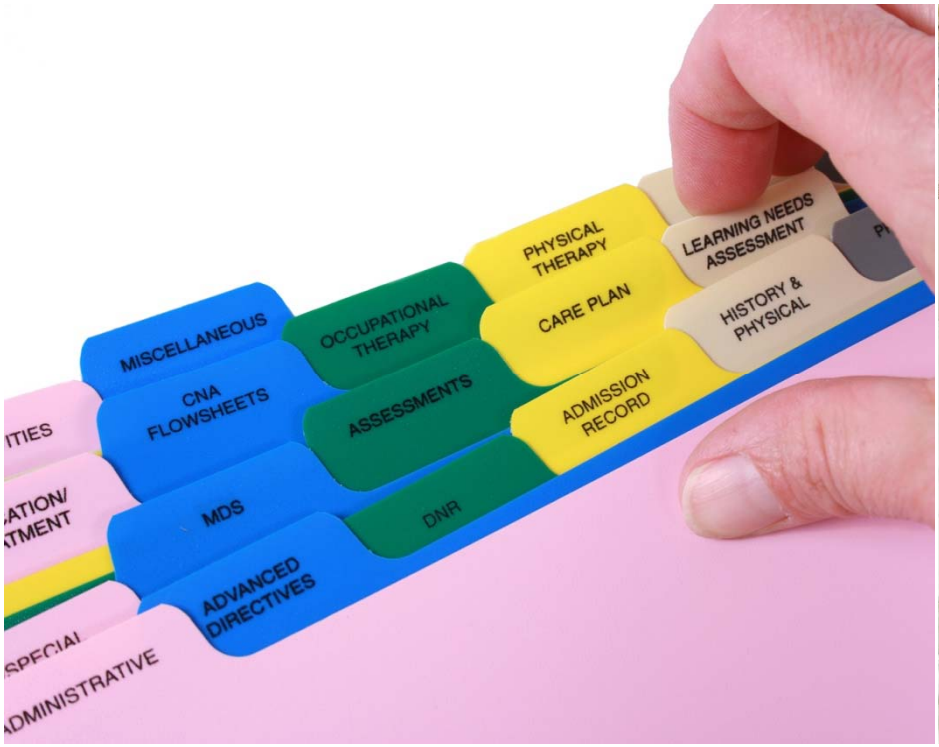
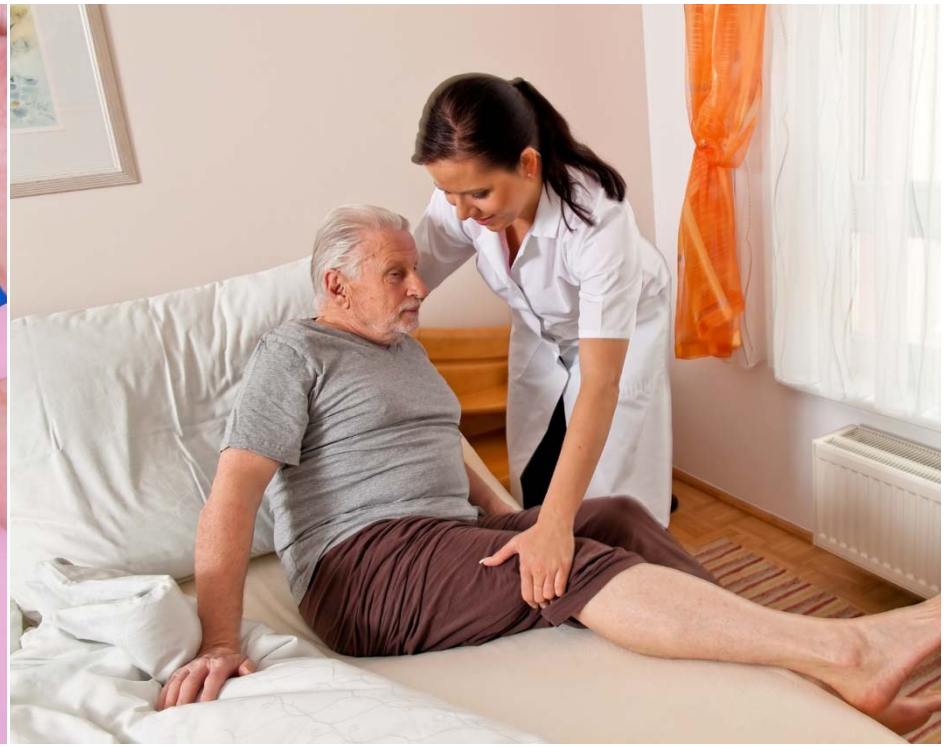
KCE REPORT 193B

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

RECOMMANDATIONS NATIONALES POUR LA PRÉVENTION DES ESCARRES DE DÉCUBITUS





Le Centre Fédéral d'Expertise des Soins de Santé

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Contact

Centre Fédéral d'Expertise des Soins de Santé (KCE)
Doorbuilding (10e étage)
Boulevard du Jardin Botanique, 55
B-1000 Bruxelles
Belgique

T +32 [0]2 287 33 88
F +32 [0]2 287 33 85
info@kce.fgov.be
http://www.kce.fgov.be

KCE REPORT 193B
GOOD CLINICAL PRACTICE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

RECOMMANDATIONS NATIONALES POUR LA PRÉVENTION DES ESCARRES DE DÉCUBITUS

DIMITRI BEECKMAN, CATHY MATHEÏ, AURÉLIE VAN LANCKER, SABINE VAN HOUDT, GEERT VANWALLEGHEM, LUC GRYSON, HILDE HEYMAN, CHRISTIAN THYSE, ADINDA TOPPETS, SABINE STORDEUR, KOEN VAN DEN HEEDE

COLOPHON

Titre :	Recommandations nationales pour la prévention des escarres de décubitus
Auteurs :	Dimitri Beeckman (UGent), Cathy Matheï (KULeuven), Aurélie Van Lancker (UGent), Sabine Van Houdt (KULeuven), Geert Vanwalleghem (CNC vzw/ WCS/ H.-Hartziekenhuis Roeselare-Menen vzw), Luc Gryson (CNC vzw), Hilde Heyman (WCS), Christian Thyse (AFISCeP.be), Adinda Toppets (UZLeuven), Sabine Stordeur (KCE), Koen Van den Heede (KCE)
Relecture :	Marijke Eyssen (KCE); Dominique Paulus (KCE)
Experts externes :	Diégo Backaert (Thuiszorg Groep Backaert); Hilde Beele (UZ Gent); Lieven Decaevele (OLV-Ziekenhuis, Aalst); Daniëlle Declercq (Institut Jules Bordet); Véronique del Marmolle (Hopital Erasme, ULB); Aurélia Bustillo (Hôpital Erasme, ULB); Anne Hermand (Cliniques universitaires Saint-Luc, Bruxelles); Miguel Lardennois (SPF Santé Publique - FOD Volksgezondheid); Louis Paquay (Wit-Gele Kruis); Dominique Putzeys (CIPIQ-s); Lisette Schoonhoven (Radboud Universiteit Nijmegen); Evelien Touriany (Militair Hospitaal Koningin Astrid); Dirk Van De Looverbosch (Zelfstandig Huisarts); Katrien Vanderwee (O.L.V. van Lourdes Ziekenhuis Waregem); Pascal Van Waeyenberghe (Home Health Care wound care BVBA); Christiane Vranken (CHU Liège)
Remerciements :	Nous remercions Liz Avital (NCGC, UK), Katie Jones (NCGC, UK) et Julie Neilson (NCGC, UK) pour leur collaboration à la préparation du rapport scientifique
Validateurs externes :	Nicky Cullum (University of Manchester); Siegfried Geens (CEBAM); Philippe Hanson (CHU UCL Mont-Godinne)
Conflits d'intérêt :	Dominique Putzeys déclare avoir reçu des fonds pour la recherche au sujet de la prévention des escarres de décubitus. Diégo Backaert, Hilde Beele, Anne Hermand, Adinda Toppets, Geert Vanwalleghem, Pascal Van Waeyenberghe ont déclaré avoir reçu des honoraires pour des conférences ou le remboursement de frais de formation, de voyage ou pour leur participation à des conférences au sujet de la prévention des escarres de décubitus.
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PRÉFACE

Pour les patients à mobilité réduite, la qualité des soins dont ils bénéficient, que ce soit au lit ou au fauteuil, peut faire une énorme différence. À cet égard, la prévention des plaies de décubitus ou escarres est essentielle. Ces lésions surviennent de manière typique au niveau du coccyx, des talons et de l'occiput, en raison de forces de pression et de cisaillement importantes exercées sur la peau et les tissus sous-jacents. Il ne s'agit en aucun cas d'une complication bénigne : les escarres peuvent prendre des proportions importantes et s'accompagner d'un sérieux inconfort de longue durée, avec à la clé, des coûts supplémentaires pour le patient et la société. A juste titre, la prévention des escarres est considérée au niveau national et international comme un aspect crucial de la politique de la qualité, tant dans les hôpitaux, les maisons de repos, les centres de revalidation qu'au domicile des patients.

Le Service Publique Fédéral Santé publique a mandaté le KCE pour qu'il formule des recommandations visant à soutenir les bonnes pratiques des prestataires de soins grâce aux découvertes scientifiques les plus actualisées en la matière.

Fort heureusement, il existait déjà en Belgique une expertise considérable dans la prise en charge des escarres. Pour mener à bien ce projet, le KCE a pu faire appel aux contributions d'experts membres d'équipes scientifiques de l'Universiteit Gent et de la Katholieke Universiteit Leuven. Nous sommes également allés chercher d'autres collaborations au-delà de nos frontières. Pour la première fois, dans le cadre de ce projet, le KCE a collaboré étroitement avec l'éminent National Institute for Health and Clinical Excellence (NICE) britannique, de même qu'avec son collaborateur externe, le National Clinical Guideline Centre (NCGC) de Londres. Cette coopération a entraîné d'intenses interactions entre les diverses équipes à propos des méthodes utilisées. Ces échanges ont abouti à un résultat scientifique final cautionné par toutes les parties impliquées.

En collaboration avec les associations belges spécialisées dans les soins de plaies (CNC vzw, WCS, AFISCeP.be), les constats scientifiques ont été transposés en recommandations pour la pratique clinique. Bien entendu, le présent guideline ne constitue pas la solution miracle pour prévenir les escarres. Mais une bonne prise en charge combinée, taillée sur mesure pour chaque patient, permettra d'épargner à nombre d'entre eux beaucoup de souffrances.

Raf MERTENS
Directeur Général

RÉSUMÉ

INTRODUCTION

L'EPUAP (European Pressure Ulcer Advisory Panel) définit l'escarre (plaie de décubitus) comme une lésion ischémique localisée au niveau de la peau et/ou des tissus sous-jacents, résultant d'une réponse interne à une charge mécanique externe appliquée aux tissus mous, en général sur une saillie osseuse. Cette charge mécanique externe peut être une force perpendiculaire à la surface de la peau (pression), une force parallèle à la surface de la peau (cisaillement) ou résulter d'une pression associée à un cisaillement.

