National Clinical Guideline Centre

Appendix C

Pressure ulcer prevention and management

Review protocols

Commissioned by the National Institute for Health and Care Excellence

Disclaimer
Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their guardian or carer.

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Contents

Appendix C: Review protocols

C.1 Pressure ulcer prevention

C.1.1 Risk assessment

Review question	What is the predictive ability of risk assessment tools for pressure ulcer risk?
Objectives	To estimate the ability of risk assessment tools to predict pressure ulcer development.
Criteria	Population : Individuals of all ages
	Risk tools: • Risk assessment tool (any reported cut-off score): • Braden • Norton • Waterlow • Cubbin-Jackson • Braden-Q • Other scales (e.g. Gosnell scale, Knoll scale, Andersen, Pressure Sore Prediction Score, Risk Assessment Pressure Sore, Douglas, Emina, Glamorgan) • Clinical judgement based on risk factors
	Outcomes: Patient outcomes: • Incidence of pressure ulcers (all grades and grades 2-4)– up to one week • Incidence of pressure ulcers (all grades and grades 2-4) – up to three months Statistical measures: • Sensitivity and specificity for a defined threshold • Area under the ROC curve (AUC) • Diagnostic odds ratio for a particular threshold
	Study design: • Systematic reviews of prospective cohort studies • Prospective cohort studies in which the patients considered did not have pressure ulcers at the beginning of the study and with a follow-up in a systematic way during an established period
Search	The electronic databases to be searched are: • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years Exclusions: • non-English, non-French, non-Dutch language papers • Minimum follow up = no minimum • Minimum total size = no minimum

Review strategy	Meta-analysis will not be conducted for these prognostic studies, but data will be summarised across studies, based on the median values. • The following groups will be considered separately if data are present: • ICU patients, patients with a spinal cord injury, palliative patients, paediatric patients and adults (if not in other subgroups) • The following analyses will be performed: • The AUC and 95% CI for each scale (within studies and between studies; if data are available) will be extracted and used to calculate the median AUC and range. • Three cut-off scores will be determined for each scale with an acceptable median AUC. • The focus will be on sensitivity. The sensitivity and specificity for these three cut-off scores will be defined by the study having the median sensitivity.

Review question	**What is the clinical and cost effectiveness of risk assessment tools in the prevention of pressure ulcers?**
Objectives	To estimate the clinical effectiveness of risk assessment tools together with targeted interventions in the prevention of pressure ulcers?
Criteria	Population: Individuals of all ages Intervention: risk assessment tools/clinical judgement plus preventative treatment • Clinical judgement based on risk factors • Risk assessment tool (any reported cut-off score) o Braden, o Norton, o Waterlow, o Cubbin-Jackson, o Braden-Q, o Other scales (e.g. Gosnell scale, Knoll scale, Andersen, Pressure Sore Prediction Score, Risk Assessment Pressure Sore, Douglas, Emina, Glamorgan) • NB Risk assessment is used to target preventative treatment – so this is a complex intervention of test and treat. Part of the test is the people conducting it and their levels of competence and training. Comparisons: • Each other • No risk assessment and no preventative treatment • No risk assessment but preventative treatment for all patients Outcomes: Critical outcome for decision-making o Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) Important outcomes • Patient acceptability • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised) o Short-form health survey (SF36)

Review question	What is the clinical and cost effectiveness of risk assessment tools in the prevention of pressure ulcers?
	○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHOQOL-BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki) Study design: High quality systematic reviews of RCTs or RCTs only. Cohort studies will be considered if no RCTs are available.
Search	The electronic databases to be searched are: • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, The Cochrane Library • All years Exclusions: • Non-English • Non-French • Non-Dutch language papers
Review strategy	• Studies will be combined across all populations • Minimum follow up = no minimum • Minimum total size = no minimum Strata: • The following groups will be considered separately if data are present: ICU patients, patients with a spinal cord injury, palliative patients, paediatric patients

C.1.2 Skin assessment

Review question	What is the predictive ability of skin assessment tools for pressure ulcer risk?
Objectives	To estimate the predictive ability of skin assessment tools for pressure ulcer risk?
Criteria	Population: Individuals of all ages • Predictive factors (skin assessment tools) - Structured, systematic skin assessment methods/tools • Ultrasonography • Ultrasound • Durometer/durometry • Diascopy: finger method and transparent disk • Elastometer • Haptic finger • Multispectral imaging device • Multiwavelength imaging • Multispectral images • Digital color images • Clinical assessment • Transcutaneous oximetry • Termographic scanner • Tympanic thermometers (to measure skin temperature) • Doppler blood flowmetry • Laser Doppler imaging • Outcomes

Review question	What is the predictive ability of skin assessment tools for pressure ulcer risk?
	• Incidence of pressure ulcers (all grades and grades 2-4) – up to one week • Incidence of pressure ulcers (all grades and grades 2-4) – up to three months Statistical Measures • Adjusted odds ratio, preferably from multivariable analysis • Sensitivity • Specificity • Area under the ROC curve (AUC) (for skin temperature) Study designs • High quality systematic reviews of prospective cohort studies. • Prospective and retrospective cohort studies • Preferably those in which the patients considered did not have pressure ulcers at the beginning of the study and with a follow-up in a systematic way during an established period
Search	Search strategy: • MEDLINE (OVID interface), CINAHL (EBSCO-interface), EMBASE, The Cochrane Library • All years Exclusions: • Non-English • Non-French • Non-Dutch language papers
Review strategy	Meta-analysis will not be conducted, but summaries across similar studies will be given. Studies will be grouped as follows: All populations will be initially grouped, but if there are sufficient data, the following subpopulations will be examined separately: • ICU patients • Spinal cord injury patients • Palliative care patients • Paediatric patients There is no minimum follow up period and no minimum size of study The GDG agreed that the key confounders for pressure ulcers were: age and BMI, with the confounder diabetes also being considered important. Multivariable analyses were assessed against the presence or absence of these key factors.

