copenhagen, Denmark
- Proceedings of the 5th European Conference on Advances in Wound Management, November 1995, Harrogate, UK
- Proceedings of the 6th European Conference on Advances in Wound Management, October 1996, Amsterdam, The Netherlands
- Proceedings of the 7th European Conference on Advances in Wound Management, November 1997, Harrogate, UK
- Proceedings of the 8th European Conference on Advances in Wound Management, April 1998, Madrid, Spain
- Proceedings of the 9th European Conference on Advances in Wound Management, November 1999, Harrogate, UK
- Proceedings of the 10th European Conference on Advances in Wound Management, May 2000, Stockholm, Sweden
- Proceedings of the 11th Conference of the European Wound Management Association, May 2001, Dublin, Ireland
- Proceedings of the 12th Conference of the European Wound Management Association, May 2002, Granada, Spain
- Proceedings of the 13th Conference of the European Wound Management Association, May 2003, Pisa, Italy
- Proceedings of the 15th Conference of the European Wound Management Association, September 2005, Stuttgart, Germany
- Proceedings of the 16th Conference of the European Wound Management Association, May 2006, Prague, Czech Republic

- Proceedings of the European Wound Management Association and Journal of Wound Care Autumn Conference, November 1998, Harrogate, UK
- Proceedings of the European Wound Management Association and Journal of Wound Care Conference, April 1997, Milan, Italy
- 2nd World Union of Wound Healing Societies' Meeting, July 2004, Paris, France.
- Journal of Wound Healing 2nd Conference, September 2005, Stuttgart, Germany
- Wounds UK Conference, November 2004, Harrogate, UK
- The 1st European Pressure Ulcer Advisory Panel Open Meeting, September 1997, Oxford, UK
- The 2nd European Pressure Ulcer Advisory Panel Open Meeting, September 1998, Oxford, UK
- The 3rd European Pressure Ulcer Advisory Panel Open Meeting, September 1999, Amsterdam, The Netherlands
- The 4th European Pressure Ulcer Advisory Panel Open Meeting, September 2000, Pisa, Italy
- The 5th European Pressure Ulcer Advisory Panel Open Meeting, September 2001, Le Mans, France
- The 6th European Pressure Ulcer Advisory Panel Open Meeting, September 2002, Budapest, Hungary
- The 7th European Pressure Ulcer Advisory Panel Open Meeting, September 2003, Tampere, Finland
- The 8th European Pressure Ulcer Advisory Panel Open Meeting, May 2005, Aberdeen, Scotland

Hand searched the EPUAP Reviews from Volume 1, issue 2, 1999 until volume 7, issue 2, 2006

- European Tissue Repair Society, Focus Meeting, November 2000, St Anne's College, Oxford
- European Tissue Repair Society, Annual Conference, September 2001, Cardiff, UK
- European Tissue Repair Society, Focus Meeting, September 2002, Nice, France
- 13th Annual European Tissue Repair Society Meeting, September 2003, Amsterdam, The Netherlands
- European Tissue Repair Society, Focus Meeting, March 2005, Southampton, UK

Appendix 7 Skin Conditions Evidence Tables

Find below the detailed evidence tables relating to skin condition. NB: the studies with an asterisk * or green background are studies where the specific variable emerged as a risk factor in multivariable analyses, while the ones without an asterisk or background didn't. A # sign indicates studies with variables that have emerged in the model as well as related variables that have not.

Stage/Grade 1

Author and Year	Study Limitations	Study Limitation Notes	Study Design	PU Events/ Sample	Specific Variable	Odds Ratio	Confidence Interval	Study Population
*Reed et al 2003	High Quality Study	Record review.	Record Review	406/2771	Stage 1 PU	3.13	2.41-4.06	Chronic care hospital, medicine, non-surgical
*Nixon et al 2006	High Quality Study	Minor limitation - number of patient in final model not reported.	RCT	207/1971	Baseline grade 1	1.95	1.31-2.91	Acute care hospital, multiple specialities, mixed
*Allman et al 1995	Low Quality Study	Insufficient number of events.	Cohort	37/286	Non blanchable erythema of sacral skin	RRa 7.52	1.00 - 59.12	Acute care hospital, multiple specialties, mixed
*Nixon et al 2007	Low Quality Study	Inadequate number of events. Included time dependent variables in the analysis.	Cohort	15/97	Grade 1 equivalent	7.02	1.67-29.49	Acute care hospital, multiple specialities, surgical

Existing PU

Author and Year	Study Limitations	Study Limitation Notes	Study Design	PU Events/ Sample	Specific Variable	Odds Ratio	Confidence Interval	Study Population
*Defloor & Grypdonck 2005	High Quality Study	Limitation partial reporting of baseline.	RCT	302/1458	Existing PU	2.25	1.43-3.54	Long-term nursing care/nursing home, elderly/geriatric, non-surgical
*Baumgarten et al 2004	Moderate Quality Study	All risk factors are categorical data rather than continuous. 20% missing data from final model.	Cohort	450/1938	PU on admission	HR 1.8	1.40-2.32	Long-term nursing care/nursing home, non-surgical
Nixon et al 2006	High Quality Study	Minor limitation - number of patient in final model not reported.	RCT	207/1971	Existing PU	0.97	0.52-1.79	Acute care hospital, multiple specialities, mixed
Tourtual et al 1997	Low Quality Study	Insufficient number of events and confidence intervals not reported.	Cohort	63/291	Admitted with PU	nr	nr	Acute care hospital, medicine, non-surgical
Stordeur et al 1998	Low Quality Study	Insufficient number of events and confidence intervals not reported.	Cohort	48/163	PU at baseline	nr	nr	Acute care hospital, cardiac/vascular, surgical

Previous PU

Author and Year	Study Limitations	Study Limitation Notes	Study Design	PU Events/ sample	Specific mobility Variable	Odds Ratio	Confidence Interval	Study Population
Allman et al 1995	Low Quality Study	Insufficient number of events.	Cohort	37/286	Previous PU	nr	nr	Acute care hospital, multiple specialities, mixed
Halfens et al 2000	Low Quality Study	Partial reporting of baseline characteristics and insufficient number of events.	Cohort	47/320	PU in the past	nr	nr	Acute care hospital, multiple specialities, mixed

General Skin Status

Author and Year	Study Limitations	Study Limitation Notes	Study Design	PU Events/ Sample	Specific Variable	Odds Ratio	Confidence Interval	Study Population
*Defloor & Grypdonck 2005	High Quality Study	Limitation partial reporting of baseline.	RCT	302/1458	Skin condition	1.49	1.21-1.85	Long-term nursing care/nursing home, elderly/geriatric, non-surgical
*Nixon et al 2006	High Quality Study	Minor limitation - number of patient in final model not reported.	RCT	207/1971	Baseline skin trauma	1.67	0.999-2.80	Acute care hospital, multiple specialties, mixed
*Compton et al 2008	Low Quality Study	Record review. Large number of events but it used 32 variables in model. No confidence intervals reported.	Record Review	121/698	Mottled skin	2.021	nr	Acute care hospital , ICU, non-surgical
					Reddened skin	2.305	nr	
*Schnelle et al 1997	Low Quality Study	Insufficient number of events and analysis reporting inadequate. No p values or confidence intervals reported.	Cohort	19/91	Blanchable erythema severity	nr	nr	Long-term nursing care/nursing home, elderly/geriatric, non-surgical
*Allman et al 1995	Low Quality Study	Insufficient number of events.	Cohort	37/286	Dry sacral skin	RR 2.31	1.02 - 5.21	Acute care hospital, multiple specialties, mixed
*Bates-Jensen et al 2007	Low Quality Study	Inadequate sample size resulting in wide confidence intervals.	Cohort	16/35	Sub epidermal moisture at 1 week	1.008	1.004-1.012	Nursing home, elderly/geriatric, non-surgical