Le degré de gravité d'une escarre varie de l'érythème (rougeur) ne disparaissant pas à la pression à la destruction tissulaire impliquant la peau, la graisse sous-cutanée, les muscles et les os. Dans sa classification, l'EPUAP a défini l'escarre de catégorie I comme étant l'érythème persistant ou qui ne blanchit pas à la pression, l'escarre de catégorie II comme une abrasion superficielle du derme ou une phlyctène, l'escarre de catégorie III comme un ulcère superficiel et l'escarre de la catégorie IV comme une ulcération profonde.

Les taux de prévalence des escarres rapportés dans les pays européens restent élevés puisqu'ils sont compris entre 8,9% et 18,1% dans les hôpitaux et entre 6,4% et 31,4% dans les maisons de repos (et de soins). En Belgique, la prévalence des escarres n'a été étudiée au niveau national que dans le contexte hospitalier avec une prévalence rapportée de 12,1% (Catégories I-IV). Les escarres sont associées à un inconfort considérable, une comorbidité importante et des coûts élevés. En conséquence, la prévention des escarres constitue l'une des interventions en soins infirmiers les plus fréquentes dans divers milieux de vie et de soins (hôpitaux, maisons de repos (et de soins) et soins à domicile).

L'objectif de la présente étude était de développer une recommandation de bonne pratique (RBP) portant sur l'évaluation du risque et la prévention des escarres chez les adultes et les enfants admis à l'hôpital, dans des institutions de soins de longue durée (y compris les maisons de repos (et de soins), les centres de revalidation) et chez les personnes qui reçoivent des soins à domicile. Cette RBP a pour vocation de soutenir les prises de décisions cliniques pour tous les professionnels de la santé engagés dans la prise en charge de personnes à risque de développer des escarres.

Dans la pratique clinique, la dermatite associée à l'incontinence est fréquemment considérée à tort comme une escarre. Aussi, la RBP n'englobera pas l'évaluation du risque et la prise en charge de la dermatite associée à l'incontinence, en raison de la nature unique et de l'étiologie spécifique de cette affection cutanée. Le traitement des escarres fera l'objet d'une RBP nationale distincte.

CHAMP D'APPLICATION ET MÉTHODES

Les questions cliniques suivantes ont été étudiées :

1. Quelle est l'efficacité clinique des outils d'évaluation du risque dans la prévention des escarres ?
2. Quelle est la capacité prédictive des outils d'évaluation du risque de développement des escarres ?
3. Quelle est l'efficacité clinique des méthodes d'évaluation cutanée dans la prévention des escarres ?
4. Quelle est la capacité prédictive des méthodes d'évaluation cutanée dans le développement des escarres ?
5. Quelle est l'efficacité clinique du massage cutané dans la prévention des escarres ?
6. Comment et à quelle fréquence faut-il procéder au repositionnement de l'individu pour la prévention des escarres ?
7. Quels sont les dispositifs de redistribution de la pression les plus efficaces d'un point de vue clinique aux fins de la prévention des escarres ?
8. Quels sont les dispositifs de redistribution de la pression les plus efficaces d'un point de vue clinique aux fins de la prévention des escarres du talon ?
9. Quelles sont les interventions d'hydratation et de nutrition les plus efficaces d'un point de vue clinique afin de prévenir les escarres chez les sujets présentant ou ne présentant pas de carence nutritionnelle ?

Le présent guideline a été élaboré en collaboration avec le National Clinical Guideline Centre (NCGC, Royaume-Uni) ; l'étude approfondie des différents thèmes a été répartie entre les deux organisations (KCE et NCGC).

La recherche de littérature conduite dans OVID Medline, EMBASE, CINAHL et la Cochrane Library (entre mars et septembre 2012) a ciblé les revues systématiques de la littérature et les essais cliniques contrôlés randomisés (RCT) pour l'évaluation des interventions, et les études de cohorte prospectives pour les évaluations de pronostic. Aucune restriction de date n'a été imposée.

Sur la base des bilans de preuves (y compris le niveau de preuve formulé selon la méthode GRADE), l'équipe de recherche a formulé des recommandations. A ces recommandations s'ajoute une liste des meilleures pratiques par thème étudié. Ces dernières ne se fondant pas sur les bilans de preuves, mais sur deux guidelines existants (à savoir, celui de l'EPUAP/NPUAP de 2009 & du National Institute for Clinical Excellence – NICE – de 2001) sélectionnés lors d'une recherche systématique de la littérature et sur la base d'une évaluation de leur qualité (par la notation AGREE II) conduites par trois examinateurs indépendants. Toutes les recommandations et les meilleures pratiques ont été examinées par un panel d'experts (le 19/10/2012) selon une procédure formelle.

Tableau 1 – Niveaux de preuve selon le système GRADE.

Niveau de qualité	Définition	Qualité méthodologique des preuves à l'appui
Elevé	Nous sommes très confiants que l'effet réel est proche de l'estimation de l'effet.	RCT sans limitations importantes ou preuves irréfutables provenant d'études d'observation
Modéré	Nous sommes modérément confiants en l'estimation de l'effet : l'effet réel est probablement proche de l'estimation, mais il y a une possibilité qu'il soit considérablement différent.	RCT comportant des limitations importantes (résultats incohérents, faiblesses méthodologiques, méthodes indirectes ou imprécises) ou exceptionnellement des preuves solides émanant d'études d'observation
Faible	Notre confiance en l'estimation est limitée : l'effet réel peut être considérablement différent de l'estimation.	RCT comportant des limitations très importantes ou études d'observation ou séries de cas
Très faible	Nous avons très peu confiance en l'estimation de l'effet : l'effet réel est probablement considérablement différent de l'estimation.	

Tableau 2– Force des recommandations selon le système GRADE.

Grade	Définition
Forte	Les effets bénéfiques de l'intervention l'emportent très certainement sur les risques (*l'intervention est à mettre en pratique*) ou les effets indésirables de l'intervention l'emportent très certainement sur les bénéfices attendus (*l'intervention est à éviter*).
Faible	Les effets bénéfiques de l'intervention l'emportent probablement sur les risques (*l'intervention est probablement à mettre en pratique*) ou les effets indésirables de l'intervention l'emportent probablement sur les bénéfices attendus (*l'intervention est probablement à éviter*).

RECOMMANDATIONS CLINIQUES POUR LA PRÉVENTION DES ESCARRES

Tous les détails de la base scientifique sur laquelle s'appuient ces recommandations peuvent être consultés dans le rapport scientifique et son supplément. Les tableaux ci-dessous contiennent les recommandations ainsi que les meilleures pratiques. Les tableaux respectent la succession des chapitres du rapport scientifique.

Généralités

Individualisation du plan de prévention des escarres pour chaque individu

Meilleures pratiques

La prévention des escarres de décubitus doit relever d'une approche combinée, adaptée aux besoins individuels et au contexte, et doit être basée sur les principes de la prise de décision partagée :

- La prévention doit tenir compte de différents facteurs comme l'état général de l'individu, le plan de soins global et les préférences de l'individu. Les besoins de l'individu et le contexte de prise en charge doivent être réévalués régulièrement ;
- Un plan de soins individualisé doit être adopté, basé sur les données d'évaluation, les facteurs de risque identifiés et les objectifs et préférences de l'individu. Ce plan est élaboré en interaction avec l'individu, les aidants informels et les professionnels de la santé. Les actions planifiées et acceptées/refusées sont notifiées dans le dossier de l'individu et communiquées à tous les soignants (y compris lors de la transition vers un autre environnement de soins).

Eduquer et former les professionnels de la santé à la prévention des escarres

Meilleures pratiques

L'éducation et la formation doivent être adaptées aux besoins du soignant individuel et aux responsabilités du groupe de professionnels de la santé.

Les éléments suivants doivent être inclus dans chaque programme d'éducation/de formation :

- Etiologie et facteurs de risque de développement des escarres ;
- Classification des escarres ;
- Diagnostic différentiel des escarres de décubitus et d'autres lésions cutanées ;
- Evaluation du risque ;
- Evaluation de l'état de la peau ;
- Sélection et utilisation du matériel de redistribution de pression ;
- Changements de position ;
- Aspects nutritionnels ;

- Méthodes de documentation de l'évaluation du risque et des actions de prévention ;
- Importance de la prise en charge multidisciplinaire ;
- Education de l'individu et des aidants informels.

Évaluation du risque

Recommandations	Force de le recommandation	Niveau de preuve
Une méthode structurée d'évaluation du risque doit être utilisée afin d'identifier les individus à risque de développer des escarres. Cette approche structurée doit comprendre les éléments suivants : • Le jugement clinique, basé sur la connaissance des facteurs de risque principaux ; • L'utilisation d'un outil d'évaluation des risques. Etant donné que les études cliniques ne démontrent pas la supériorité d'un outil d'évaluation par rapport à un autre, le choix d'un outil d'évaluation (Braden, Norton, Waterlow…) doit être orienté selon les individus concernés (adultes, enfants, personnes âgées…), l'unité de soins concernée (soins intensifs, unités de soins généraux, pédiatrie, soins à domicile…) et selon la compétence et l'expertise de l'équipe de soins ; • Une évaluation globale de la peau permettant de détecter toute altération survenue sur une peau jusque-là intacte.	Forte	Très faible

Meilleures pratiques
L'évaluation des risques de développement d'escarres doit être effectuée lors du premier contact avec l'individu. Une réévaluation doit être réalisée à intervalles réguliers et lors de toute modification de l'état de santé de l'individu. Le choix de l'intervalle entre deux évaluations doit être déterminé sur base individuelle.
Le jugement clinique doit prendre en compte plusieurs facteurs de risque importants comme la mobilité réduite, l'immobilité, la pression, le cisaillement, la déficience sensorielle, la détérioration aiguë de l'état de santé général, l'incontinence, la réduction du niveau de conscience, l'âge avancé, les antécédents de lésions de pression, les maladies vasculaires, la dénutrition et l'hydratation insuffisante (liste non limitative).
L'évaluation des risques doit être documentée et rendue accessible à tous les membres de l'équipe multidisciplinaire.

Évaluation cutanée

Recommandation	Force de le recommandation	Niveau de preuve
L'inspection complète de la peau, de la tête aux pieds avec une attention particulière portée aux endroits sensibles (en particulier aux saillies osseuses), doit faire partie intégrante de l'évaluation structurée du risque.	Forte	Faible

Meilleures pratiques
L'inspection de la peau fait partie intégrante des soins de routine. La fréquence de l'inspection cutanée peut être adaptée en réponse à l'évolution clinique de l'individu (amélioration ou détérioration) et du niveau de risque.
La peau est inspectée régulièrement afin de détecter les signes de rougeur et les érythèmes non réductibles à la pression. L'inspection cutanée doit inclure une évaluation de la chaleur locale, de la présence d'œdèmes ou de zones cutanées indurées.
L'observation cutanée porte aussi sur la recherche de dommages cutanés occasionnés par le matériel médical.
Si l'individu présente une peau à pigmentation foncée, il faut considérer que l'individu est à risque d'escarres en présence : • de zones cutanées localement bleutées ou violacées ; • d'une chaleur localisée qui devient une zone plus froide lorsque la peau est endommagée ; • d'un œdème localisé ; • d'une induration locale.
Toute modification de l'état cutané du patient doit être documentée, communiquée et rendue disponible pour les membres de l'équipe multidisciplinaire.