Review question	What is the clinical and cost effectiveness of skin assessment methods in the prevention of pressure ulcers?
Objectives	To estimate the clinical and cost effectiveness of skin assessment methods together with targeted preventative treatment in the prevention of pressure ulcers.
Criteria	Population: Individuals of all ages without a pressure ulcer Intervention: • Diascopy: finger method and transparent disk • Measuring of skin temperature • Plus preventative treatment of people at high risk Comparison: • Each other • No skin assessment but preventative treatment for all patients • Other Outcomes:

	Critical outcome for decision-making • Proportion of participants developing new PU (dichotomous outcome) (describe different categories of ulcer) Important outcomes • Rate of development of PU • Time to develop new PU (time to event data) • Time in hospital (continuous data) • Patient acceptability • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in PU patients, therefore may have to be narratively summarised) ○ Short-form health survey (SF36) ○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHOQOL-BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki) Study design: • High quality systematic reviews of RCTs or RCTs only • Cohort studies will be considered if no RCTs are available.
Search	The electronic databases to be searched are: Medline (OVID interface), Cinahl (EBSCO-interface), Embase, *The Cochrane Library* (All years) Exclusion: • Non-English • Non-French • Non-Dutch language papers
Review strategy	• Population: any populations will be combined except those specified in the strata • Outcomes – same outcomes will be combined • Minimum follow up = no minimum • Minimum total size = no minimum The following groups will be considered separately if data are present: • Intensive Care Unit patients • Spinal cord injury patients • Palliative care patients • Paediatric patients

C.1.3 Repositioning

Review question	**How and at what frequency should repositioning be undertaken for the prevention of pressure ulcers?**
Objectives	To estimate the effectiveness and cost effectiveness of different positions and frequency of position changes for the prevention of pressure ulcers
Criteria	Population: Patients of all ages in all settings Intervention: • Repositioning • Frequency of repositioning • Different positions (e.g. 90-degree lateral rotation, 30 degree tilt) Devices included for repositioning:

	• Profiling bed • Tilt in space chairs Comparison: • No repositioning • Different frequencies of repositioning • Different positions for repositioning Outcomes: • Critical outcomes for decision-making: • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) • Patient acceptability Important outcomes: • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-Quality of life BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki) Study design: • High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available
Search	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined in a meta-analysis?: • Population - any population will be combined for meta-analysis except for different strata. • Intervention – different types of frequency will be meta-analysed, different positions will be meta-analysed. • Outcomes – single side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer). • Describe which support surfaces are used.

	• Minimum duration of treatment = no minimum, but would expect at least a fortnight before they show improvements. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables. Analysis: Strata - where included studies are split up at outset as separate reviews (dissimilar groups and we need to be confident that the intervention will work very differently in the two (or more) strata. The GDG will make separate recommendations on these. The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • Self-repositioning versus manual repositioning versus repositioning by a device • People with sensory impairment • Subgroup analysis - combining all the studies together initially and then looking at any inconsistency between studies on the basis of pre-defined subgroups. The following groups will be considered separately as subgroups (if there is heterogeneity): • different risk stratification • different clinical populations

C.1.4 Skin massage

Review question:	**What is the clinical and cost effectiveness of skin massage in the prevention of pressure ulcers?**
Population	Individuals of all ages
Intervention	Skin massage (method, frequency)
Comparison	• No skin massage • Other preventive methods

Outcomes	Critical outcomes for decision-making:
	• Proportion of participants developing new pressure ulcers (dichotomous outcome)
	• Patient acceptability
	• Skin damage
	
	Important outcomes:
	• Rate of development of pressure ulcers
	• Time to develop new pressure ulcer (time to event data)
	• Time in hospital or other healthcare settings (continuous data)
	• Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised)
	  ○ Short-form health survey (SF36)
	  ○ Manchester Short Assessment of Quality of Life
	  ○ EQ-5D
	  ○ WHO-Quality of life BREF

Review question:	What is the clinical and cost effectiveness of skin massage in the prevention of pressure ulcers?
	○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome. • Non-English, non-French, non-Dutch language papers
Search strategy	The electronic databases to be searched are: • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population – any population will be combined for meta-analysis except combination of children and adults. • Intervention – different types of methods will be combined for meta-analysis; different products will be combined for meta-analysis; different types of frequency will be combined for meta-analysis. • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – same outcomes will be combined for meta-analysis; single side effects will be meta-analysed separately from other side effects • Blinding – Blinded and unblinded studies will be meta-analysed together. • Unit of analysis – patients, individual pressure ulcers • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum.
Analysis	The following groups will be considered separately if data are present: • Children and adults (neonates, infants, children). The following groups will be considered separately as subgroups if data are present: • Different categories of pressure ulcers(from category 2 upwards where outcomes are reported separately); • Different locations of pressure ulcers: sacral, heel and others.