*Pancorbo Hidalgo & Garcia Fernandez 2001	Low Quality Study	Article was translated so unable to undertake detailed quality assessment. Limitations based on inadequate number of events. Time dependent variables included in the analysis.	Cohort	31/187	Skin alterations diminished	1.39	1.03-1.86	Acute care hospital, multiple specialities, mixed
*Rose et al 2006	Very Low Quality Study	Abstract only. Inadequate information on methodology and analysis. No p values or confidence intervals.	Cohort	48/111	Skin quality	nr	nr	Acute care hospital, ICU,
*Marchette et al 1991	Very Low Quality Study	Inadequate reporting of methods and analysis. No confidence intervals. Included time dependent variables in the analysis. Adequacy of number of events cannot be assessed.	Record Review	63/161	Skin redness	nr	nr	Acute care hospital, ICU, surgical
Boyle & Green 2001	Low Quality Study	Baseline characteristics not reported. Insufficient number of events.	Cohort	28/534	Unhealthy skin	nr	nr	Acute care hospital, ICU, mixed
#Bates-Jensen et al 2007	Low Quality Study	Inadequate sample size resulting in wide confidence intervals.	Cohort	16/35	Sub epidermal moisture at baseline	1.002	0.996-1.008	Nursing home, elderly/geriatric, non-surgical
#Compton et al 2008	Low Quality Study	Record review. Large number of events but it used 32 variables in model. No confidence intervals reported.	Record Review	121/698	Skin condition, hyperaemic skin	nr	nr	Acute care hospital , ICU, non-surgical
					Skin condition livid skin	nr	nr	

Appendix 8 SHREC approval for consensus study

Dr Janet Holt
0113 343 1296
hcsjh@leeds.ac.uk

14th September 2010

Professor Jane Nixon
CTRU
Leeds Institute of Molecular Medicine
University of Leeds
Clarendon Road
LEEDS
LS2 9JT

Dear Jane

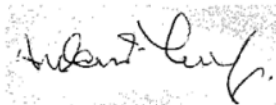
Re: Research Project for Ethical Approval (SHREC/RP/193) *The development of an international pressure ulcer minimum data set (PU-MDS) and pressure ulcer risk assessment framework (PURAF)*

Thank you for making the necessary changes to your documents for approval.

The changes been reviewed and I can confirm that the issues raised by the School of Healthcare Research Ethics Committee (SHREC) have been fully addressed and consequently ethical approval is granted.

The committee wishes you every success with your project.

Yours sincerely



Professor Andrew Long
Deputy Chair, School of Healthcare Research Ethics Committee

Appendix 9 Nominal Group Information Sheet for Consensus Study



Pressure Ulcer Programme Of ReSearch

The Development of a Pressure Ulcer Minimum Dataset (PU-MDS) and Pressure Ulcer Risk Assessment Framework (PURAF) Study

PU-MDS NOMINAL GROUP PARTICIPANT INFORMATION SHEET

You have been invited to take part in the study detailed above. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and ask us if anything is unclear, or if you would like more information.

What is the purpose of the study?

The purpose of this study is to agree a Pressure Ulcer Minimum Data Set (PU-MDS) and develop an evidence based Pressure Ulcer Risk Assessment Framework (PURAF) for use in clinical practice. This information sheet relates to the PU-MDS element of the study.

Why have I been chosen?

You have been invited to be a member of the Nominal Group because of your subject expertise, which is relevant to the assessment or measurement of pressure ulcer risk factors.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and asking any questions you may have. If you wish to participate you will be asked to provide consent by returning a Word Document with your electronic signature. You will be able to retain a copy of this for your records and one will be held by the researcher. You will be free to withdraw from the study at any time including before, during or after nominal group meetings and before, during or after questionnaire completion, without giving a reason. Data collected from you prior to withdrawal will be used in the final study analysis. However if you do not want your existing data from nominal group meetings or completed questionnaires to be used you can inform the researcher and this data will be destroyed and excluded from the study.

What does Nominal Group Membership involve?

If you agree to take part in the study, you will be required attend two meetings over a 12- 18 month period. Standard rate travel expenses will be reimbursed. The meetings will involve 12-14 academic or healthcare experts from a number of countries and will include in-depth discussions and debate about the factors for inclusion in a PU-MDS. Each meeting will last approximately 3.5 hours and will include refreshments and comfort breaks. The meetings will be led by trained facilitators and will be audio-taped and transcribed to allow thematic analysis of the meeting to occur. You will also be required to read a pressure ulcer systematic review summary report, comment on the content of consensus questionnaires and to complete two web-based consensus questionnaires. Within the questionnaire you will also be asked to provide anonymous demographic data including: age, gender, nationality, area of expertise, role and sector i.e. university, community or acute hospital to allow the nominal group characteristics to be described. The summary report will take approximately 30 minutes to read and each questionnaire will take approximately 15 minutes to complete. Further email and telephone correspondence may also be required.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and this may involve you travelling for meetings.

What are the possible benefits of taking part?

You will be contributing to the development of a PU-MDS which will facilitate the interpretation and further use of pressure ulcer research data and meta-analysis. This will contribute to the development of an evidence based PURAF which could lead to improvements in patient care. Nominal group members will be listed as contributors for the main study publication, subject to your agreement. The researcher will write to you prior to publication to ask you about this. If you agree to this you will be asked to complete a short form indicating that you agree to be listed as a contributor.

Will my taking part be kept confidential?

As part of the nominal group your identity would be apparent to other group members due to the face to face meetings but your questionnaire responses would be anonymised before being presented to the nominal group or being detailed in any reports. Your individual responses would not be revealed by the Clinical Trials Research Unit (CTRU). However, whilst under no obligation to do so, you would be free to share this with the group should you wish to.

All information collected will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. Where personal data is provided this will be stored separately to questionnaire data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. Anonymous questionnaire responses will be held on the secure web-based survey platform and will only be accessible by the web-based survey provider and the CTRU research team on a password protected restricted access database. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the CTRU at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further information and contact details

If you have any questions please contact:

Susanne Coleman
PU-MDS and PURAF Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
Fax: 0113 343 1471
Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If you wish to participate please provide consent by returning the Word Document (attached in the introductory email) with your electronic signature.

Appendix 10 Nominal Group Participant Consent Form for Consensus Study

Participant Study Number: <i>Office use only</i>	Participant initials:
--	-----------------------

PU-MDS NOMINAL GROUP PARTICIPANT CONSENT FORM



Pressure Ulcer Programme Of ReSearch

The Development of a Pressure Ulcer Minimum Dataset (PUMDS) and Pressure Ulcer Risk Assessment Framework (PURAF) Study

The participant should complete the whole of this sheet himself/herself

	Please confirm the statements by putting your initials in the box below
I confirm that I have read and understand the information sheet (dated 14 th September 2010, version 2), for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	
I agree to allow any information or results arising from the study to be used for training and developing new research.	
I understand that my questionnaire data may be looked at by responsible individuals from the study office where it is relevant to my taking part in the study. I give permission for these individuals to have access to my information and questionnaire data.	
I consent to the storage including electronic, of personal information (name, contact details and place of work) which will be used by the researcher for ongoing contact with me for the purposes of this study only. I understand that my completed questionnaire data will remain anonymous.	
I consent to being audio-taped in nominal group meetings.	
I agree to take part in this study	
Participant Name: Date:	Participant Electronic Signature:

Thank you for agreeing to take part in this study.