Massage de la peau

Recommandation	Force de le recommandation	Niveau de preuve
Eviter les frictions et les massages cutanés intensifs, réalisés en vue de prévenir le développement d'escarres, et ce, en particulier au niveau des saillies osseuses.	Forte	Très faible

Meilleures pratiques

L'efficacité clinique de différents produits pour la peau (crèmes, onguents ou pommades) utilisés à d'autres fins (telle l'hydratation ou la protection de la peau) n'a pas été étudiée dans le cadre de l'élaboration de ces recommandations cliniques. L'application de tels produits doit être réalisée par effleurement cutané en évitant les massages.

Repositionnement

Recommandations	Force de le recommandation	Niveau de preuve
Un protocole de changement de position (comprenant des spécifications de la fréquence et du type de position) doit être proposé et notifié pour tous les individus à risque d'escarres.	Forte	Très faible
Les individus à risque de développement d'escarres doivent être changés de position. La fréquence et la méthode utilisée pour le changement de position doivent être déterminées et adaptées sur base d'une évaluation de l'état de l'individu et doivent prendre en compte : • Le niveau de risque de l'individu ; • La situation médicale de l'individu ; • L'état cutané de l'individu ; • Le niveau d'activité et de mobilité de l'individu ; • Le confort de l'individu ; • Le plan de soins global de l'individu ; • Les caractéristiques de la surface de support sur laquelle l'individu est couché ou assis.	Forte	Très faible
Changements de position en position couchée : • Il est recommandé de changer l'individu de position en le plaçant en position latérale, rehaussée à 30° (dos soutenu et sacrum libre), si l'individu le tolère et si son état le permet.	Forte	Très faible

Meilleures pratiques

Technique de changement de position :

- Le changement de position doit être appliqué (en alternance à droite, à gauche et sur le dos) si l'individu peut le tolérer et si son état clinique le permet. La position ventrale peut aussi être envisagée. Il faut éviter les positions qui augmentent la pression telles que la position latérale rehaussée à 90° et la position semi-assise.
- La superficie de contact entre l'individu et la surface d'appui doit être augmentée pour répartir uniformément et diminuer la pression qui s'exerce sur la peau et les tissus sous-jacents de l'individu.
- Eviter que la peau ne soit soumise à des forces de pression ou de cisaillement.
- Eviter de placer l'individu sur une saillie osseuse, particulièrement si un érythème non réductible à la pression est déjà présent.
- Les dispositifs de manutention manuels doivent être utilisés correctement afin de minimiser les dommages liés au cisaillement et à la friction (soulever l'individu et ne pas le glisser). Après avoir repositionné l'individu, tous les éléments du dispositif de manutention doivent être enlevés immédiatement (écharpes, ceintures, courroies), si ils sont susceptibles de causer des dommages cutanés (un fin drap de transfert peut être toléré pour prévenir les forces de cisaillement, en combinaison avec une position adéquate de l'individu).
- Si le patient doit rester alité en position assise, une élévation de la tête de lit supérieure à 30° et une position avachie (augmentant la pression et le frottement sur le sacrum et le coccyx) doivent absolument être évitées. La position semi-Fowler sera préférée lorsque le patient est couché sur le dos. Pour cela, la tête de lit sera relevée à 30° et les genoux seront en flexion à 30°.
- Il faut éviter que le matériel médical ou tout autre matériel n'exerce une pression sur la peau et les tissus sous-jacents (ex. tubulures, drains, seringues, robinets, capuchons, emballage,…).

Calendrier de changement de position :

- L'état cutané et le confort général de l'individu doivent être évalués régulièrement. Si l'individu ne répond pas aux changements de position comme souhaité (par exemple si une escarre de catégorie I, non présente jusque-là, se développe), la fréquence, la méthode et les positions adoptées dans le schéma de repositionnement doivent être reconsidérées, documentées et rendues accessibles à tous les membres de l'équipe multidisciplinaire.

Changement de position en position assise **:**

- L'individu doit être positionné de façon à ce qu'il puisse exercer ses activités normales. S'assurer que tout ce dont l'individu a besoin soit à sa portée.
- Chez les individus à risque de développer des escarres, veiller à limiter le temps passé en position assise. La durée en position assise sur une chaise doit être déterminée et continuellement adaptée sur base individuelle et doit considérer le respect du confort et de la dignité, le plan de soins global, l'état de santé mais aussi les caractéristiques du matériel de répartition de pression utilisé.
- Positionner l'individu dans une position assise qui lui permette de maintenir son niveau d'activités tout en évitant les forces de pression et de cisaillement sur la peau et les tissus sous-jacents. Lorsque l'individu est assis bien droit, s'assurer que ses membres inférieurs soient dans un alignement optimal (par exemple, angle de 90° au niveau de la hanche, du genou et du pied). Eviter de positionner les hanches selon un angle supérieur à 90° afin de

minimiser la pression sur les ischions. Placer les pieds de l'individu sur le sol ou sur un repose-pieds lorsque les pieds ne touchent pas le sol. Lorsque l'individu est assis dans un fauteuil, ses pieds et ses talons doivent être placés en décharge.

Changement de position – salle d'opération :

En plus de l'utilisation d'un matelas spécifique sur la table d'opération, d'autres mesures de prévention doivent être prises pendant la chirurgie :

- Positionner l'individu de façon à réduire le risque de développer des escarres, particulièrement en évitant les forces de cisaillement ;
- Surélever complètement les talons (en décharge) de manière à répartir le poids de la jambe le long du mollet sans concentrer la pression sur le tendon d'Achille. Le genou sera en flexion et soutenu.

Changement de position – éducation du patient **:**

- Les individus (ou les soignants informels) qui sont disposés et aptes à le faire, devraient être informés des principes de la répartition du poids et des façons d'y arriver (dans la mesure du possible, en combinaison avec des exercices actifs).

Dispositifs de redistribution de la pression

Recommandations	Force de le recommandation	Niveau de preuve
L'utilisation de dispositifs de répartition de la pression (matelas de faible technologie maintenant une basse pression continue ou dispositifs de haute technologie) est recommandée chez les patients à risque de développement d'escarres. Comme les études cliniques ne démontrent pas la supériorité d'un dispositif de distribution de pression par rapport à un autre, le choix du matériel doit reposer sur l'évaluation globale de l'individu, tenant compte du niveau de risque, du confort, et de l'état général de l'individu. L'adéquation de chaque dispositif à l'environnement de soins, et d'autres facteurs (ex. nettoyage du matériel, type de housse de protection, possibilité de réanimation cardio-pulmonaire, désinfection et coût) peuvent contribuer à orienter le choix.	Forte	Très faible
L'utilisation de matelas sans fonction de répartition de pression ou ne permettant pas d'alléger la pression doit être évitée chez les individus à risque de développement d'escarres.	Forte	Très faible
Sur la table d'opération, un matelas répartiteur de pression est recommandé, de préférence un matelas visco-élastique de polymère. Plusieurs dispositifs sont disponibles pour redistribuer la pression (par ex. calotte de tête faciale pour les patients en position ventrale sur la table d'opération), mais aucun dispositif n'a démontré sa supériorité par rapport aux autres. Aussi, aucune recommandation ne peut être formulée permettant d'orienter le choix sur un type de dispositif en particulier, pour la prévention des escarres.	Forte	Faible

Meilleures pratiques
Le bon fonctionnement des systèmes de répartition de pression doit être vérifié régulièrement.
Il convient d'utiliser un coussin de siège répartiteur de pression pour tout individu à risque de développement d'escarres, lorsqu'il est en position assise : • Il n'existe pas de preuves concluantes de la supériorité d'un type de coussin de siège répartiteur de pression sur un autre ; aussi, aucune recommandation ne peut être formulée permettant d'orienter le choix sur un type de coussin de siège en particulier, pour la prévention des escarres. La décision portant sur le choix d'un coussin de siège répartiteur de pression doit être adaptée aux besoins de l'individu et au contexte de la prise en charge.

Prévention des escarres du talon

Recommandation	Force de le recommandation	Niveau de preuve
L'utilisation de dispositifs permettant de surélever les talons dans le vide en combinaison avec un matelas répartiteur de pression est recommandée chez les patients à risque de développer des escarres. Aucun dispositif n'ayant démontré sa supériorité par rapport aux autres, aucune recommandation ne peut être formulée permettant d'orienter le choix sur un type de dispositif en particulier, pour la prévention des escarres.	Forte	Très faible

Meilleures pratiques
Pour les individus alités et les individus assis dans un fauteuil, inclinés en arrière avec les pieds surélevés, un dispositif permettant la décharge complète des talons devrait être utilisé. Ceci peut être obtenu en répartissant le poids de la jambe le long du mollet sans concentrer la pression sur le tendon d'Achille. Le genou sera légèrement fléchi et soutenu.
Vérifier régulièrement l'état de la peau des talons.

Nutrition et hydratation

Meilleures pratiques
Les bonnes pratiques cliniques incluent la surveillance de l'état nutritionnel comme part intégrante de l'évaluation globale de l'individu et comme processus continu tout au long de sa prise en charge. Cette évaluation doit comprendre la documentation et le suivi des facteurs suivants : • Le poids et la taille actuels de l'individu ; • La perte récente de poids ; • Les habitudes alimentaires ; • Les modifications récentes dans les habitudes alimentaires et dans la consommation alimentaire.
Si un risque nutritionnel est suspecté, les praticiens doivent réaliser une évaluation approfondie. L'utilisation d'une échelle d'évaluation du risque nutritionnel peut être utile. Les individus présentant un (risque accru de) déficit nutritionnel doivent être discutés en équipe multidisciplinaire.

Recommandation	Force de le recommandation	Niveau de preuve
Comme les études cliniques ne démontrent pas la supériorité d'une intervention nutritionnelle (telle que les suppléments nutritionnels administrés par voie orale et/ou l'alimentation par sonde) sur une autre, aucun régime alimentaire enrichi de suppléments nutritionnels ne peut être recommandé pour la prévention des escarres.	Forte	Très faible

DISCUSSION

La prévention des escarres revêt une importance majeure pour la qualité des soins, aussi bien à domicile qu'à l'hôpital ou dans d'autres environnements. Dans un tel contexte, ce guideline dispense des recommandations utiles pour guider la pratique quotidienne des dispensateurs de soins, de préférence sur la base des meilleures preuves disponibles.