C.1.5 Nutritional supplementation and hydration strategies

Review question	What are the most clinically and cost effective interventions with nutrition or hydration for the prevention of pressure ulcers for people with and without nutritional deficiency?
Population	Patients of all ages in all settings, with and without nutritional deficiencies.
Intervention	• Nutritional interventions (supplementation or special diet) as preventive strategies • Hydrational strategies as preventive strategies
Comparison	• Usual diet (participant's usual diet or the standard hospital diet) • Other supplementation • Other special diet
Outcomes	Critical outcomes for decision-making:

Review question	What are the most clinically and cost effective interventions with nutrition or hydration for the prevention of pressure ulcers for people with and without nutritional deficiency?
	• Proportion of participants developing new pressure ulcers (dichotomous outcome) (describe different categories of ulcer) • Patients acceptability of supplements – e.g. measured by compliance, tolerance, reports of unpalatability • Important outcomes: • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or other health care institution (continuous data) • Side effects (nausea, vomiting, diarrhoea) (dichotomous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised ○ Short-form health survey (SF36) ○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHO-Quality of life BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
Search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined in a meta-analysis?: • Population - any population will be combined for meta-analysis except for different strata • Intervention - Different types of nutritional supplementation and hydratation strategies and nutritional interventions will not be combined for meta-analysis • Outcomes – single side effects eg nausea will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer) • Minimum duration of treatment = no minimum, but would expect at least a fortnight before they show improvements. • Minimum follow up = no minimum.

Review question	What are the most clinically and cost effective interventions with nutrition or hydration for the prevention of pressure ulcers for people with and without nutritional deficiency?
	• Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data.
Analysis	Strata - where included studies are split up at outset as separate reviews (dissimilar groups and we need to be confident that the intervention will work very differently in the two (or more) strata. The GDG will make separate recommendations on these. The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • With and without nutritional deficiency • Different nutritional supplements • Hydratational strategies and nutritional interventions Subgroup analysis - combining all the studies together initially and then looking at any inconsistency between studies on the basis of pre-defined subgroups. The following groups will be considered separately as subgroups: • different risk stratification
Notes	Where have said 'describe' or 'descriptive' this will be noted in the summary table.

C.1.6 Pressure redistributing devices

Review question	What are the most clinically and cost effective pressure re-distributing devices for the prevention of pressure ulcers?
Population	Patients of all ages in all settings
Intervention	• Mattresses/overlays ○ Standard foam mattresses (needs to be identified) ○ Alternative foam mattresses/ overlays (e.g. convoluted foam, cubed foam) ○ Specialised foam mattresses ○ Gel-filled mattresses/ overlays ○ Fibre-filled mattresses/ overlays ○ Air-filled mattresses/ overlays ○ Water-filled mattresses/ overlays ○ Bead-filled mattresses/ overlays ○ Low-air-loss mattresses ○ AP mattresses/ overlays (air-filled sacs which inflate and deflate) ○ Operating-table overlays ○ Sheepskins (synthetic/natural) • Beds ○ Air-fluidised beds ○ Low-air-loss beds – patients are supported on a series of air sacs through which warmed air passes ○ Air flotation beds ○ Bead-filled beds • Seating ○ Standard Chair

	○ Tilt in space ○ Pressure relieving chairs ○ Cushions ○ foam-filled cushions ○ gel-filled cushions ○ fluid-filled cushions ○ air/dry flotation cushions ○ alternating pressure cushions ○ tilt-in-space cushions ○ Wheelchair support surfaces • Other ○ Pillows ○ Postural support ○ Limb protectors: pads and cushions of different forms to protect bony prominences ○ As prevention strategies
Comparison	• Each other • No intervention
Outcomes	Critical outcomes for decision-making: • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) • Patient acceptability Important outcomes: • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised ○ Short-form health survey (SF36) ○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHO-Quality of life BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
Search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only

Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population - any population will be combined for meta-analysis except for different strata • Intervention - Different categories of device will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials. • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer) • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot work out the available case analysis will take the author's data. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • People with sensory impairment • Bariatric patients (BMI >40) Subgroups: The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately) • Different ulcer locations
Other terms	Support surfaces, pressure relieving, pressure reducing, pressure preventing
Notes	Where have said 'describe' or 'descriptive' this will be noted in the summary table.

C.1.7 Pressure redistributing devices for the prevention of heel ulcers

Review question	**What are the most clinically effective pressure re-distributing devices for the prevention of heel pressure ulcers?**
Population	Patients of all ages in all settings
Intervention	• Air-filled booties • Foam foot protectors • Gel foot protectors • Pillows and other aids • Splints or other medical devices • Sheepskins for heels (synthetic and natural) • Pressure Relief Ankle Foot Orthosis As prevention strategies

Comparison	• Each other • No intervention
Outcomes	Critical outcomes for decision-making: • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) • Patient acceptability • Important outcomes: • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or in other healthcare institution (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-Quality of life BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only • Cochrane reviews will be included if they match our inclusion criteria and have appropriate assumptions for missing data such as available case analysis or ITT (with the appropriate assumptions) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
Search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined in a meta-analysis?: • Population - any population will be combined for meta-analysis except for different strata • Intervention - Different categories of device will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer) • Minimum duration of treatment = no minimum, but would expect at least a fortnight before they show improvements. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use available case analysis for dealing with missing data if there is a 10% differential or higher between the groups or if the missing data is higher than the event rate, if cannot

	work out the available case analysis will take the author's data.
Analysis	The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • People with sensory impairment • Bariatric patients (BMI >40) The following groups will be considered separately as subgroups: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately) • Different ulcer locations
Other terms	Support surfaces, pressure relieving, pressure reducing, pressure preventing
Notes	Where have said 'describe' or 'descriptive' this will be noted in the summary table.