Appendix 11 SHREC Approval for Pre-test Study

School of Healthcare

Dr Janet Holt
0113 343 1296
hcsjh@leeds.ac.uk

Baines Wing
University of Leeds
Leeds LS2 9JT



UNIVERSITY OF LEEDS

31.01.2012

Prof. Jane Nixon
Deputy Director CTRU
Professor of Tissue Viability and Clinical Trials Research
Clinical Trials Research Unit
University of Leeds
Leeds LS2 9JT

Dear Jane,

Re: Research Project for Ethical Approval

Ref: SHREC/RP/244

Title: Pressure Ulcer Risk Assessment Framework (PURAF) Phase 2 Pre-Test

Thank you for making the requested amendments to the documentation for the above project following review by the School of Healthcare Research Ethics Committee (SHREC). I can confirm a favourable ethical opinion based on the documentation received at date of this letter.

Ethical approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The SHREC takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, and other documents relating to the study. This should be kept in your study file, and may be subject to an audit inspection. If your project is to be audited, you will be given at least 2 weeks notice.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

The committee wishes you every success with your project.

Yours sincerely

Dr Ruth Brooke
Deputy Chair, School of Healthcare Research Ethics Committee

Professor Andrea Nelson
Head of School of Healthcare



Appendix 12 Participant Information Sheet for Pre-test Study



Pressure Ulcer Programme Of Research

The Pressure Ulcer Risk Assessment Framework (PURAF) Pre-Test Study

NURSE PARTICIPANT INFORMATION SHEET

You have been invited to take part in the study detailed above. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and ask us if anything is unclear, or if you would like more information.

What is the purpose of the study?

The clinical guidelines and policies in place in the NHS focus on risk assessment as being the key to prevention of PUs but risk assessment tools have not been updated for decades. While existing tools offer some structure to PU risk assessment they were developed in the 1970-80s through expert opinion and outdated literature reviewing methods when the evidence was limited. The preliminary PURAF (Pressure Ulcer Risk Assessment Framework) was developed following a systematic review of pressure ulcer risk factors and a consensus study involving international experts in the pressure ulcer field to establish what elements need to be included in pressure ulcer risk assessment. The purpose of this study is to assess the acceptability of the preliminary PURAF amongst nurses in relation its clarity and ease of use.

Why have I been chosen?

You have been invited to participate in this study as you are a practising Registered Nurse who is involved with the planning and delivery of pressure area care.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and asking any questions you may have. If you wish to participate you will be asked to provide informed written consent. You will be able to retain a copy of this for your records and one will be held by the researcher. You will be free to withdraw from the study at any time including before, during or after the PURAF training, focus group or one-to-one interview, without giving a reason. Data collected from you prior to withdrawal will be used in the final study analysis.

What does the study involve?

If you agree to take part in the study, you will be required to attend a 4 hour PURAF session. The session will incorporate training in the use of the PURAF which will be followed by your participation in either a focus group meeting or one-to-one interview. It will involve you travelling to the venue in Leeds and standard rate travel expenses will be reimbursed.

The training will involve 8-12 other nurses in similar roles to yourself and will involve the researcher explaining how to use the PURAF and demonstrating this with a simulated patient (an actor taking on the role of a patient). You will then be asked to practice using the PURAF with a training case study relevant to your area of practice and photographs of pressure ulcers/areas, noting any areas of confusion on the PURAF form.

Following training you will then participate in either the focus group with approximately 4-8 other nurses or a one-to-one interview with the researcher. Allocation to the focus group and one-to-one interview will be done using randomisation in advance of the session.

If you are assigned to the focus group you will be asked to complete the PURAF again using another case study before the focus group meeting; you will be encouraged to highlight any areas which you find confusing on the PURAF documentation form which will inform the discussions of the focus group meeting. This is not a test and there are no 'right or wrong' answers. At the focus group meeting you will be invited to discuss your thoughts about using the PURAF in a group setting. It is anticipated that working in a group may spark further discussion and highlight any issues you found difficult or unclear when using the PURAF. The focus group will be led by a trained facilitator and will be audio-taped.

If you are assigned to the one-to-one interview you will be asked to complete the PURAF again using another case study. The researcher will ask you to 'think out loud' as you complete the PURAF. This is not a test and there are no 'right or wrong' answers; it will allow the researcher to get a better understanding of areas of the PURAF which nurses find confusing to complete. The interview will be audio-recorded.

The audio-tapes from the interview and the focus group will be transcribed to allow thematic analysis of the issues relating to PURAF. At the session you will also be asked to provide anonymous demographic data including: age, gender, nationality, role and sector i.e. community or acute hospital to allow the group characteristics to be described.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and this will involve you travelling to the session.

What are the possible benefits of taking part?

You will be contributing to the development of a PURAF which could lead to more useful nurse assessment and improvements in patient care. You would also be involved in research which would help you to develop your professional portfolio in relation to being involved in research to enhance patient care. As this is dedicated research activity outside of clinical hours, the payment of £105 (subject to deductions for national insurance and tax) will be made to participants to attend the session.

Will my taking part be kept confidential?

As part of the PURAF session your identity would be apparent to other group members due to the face to face nature of the session. Focus group and individual interview responses would not be revealed by the Clinical Trials Research Unit (CTRU).

All information collected will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. Where personal data is provided this will be stored separately to focus group and interview data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the CTRU at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further information and contact details

If you have any questions please contact:

Susanne Coleman
PURA Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
Fax: 0113 343 1471
Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If you wish to participate please provide written consent.

Appendix 13 Consent Form for Pre-test Study

Participant Study Number: <i>Office use only</i>	Participant initials:
--	-----------------------

PURAF PRE-TEST NURSE PARTICIPANT CONSENT FORM



Pressure Ulcer Programme Of ReSearch

The Pressure Ulcer Risk Assessment Framework (PURAF) Pre-Test Study


The participant should complete the whole of this sheet himself/herself

	Please confirm the statements by putting your initials in the box below
I confirm that I have read and understand the information sheet dated 31/01/2012 (version 1.1) for the above study.	
I have had the opportunity to ask questions and have had these answered satisfactorily.	
I agree to allow any information or results arising from the study to be used for training and developing new research.	
I understand that my focus group and interview data may be looked at by responsible individuals from the study office where it is relevant to my taking part in the study and I give permission for these individuals to have access to my information and data.	
I consent to the storage including electronic, of personal information (name, contact details and place of work) which will be used by the researcher for ongoing contact with me for the purposes of this study only.	
I understand that my completed interview and focus group data will remain anonymous.	
I consent to being audio-taped in the focus group meeting or one-to-one meeting.	
I agree to take part in this study	
Participant Name: _____ Participant Signature: _____ Date: _____	

Thank you for agreeing to take part in this study.
I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

Name of Person Taking Consent Date Signature
1 copy for nurse, 1 copy for Investigator Site File, 1 copy CTRU.

Appendix 14 Agenda for Pre-test session

 Pre-Test Agenda	Date: Tuesday 19th June 2012 Time: 12.45-16.45 Venue: CTRU, University of Leeds		
Time	Agenda		
12.45	Coffee		
13.00	Introductions		SC
13.15	Introduction to PURAF studies Aims of Pre-Test Scope of PURAF PURAF		SC
13.45	Demonstration of PURAF with simulated patient		LW/DM
14.05	PURAF Practice training session using Case Studies		All
14.45	Coffee		
15.00	Focus Group Use of PURAF with Case study Focus Group Meeting	Think out Loud Introduction and Interviews	All
16.30	Summary of Day		SC
16.45	Close of day		

Appendix 15 Vignette Case Studies for Pre-test Study

Acute Sector Case Studies

Case Study 1

Trudie is a 75 year old lady who lives with her husband. She is admitted to hospital for investigations into her intermittent abdominal pain. She is active and mobile and other than intermittent abdominal pain reports being fit and well. Trudie walked on to the ward unaided. She reports no skin problems.

Case Study 2

Susan is a 21 year old student who is admitted with a severe headache. She is a keen hockey player and reports being usually fit and well. Susan refuses analgesia as it makes her feel 'strange'. She is fully mobile: due to her pain she can't get comfortable and moves from bed to chair frequently and walks to the toilet. She reports no skin problems.