Utilisation du guideline

Ce guideline doit être considéré comme un point de départ pour organiser une vaste campagne de sensibilisation de tous les prestataires de soins concernés.

D'une part, il peut être utilisé dans le cadre de programmes complets de prévention des escarres (par exemple la mise en œuvre des cadres de meilleures pratiques, la formation du personnel, les campagnes de sensibilisation, d'évaluation et de feedback, les infirmières ressources en soins de plaies). En effet, un nombre croissant d'études montre que les organisations qui utilisent une telle approche dans le cadre de leur politique d'amélioration de la qualité sont efficaces pour réduire l'incidence des escarres.

D'autre part, le contenu scientifique de ce guideline est destiné à être diffusé par les organisations scientifiques et professionnelles qui peuvent à leur tour le décliner en outils attrayants et conviviaux, personnalisés en fonction des groupes de prestataires de soins. Ces mêmes organisations vont également jouer un rôle clé dans le processus de diffusion qui mettra à profit divers canaux, notamment des sites Internet ou des sessions de formation continue.

Meilleures preuves disponibles

Il convient de noter que pour de multiples mesures de prévention actuellement déployées dans la pratique clinique quotidienne, il n'y a que peu ou pas de preuves scientifiques disponibles, ou bien celles-ci sont entachées de lacunes méthodologiques importantes. Néanmoins, l'absence de preuves scientifiques ne signifie pas que nous ayons la preuve de l'absence d'un effet. Dans l'attente d'autres études de qualité méthodologique élevée dans ce domaine, les options offertes reposent sur un consensus international qui a été confirmé par les experts belges consultés durant le présent projet. Compte tenu de l'absence de preuves solides, il est essentiel de personnaliser le présent guideline en fonction des besoins spécifiques de l'organisation ou de l'environnement de soins, de même que des besoins et préférences de chaque individu.

Besoins en études ultérieures

En conséquence, des recherches ultérieures sont nécessaires, compte tenu du fossé qui se creuse entre l'importance de la prévention dans le développement des escarres et l'indigence en études cliniques méthodologiquement solides. Deux priorités se dégagent de notre étude :

- Dans un premier temps, il convient de concevoir de nouvelles études afin d'évaluer l'utilité des méthodes d'évaluation du risque et d'évaluation cutanée. Le problème qui se pose avec les études existantes réside dans leur hétérogénéité au niveau de : la population cible, de la description de l'état de la peau, des facteurs de risque à prendre en considération, des mesures de prévention déployées. Partant, des études ultérieures tireraient parti d'une amélioration et d'une standardisation de la description de ces éléments, afin de permettre un calcul plus précis de la capacité prédictive des méthodes d'évaluation du risque et d'évaluation cutanée.
- Deuxièmement, des études comparant les matelas à pression variable 'de haute technologie' et les matelas à basse pression continue 'de faible technologie' s'imposent. De même, il est nécessaire de réaliser des recherches sur la fréquence optimale de changement de position de l'individu (également en association avec d'autres mesures, notamment le recours à des dispositifs de redistribution de la pression), et ce afin d'affecter les effectifs en personnel de la façon la plus efficiente. En plus de comparer l'efficacité clinique, ces études devraient également inclure l'évaluation du rapport coût-efficacité des mesures préventives.

RECOMMANDATIONS POLITIQUES[a]

A l'attention des responsables du Health Research System :

- **Réaliser une évaluation de la littérature tous les cinq ans afin de déterminer si des changements survenus au niveau des preuves justifient une mise à jour de tout ou partie du présent guideline.**

A l'attention du Conseil fédéral pour la Qualité de l'activité infirmière en concertation avec le Conseil National pour la Promotion de la Qualité :

- **Définir et mettre en œuvre des indicateurs de processus et de résultats basés sur le contenu du présent guideline. Ces indicateurs doivent être alignés sur les initiatives existantes en matière d'indicateurs pour les escarres.**

A l'attention du SPFSanté publique, Sécurité de la chaîne alimentaire et Environnement :

- **Décliner le présent guideline en procédures, protocoles, programmes d'éducation, etc. dans un format qui soit facile à utiliser dans la pratique quotidienne. Cette initiative doit être concrétisée en étroite collaboration avec les *organisations professionnelles.***

A l'attention des professionnels responsables des changements de pratique dans les maisons de repos (et de soins), les hôpitaux et les autres environnements de soins :

- **Intégrer les programmes complets de prévention des escarres (par exemple la mise en œuvre des cadres de meilleures pratiques, la formation du personnel, les campagnes de sensibilisation, d'évaluation et de feedback, les infirmières référentes en soins de plaies, les comités multidisciplinaires de prévention des escarres de décubitus) dans la politique d'amélioration de la qualité de l'organisation. Outre le personnel infirmier, cette approche multidisciplinaire devrait aussi impliquer les gériatres et dermatologues, au niveau de l'hôpital, le Médecin Coordinateur et Conseiller (MCC) dans les MRS/MRPA, le médecin généraliste pour les patients à domicile.**

[a] Le KCE reste seul responsable des recommandations adressées aux autorités publiques

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
A&E	Accident & Emergency
AFM	Alternative Foam Mattress
AP	Alternating Pressure
AUC	Area Under the Curve (ROC-curve)
CI	Confidence Interval
CLP	Constant Low Pressure
CNC	Clinical Nursing Consulting
CPG	Clinical Practice Guideline
DMSO	Dimethyl Sulfoxide
EPUAP	European Pressure Ulcer Advisory Panel
GDG	Guideline Development Group
IAD	Incontinence Associated Dermatitis
ICU	Intensive Care Unit
IDL	Indentation Load Deflection
KCE	Belgian Healthcare Knowledge Centre
KUL	Katholieke Universiteit Leuven
NBE	Non-Blanchable Erythema
NCGC	National Clinical Guideline Centre
NICE	National Institute for Health and Clinical Excellence
NPUAP	National Pressure Ulcer Advisory Panel
PICO	Population, Intervention, Comparison, Outcome
PU	Pressure Ulcer
RCT	Randomized Controlled Trial
SFM	Standard Foam Mattress
UGENT	Universiteit Gent
WCS	VZW Wondzorgvereniging

SCIENTIFIC REPORT

1 INTRODUCTION

1.1 What are Pressure Ulcers?

A pressure ulcer can be defined as a localized injury of the skin and/or underlying tissue resulting from an internal response to an external mechanical load, applied to soft biological tissues, generally over a bony prominence. This external mechanical load can be a force perpendicular to the skin surface (pressure), a force parallel to the skin surface (shear), or a combination of pressure and shear.

The aetiology of pressure ulcer development is multi-factorial. The role of individual factors, their importance and their interaction remains unknown.[1] Biomechanical research shows that a mechanical load will lead to (1) a reduced supply of oxygen in the tissue (leading to ischemia, including hypoxia, glucose depletion, and tissue acidification), (2) a reduced supply of nutrients, and (3) an accumulation of waste products.[1,2] The role of other contributing factors, such as (1) direct cell deformation, (2) impaired lymphatic drainage, and (3) reperfusion damage is not yet fully understood.[2] Pressure ulcers most often develop over the sacrum, ischial tuberosities, trochanters, femoral condyles, malleoli, and heels.[3] Additionally, the National Pressure Ulcer Advisory Panel (NPUAP, USA) also recognizes the risk of pressure ulcer development beneath medical devices such as catheters, oxygen tubes, ventilator tubes, semi-rigid cervical collars.[4,5]

The severity of a pressure ulcer varies from non-blanchable erythema of the intact skin to tissue destruction involving skin, subcutaneous fat, muscle and bone. Numerous tools have been developed to classify the severity of a pressure ulcer.[6,7] In 1989, NPUAP developed a classification using four grades (Table 1). This classification was adopted by the European Pressure Ulcer Advisory Panel (EPUAP) in 1999 with some minor textual changes.[6] As part of a 2009 international guideline development process, NPUAP and EPUAP developed a common international classification system for pressure ulcers.[5]

In this classification system a pressure is defined as:

- Category I as a non-blanchable erythema of the intact skin;
- Category II as an abrasion or a blister;
- Category III as a superficial ulcer;
- Category IV as a deep ulcer.[5]

A Category II lesion should not be used to describe other superficial skin lesions such as skin tears, tape burns, incontinence associated dermatitis (IAD), maceration or excoriation.[5]

Table 1 – Classification of Pressure Ulcers according to NPUAP/EPUAP[5]

Category	Description
Category/Stage I Non-blanchable erythema	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its colour may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons.
Category/Stage 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 or sero-sanguineous filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising. This category should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration or excoriation.
Category/Stage III Full thickness skin loss	Full thickness skin 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 tunnelling. 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 (adipose) 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 or directly palpable.
Category/Stage IV Full thickness tissue loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often includes undermining and tunnelling. 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 (adipose) 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 or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.

1.2 Relevance of the guideline

In several European countries (Table 2), national prevalence studies had been conducted.[3,8,9,10,11] The reported prevalence rates ranged from 8.9% to 18.1% in hospitals and from 6.4% to 31.4% in nursing homes. In Belgium, the prevalence of pressure ulcers had only been studied on a national level within the hospital setting (19 968 patients; 1 005 nursing units; 84 acute hospitals). Vanderwee et al. (2011)[3] reported a prevalence of 12.1% (Category I-IV). The comparison between countries remains difficult because of differences in pressure ulcer definitions, methods of data collection and patient population.[3]

Pressure ulcers are more likely to occur in sub-groups like spinal-cord injury patients[12], cachectic patients[13], patients treated in intensive care[3,14,15] or geriatric units[15], patients with advanced incurable illness[16] and wheelchair bound patients[17].

Pressure ulcers may cause pain and discomfort to the affected patients[18,19], a prolonged and/or more frequent contact with the healthcare system[20,21,22] and their presence has been associated with an increased risk of mortality.[23,24] In addition, the treatment of pressure ulcers is associated with considerable costs. Studies estimated the cost for treating pressure ulcers between 1% (the Netherlands)[25] and 4% (England)[26] of the total healthcare budget. A significant increase of the economic burden is expected because of the ageing population and an increase of patient co-morbidities.

Table 2 – Prevalence of pressure ulcers in adults in a selection of European countries

Country	Setting	Study year	Prevalence (Grade I-IV)	Sample size (n)	Reference
Belgium	Hospitals	2008	12.1%	19 968	Vanderwee et al., 2011[3]
France	Hospitals	2004	8.9%	37 307	Barrois et al., 2008[8]
Germany	Hospitals	2004	9.0%	8 515	Tannen et al., 2008[11]
	Nursing Homes	2004	6.4%	2 531	Tannen et al., 2008[11]
Italy	Hospitals	2005	8.3%	1 097	Vanderwee et al., 2007a[15]
	Long- term care	2005	27.0%	571	Capon et al., 2007[9]
Portugal	Hospitals	2005	12.5%	786	Vanderwee et al., 2007a[15]
Sweden	Hospitals	2011	16.6%	16 466	Gunningberg et al., 2012[10]
	Nursing Homes	2011	14.5%	18 592	Gunningberg et al., 2012[10]
The Netherlands	Hospitals	2004	18.1%	10 237	Tannen et al., 2008[11]
	Nursing Homes	2004	31.4%	10 098	Tannen et al., 2008[11]

1.3 Scope

The aim of this study was to develop a clinical practice guideline (CPG) on risk assessment and prevention of pressure ulcers in adults and children being admitted to hospitals, long-term care facilities (including nursing homes, rehabilitation facilities and long-term chronic care hospitals) and those receiving home care. The CPG will cover the following topics:

- Risk assessment;
- Skin assessment;
- Skin massage;
- Repositioning;
- Devices for prevention (mattresses, overlays, cushions);
- Devices for heel ulcer prevention;
- Nutrition and hydration for prevention.