C.1.8 Barrier creams

Review question:	**What are the most clinically and cost-effective topical barrier preparations for the prevention of pressure ulcers (and moisture lesions)?**
Population	Patients of all ages in all settings
Intervention	• Topical barrier preparations, including: ○ Secura Wash and Cream (used to be known as Triple Care) Smith and Nephew and ○ Cavilon Barrier Cream (3M)/film ○ Petroleum jelly/paraffin ○ Sudocrem ○ Metanium ○ Zinc oxide ○ Zinc and castor oil ○ Silicone (Dimethicone) ○ E45 ○ Aqueous cream ○ Emollients ○ Humectants (holds water) ○ Moisturisers
Comparison	• Each other • No intervention (standard care) • Other prevention strategies
Outcomes	Critical outcomes for decision-making: • Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer) • Proportion of participants developing moisture lesions (incontinence associated dermatitis, perineal dermatitis) • Patient acceptability Important outcomes: • Rate of development of pressure ulcers • Time to develop new pressure ulcer (time to event data) • Time in hospital or NHS care (continuous data) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively

Review question:	What are the most clinically and cost-effective topical barrier preparations for the prevention of pressure ulcers (and moisture lesions)?
	summarised), including: ○ Short-form health survey (SF36) ○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHO-Quality of life BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews): • Population - any population will be combined for meta-analysis except for different strata • Intervention - Different barrier creams will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers – for those where patients are the unit of analysis and the patient has multiple ulcers it should be the first pressure ulcer occurring (describe different categories of ulcer) • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • People with sensory impairment • Patients with a BMI > 40 Subgroups: The following groups will be considered separately as subgroups if data are present and there is inconsistency:

Review question:	What are the most clinically and cost-effective topical barrier preparations for the prevention of pressure ulcers (and moisture lesions)?
	• Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately) • Different ulcer locations • Moisture lesion vs. pressure ulcer
Other terms	A moisture lesion is also known as incontinence-associated dermatitis
Notes	Where have said 'describe' or 'descriptive' this will be noted in the summary table.

C.1.9 Information for patients and carers

Review question:	What information is required for patients/carers to prevent the occurrence of pressure ulcers?
Population	Information will be for all people who are at risk of pressure ulcers or for carers or those with long-term conditions who have not had a pressure ulcer previously. The population whose views will be obtained is those who are at risk or who have had pressure ulcers or their carers.
Intervention	Patient (or carer) information (any type of written or verbal information) about how patients with pressure ulcers feel their pressure ulcers could have been prevented.
Comparison	No comparison
Objectives	To examine what information patients with pressure ulcers (or their carers) felt they required to prevent the occurrence of their pressure ulcers.
Setting	• Primary care settings, such as general practices, health centres and polyclinics. • Community care settings (including the persons' home) where NHS healthcare is provided or commissioned. • Secondary-care settings where NHS healthcare is provided or commissioned.
Study design	• Qualitative data (e.g. interviews, focus groups) • Surveys • High quality systematic review of qualitative data
Exclusion	• Abstracts unless other studies are not found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	• Studies will be evaluated to assess their relevance to the question asked. • Analysis of studies that are most relevant to the review question in terms of population, setting, context and objectives will be carried out • Thematic analysis will be conducted, and common themes across studies will be extracted and reported. The review will be considered as complete when no new themes are found within the area (theme saturation reached).
Analysis	Strata: The following groups will be considered separately as strata if data are present: • those with spinal cord damage or injury
Notes	Useful to include the information needs of those with long-term conditions who have not had a pressure ulcer before.

C.1.10 Training and education for healthcare professionals

Review question:	What training and education is required for healthcare professionals to prevent the occurrence of pressure ulcers?

Review question:	What training and education is required for healthcare professionals to prevent the occurrence of pressure ulcers?
Population	All healthcare professionals who deal with people who are at risk of pressure ulcers.
Intervention	Training and education of healthcare professionals
Comparison	None
Objectives	Main objective is to provide a systematic narrative review of the relevant literature that will aid the GDG towards consensus recommendations. Training and education of healthcare professionals involved in patient care where pressure ulcers may be a risk.
Setting	• Primary care settings, such as general practices, health centres and polyclinics. • Community care settings (including the persons' home) where NHS healthcare is provided or commissioned. • Secondary-care settings where NHS healthcare is provided or commissioned.
Study design	• Qualitative studies • High quality systematic review and qualitative studies (if available).
Exclusion	• Abstracts unless other studies are not found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	• Studies will be evaluated to assess their relevance to the question asked. • The review will start with focusing on studies which are conducted in a setting relevant to the NHS setting and the scope of the guideline. • Analysis of studies that are most relevant to the review question in terms of population, setting, context and objectives will be carried out • Thematic analysis will be conducted, and common themes across studies will be extracted and reported. The review will be considered as complete when no new themes are found within the area (theme saturation reached).
Other terms	None.
Notes	Will not exclude papers from outside the UK.