Case Study 3

John is a 29 year old gentleman who is admitted with acute appendicitis. John is a keen rugby player and is normally fit and well, though he is an insulin dependent diabetic which is well controlled and he does not have peripheral neuropathy. On admission John has a lot of pain, feels generally unwell and remains in bed. He has pain relief but is fully alert. John moves around in bed independently and frequently walks to the toilet unaided. John generally has a good diet and has a muscular stocky build, but is put nil by mouth on admission and is to have an IVI put up. He has no moisture or circulation problems. The staff nurse assesses John's pressure ulcer risk as part of her admission procedures.

Skin Assessment

Normal

Case Study 4

Hilda is an 80 year old lady who is admitted to the elderly care ward following a chest infection. Hilda lives in a warden controlled flat with her 85 year old husband. Hilda has a history of COPD and previous chest infections. Hilda is usually quite active and mobile within in her home but is restricted to the distance she can walk due to breathlessness.

On admission to the ward Hilda is weak and not as mobile as usual: she is able to transfer herself but needs the aid of one nurse to accompany her when walking to the toilet as she feels unsteady. She is able to change her position independently and does when she feels uncomfortable, but is lethargic and spends most of her time in the chair. Hilda has lost her appetite and says she has lost weight in the last 2-3 weeks and appears to be very thin and bony. She has been taking steroids and her skin appears thin and dry. She doesn't have any moisture problems and is not diabetic. The staff nurse assesses Hilda's pressure ulcer risk as part of her admission procedures.

Skin Assessment

(Insert photo of blanchable redness)

Sacrum as above

Other skin normal

Case Study 5

Jenny is an 80 year old married lady who is admitted to surgical ward with abdominal pain following an elective laparoscopic cholecystectomy 14 days ago.

On admission she has a temperature of 39 – 40 degrees C and is very sweaty. She is being treated in a side room due to a possible infection and diarrhoea. She is 'nil by mouth' and commences IV fluids and antibiotics, though normally eats well and is a healthy weight. Jenny is given morphine as pain relief which makes her very sleepy. She is very lethargic and rests in her bed. She is able to transfer to the commode with the assistance of one nurse. She is able to change her position independently in bed but due to her lethargy doesn't very often. Prior to her recent health problems Jenny was in good health, is not diabetic and doesn't have any circulatory problems. The staff nurse assesses Jenny's pressure ulcer risk as part of her admission procedures.

Skin Assessment

Normal

Case Study 6

Joan Smith, a 72 year old lady who lives alone, has just been admitted to an acute medical ward following a stroke. Joan works part-time as a florist. She was found unconscious on the floor by her friend. It is unclear how long she had been on the floor but no one had seen her for 18 hours. Prior to having the stroke Joan's son reported she was in reasonable health and was fully mobile, though she does have hypertension which is controlled with medication. He reported that she had a good appetite, was not diabetic and didn't have any problems with her circulation.

On admission Joan is conscious but dazed and had been incontinent of urine. She has a right sided hemiplegia and is unable to walk or weight bear. Joan is presently being nursed in bed and a physio assessment is being undertaken later today. She is unable to change her position in bed. Joan is to be 'nil by mouth' until she has a swallow test, was dehydrated on admission and so has an IVI in place. She is overweight.

Skin Assessment

(Insert photos of category 2's to both)

Right heel as above

Right hip as above

Other skin normal

Case Study 7

Joe is a 65 year old retired tool maker who has been in hospital for the last 4 days for investigations of vascular disease. He lives with his partner and until the last 6months was quite active enjoying gardening in his allotment. Joe reports that he used to be a heavy smoker but managed to stop smoking 18months ago. He has severe pain in his left calf when walking which has led to a reduction in mobility: he is able to walk short distances unaided. He has obvious poor peripheral circulation. He is of normal build, eats a good diet and is not diabetic

On the second day of his hospital stay Joe developed a chest infection and a high temperature and felt generally unwell. He has spent the last few days mainly in bed though has walked to the toilet occasionally and is continent. While in bed he was able to change his position when uncomfortable but remained mostly in the recumbent position. The staff nurse reassesses Joe's pressure ulcer risk in response to his changing condition and in response to him reporting a sore left heel.

Skin Assessment

(Insert photo of unstageable)

Left heel, as above

Other skin normal

Community Sector Case Studies

Case Study 1

Sally is a 19 year old student and newly diagnosed diabetic. She is visited by the Diabetic Specialist Nurse for training and support in relation to giving her own insulin. Sally leads a very active outdoor life and other than her diabetes is fit and well. She reports no skin problems.

Case Study 2

Hilda is a 70 year old lady with rheumatoid arthritis who lives with her husband. She has recently had a short hospital stay after stumbling and fracturing her humerus. Hilda normally gets about her home well often using the furniture and a walking frame when necessary (particularly outside the home). The hospital nurses were concerned that her mobility had reduced and that she needed help to walk as she couldn't use the frame due to her fractured humerus: they requested a District Nurse visit to assess her pressure ulcer risk at home.

The District Nurse visited Hilda at home on the day after her discharge from hospital. Hilda reported that other than her long-term problem of rheumatoid arthritis she was quite well and independent. She eats a balanced diet, is a normal weight and is not diabetic. She doesn't have any circulatory problems and is continent. She acknowledged that while she had found walking in the hospital difficult this has not been a problem since she had returned home: she explained that while she was unable to use the walking frame she was able to use the furniture in her home to get around and she had lots of aids and adaptations to help her– obviously this had not been possible on the hospital ward. She reported that she had been glad to get home where she had regained her independence and was enjoying 'pottering' at home and changed her position frequently. She was also glad to be enjoying home cooked food rather than the 'hospital slop'.

Skin Assessment

Normal

Case Study 3

John is an 82 year old, retired teacher who lives in his detached bungalow on his own following the death of his wife 2 years ago. His son lives away and his daughter lives in the next town 10 miles away. John has peripheral vascular disease, is diabetic and has peripheral neuropathy. John had a recent hospital stay following a chest infection and difficulties managing his diabetes with oral medication: he is now insulin dependent. Whilst in hospital John developed a category 2 pressure ulcer on his right heel but this is now reported to be healed.

The District Nurse visits John on his return home to assess his needs and pressure ulcer risk and to administer his daily insulin. He has meals on wheels and homecare to help with food preparation, cleaning and helping him to bed. He has a good appetite and is slightly overweight. John's neighbour brings him a paper each morning and checks he is ok. John spends most of the day in his chair, only moving when he needs the toilet and is continent. He is able to walk in his home with a walking frame but sometimes needs prompting.

Skin Assessment

(Insert photo of dry heels – vulnerable but not PU category)

Both heels as above

Other skin normal

Case Study 4

Eileen is a 75 year old retired secretary and is in the end stages of terminal uterine cancer. She is being cared for at home by her husband and their daughter with support from the District Nursing Team. As Eileen's condition deteriorates the District Nurse reassesses her pressure ulcer risk. Eileen is very weak and spends most of her time in bed though does get up for short periods. She has just started having a morphine syringe driver and is quite lethargic. She can independently turn over in bed but doesn't do this very often. She needs the help of another person to transfer. Eileen developed a raised temperature and was found to have a UTI for which she is having antibiotics: due to this has been incontinent of urine. Eileen has a poor appetite and is just eating small amounts, though appears to be of normal weight. She is not diabetic and does not have any circulatory problems.

Skin Assessment

Normal

Case Study 5

Jack is an 86 year old retired builder who lives in a residential home due to dementia. The District Nurse has been called to assess his pressure ulcer risk as his condition has recently deteriorated. He has developed a chest infection which is related to swallowing difficulties. Jack needs to be fed by the carers and has recently been refusing to eat and has lost weight, though appears to be of normal weight. He is not diabetic and doesn't have any circulatory problems. He is regularly incontinent of urine and faeces. Jack spends most of his time in the chair or bed and needs 2 nurses to assist him to transfer. He can only make small independent movements when in his bed or chair. He gets very agitated at times.