The CPG is intended to support clinical decision-making in all health care professionals involved in the care for the individuals at risk for pressure ulcer development.

The CPG will not cover risk assessment and management of incontinence associated dermatitis because of the unique nature and the specific aetiology of this skin disorder.[27] The treatment of pressure ulcers will be the subject of a separate CPG.

2 METHODOLOGY

2.1 Clinical questions

The clinical questions were the result of a scoping review of existing guidelines and consecutive discussions within the multidisciplinary research team (see Table 5) and the multidisciplinary expert panel (see also 2.4). The clinical questions were refined based on discussions with our international partner (see 2.2).

The CPG addresses the following clinical questions (for detailed protocols, see appendix 1-9):

1. **What is the clinical effectiveness of risk assessment tools in the prevention of pressure ulcers?**

- Population: individuals of all ages in all settings;
- Intervention: risk assessment tool, clinical judgement based on risk factors;
- Comparison: Each other, no risk assessment;
- Outcomes:
  - Critical outcomes for decision making: 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 in other health care setting (continuous data); health-related quality of life (continuous data).

2. What is the predictive ability of risk assessment tools for pressure ulcer development?

- Population: individuals of all ages in all settings without a pressure ulcer;
- Intervention: risk assessment tool, clinical judgement based on risk factors;
- Outcomes:
  - Critical 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: Area under the ROC (AUC), sensitivity for a defined threshold, specificity for a defined threshold.

3. What is the clinical effectiveness of skin assessment methods in the prevention of pressure ulcers?

- Population: individuals of all ages in all settings;
- Intervention: skin assessment methods: diascopy and skin temperature;
- Comparison: Each other, no skin assessment, other method;
- 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 health care setting (continuous data); health-related quality of life (continuous data).

4. What is the predictive ability of skin assessment methods for pressure ulcer risk?

- Population: individuals of all ages in all settings;
- Intervention: skin assessment methods: ultrasonography, ultrasound, durometer/durometry, diascopy (finger method and transparent disk), elastometer, haptic finger, multispectral imaging device, multiwavelength imaging, multispectral images, digital colour images, clinical assessment, transcutaneous oximetry, termographic scanner, tympanic thermometers (to measure skin temperature), doppler blood flowmetry, laser, doppler imaging;
- Outcomes:
  - Critical 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: Area under the ROC (AUC), sensitivity for a defined threshold, specificity for a defined threshold, Diagnostic Odds Ratio.

5. What is the clinical effectiveness of skin massage in the prevention of pressure ulcers?

- Population: individuals of all ages in all settings;
- Intervention: skin massage (method, products, frequency);
- Comparison: no skin massage; other preventive methods;
- Outcomes:
  - Critical outcomes for decision making: Proportion of participants developing new pressure ulcers (dichotomous outcome)(describe different categories of ulcer); skin damage;
  - Important outcomes: Patient acceptability; rate of development of pressure ulcers; time to develop new pressure ulcers; time in hospital or time in other healthcare setting; health related quality of life.

6. How and at what frequency should repositioning be undertaken for the prevention of pressure ulcers?

- Population: individuals of all ages in all settings;
- Intervention: repositioning technique; 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);
  - Important outcomes: patient acceptability; rate of development of pressure ulcers; time to develop new pressure ulcer (time to event data); time in hospital or in other health care setting (continuous data); health-related quality of life (continuous data).

7. What are the most clinically effective pressure re-distributing devices for the prevention of pressure ulcers?

- Population: individuals of all ages in all settings;
- Intervention: mattresses/overlays; beds; seating; others like pillows, postural support, and limb protectors;
- Comparison: each other or no intervention;
- Outcomes:
  - Critical outcomes for decision making: 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 other health care setting (continuous data); health-related quality of life (continuous data).

8. What are the most clinically effective pressure re-distributing devices for the prevention of heel pressure ulcers?

- Population: individuals of all ages in all settings;
- Intervention: heel-specific devices as preventive strategies (i.e. 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) and non heel-specific devices (Mattresses/overlays and beds);
- Comparison: each other or no intervention;
- Outcomes:
  - Critical outcomes for decision making: 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 other health care setting (continuous data); health-related quality of life (continuous data).

9. What are the most clinically effective interventions with nutrition or hydration for the prevention of pressure ulcers for people with and without nutritional deficiency?

- Population: individuals of all ages in all settings with and without nutritional deficiencies;
- Intervention: nutritional interventions (supplementation or special diet); 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: proportion of participants developing new pressure ulcers (dichotomous outcome);
  - Important outcomes: patients acceptability of supplements – e.g. measured by compliance, tolerance, reports of unpalatability; rate of development of pressure ulcers; time to develop new pressure ulcer (time to event data); time in hospital or other health care setting (continuous data); (dichotomous data); health-related quality of life (continuous data).

2.2 International collaboration

The National Clinical Guideline Centre[a] (NCGC), commissioned by The National Institute for Health and Clinical Excellence (NICE, United Kingdom) is currently producing a clinical guideline on the prevention and treatment of pressure ulcers to replace its existing guidelines.[28,29,30] The CPG will be developed de novo. The nine research questions regarding risk assessment, skin assessment and prevention of pressure ulcers were fully in common with those of the KCE and the elaboration of the topics was divided between both organisations.

A collaboration agreement was set up between NCGC and KCE concerning the following:

1. **Scope**: the collaboration concerned the search for evidence (search strategy + selection), quality appraisal, evidence tables and the development of the evidence reports. The formulation of evidence statements and recommendations was the responsibility of the two organisations separately.
2. **Form of cooperation**: five research questions were elaborated by KCE (questions 1-5), while the four other common questions were elaborated by NCGC (questions 6-9).
3. **Cross-validation was done after each of the following steps**:
   - Development of the search strategy;
   - Selection of the literature;
   - Quality appraisal and elaboration of evidence tables;
   - Evidence report.

[a] The National Clinical Guideline Centre (NCGC) is a multi-disciplinary health services research team funded by the National Institute for Health and Clinical Excellence (NICE). They produce evidence based clinical practice guidelines commissioned by NICE.

2.3 Literature searches

2.3.1 Search strategy

The search for peer-reviewed articles included a search in OVID Medline, EMBASE, CINAHL and the Cochrane Library (see appendices 1-9 for search strings). The search was limited to articles published in English, French and Dutch for the evidence reports produced by KCE (Questions 1-5, performed by the KCE-team) while for the evidence reports that were produced by NCGC (Questions 6-9, performed by the NCGC-team) searches were restricted to articles published in English in line with the NCGC methodology. No date restriction was used. For most questions, the search focused on high-quality systematic reviews (i.e. reviews matching the PICO's; extensive quality assessment; data available for GRADE input) and randomized controlled trials (RCTs) (see protocols in appendices 1-9 for more details). However, when RCTs were unavailable the search was expanded to observational studies (see protocols in appendices 1-9 for details). For the prognostic research questions (risk assessment – Q2 and skin assessment – Q4), the search focused on prospective cohort studies (see protocols in appendices 2 and 4 for details).

All literature searches were done between March and September 2012. Search strategies were checked by reviewing the reference lists of relevant key papers and requesting the advice of the expert panel about additional papers.

The identified studies were selected by one reviewer based on title and abstract. For all eligible studies, the full-text was retrieved. Studies were selected if relevant to the review question (PICO: population, intervention, comparison, outcome). A quality assurance check was performed by a second reviewer on 10% of the search results. In case no full-text was available, the study was not taken into account to develop the final recommendations.

2.3.2 Quality appraisal

A quality appraisal was done for each individual study and for each outcome. All critical appraisals were done by one researcher. The quality of the retrieved RCTs and observational studies was assessed using the corresponding checklists of the National Institute for Health and Clinical Excellence (NICE).[31]

For each clinical question the quality of the available evidence was summarized for each outcome using the GRADE-system and GRADEpro software (http://ims.cochrane.org/gradepro). The latter could not be used for the prognostic research question on risk – and skin assessment.

Levels of evidence were regarded as being 'HIGH' for RCTs and 'LOW' for observational studies. In a subsequent step, the level of evidence was downgraded (and/or upgraded in case of observational studies) based on the assessment of the risk of bias, inconsistency, indirectness, imprecision, publication bias (see description in Table 3). Each quality element being considered to have "serious" or "very serious" risk of bias was downgraded with 1 or 2 points respectively. The downgraded/upgraded scores were then summed and an overall quality rating was assigned (see Table 4). An outcome with only RCTs, for example, starts 'HIGH' but can be downgraded to 'MODERATE', 'LOW' or 'VERY LOW' when 1, 2 or 3 points were deducted, respectively. The reasons or criteria used for downgrading were specified in the footnotes.

Table 3 – Description of GRADE elements for intervention studies (Source: NCGC, 2012)[32]

Quality element	Description
Study limitations (Risk of bias)	Limitations in the study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect.
Inconsistency	Inconsistency refers to an unexplained heterogeneity of results.
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the protocol.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide Confidence Intervals around the estimate of the effect relative to the clinically important threshold.
Publication bias	Publication bias is a systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies.

Table 4 – Levels of evidence (Source: Balshem et al. 2011)[33]

Quality level	Definition	Methodological quality of supporting evidence
High	We are very confident that the true effect lies close to that of the estimate of the effect	RCTs without important limitations or overwhelming evidence from observational studies
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect	RCTs with very important limitations or observational studies or case series
Very Low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect	

A more detailed description of the GRADE elements can be found in appendix 10.

2.3.3 Data extraction and analysis

For each primary study, data were extracted by one reviewer. Following study characteristics were tabulated using a standard template: reference, patient characteristics, intervention/comparison, outcome measures, effect size, comments. An adapted version of the template was used to extract data for prognostic research questions (see appendices 2 and 4).

A meta-analysis was done if possible using Revman-software (http://ims.cochrane.org/revman). The specific review strategies were defined in the study protocols (see appendices 1-9).

In general, studies were combined in a meta-analysis if the clinical (e.g. similar patient population, intervention, comparison, outcome) and statistical heterogeneity were acceptable. The unit of analysis was separated in studies measuring outcomes at the patient or ulcer level. The following groups were considered separately as strata (children and adults) or subgroups (different categories of pressure ulcers; different ulcer locations). In absence of appropriate data, forest plot(s) were generated for each outcome using single studies for didactic purposes.