C.2 Pressure ulcer management

C.2.1 Ulcer measurement

C.2.2 Categorisation

Review question	What is the best method of categorising different types of pressure ulcers?
Population	People of any age with existing pressure ulcers in any care setting
Intervention	• NPUAP/EPUAP (2009) • NPUAP (1989) – will have been superseded by NPUAP (2009) • EPUAP (1998) – will have been superseded by EPUAP (2009) • Shea (1983) • Torrance (1983) • Yarkony-Kirk (1990) • Stirling 2 digit (1994) • AHCPR (1992) – for info: an update of NPUAP (1989)

Review question	What is the best method of categorising different types of pressure ulcers?
Comparison	Each other
Outcomes	Critical outcomes • Reliability -agreement • Accuracy Important outcomes • Time and ease of use of classification system
Study design	• Studies reporting the reliability, accuracy and impact of pressure ulcer classification systems • High quality systematic review
Exclusion	• Abstracts unless other studies are not found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	Studies will be evaluated to assess their relevance to the question asked. The review will start with focusing on studies which are conducted in a setting directly relevant to the NHS setting and the scope of the guideline. Higher quality study designs will be included above lower quality study designs
Analysis	Note when they are assessing it e.g. initial assessment Subgroups: • Different colour of skin
Notes	• The review would not consider intellectual property and whether there is a cost associated with obtaining the scale; • Variation with experience and training may impact upon the time and ease of use of using the scale. • Ulcers should be classified as early as possible and then re-classified regularly – the review should consider when they are assessing • Need to consider who is carrying out the classification and whether this effect's the effectiveness of the grading scheme. • Library of pressure ulcers of confirmed grading – PUCLAS II • Grade 1 and 2 ulcers are more difficult to identify in people who have darker skin.

C.2.3 Nutritional supplementation and hydration strategies

Review question:	What are the most clinically and cost-effective interventions with nutrition or hydration for the treatment of pressure ulcers for people with and without nutritional deficiency?
Population	People of any age with existing pressure ulcers in any care setting
Intervention	• Nutritional interventions (supplementation or special diet) • Hydration • For treatment of pressure ulcers
Comparison	• Usual diet (including hospital diet) • Other supplementation • Other special diet
Outcomes	Critical outcomes for decision-making: • Time to complete healing (time to event data)

Review question:	What are the most clinically and cost-effective interventions with nutrition or hydration for the treatment of pressure ulcers for people with and without nutritional deficiency?
	• Rate of complete healing (continuous data) • Rate in change of size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period Important outcomes: • Pain (wound-related) • Time in hospital (continuous data) • Patient acceptability of supplements – eg measured by compliance, tolerance, reports of unpalatability • Side effects (nausea, vomiting, diarrhoea) • Mortality (dichotomous) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised), including: o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-Quality of life BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• Systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies of patients who do not already have active pressure ulcers at time of enrolment • Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
Search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
The review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population - any population will be combined for meta-analysis except for different strata. Must have active pressure ulcers at time of enrolment. • Intervention - Different types of nutritional supplementation will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects eg nausea will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers. We will not meta-analyse studies where patients have multiple ulcer and the unit of analysis is pressure ulcer with studies where the unit of analysis is patients.

Review question:	What are the most clinically and cost-effective interventions with nutrition or hydration for the treatment of pressure ulcers for people with and without nutritional deficiency?
	• Minimum duration of treatment = no minimum, but would expect at least a fortnight before they show improvements. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately if data are present: • Children (neonates, infants and children) • With and without nutritional deficiency • Different nutritional supplements • Hydrational strategies and nutritional interventions Subgroups: • The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately • Different ulcer locations: sacral, heel and others

C.2.4 Pressure redistributing devices

Review question	What are the most clinically and cost-effective pressure re-distributing devices for the treatment of pressure ulcers?
Population	People of any age with existing pressure ulcers in any care setting
Intervention	• Mattresses/overlays ○ Standard foam mattresses (needs to be identified) ○ Alternative foam mattresses/ overlays (e.g convoluted foam, cubed foam) ○ Specialised foam mattresses ○ Gel-filled mattresses/ overlays ○ Fibre-filled mattresses/ overlays ○ Air-filled mattresses/ overlays ○ Water-filled mattresses/ overlays ○ Bead-filled mattresses/ overlays ○ AP mattresses/ overlays (air-filled sacs which inflate and deflate) ○ Low-air-loss mattresses ○ Operating-table overlays ○ Sheepskins (synthetic/natural) • Beds ○ Air-fluidised beds ○ Low-air-loss beds – patients are supported on a series of air sacs through which warmed air passes ○ Air flotation beds ○ Bead-filled beds • Seating

Review question	What are the most clinically and cost-effective pressure re-distributing devices for the treatment of pressure ulcers?
	○ Standard Chair ○ Tilt in space ○ Pressure relieving chairs ○ Cushions ○ Foam-filled cushions ○ Gel-filled cushions ○ Fluid-filled cushions ○ Air/dry flotation cushions ○ Alternating pressure cushions ○ Tilt-in-space ○ Wheelchair support surfaces • Other ○ Pillows ○ Postural support ○ Limb protectors: pads and cushions of different forms to protect bony prominences As treatment strategies
Comparison	• Each other • No intervention
Outcomes	Critical outcomes for decision-making (what are the outcomes important to patients): • Time to complete healing (time to event data) • Rate of healing (continuous data) • Rate of change in size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period Important outcomes: • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised) including: ○ Short-form health survey (SF36) ○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHO-Quality of life BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies of patients who do not have active pressure ulcers at time of enrolment