Skin Assessment:

(Insert photo of blanchable redness)

Sacrum as above

Other skin normal

Case Study 6

Beatrice is 50 years old and has primary progressive MS. Beatrice had to give up her job as a dinner lady 7 years ago when her mobility deteriorated to the point that she could no longer work. Since that time her mobility has steadily declined and got significantly worse over the last 6 months. She is now unable to walk or talk making communication very difficult. She is cared for at home (in a ground floor flat) by her husband and 2 daughters who managed quite well up until the last 6 months when she has become very dependent. Care workers come in rarely. Her husband works full time, plus extra hours to support the family as he has a poorly paid job. The family have had little advice about how to care for Beatrice as her condition has declined. After her husband visits the GP in distress saying they are struggling to cope and Beatrice is becoming sore, a District Nurse is requested to visit to assess Beatrice's care needs and her pressure ulcer risk.

Beatrice is doubly incontinent with her urinary incontinence being a constant problem. They use pads in bed, but this has been difficult as they don't have an adequate supply. She spends all her time in her single divan bed. She is unable to move independently and is not turned regularly as her daughters have not been told what to do to help her. No one inspects her skin condition regularly at home. She cannot eat properly and is losing weight, though is of normal build and is not diabetic. She doesn't have any circulatory problems. She is unable to tell anyone if she is in pain and is unable to move herself to get comfortable.

Skin Assessment

(Insert photos of category 2 and 3)

Sacrum and buttocks as above

left heel as above

Other skin normal

Case Study 7

Stephen is a 35 year old gentleman who was left paralysed from the waist down following a motorbike accident 10 years ago: he is a full-time wheelchair user. He lives with his partner and their son. He runs his own IT Company. Stephen eats a good diet and is a healthy weight. He does not have any circulatory problems or diabetes. He uses intermittent catheterisation. He transfers from his chair independently. Stephen has been under a lot of pressure at work and has not been undertaking skin inspections or position changes as he was taught and has been spending long periods of time in the same position working at his desk. He has also had a recent urine infection but continued to work without taking a break. The GP was called after Stephen's wife noticed blood on the bed sheets and a District Nurse visit was requested to undertake a pressure ulcer risk assessment.

Skin Assessment

(Insert photo of category 3)

Sacrum as above

Other skin normal

Appendix 16 Pre-Test Focus Group Topic Guide

1. Introduction of moderators and group members by name
2. The overall aims of the study and how the focus group contributes to this will be explained by the moderator.
3. Aims of the session: to consider the acceptability of using PURAF incorporating:
 - What was liked about the PURAF
 - What was disliked about the PURAF
 - Usability of the PURAF and nurses found using the PURAF overall (were there any confusing areas)
 - If nurses anticipate any problems in using the PURAF in clinical practice
4. Ground rules: Everyone will have chance to speak and be heard. There are not right or wrong answers. The moderator will remind the group that the meeting will be audio-taped, answer any questions and confirm that everyone is happy to proceed with the meeting.
5. Ice breaker: discussion in pairs of what was liked about the PURAF and list on a flip chart and group feedback.
6. Group discussion of what was disliked like about the PURAF. Note on flip chart.
7. Group discussion of the usability of the PURAF and the nurses found using the PURAF overall (were there any confusing areas). The moderator will use the data completeness forms taken from the training element to inform discussions. Note on flip chart.
8. Group discussion of any anticipated problems in using the PURAF in clinical practice. Note on flip chart.
9. Potential areas for discussion (dependent on what is raised):
 - Magnitude of movement
 - Skin Vulnerability
 - Moisture constant/frequent
 - Usability of the PURAF and nurses found using the PURAF overall (were there any confusing areas)
 - Movement from stage 1 to 2 – is it clear
 - Was it clear that you needed to complete all of stage 2
 - Did you understand how to decide which intervention pathway the patient is on
 - Is there anything missing in the interventions section
 - Would you want to document the applicable interventions at this point
 - Anticipatory risk
 - Jasper case study

Appendix 17 Pre-Test Think out loud Topic Guide

1. Introduction of researcher to nurse.
2. Reminder of background to PURAF – systematic review and consensus study. Emphasise that PURAF still in the development stage and it's not the final version.
3. To develop the PURAF further so it can be used in clinical practice we want to know how the specific items in the current PURAF are interpreted and if they are consistently interpreted in the same way. We want to identify any specific items which cause confusion when using the PURAF as well as the PURAF as whole. Stress that there are no right or wrong answers.
4. Tell the nurse about the 'think out loud' technique – you will be asked to complete the PURAF using a case study. As you complete it I want you to tell me everything you are thinking as you do it, however insignificant it may seem to you. I am interested in everything that you have considered during the process of formulating your answer/response
5. Ask them to have a go thinking out loud: visualise the place where they live, and think about how many windows there are. As you count the windows tell me what you are seeing and thinking about.
Demonstrate what you mean using the PURAF: 'so I am looking at the PURAF after reading the case study. I'm looking at the question relating to 'reported history of PU'. I wonder if this is reported by the patient or their carer. Sometimes they don't know if they've had one so we could look in their medical/nursing records. From the case study I think we can say that they don't have a reported history of PU because this particular patient is fully alert and would know'.
6. Remind the nurse that interview will be audio-taped, answer any questions and confirm that she is happy to proceed with the interview.
7. Throughout the interview you may need to prompt the nurse to 'think out loud' as she completes the PURAF (some will find this more difficult than others). If she/he just ticks the boxes without explaining what she is thinking ask her to explain. You can ask for clarification on things as they think out loud, as they go along or if this is disrupting the nurse's flow and thoughts, you can go back to the areas at the end of the interview. You can also ask the nurse to mark any areas they want to discuss at the end of the interview and go back to them.
8. If the nurse asks questions to clarify the meaning of the PURAF and its items, explain that we are interested in what they think they mean and reassure them that there is no wrong or right answer, we are still in the development stage
9. The anticipatory prompts below have been put together, but obviously the prompts you use will depend on how clear and articulate the nurse is. We cannot foresee all the prompts you may require for specific items. Keep in mind that we are interested in how things are interpreted and if there are any areas of confusion, we do not want to lead the nurse.
 - a. Do you think the PURAF (specific) item is easy to understand?
 - b. How do you interpret the (specific) item (what do you think it means/is asking)?
 - c. Is there anything about the (specific) item that you find confusing?
 - d. Does the 1st stage of the PURAF make sense to you?
 - e. After completing the 1st stage of the PURAF do you feel clear about when someone is presently not at risk?
 - f. After completing the 1st stage of the PURAF do you feel clear about when you should proceed to the 2nd stage?
 - g. After completing the 2nd stage of the PURAF are you able to identify if the patient is at risk?
 - h. Is there anything about the 2nd stage that you find confusing
 - i. After completing the 2nd stage of the PURAF are you able to identify which pathway the patient should be on?

- j. How do you interpret the interventions?
- k. Is there anything you find unclear about the interventions?
- l. Overall how did you find the PURAF to complete?
- m. Are there any areas of the PURAF that you think need to be further developed?
- n. What could we change/add to make the PURAF easier to complete?

Appendix 18 Risk Assessment Framework User Guide

Pressure Ulcer Risk Assessment Framework- PURPOSE T User Guide

Summary of PURPOSE T

PURPOSE T (Pressure Ulcer Risk Primary or Secondary Evaluation Tool) is a pressure ulcer risk assessment framework (PURAF) intended to identify adults at risk of pressure ulcer development and makes a distinction between primary prevention (applicable to those at risk of pressure ulcer development) and secondary prevention (applicable to those who already have a pressure ulcer). It has been developed for use in adult populations in hospital and community settings by qualified nursing staff.

NB: PURPOSE T is not intended to assess the risk of pressure from external devices such as naso-gastric tubes and catheters etc.