Fixed-effects (Mantel-Haenszel) techniques were used to calculate risk ratios (relative risk) for the binary outcomes. The continuous outcomes were analysed using an inverse variance method for pooling weighted mean differences and where the studies had different scales, standardised mean differences were used. Statistical heterogeneity was assessed by considering the chi-squared test for significance at $p<0.1$ or an I-squared inconsistency statistic of >50% to indicate significant heterogeneity. In case of heterogeneity and a sufficient number of studies, sensitivity analyses were conducted based on risk of bias and pre-specified subgroup analyses were carried out as defined in the protocol. Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. If no sensitivity analysis was found to completely resolve statistical heterogeneity then a random effects (DerSimonian and Laird) model was employed to provide a more conservative estimate of the effect.

The means and standard deviations of continuous outcomes were required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated if the p-values or 95%

confidence intervals (CIs) were reported and meta-analysis was undertaken with the mean difference and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5) software. Where p-values were reported as “less than”, a conservative approach was undertaken. For example, if p value was reported as “p<0.001”, the calculations for standard deviations were based on a p-value of 0.001.

The authors used the area under the receiver operating characteristic (AUC) to illustrate and evaluate the prognostic performance of risk assessment tools. In addition, the 95% CI for each scale (within studies and between studies; if data are available) was extracted and used to calculate the median AUC and range. The determination of an "ideal" cut-off value is almost always a trade-off between sensitivity (true positives) and specificity (true negatives). As both change for each "cut-off" value, it becomes difficult for the reader to imagine which cut-off is ideal. The AUC curve offers a graphical illustration of these trade-offs for each "cut-off" value. The maximum value for the AUC is 1.0, indicating a (theoretically) perfect test (i.e., 100% sensitive and 100% specific). An AUC of 0.5 indicates no discriminative value (i.e., 50% sensitive and 50% specific). Three cut-off scores were determined for each scale with an acceptable median AUC for the purpose of the risk assessment review. The sensitivity and specificity of these cut-off scores were determined by the median sensitivity. The sensitivity, specificity and diagnostic odds ratio for the prognostic question on skin assessment were calculated.

2.4 Formulation of recommendations: Collaboration between research team, Guideline Development Group and external experts

A subgroup of researchers (see Table 5) was responsible for systematic searches, retrieval and appraisal of the evidence and the writing of the evidence report (procedure used to draft evidence statements is described in appendix 10; 1.7). A second group within the research team drafted recommendations based on the retrieved evidence (Table 5) and assigned a grade of recommendation to each recommendation using the GRADE system (see appendix 10). Researchers responsible for drafting the recommendations were involved in the expert panel to discuss the evidence reports and vice versa.

The draft of the recommendations and the evidence tables were circulated to the expert panel prior to each face-to-face meeting. The expert panel that consisted of 4 home care nurses, 8 hospital nurses, 2 nursing home nurses, 1 general practitioner, 1 dermatologist and 1 representative of the Belgian Ministry of Public Health (FOD Volksgezondheid – SPF Santé Publique) had the following tasks:

- To verify that the research is complete and that the interpretation of the evidence is correct;
- To assess the relevance of the conclusions and the selected studies in relation to the Belgian context;
- To verify the evidence statements;
- To participate in the drawing up of recommendations.

The expert panel met on 3 occasions: 12 March 2012; 10 September 2012; 19 October 2012.

Based on the evidence review, the research team (i.e. authors of this report) formulated recommendations. In addition Best practices were formulated. The latter were not based on the evidence reviews but on two existing guidelines (i.e. EPUAP/NPUAP 2009[5] & NICE 2001, 2003, 2005[28,29,30,34,35,36]) that were retained after a comprehensive systematic search (see appendix 11 for details).

Table 5 – Research team and responsibilities

Expert	Organisation	Area of expertise	Researchers team responsible for evidence reports[b]	Working group responsible for drafting recommendations	Guideline Development Group (GDG)
Dimitri Beeckman	UGENT	Assistant Professor in Nursing Science	X		X
Cathy Matheï	KUL	Professor in General Medicine	X		X
Aurélie Van Lancker	UGENT	Researcher	X		X
Sabine Van Houdt	KUL	Researcher	X		X
Geert Vanwalleghem	Clinical Nursing Consulting or CNC/WCS (VZW Wondzorgvereniging)	Clinical nurse specialist wound care – Hospital setting		X	X
Luc Gryson	CNC	Clinical nurse specialist wound care		X	X
Hilde Heyman	WCS	Clinical nurse specialist wound care – Nursing home setting		X	X
Christian Thyse	AFIScep.be	Clinical nurse specialist wound care		X	X
Adinda Toppets	UZLeuven	Clinical nurse specialist wound care		X	
Sabine Stordeur	KCE	KCE-senior expert	X	X	X
Koen Van den Heede	KCE	KCE-expert	X	X	X

[b] Evidence reports for clinical questions 4-7 were produced by NCGC (Liz Avital, Katie Jones, Julie Neilson)

All recommendations and Best practices were reviewed by a panel of experts (i.e. 19/10/2012) using a formal procedure. Two weeks before the final expert meeting, all experts received the recommendations and Best practices. As a preparation of the meeting all invited experts were asked to score each recommendation on a 5-point Likert-scale, with a score of '1' indicating 'completely disagree', '2' indicating 'somewhat disagree', '3' indicating 'unsure', '4' indicating 'somewhat agree', and '5' indicating 'completely agree' (the experts were also able to answer 'not applicable' in case they were not familiar with the underlying evidence or rationale). In case an expert disagreed with the recommendation or Best practice (score '1' or '2'), (s)he was asked to provide appropriate evidence or rationale, respectively. All scores were then anonymized and summarized into a median score, minimum score, maximum score and % of 'agreement-scores (score '4' and '5') to allow a targeted discussion (see appendix 12). The recommendations were then discussed during a face-to-face meeting on 19/10/2012. Based on this discussion a final draft of the recommendations and Best practices was prepared. In appendix 12, an overview is provided of how the comments of the external experts were taken into account.

Recommendations and Best practices were only changed if important evidence or rationale supported this change. Based on the discussion meeting a final draft of recommendations and Best practices was prepared and circulated to the expert panel.

3 FINAL RECOMMENDATIONS

3.1 Introduction

In this chapter we will describe for each of the research questions a summary of the available evidence as well as the recommendations for clinical practice. In addition to the recommendations also Best practices are described. The formulations of the latter are based on expert discussions of existing guidelines.

Two sets of general 'Best practices' were formulated:

- Tailoring pressure ulcer prevention to individual needs based on the principles of shared decision making;
- Education and training.

Best Practices

Pressure ulcer prevention should be a combined approach, tailored to individual needs and situations, and should be based on the principles of shared decision making:

- Prevention should take into account several factors such as the individual's medical condition, the overall plan of care and the individual's preferences. The needs of the individual and the context should be re-assessed regularly;
- An individual plan of care should be adopted based on assessment data, identified risk factors and individual goals and preferences. The plan is developed in interaction with the individual, informal caregivers and the healthcare professional. The planned and agreed/refused actions are documented and communicated to all relevant caregivers (also in case transition between care settings takes place).

Training and education should be tailored both to the needs of individual caregiver and to the responsibilities of the group of professionals.

Following components should be considered as part of each educational/training programme:

- Aetiology and risk factors predisposing to pressure ulcers;
- Classification of pressure ulcers;
- Differential diagnosis with other types of skin lesions;
- Risk assessment;
- Skin assessment;
- Selection and use of pressure redistributing devices;
- Repositioning;
- Nutritional aspects;
- Methods of documenting risk assessments and preventive activities;
- The importance of an interdisciplinary approach;
- The education of the individual and their informal caregivers.

3.2 Risk assessment

3.2.1 Introduction

Risk assessment aims to identify susceptible patients for pressure ulcer development in order to target appropriate preventive interventions. Both risk assessment scales and clinical judgment are widely described as methods being used in day-to-day practice. Risk assessment scales are based on risk factors associated with pressure ulcer development.[37] In a risk assessment scale, risk factors are listed and clinicians are expected to denote the presence, degree, or absence of the risk factor.[37] Such a list of risk factors aims to provide guidance to the specific cut-off point for risk or to specific preventive interventions that should be initiated.[37] A scale must accurately identify these individuals who are at risk, as well as those who are not- and do this consistently. Several risk assessment scales have been developed in the past[38].

Numerous risk assessment scales exist. We will organise the results according to the most commonly reported[39] and used risk assessment scales:

- The Braden-scale (includes the following subscales: nutrition, mobility, sensory perception, moisture, activity, friction and shear);
- The Norton-scale (includes the following subscales: mobility, continence, mental status, general health, activity);
- The Waterlow-scale (includes the following subscales: nutrition/appetite, mobility, build/weight, continence, sex/age, skin type, tissue malnutrition, neurological deficit, major surgery/trauma, medication);
- The Cubbin-Jackson which is adapted from the Norton scale (includes the following subscales: nutrition, mobility, build/weight, continence, mental status, age, skin condition, hygiene, hemodynamic status, respiration);
- The Braden-Q which is adapted from Braden for paediatric population (includes the following subscales: activity, nutrition, mobility, sensory perception, moisture, friction and shear, tissue perfusion and oxygenation).

Next to the use of a risk assessment scale, clinical judgment can be used to assess the level of risk for pressure ulcer development.[5]

The aim of this review was to guide health care professionals in their decision making about which method for risk assessment is most appropriate to detect individuals at risk for pressure ulcer prevention. The review on risk assessment includes two parts. In a first review (see 3.2.2) we will focus on the clinical effectiveness of risk assessment as part of a complex intervention for pressure ulcer prevention. A second review (see 3.2.3) will focus on the prognostic ability of risk assessment (scales and clinical judgment).

3.2.2 Clinical effectiveness

3.2.2.1 Review question

What is the clinical effectiveness of risk assessment tools in the prevention of pressure ulcers?

3.2.2.2 Clinical evidence

A Cochrane review by Moore and Cowan (2010)[40] was identified and used as reference for this review. The Cochrane review was an update of three systematic reviews by Cullum (1995)[41], McGough (1999)[42] and Pancorbo-Hidalgo (2006)[39]. None of the studies included in these systematic reviews were included in the Cochrane review as none of them were randomized controlled trials.

The Cochrane review by Moore and Cowan (2010)[43], included one RCT[44]. The Cochrane review was updated through a systematic search of multiple electronic databases. This resulted in 241 records: 47 in Medline (OVID), 36 in CINAHL, 108 in Embase and 50 in the Cochrane Library, of which 52 duplicates were removed. Based on screening of title and/or abstract 188 records were excluded. One study (a RCT published by Webster 2011[45]) was reviewed in detail and retained in addition to the RCT included in the Cochrane review.

Both RCTs included patients with and without a pressure ulcer at baseline and in both studies preventive measures were given to patients.