Review question	What are the most clinically and cost-effective pressure re-distributing devices for the treatment of pressure ulcers?
	• Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population - any population will be combined for meta-analysis except those specified in the strata. Must have active pressure ulcers at time of enrolment. • Intervention - Different types of devices will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers. We will not meta-analyse studies where patients have multiple ulcer and the unit of analysis is pressure ulcer with studies where the unit of analysis is patients. • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal cord damage or injury • People with sensory impairment • Patients with a BMI >40 Subgroups: The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately • Different ulcer locations • Adjunctive therapies
Other terms	Support surfaces, pressure relieving, pressure reducing

C.2.5 Adjunctive therapies

Review question	What is the clinical and cost-effectiveness of hyperbaric oxygen therapy for the treatment of pressure ulcers?
Population	People of any age with existing pressure ulcers in any care setting

Review question	What is the clinical and cost-effectiveness of hyperbaric oxygen therapy for the treatment of pressure ulcers?
Intervention	Hyperbaric oxygen therapy as treatment for people with pressure ulcers.
Comparison	• Other type of therapy for pressure ulcer treatment • Standard wound care
Outcomes	Critical outcomes for decision-making (what are the outcomes important to patients): • Time to complete healing (time to event data) • Rate of healing (continuous data) • Rate of change in size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period Important outcomes: • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised), including: o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHO-Quality of life BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies of patients who do not have active pressure ulcers at time of enrolment • Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population - any population will be combined for meta-analysis except for different strata. Must have active pressure ulcers at time of enrolment. • Intervention - any type of hyperbaric oxygen therapy • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials

Review question	What is the clinical and cost-effectiveness of hyperbaric oxygen therapy for the treatment of pressure ulcers?
	• Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers. We will not meta-analyse studies where patients have multiple ulcer and the unit of analysis is pressure ulcer with studies where the unit of analysis is patients. • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults Subgroups: The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately • Different ulcer locations: sacral, heel and others
Other terms	HBOT

Review question	What is the clinical and cost-effectiveness of electrotherapy for the treatment of pressure ulcers?
Population	People of any age with existing pressure ulcers in any care setting
Intervention	Electrotherapy as treatment for people with pressure ulcers.
Comparison	Other type of therapy for pressure ulcer treatment. Standard wound care
Outcomes	Critical outcomes for decision-making (what are the outcomes important to patients): • Time to complete healing (time to event data) • Rate of healing (continuous data) • Rate of change in size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period Important outcomes: • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised), including: o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life

Review question	What is the clinical and cost-effectiveness of electrotherapy for the treatment of pressure ulcers?
	○ EQ-5D ○ WHO-Quality of life BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies of patients who do not have active pressure ulcers at time of enrolment • Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
• Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population - any population will be combined for meta-analysis except children and adults. Must have active pressure ulcers at time of enrolment. • Intervention - any type of electrotherapy • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers. We will not meta-analyse studies where patients have multiple ulcer and the unit of analysis is pressure ulcer with studies where the unit of analysis is patients. • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults Subgroups: The following groups will be considered separately as subgroups if data are present and there is heterogeneity: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately • Different ulcer locations: sacral, heel and others
Other terms	Electrical stimulation

Review question	What is the clinical and cost-effectiveness of negative pressure wound therapy for the treatment of pressure ulcers?
Population	People of any age with existing pressure ulcers in any care setting
Intervention	Negative pressure wound therapy as treatment for people with pressure ulcers.
Comparison	Other type of therapy for pressure ulcer treatment.
Outcomes	Critical outcomes for decision-making (what are the outcomes important to patients): • Time to complete healing (time to event data) • Rate of healing (continuous data) • Rate of change in size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period Important outcomes: • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects (pain, problems with vacuum sealing, reaction of foam) • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised) including: ○ Short-form health survey (SF36) ○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHO-Quality of life BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies of patients who do not have active pressure ulcers at time of enrolment • Studies with outcomes that do not involve pressure ulcers • Abstracts unless no RCTs are foundNon-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population - any population will be combined for meta-analysis except for different strata. Must have active pressure ulcers at time of enrolment. • Intervention - any type of negative pressure wound therapy • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials

Review question	What is the clinical and cost-effectiveness of negative pressure wound therapy for the treatment of pressure ulcers?
	• Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers. We will not meta-analyse studies where patients have multiple ulcer and the unit of analysis is pressure ulcer with studies where the unit of analysis is patients. • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults Subgroups: The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately • Different ulcer locations: sacral, heel and others
Other terms	Vacuum-assisted wound closure; topical negative pressure therapy

C.2.6 Debridement

Review question	What are the most clinically effective methods of debridement of non-viable tissue for treatment of pressure ulcers?
Population	Individuals of all ages, with at least 1 pressure ulcer with non-viable tissue.
Intervention	Debridement (sharp debridement, dressings which promote autolysis e.g. hydrogels and hydrocolloids enzymatic, mechanical, maggot)
Comparison	• No debridement • Comparison between debridement methods • Other type of therapy for pressure ulcer treatment
Outcomes	Critical outcomes for decision-making • Time to complete healing (time to event data) • Rate of healing • Rate of reduction in size and volume of pressure ulcer • Proportion of patients completely healed within trial period Important outcomes • Wound related pain • Health-related quality of life • Acceptability of treatment (e.g. compliance, tolerance) • Time in hospital • Side effects (skin irritation skin, treatment related pain, bleeding, healthy tissue damage, health skin damage, rash, toxicity) • Mortality
Study design	• High quality systematic reviews of RCTs and/or RCTs only.

	• Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome. • Non-English papers
Search strategy	• The electronic databases to be searched are: • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population – any population will be combined for meta-analysis except combination of children and adults. Must have active pressure ulcers at time of enrolment. • Intervention – any type of debridement will be combined for meta-analysis. • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – same outcomes will be combined for meta-analysis. • Blinding – Blinded and unblinded studies will be meta-analysed together. • Unit of analysis – patients, individual pressure ulcers • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	The following groups will be considered separately if data are present: • Children and adults (neonates, infants, children); Subgroups: • The following groups will be considered separately as subgroups if data are present: • Different categories of pressure ulcers (from category 2 upwards where outcomes are reported separately) • Different locations of pressure ulcers: sacral, heel and others • Infection

C.2.7 Systemic antibiotics

Review question	**What are the most clinically and cost effective systemic agents for the treatment of pressure ulcers?**
Population	Individuals of all ages, with at least 1 pressure ulcer of any category/grade.
Intervention	Systemic antimicrobials: systemic antibiotics, systemic antifungals.
Comparison	• No systemic antimicrobials • Placebo • Comparison between types of systemic antimicrobials • Other types of therapy for pressure ulcer treatment
Outcomes	Critical outcomes for decision-making • Time to complete healing (time to event data) • Rate of healing

	• Rate of reduction in size and volume of pressure ulcer • Reduction in size and volume of pressure ulcer • Proportion of patients completely healed within trial period Important outcomes • Wound related pain • Health-related quality of life • Acceptability of treatment (e.g. compliance, tolerance) • Time in hospital • Side effects (irritation skin, rash, itching, allergic reaction, normal flora disruption, toxicity, treatment related pain) • Mortality
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome. • Non-English language papers
Search strategy	The electronic databases to be searched are: • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population – any population will be combined for meta-analysis except combination of children and adults. Must have active pressure ulcers at time of enrolment. • Intervention – any type of systemic antifungal will be combined for meta-analysis.; any type of systemic antibiotic will be combined for meta-analysis. • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – same outcomes will be combined for meta-analysis. • Blinding – Blinded and unblinded studies will be meta-analysed together. • Unit of analysis – patients, individual pressure ulcers • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	The following groups will be considered separately if data are present: • Children and adults (neonates, infants, children); Subgroups: • The following groups will be considered separately as subgroups if data are present: • Different categories of pressure ulcers (from category 2 upwards where outcomes are reported separately) • Different locations of pressure ulcers: sacral, heel and others

C.2.8 Topical antimicrobials and antibiotics

Review question	What are the most clinically and cost effective topical antimicrobials for the treatment of pressure ulcers?
Population	Individuals of all ages, with at least one pressure ulcer of any category/stage.
Intervention	Topical antimicrobials: topical antibacterials, topical antifungals, topical antibiotics.
Comparison	• No topical antimicrobial • Placebo • Comparison between topical antimicrobial • Other type of therapy for pressure ulcer treatment
Outcomes	Critical outcomes for decision-making • Time to complete healing (time to event data) • Rate of healing • Rate of reduction in size and volume of pressure ulcer • Reduction in size and volume of pressure ulcer • Proportion of patients completely healed within trial period Important outcomes • Wound related pain • Health-related quality of life (continuous data) o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHOQOL-BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki) • Acceptability of treatment (e.g. compliance, tolerance) • Time in hospital • Side effects (irritation skin, rash, itching, allergic reaction, normal flora disruption, toxicity, treatment related pain) • Mortality
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome. • Non-English language papers
Search strategy	The electronic databases to be searched are: • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population – any population will be combined for meta-analysis except combination of children and adults. Must have active pressure ulcers at time of enrolment. • Intervention – any type of topical antifungal will be combined for meta-analysis; any type of topical antibacterial will be combined for meta-analysis; any type of topical antibiotic will be combined for meta-analysis.. • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – same outcomes will be combined for meta-analysis.

	• Blinding – Blinded and unblinded studies will be meta-analysed together. • Unit of analysis – patients, individual pressure ulcers • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	The following groups will be considered separately if data are present: • Children and adults (neonates, infants, children); Subgroups: The following groups will be considered separately as subgroups if data are present: • Different categories of pressure ulcers (from category 2 upwards where outcomes are reported separately) • Different locations of pressure ulcers: sacral, heel and others