The development of PURPOSE T incorporated a systematic review of pressure ulcer risk factors and a consensus study involving international experts in the pressure ulcer field (including review of pressure ulcer evidence): this allowed the numerous risk factors associated with pressure ulcer development to be carefully considered and only the most important risk factors to be included in PURPOSE T. Furthermore the use of colour within the tool allows us to identify the presence of key and less influential pressure ulcer risk factors. PURPOSE T was also pre-tested with practicing nurses allowing ambiguous or confusing elements to be identified and clarified in Field test version of PURPOSE T.

PURPOSE T does not utilise a score as other tools do - it encourages nurses to consider the profile of a patients' risk (PU risk factors present) to identify whether they are 'not currently at risk', 'at risk', or have an existing pressure ulcer and allocate them to the appropriate care pathway.

PURPOSE T has 3 steps including:

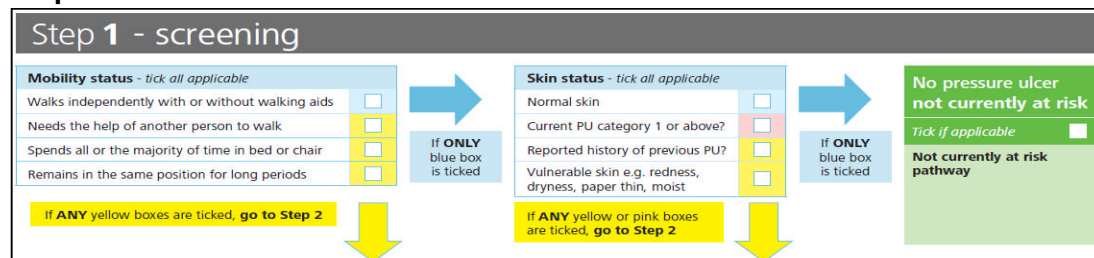
- Step 1 – Screening: complete for all patients
- Step 2 - Full Assessment: complete for those potentially at risk as determined by step 1
- Step 3 – Assessment Decision: to be undertaken for all patients who have undergone step 2

1. Step 1 – Screening: Complete for all patients

Step 1 comprises of two possible sections to complete:

- Mobility Status
- Skin status

Step 1 Assessment



1.1 Mobility Status

This section examines mobility status items that have been developed to assess varying levels of mobility. Mobility is a key pressure ulcer risk factor, which is why it is included in the first step of the assessment.

It is important that you consider and tick **all** the item boxes that **apply** to your patient: a patient may walk independently but remain in the same position for long periods and /or spend the majority of time in bed or chair.

Mobility Status Items

Mobility status - tick all applicable	
Walks independently with or without walking aids	<input type="checkbox"/>
Needs the help of another person to walk	<input type="checkbox"/>
Spends all or the majority of time in bed or chair	<input type="checkbox"/>
Remains in the same position for long periods	<input type="checkbox"/>

‘Walks independently’ means they don’t need assistance from another person, and ‘walking aid’ could be a walking stick, walking frame or even furniture. The second item ‘help of another person’ could involve physical assistance or verbal prompting. The latter 2 items require an element of judgement by the nurse in terms of whether the patient’s length of time in one position is considered normal.

1.2 Mobility Decision Boxes

The decision boxes and colour coding will help you decide if you need to go to step 2 of the assessment straight away or if you need to complete the Step 1 skin status items: if you have ticked any yellow boxes you should progress to Step 2 without completing the Step 1 skin status items. If you have **only** ticked the blue box you should complete the Step1 skin status items.

1.3 Skin Status

This section examines skin status items which have been developed in recognition of the importance of skin status in the assessment of pressure ulcer risk. The items give a range of possibilities of pressure area skin status as commonly encountered in clinical practice.

Skin Status Items

Skin status - tick all applicable	
Normal skin	<input type="checkbox"/>
Current PU category 1 or more?	<input type="checkbox"/>
Reported history of previous PU?	<input type="checkbox"/>
Vulnerable skin e.g. redness, dryness, paper thin, moist	<input type="checkbox"/>

It is important that you tick all of the boxes that apply to your patient as they may have more than one, for example a patient may have a reported history of previous pressure ulcer **and** skin vulnerability.

The item 'normal skin', requires judgement since there is no clear definition of what constitutes normal skin. It would certainly include the absence of skin vulnerability or pressure ulcers: nurses should use their clinical judgement to determine if a patient's skin is normal. The 'vulnerability' skin item gives examples of redness, dryness, paper thin and moist: these describe the visual appearance of vulnerable skin but this is not exhaustive list and you may also consider other factors.

The nurse will need to make a judgement about the approach required to complete this section (i.e. history taking/ clinical records/ full skin inspection), while recognising that the most accurate way to assess skin status is to visually examine the skin: this may be influenced by the context of care and level of patient dependency. Any patients with a skin status problem (vulnerable, current or previous PU) will progress to Step 2 of the assessment (incorporating full visual skin inspection).

1.4 The Skin Status Decision Boxes

The decision boxes and colour coding will help you decide if you need to go to Step 2 of the assessment, or if the patient is not currently at risk.

If you have ticked any yellow or pink boxes you should progress to Step 2 of the assessment. If you have only ticked the blue box then the patient is not currently at risk and you should indicate this by ticking the 'not currently at risk' box and end the assessment without progressing to Step 2.

2. Step 2 - Full Assessment: Complete for those potentially at risk as determined by step 1

Step 2 consists of 8 sections which must be fully completed. The sections comprise:

- Analysis of independent movement
- Sensory perception and response
- Current detailed skin assessment
- Previous pressure ulcer history
- Perfusion
- Nutrition
- Moisture
- Diabetes