Quality of Studies

The methodological quality of the two RCTs was poor. The study of Saleh (2009)[44] had the most methodological flaws: absence of sequence generation, blinding, intention-to-treat analysis, and a priory sample size calculation. In addition, the allocation concealment was poor and the study had a high drop-out rate.

The study of Webster (2010)[45] was of higher quality. However, there was no blinding of health care professional and the sample size was lower than calculated.

In addition, both studies included patients with pressure ulcers at baseline. In appendix 1 the level of evidence can be found per outcome after applying the GRADE-methodology. The evidence base for all outcomes has been rated as low to very low quality.

Evidence statements

- One study (n=180) showed that clinical judgement is potentially more clinical effective at reducing pressure ulcer incidence (all grades) compared to the Braden scale (VERY LOW QUALITY). [44]
- One study (n=180) showed there may be no clinical difference between the group that used the Braden scale and received a wound management training and the group that only received the training (all grades) (VERY LOW QUALITY).[44]
- One study (n=180) showed that clinical judgement without training is potentially more clinical effective at reducing pressure ulcer incidence (all grades) compared to the group receiving training only (VERY LOW QUALITY). [44]
- One study (n=821) showed there may be no clinical difference between the group that used the Waterlow scale and the group that used clinical judgement (all grades), but the direction could favour clinical judgement (LOW QUALITY).[45]
- One study (n=820) showed there may be no clinical difference between the group that used the Waterlow scale and the group that used clinical judgement (grade 2), but the direction could favour clinical judgement (LOW QUALITY).[45]
- One study (n=821) showed that the Ramstadius scale is potentially more clinical effective at reducing pressure ulcer incidence (all grades) compared to the Waterlow scale (MODERATE QUALITY).[45]
- One study (n=820) showed that the Ramstadius scale is potentially more clinical effective at reducing pressure ulcer incidence (grade 2) compared to the Waterlow scale (MODERATE QUALITY).[45]
- One study (n=821) showed that the Ramstadius scale may be more clinical effective at reducing pressure ulcer incidence (all grades) compared to clinical judgement (LOW QUALITY).[45]
- One study (n=821) showed that the Ramstadius scale may be more clinical effective at reducing pressure ulcer incidence (grade 2) compared to clinical judgement (LOW QUALITY).[45]

3.2.3 Prognostic

3.2.3.1 Review question

What is the predictive ability of risk assessment tools for pressure ulcer development?

3.2.3.2 Clinical evidence

The systematic review by Pancorbo-Hidalgo (2006)[39] was used as a reference for this review. All studies included in the Pancorbo-Hidalgo (2006) [39] review, identified through the update and meeting the criteria of our review were reviewed in detail. Sensitivity and specificity of each scale and cut-off score were re-calculated by using the raw data as presented in the individual studies.

Some adjustments were made to the Pancorbo-Hidalgo review[39]. The review by Pancorbo-Hidalgo et al. (2006)[39] included 32 studies, of which five were excluded because they didn't meet the inclusion criteria of our review:

- One was excluded as it was a retrospective cohort study[46];
- Another study was removed as it was written in Spanish[47];
- Three other studies were excluded as they included patients with a pressure ulcer at start of the study.[48,49,50]

The update of the Pancorbo-Hidalgo (2006)[39] review yielded 16 additional articles resulting in a final inclusion of 44 studies.[51-93]

Quality of Studies

In general there were many concerns regarding the quality of the included studies. The absence of a description of patient enrolment, of time points when patients dropped out (discharge, death, transfer, pressure ulcer development) from the study, of an imputation technique, a poor description of definition and measurement of index test, and an event rate lower than 100 were the most important methodological flaws. In addition, patients received preventive measure which influenced the results on predictive validity.

In five studies it was unclear if patients with pressure ulcers at start of the study were included.[62,75,84,86,87] The results from these studies should be interpreted with caution.

In appendix 2 the level of evidence can be found per scale for studies reporting on the area under the receiver operating characteristics curve. The evidence base for all scales has been rated as being of low to very low quality.

Evidence statements

Braden scale:

- Area under the receiver-operating curve:
  - Nine studies showed a median AUC of 79.0 (range 55.0 to 88.0) for the Braden scale (all populations) indicating a fair discriminating power (VERY LOW QUALITY).[59,62,67,69,80,83,84,88,94]
  - Five studies showed a median AUC of 68.0 (range 55.0 to 81.0) for the Braden scale (general population) indicating a poor discriminating power (VERY LOW QUALITY).[59,62,67,80,83]
  - Four studies showed a median AUC of 79.0 (range 71.0 to 88.0) for the Braden scale (intensive care population) indicating a fair discriminating power (VERY LOW QUALITY).[69,84,88,94]
  - One study showed a median AUC of 74.0 (95% CI: 63.0-84.0) for the modified Braden scale (general) indicating a fair discriminating power (LOW QUALITY).[59]
- Predictive ability for different cut-off values:
  - Two studies (one of the studies consisted of three independent samples) (general population) showed a median sensitivity of 59.0 (range 50.0-78.0) and a corresponding specificity of 70.5 (range 52.0-81.0) for the Braden scale based on a cut-off score of ≤ 17 and a follow-up period < 1 week (LOW QUALITY).[56,57]
  - Two studies (one of the studies consisted of three independent samples) (general population) showed a median sensitivity of 70.0 (range 60.0-88.0) and a corresponding specificity of 58.0 (range 48.0-81.0) for the Braden scale based on a cut-off score of ≤ 18 and a follow-up period < 1 week (LOW QUALITY).[56,57]
  - Two studies (one of the studies consisted of three independent samples) (general population) showed a median sensitivity of 83.5 (range 51.0-100.0) and a corresponding specificity of 60.5 (range 42.0-73.0) for the Braden scale based on a cut-off score of ≤ 19 and a follow-up period point < 1 week (LOW QUALITY).[56,57]
  - One study (ICU population) showed a sensitivity of 87.5 and a specificity of 64.1 for the Braden scale based on a cut-off score of ≤ 12 and a follow-up period point of 48 hours (VERY LOW QUALITY).[94]
  - One study (ICU population) showed a sensitivity of 75.0 and a specificity of 82.1 for the Braden scale based on a cut-off score of ≤ 13 and a follow-up period point < 1 week (VERY LOW QUALITY).[94]
  - One study (ICU population) showed a sensitivity of 76.9 and a specificity of 29.6 for the Braden scale based on a cut-off score of ≤ 16 and a follow-up period point < 1 week (LOW QUALITY).[64]
  - Ten studies (some studies had multiple samples) (general population) showed a median sensitivity of 79.5 (range 46.2-100.0) and a corresponding specificity of 73.6 (range 14.0-100.0) for the Braden scale based on a cut-off score of ≤ 18 and a follow-up period point > 1 week (VERY LOW QUALITY).[55-59,65,71,76,79,82]
  - Five studies (some studies had multiple samples) (general population) showed a median sensitivity of 86.3 (range 71.4-100.0) and a corresponding specificity of 67.5 (range 42.9-77.8)

for the Braden scale based on a cut-off score of ≤ 19 and a follow-up period point > 1 week (LOW QUALITY).[55-58,82]

- Five studies (some studies had multiple samples) (general population) showed a median sensitivity of 93.2 (range 43.2-100.0) and a corresponding specificity of 53.5 (range 31.6-66.7) for the Braden scale based on a cut-off score of ≤ 20 and a follow-up period point > 1 week (LOW QUALITY).[55-58,82]
- One study (ICU) showed a sensitivity of 75.0 and a specificity of 66.7 for the Braden scale based on a cut-off score of ≤ 15 and a follow-up period point > 1 week (LOW QUALITY).[57]
- Two studies (ICU) showed a mean sensitivity of 90.2 (range 83.3-97.1) and a corresponding specificity of 45.0 (range 26.0-63.9) for the Braden scale based on a cut-off score of ≤ 16 and a follow-up period point > 1 week (LOW QUALITY).[57,84]
- One study (ICU) showed a sensitivity of 87.5 and a specificity of 50.0 for the Braden scale based on a cut-off score of ≤ 17 and a follow-up period point > 1 week (LOW QUALITY).[57]
- One study (general population) showed a sensitivity of 42.9 and a specificity of 63.4 for the Braden scale (grade 2+ PU) based on a cut-off score of ≤ 17, a follow-up period point > 1 week (LOW QUALITY).[81]
- One study (general population) showed a sensitivity of 100.0 and a specificity of 34.1 for the Braden scale (grade 2+ PU) based on a cut-off score of ≤ 18, a follow-up period point > 1 week (LOW QUALITY).[81]
- One study (general population) showed a sensitivity of 100.0 and a specificity of 22.0 for the Braden scale (grade 2+ PU) based on a cut-off score of ≤ 19, a follow-up period point > 1 week (LOW QUALITY).[81]

Norton scale:

- Area under the receiver-operating curve:
  - Two studies showed a mean AUC of 65.0 (range 56.0 to 74.0) for the Norton scale (general population) indicating a poor discriminating power (LOW QUALITY).[80,83]
- Predictive ability for different cut-off values:
  - Four studies (general population) showed a median sensitivity of 45.7 (range 0.0-88.9) and a corresponding specificity of 80.6 (range 61.0-94.4) for the Norton scale based on a cut-off score of ≤ 14 and a follow-up period point > 1 week (VERY LOW QUALITY).[70,73,87,92]
  - One study (general population) showed a sensitivity of 45.9 and a specificity of 60.3 for the Norton scale based on a cut-off score of ≤ 15, a follow-up period point > 1 week (LOW QUALITY).[83]
  - Two studies (general population) showed a mean sensitivity of 70.5 (range 60.0-81.0) and a corresponding specificity of 44.9 (range 31.0-58.8) for the Norton scale based on a cut-off score of ≤ 16 and a follow-up period point > 1 week (VERY LOW QUALITY).[79,86]

Waterlow scale:

- Area under the receiver-operating curve:
  - Four studies showed a median AUC of 60.0 (range 54.0 to 90.0) for the Waterlow scale (all populations) indicating a poor discriminating power (VERY LOW QUALITY).[52,60,83,85]
  - Three studies showed a median AUC of 61.0 (range 54.0 to 90.0) for the Waterlow scale (general population) indicating a poor discriminating power (VERY LOW QUALITY).[52,60,83,85]
  - One study showed an AUC of 59.0 (95% CI 54.0-65.0) for the Waterlow scale (intensive care population) indicating that the scale fails to discriminate (LOW QUALITY).[60]
- Predictive ability for different cut-off values:
  - One study (general population) showed a sensitivity of 71.4 and a specificity of 67.0 for the Waterlow scale based on a cut-off score of ≥ 17, a follow-up period of 48 hours (VERY LOW QUALITY).[85]