C.2.9 Dressings

Review question	**What are the most clinically and cost effective dressings for the treatment of pressure ulcers?**
Population	Individuals of all ages, with at least 1 pressure ulcer of any category/stage
Intervention	• Dressings (absorbing, impregnated, alginate, capillary, hydrocolloid, hydrofibre, foam, collagen, hyaluronic acid, film, hydrogels)
Comparison	• No dressing • Comparison between dressings • Other type of therapy for pressure ulcer treatment
Outcomes	Critical outcomes for decision-making • Time to complete healing (time to event data) • Rate of healing • Rate of reduction in size and volume of pressure ulcer • Reduction in size and volume of pressure ulcer • Proportion of patients completely healed within trial period Important outcomes • Wound related pain • Health-related quality of life o Short-form health survey (SF36) o Manchester Short Assessment of Quality of Life o EQ-5D o WHOQOL-BREF o Cardiff HRQoL tool o HUI o Pressure ulcer quality of life (Gorecki) • • Acceptability of treatment (e.g. compliance, tolerance) • Time in hospital

	• Side effects (infection, health skin damage, healthy tissue damage, maceration, treatment related pain, skin irritation, allergic reaction, itching, odor, bleeding, rash, toxicity) • Mortality
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria) • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies with another population, intervention, comparison or outcome. • Non-English language papers
Search strategy	The electronic databases to be searched are: • Medline (OVID interface), Cinahl (EBSCO-interface), Embase, Library of the Cochrane Collaboration • All years
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population – any population will be combined for meta-analysis except combination of children and adults. Must have active pressure ulcers at time of enrolment. • Intervention – any type of dressings will be combined for meta-analysis. • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – same outcomes will be combined for meta-analysis. • Blinding – Blinded and unblinded studies will be meta-analysed together. • Unit of analysis – patients, individual pressure ulcers • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	The following groups will be considered separately if data are present: • Children and adults (neonates, infants and children); Subgroups: • The following groups will be considered separately as subgroups if data are present: • Different categories of pressure ulcers (from category 2 upwards where outcomes are reported separately) • Different locations of pressure ulcers: sacral, heel and others

C.2.10 Management of heel pressure ulcers

Review question	**What is the most clinically and cost-effective method for management of pressure ulcers of the heel?**
Population	People of any age with existing heel pressure ulcers in any care setting
Intervention	• Interventions for management of heel ulcers: ○ Pressure-redistributing devices ○ Repositioning ○ Nutrition and hydration ○ Electrotherapy

Review question	What is the most clinically and cost-effective method for management of pressure ulcers of the heel?
	○ NPWT ○ HBOT ○ Debridement ○ Antimicrobials ○ Antibiotics ○ Dressings ○ Skin massage/rubbing
Comparison	• Each other • No intervention
Outcomes	Critical outcomes for decision-making (what are the outcomes important to patients): • Time to complete healing (time to event data) • Rate of healing (continuous data) • Rate of change in size of ulcer (absolute and relative) (continuous data) – reduction in size of ulcer and volume of ulcer. • Proportion of patients completely healed within trial period Important outcomes: • Pain (wound-related) • Time in hospital or NHS care (continuous data) • Patient acceptability eg measured by compliance and tolerance • Side effects • Mortality (all cause) (dichotomous) • Health-related quality of life (continuous data) (although unlikely to be sensitive enough to detect changes in pressure ulcer patients, therefore may have to be narratively summarised), including: ○ Short-form health survey (SF36) ○ Manchester Short Assessment of Quality of Life ○ EQ-5D ○ WHO-Quality of life BREF ○ Cardiff HRQoL tool ○ HUI ○ Pressure ulcer quality of life (Gorecki)
Study design	• High quality systematic reviews of RCTs and/or RCTs only. • Cochrane reviews will be included if they match our inclusion criteria • Cohort studies will be considered if no RCTs are available.
Exclusion	• Studies of patients who do not have active heel pressure ulcers at time of enrolment • Studies with outcomes that do not involve heel pressure ulcers • Abstracts unless no RCTs are found • Non-English language papers
The search strategy	The databases to be searched are: • Medline, Embase, Cinahl, the Cochrane Library. • All years. • Studies will be restricted to English language only
Review strategy	How will individual PICO characteristics be combined across studies in a meta-analysis (for intervention reviews) • Population - any population will be combined for meta-analysis except for different strata. Must have active heel pressure ulcers at time of enrolment.

Review question	What is the most clinically and cost-effective method for management of pressure ulcers of the heel?
	• Intervention - Different types of devices will not be combined for meta-analysis • Comparison – any comparison which fits the inclusion criteria will be meta-analysed • Outcomes – single side effects will be meta-analysed separately from other side effects • Study design – randomised and quasi-randomised studies will be meta-analysed together. Blinded and unblinded studies will be meta-analysed together. Crossover trials will be meta-analysed together with parallel trials • Unit of analysis – patients, clusters (hospital wards), individual pressure ulcers. We will not meta-analyse studies where patients have multiple ulcer and the unit of analysis is pressure ulcer with studies where the unit of analysis is patients • Minimum duration of treatment = no minimum. • Minimum follow up = no minimum. • Minimum total sample size = no minimum. • Use authors data. If there is a 10% differential or higher between the groups or if the missing data is higher than the event rate downgrade on risk of bias. If authors use ACA and ITT, ACA is preferable over ITT. • MIDs: 0.75 to 1.25 for dichotomous variables and 0.5 x standard deviation for continuous variables.
Analysis	Strata: The following groups will be considered separately as strata if data are present: • Children (neonates, infants, children) and adults • People with neurological impairment or spinal injury or damage • People with sensory impairment • Patients with a BMI >40 Subgroups: The following groups will be considered separately as subgroups if data are present and there is inconsistency: • Different categories of pressure ulcer (from category 2 upwards where outcomes are reported separately) • Adjunctive therapies