Step 2 – Full Assessment

Step 2 - full assessment										Complete ALL sections																																																																																																															
Analysis of independent movement					Sensory perception and response <i>tick as applicable</i>					NPUAP/EPUAP Pressure Ulcer Classification System (2009) Category I: Non-blanchable redness of intact skin Category II: Partial thickness skin loss or blister Category III: Full thickness skin loss (fat visible) Category IV: Full thickness tissue loss (muscle/bone visible) Category U: (Unstageable/Unclassified): full thickness skin or tissue loss - depth unknown For descriptions please see full classification system (NPUAP/EPUAP 2009)																																																																																																															
Tick the applicable box (where frequency and extent categories meet) <table border="1"> <thead> <tr> <th colspan="2"></th> <th colspan="3">Extent of independent movement Relief of all pressure areas</th> </tr> <tr> <th colspan="2"></th> <th>Doesn't move</th> <th>Slight position changes</th> <th>Major position changes</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Frequency of position changes</td> <td>Doesn't move</td> <td><input type="checkbox"/></td> <td>N/A</td> <td>N/A</td> </tr> <tr> <td>Moves occasionally</td> <td>N/A</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Moves frequently</td> <td>N/A</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>							Extent of independent movement Relief of all pressure areas										Doesn't move	Slight position changes	Major position changes	Frequency of position changes	Doesn't move	<input type="checkbox"/>	N/A	N/A	Moves occasionally	N/A	<input type="checkbox"/>	<input type="checkbox"/>	Moves frequently	N/A	<input type="checkbox"/>	<input type="checkbox"/>	No problem <input type="checkbox"/> Patient is unable to feel and/or respond appropriately to discomfort from pressure <input type="checkbox"/>																																																																																								
		Extent of independent movement Relief of all pressure areas																																																																																																																							
		Doesn't move	Slight position changes	Major position changes																																																																																																																					
Frequency of position changes	Doesn't move	<input type="checkbox"/>	N/A	N/A																																																																																																																					
	Moves occasionally	N/A	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																					
	Moves frequently	N/A	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																					
Current Detailed Skin Assessment - tick applicable column for <i>each skin site</i> . Record the category of current PU if applicable.										Previous PU history <i>tick as applicable</i>																																																																																																															
<table border="1"> <thead> <tr> <th rowspan="2">Skin site</th> <th>Normal skin</th> <th>Vulnerable skin (precursor to PU eg. red, dry, most paper thin)</th> <th>PU category (NPUAP/EPUAP)</th> <th rowspan="2">Skin site</th> <th>Normal skin</th> <th>Vulnerable skin (precursor to PU eg. red, dry, most paper thin)</th> <th>PU category (NPUAP/EPUAP)</th> <th rowspan="2">Skin site</th> <th>Normal skin</th> <th>Vulnerable skin (precursor to PU eg. red, dry, most paper thin)</th> <th>PU category (NPUAP/EPUAP)</th> </tr> <tr> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> <th><input type="checkbox"/></th> </tr> </thead> <tbody> <tr> <td>Sacrum</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>R Hip</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>R Elbow</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>L Buttock</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>L Heel</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td colspan="4">Other - detail below if applicable</td> </tr> <tr> <td>R Buttock</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>R Heel</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>L Ischial</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>L Ankle</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>R Ischial</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>R Ankle</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>L Hip</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>L Elbow</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>										Skin site	Normal skin	Vulnerable skin (precursor to PU eg. red, dry, most paper thin)	PU category (NPUAP/EPUAP)	Skin site	Normal skin	Vulnerable skin (precursor to PU eg. red, dry, most paper thin)	PU category (NPUAP/EPUAP)	Skin site	Normal skin	Vulnerable skin (precursor to PU eg. red, dry, most paper thin)	PU category (NPUAP/EPUAP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sacrum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other - detail below if applicable				R Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	No known PU history <input type="checkbox"/> PU history - complete below <table border="1"> <thead> <tr> <th>Approx date</th> <th>Site</th> <th>PU cat (NPUAP/EPUAP)</th> <th>Scar (if applicable)</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td></td> <td></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>					Approx date	Site	PU cat (NPUAP/EPUAP)	Scar (if applicable)			<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin site	Normal skin	Vulnerable skin (precursor to PU eg. red, dry, most paper thin)	PU category (NPUAP/EPUAP)	Skin site	Normal skin	Vulnerable skin (precursor to PU eg. red, dry, most paper thin)	PU category (NPUAP/EPUAP)	Skin site	Normal skin		Vulnerable skin (precursor to PU eg. red, dry, most paper thin)	PU category (NPUAP/EPUAP)																																																																																																													
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																												
Sacrum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																														
L Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other - detail below if applicable																																																																																																																	
R Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																														
L Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																														
R Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																														
L Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																																																																																																														
Approx date	Site	PU cat (NPUAP/EPUAP)	Scar (if applicable)																																																																																																																						
		<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																						
		<input type="checkbox"/>	<input type="checkbox"/>																																																																																																																						
Perfusion - tick all applicable					Nutrition - tick all applicable					Moisture due to perspiration, urine, faeces or exudate - tick as applicable																																																																																																															
No problem <input type="checkbox"/> Conditions affecting central circulation eg. shock, heart failure, hypotension <input type="checkbox"/> Conditions affecting peripheral circulation eg. peripheral vascular/arterial disease <input type="checkbox"/>					No problem <input type="checkbox"/> Unplanned weight loss <input type="checkbox"/> Poor nutritional intake <input type="checkbox"/> Low BMI (less than 18.5) <input type="checkbox"/> High BMI (30 or more) <input type="checkbox"/>					No problem/Occasional <input type="checkbox"/> Frequent (2-4 times a day) <input type="checkbox"/> Constant <input type="checkbox"/>																																																																																																															
										Diabetes - tick as applicable																																																																																																															
										Not diabetic <input type="checkbox"/> Diabetic <input type="checkbox"/>																																																																																																															

Each section will give a range of possibilities as you would encounter in clinical practice. It is important that if the patient does not have a problem with a particular risk factor that this is indicated by ticking the 'no problem' item showing the assessment has been undertaken. If you follow the flow of the sections from top to bottom and left to right you are less likely to miss any sections out, though some nurses have found it more practical to complete the visual skin inspection at the end of the assessment.

2.1 Analysis of Independent Movement

This section was developed to capture information about the patients' independent movement. 'Independent movement' relates to movement that is undertaken by the patient without the assistance of another person, i.e. it does not relate to the movement encountered when nurses changes the patients' position or turns the patient.

Analysis of Independent Movement Item

Analysis of independent movement				
Tick the applicable box (where frequency and extent categories meet)		Extent of independent movement Relief of all pressure areas		
		Doesn't move	Slight position changes	Major position changes
Frequency of position changes	Doesn't move	<input type="checkbox"/>	N/A	N/A
	Moves occasionally	N/A	<input type="checkbox"/>	<input type="checkbox"/>
	Moves frequently	N/A	<input type="checkbox"/>	<input type="checkbox"/>

A matrix is used to bring the frequency (i.e. how often) and extent (i.e. amount) of movement together and each component has a range of options for you to consider in light of patients movement pattern. When completing the frequency element the nurse must consider what would be considered normal frequency of movement and use her clinical judgement to inform which category the patient falls into.

The 3 options relating to the extent of movement include 'the patient doesn't move', 'minor position changes' and 'major position changes'. Major position changes could include the patient turning over in bed or standing up resulting in complete pressure relief. Minor position changes could include the patient shifting their position a little when in the bed or chair which may result in some but not complete pressure relief. The patient doesn't move item relates to no pressure relief of pressure areas.

To complete the section the nurse must consider both frequency and extent of independent movement in the matrix and tick the box where the two elements meet.

2.2 Sensory Perception and Response

This section relates to sensory perception and response and comprises just 2 items. It is a tick **as** applicable section and only **one** item applies, i.e. does the patient have a problem with sensory perception and response or not.

Sensory Perception and Response Items

Sensory perception and response <i>tick as applicable</i>	
No problem	<input type="checkbox"/>
Patient is unable to feel and/or respond appropriately to discomfort from pressure	<input type="checkbox"/>

In your assessment you need to consider if the patient is unable to feel and/or respond appropriately to discomfort from pressure. This item recognises that patients will vary in terms of whether they can do both i.e. some patients will not be able to feel discomfort from pressure and so will not respond, while others may be able to feel but not respond appropriately. Either of these scenarios indicates there is a problem with sensory perception and could lead to reduced movement and pressure relief. Factors that *may* (though not always) influence the patients' ability to feel and respond appropriately to discomfort from pressure, comprise underlying medical conditions or treatments such as MS, CVA, head injury, spinal injury, neuropathy, dementia, depression, epidural, anaesthetics and opiates. When undertaking the assessment the nurse must consider whether the presence of such factors affects the patients' sensory perception.

2.3 Current Detailed Skin Assessment

Requires a visual skin inspection and assessment of skin sites listed in the table: these include the most common pressure area skin sites though patients sometimes develop pressure ulcers in other areas and there is space for 'other' skin sites if required. This should be completed for **all** skin sites shown in the table.

Current Detailed Skin Assessment Items

Current Detailed Skin Assessment - tick applicable column for <i>each</i> skin site. Record the category of current PU if applicable.												
Skin site	Normal skin	Vulnerable skin (precursor to PU) eg, red, dry, moist, paper thin	PU category NPUAP/EPUAP	Skin site	Normal skin	Vulnerable skin (precursor to PU) eg, red, dry, moist, paper thin	PU category NPUAP/EPUAP	Skin site	Normal skin	Vulnerable skin (precursor to PU) eg, red, dry, moist, paper thin	PU category NPUAP/EPUAP	
Sacrum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
L Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other - detail below if applicable				
R Buttock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
L Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
R Ischial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R Ankle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
L Hip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	L Elbow	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Each skin site should be inspected to assess if the skin is normal, vulnerable (red, dry, moist, paper thin) or if there is an existing pressure ulcer (also see section 1.3). The nurse should only choose one of these options for each skin site by ticking the appropriate box. The category of any existing pressure ulcer is recorded in the pink column. The abbreviated NPUAP/EPUAP Pressure Ulcer Classification System (2009) is listed to help you and the full version of this will be available in the study documentation.

2.4 Previous Pressure Ulcer History

The first 2 items relate to whether the patient has a reported history of a pressure ulcer and is a tick **as** applicable section and only **one** item applies, i.e. the patient either has a reported history of pressure ulcer or they don't. Some patients may not know and the patients' clinical record could provide a good source of information.

Previous Pressure Ulcer History Items

Previous PU history tick as applicable			
No known PU history			<input type="checkbox"/>
PU history - complete below			<input type="checkbox"/>
Approx date	Site	PU cat NPUAP/EPUAP	Scar (if applicable)
			<input type="checkbox"/>
			<input type="checkbox"/>

If the patient has a reported history of pressure ulcer development the approximate date, site and PU category should be recorded. The nurse should also indicate if a scar is present which could be ascertained when undertaking the current detailed skin assessment. This is important as scarring results in ongoing skin vulnerability to pressure.

2.5 Perfusion

The perfusion section includes 'no perfusion problems' and 2 items relating to conditions that affect the central circulation (shock, heart failure or hypotension) and conditions that affect peripheral circulation (peripheral vascular/arterial disease). These give some examples of conditions affecting perfusion, but this is not exhaustive list and you may also consider other factors such as poor capillary refill.

If the patient doesn't have any perfusion problems then the nurse should tick 'no problem'. If the patient does have perfusion problems the nurse should tick the **all** applicable items as some patients' may have both central and peripheral circulatory problems.

Perfusion Items

Perfusion - tick all applicable	
No problem	<input type="checkbox"/>
Conditions affecting central circulation eg. shock, heart failure, hypotension	<input type="checkbox"/>
Conditions affecting peripheral circulation eg. peripheral vascular/arterial disease	<input type="checkbox"/>

2.6 Nutrition

The nutrition items have been developed to capture patients with the varying nutrition problems as you would encounter in clinical practice. It is important that you consider all the items and tick **all** the item boxes that **apply** to your patient as there may be more than one applicable item. However, if your patient has no problems with nutrition you will only tick the applicable box.

Nutrition Items

Nutrition - tick all applicable	
No problem	<input type="checkbox"/>
Unplanned weight loss	<input type="checkbox"/>
Poor nutritional intake	<input type="checkbox"/>
Low BMI (less than 18.5)	<input type="checkbox"/>
High BMI (30 or more)	<input type="checkbox"/>

The 4 items indicating there is a problem with nutrition comprise 'unplanned weight loss', 'poor nutritional intake', 'low BMI' and high 'BMI'. 'Unplanned weight loss' relates to weight loss that isn't sought by the patient, i.e. they haven't been trying to lose weight and may have lost it due to illness. 'Poor nutritional intake' may be relevant to patients with poor appetite who are not eating well. It may also be applicable for those are nil by mouth and obtaining no other form of nutritional support. Low BMI is less than 18.5 and high BMI is 30 or more.

2.7 Moisture

The moisture section comprises of 3 items and relates to moisture due to perspiration, urine, faeces or exudates. This is a tick **as** applicable section and only **one** item applies. The first item relates to patients' without a moisture problem or with occasional moisture which does not impact on the patients' risk of pressure ulcer development. The other items relate to the frequency of moisture with some guidance of these parameters i.e. 'frequent (2-4 times a day)' and 'constant' meaning all of the time.

Moisture Items

Moisture due to perspiration, urine, faeces or exudate - tick as applicable	
No problem/Occasional	<input type="checkbox"/>
Frequent (2-4 times a day)	<input type="checkbox"/>
Constant	<input type="checkbox"/>

2.8 Diabetes

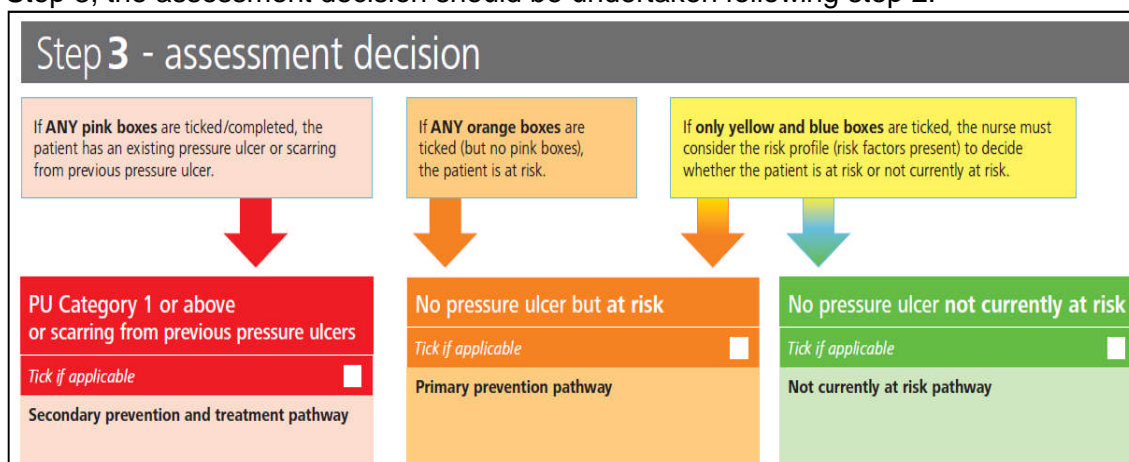
This item relates to the presence of diabetes and gives 2 options. This is a tick **as** applicable section and only **one** item applies.

Diabetes Items

Diabetes - tick as applicable	
Not diabetic	<input type="checkbox"/>
Diabetic	<input type="checkbox"/>

3. Step 3 – Assessment Decision

Step 3, the assessment decision should be undertaken following step 2.



Each item in Step 2 is highlighted by a blue, yellow, orange or pink box. These colours represent the importance of the risk factors as indicated by the level of scientific or epidemiological evidence and/or the results of the consensus study:

- Pink box items indicate the patient has an existing pressure ulcer or scarring from a previous pressure ulcer
- Orange box items indicate the presence of a key pressure ulcer risk factor
- Yellow box items indicate the presence of less influential pressure ulcer risk factors (but still important in considering the overall risk profile of a patient and in the delivery of appropriate preventative care)
- Blue box items indicate the absence of a risk factor.

When completing step 3 the nurse must carefully review the step 2 assessment to decide whether the patient should be allocated to the secondary prevention and treatment pathway, primary prevention pathway or the not currently at risk pathway.

This is facilitated by decision boxes in the PURPOSE T which indicate:

- If any pink boxes are ticked it indicates that the patient has an existing pressure ulcer or scarring from a previous pressure ulcer. The patient should be allocated to the secondary prevention and treatment pathway indicated by ticking the red box in the pathway.
- If any orange boxes (but no pink boxes) are ticked the patient does not have a pressure ulcer but is at risk of pressure ulcer development and should be allocated to the primary prevention pathway indicated by ticking the orange box in the pathway.
- If only yellow or blue boxes are ticked the nurse must consider the risk profile of the patient and use clinical judgement to determine whether the patient is 'at risk' or 'not currently at risk'. The nurse should consider the number of yellow boxes ticked and the patients' individual circumstance, for example a patient may only have the presence of unplanned weight loss but may be terminally ill and nearing the end of life where the general trajectory of dependence will increase and the nurse may therefore consider the patient to be 'at risk' or a young diabetic patient may have undergone acute surgery but be recovering well where the general trajectory is increasing independence so the nurse may consider the patient to be 'not currently at risk', but would want to review this if the patients' condition changed. Patients with a number of yellow boxes ticked are more likely to be considered 'at risk'.