- One study (general population) showed a sensitivity of 85.7 and a specificity of 36.9 for the Waterlow scale based on a cut-off score of ≥ 20, a follow-up period of < 1 week (VERY LOW QUALITY).[85]
- Three studies (general population) showed a median sensitivity of 87.5 (range 82.3-89.6) and a corresponding specificity of 28.2 (range 22.4-85.2) for the Waterlow scale based on a cut-off score of ≥ 10 and a follow-up period point > 1 week (LOW QUALITY).[52,83,92]
- One study (general population) showed a sensitivity of 48.8 and a specificity of 94.4 for the Waterlow scale based on a cut-off score of ≥ 15, a follow-up period of < 1 week (LOW QUALITY).[52]
- Two studies (general population) showed a mean sensitivity of 84.3 (range 73.3-95.2) and a corresponding specificity of 40.8 (range 38.0-43.5) for the Waterlow scale based on a cut-off score of ≥ 16 and a follow-up period point > 1 week (VERY LOW QUALITY).[79,86]
- One study (general population) showed a sensitivity of 80.9 and a specificity of 28.5 for the Waterlow scale (grade 2+ PU) based on a cut-off score of ≤ 15, a follow-up period point > 1 week (LOW QUALITY).[93]

Cubbin-Jackson scale:

- Area under the receiver-operating curve:
  - Two studies showed a mean AUC of 87.0 (range 83.0 to 90.0) for the Cubbin-Jackson scale (ICU) indicating a good discriminating power (LOW QUALITY).[69,84]
- Predictive ability for different cut-off values:
  - One study (ICU population) showed a sensitivity of 88.6 and a specificity of 61.0 for the Cubbin-Jackson scale based on a cut-off score of ≤ 24 and a follow-up period point > 1 week (LOW QUALITY).[84]
  - One study (ICU population) showed a sensitivity of 95.0 and a specificity of 81.6 for the Cubbin-Jackson scale based on a cut-off score of ≤ 28 and a follow-up period point > 1 week (LOW QUALITY).[69]

Braden-Q scale:

- Area under the receiver-operating curve:
  - One study showed an AUC of 83.0 (95% CI 76.0-91.0) for the Braden-Q scale (paediatric ICU) indicating a good discriminating power (LOW QUALITY).[61]
- Predictive ability for different cut-off values:
  - One study (paediatric ICU population) showed a sensitivity of 75.6 and a specificity of 67.8 for the Braden-Q scale based on a cut-off score of ≤ 15 and a follow-up period point > 1 week (LOW QUALITY).[61]
  - One study (paediatric ICU population) showed a sensitivity of 88.4 and a specificity of 58.1 for the Braden-Q scale based on a cut-off score of ≤ 16 and a follow-up period point > 1 week (LOW QUALITY).[61]
  - One study (paediatric ICU population) showed a sensitivity of 91.9 and a specificity of 44.1 for the Braden-Q scale based on a cut-off score of ≤ 17 and a follow-up period point > 1 week (LOW QUALITY).[61]

Clinical judgement:

- Predictive ability:
  - Two studies (general population) showed a mean sensitivity of 50.9 (range 50.0-51.7) and a corresponding specificity of 68.9 (range 58.1-79.7) for clinical judgement based on a follow-up period point > 1 week (LOW QUALITY).[82,91]

Braden scale versus Norton scale versus Waterlow scale:

- Predictive ability:
  - One study examined the Braden, Norton and Waterlow scale in the same patient sample (general population). The scales had a similar discriminating power (55.0 versus 56.0 versus 61.0) (LOW QUALITY).[80,83]

Braden scale versus Norton scale versus Fragmment scale:

- Predictive ability:
  - One study examined the Braden, Norton and Fragmment scale in the same patient sample (general population). The scales had a similar discriminating power (74.0 versus 74.0 versus 79.0) (LOW QUALITY).[59,62,67,80,83]

Braden scale versus Cubbin-Jackson scale versus Douglas scale:

- Predictive ability:
  - One study examined the Braden, Cubbin-Jackson and Douglas scale in the same patient sample (ICU population). The Cubbin-Jackson scale had a higher discriminating power compared to the Braden and Douglas scale (LOW QUALITY).[69,84]

Braden scale versus Cubbin-Jackson scale versus Song and Choi scale:

- Predictive ability:
  - One study examined the Braden, Cubbin-Jackson and Song and Choi scale in the same patient sample (ICU population). The Cubbin-Jackson scale had a higher discriminating power compared to the Braden and Song and Choi scale (LOW QUALITY).[69,84]

Braden scale versus modified Braden scale

- Predictive ability:
  - One study examined the Braden and modified Braden scale in the same patient sample (general population). The Braden scale had a higher discriminating power compared to the modified Braden scale (LOW QUALITY).[59]

Braden scale at different time points

- Predictive ability:
  - One study examined the Braden scale at different times points in the same patient sample (ICU population). The Braden scale at different time point had similar discriminating power (48 hours, 4 and 6 days) (VERY LOW QUALITY).[69,84,88,94]

Waterlow scale at different time points

- Predictive ability:
  - One study examined the Waterlow scale at different times points in the same patient sample (general population). The Waterlow scale after 48 hours had the highest discriminating power compared to 4 and 6 days (VERY LOW QUALITY).[52,60 83,85]

Other scales:

- The Douglas scale, the Fragmment scale, the Song and Choi scale, The Northern Hospital Pressure Ulcer Prevention Plan were examined in four studies and revealed a fair to good discriminating power (MODERATE TO LOW QUALITY).[69,78,80,84]

3.2.4 Conclusion

- **Clinical effectiveness**
  - **There is no sound evidence base that supports superior clinical effectiveness of one risk assessment approach over another in the prevention of pressure ulcer development.**
  - **In addition, study results should be interpreted with caution, because studies had a very low quality and included patients with and without a pressure ulcer at start of the study.**
- **Predictive ability**
  - **No clear conclusions about the prognostic ability of risk assessment tools can be drawn.**
  - **None of the risk assessment tools being studied and none of their thresholds outperform the others. A large heterogeneity between studies in terms of population, reported cut-off scores, and time points of assessment has been illustrated. In addition, the included studies in this review had high to very high risk of bias.**
  - **Evidence on risk-assessment tools that are not wide-spread indicated a fair to very good discriminating power and good sensitivity and specificity. However, these results are based on single studies.**

3.2.5 Recommendations and Best practices for clinical practice

Recommendation	Strength of Recommendation	Level of Evidence
A structured approach for risk assessment should be used to identify individuals at risk of developing pressure ulcers. This structured approach should include all of following components: • Clinical judgement informed by knowledge of key risk factors; • The use of a risk assessment tool. As clinical studies do not demonstrate the superiority of one risk assessment tool over another, decisions about which risk assessment tool (Braden, Norton, Waterlow…) to be used should be based on the intended population (adults, children, elderly,…) and the intended care setting (intensive care units, general wards, paediatrics, home care…) and the experience and expertise of the healthcare staff; • A comprehensive skin assessment to evaluate any alterations to intact skin.	Strong	Very Low

Best Practices
Pressure ulcer risk assessment should be performed at the first contact with the individual. Reassessment should be undertaken at regular time intervals and if there is any change in the individual's medical condition. The decision on time intervals should be based on an individual basis.
Clinical judgment should take into account several key risk factors such as reduced mobility, immobility, pressure, shear, sensory impairment, acute deterioration of general health status, incontinence, reduced level of consciousness, advanced age, previous history of pressure damage, vascular disease, under-nutrition, poor hydration status (non-limitative list).
Risk assessment should be documented and made accessible to all members of the multidisciplinary team.

3.3 Skin assessment

3.3.1 Clinical effectiveness

3.3.1.1 Introduction

A structured skin assessment is widely considered to be an integral part of a comprehensive pressure ulcer prevention strategy.[5] Multiple methods can be used to observe the skin for early signs of pressure ulcer development. The most commonly used method in clinical practice is diascopy (finger method or transparent disk method). If applying the finger method, an amount of pressure is applied on the erythema of the skin (mainly over a bony prominence). If the erythema does not disappear when the finger is being removed, the erythema is considered to be non-blanchable (Category I pressure ulcer). The transparent disk method includes the use of a plastic transparent plastic to press on the erythema. If the erythema under the transparent disk does not blanch, it is regarded to be non-blanchable erythema. An increase or decrease in skin temperature can also be indicative of pressure damage. An increase in temperature at the area can indicate inflammation or infection, whereas cool skin may indicate poor perfusion and ischaemia. Assessing skin temperature may be particularly important in patients with darker skin, where the more evident area of erythema is not visible.

The aim of this review was to guide health care professionals in their decision making about which method for skin assessment is most appropriate to detect individuals at risk for pressure ulcer prevention. This review includes two parts. In a first review we will focus on the clinical effectiveness of three skin assessment methods (i.e. diascopy; finger method; skin temperature) as part of a complex intervention for pressure ulcer prevention.

A second review will focus on the prognostic ability of a wide variety of skin assessment methods (ultrasonography, ultrasound, durometer/durometry, diascopy, elastometer, haptic finger, multispectral imaging device, multi-wavelength imaging, multispectral images, digital colour images, clinical assessment, transcutaneous oximetry, thermographic scanner, tympanic thermometers (to measure skin temperature), doppler blood flowmetry, laser, doppler imaging).

3.3.1.2 Review question

What is the clinical effectiveness of skin assessment methods in the prevention of pressure ulcers?

3.3.1.3 Clinical evidence

One randomized controlled trial of Vanderwee et al. (2007b) was included in this review.[95] In this study, the authors studied the effectiveness of using "daily skin assessment with transparent disk" as the only risk assessment strategy in the prevention of pressure ulcer incidence. If non-blanchable erythema appeared, preventive measures were started. They compared this with the use of a Braden score in combination with daily skin assessment using a transparent disk. In this control group preventive measures were started when non-blanchable erythema was observed or in case of a Braden-score of ≤17.

Quality of Studies

The included study had an adequate sample size (without drop-outs), reported on sequence generation and allocation concealment. Only blinding was not possible due to practical and ethical reasons. In appendix 3 the level of evidence can be found per outcome after applying the GRADE-methodology. The evidence base for all outcomes has been rated as moderate quality.

Evidence statements

- One study (n=1 617) showed that there is no difference between skin assessment with transparent disk (NBE, non-blanchable erythema) and skin assessment with transparent disk combined with the Braden scale (control) for the assignment of preventive measures to reduce pressure ulcer incidence (grade 2-4) (MODERATE QUALITY).[95]
- One study (n=1 617) showed that time to development of pressure ulcers (grade 2-4) was shorter for skin assessment with transparent disk (NBE) than for skin assessment with transparent disk combined with the Braden scale (control) (MODERATE QUALITY).[95]

3.3.2 Prognostic

3.3.2.1 Review question

What is the predictive ability of skin assessment methods for pressure ulcer risk?

3.3.2.2 Clinical evidence

Four prognostic studies[60,96-98] were included in this review. Sensitivity and specificity were re-calculated by using the raw data as presented in the individual studies.

Quality of Studies

In general the quality of the studies was poor. The absence of a description of patient enrolment or use of a consecutive sampling, the absence of an imputation technique, and an event rate lower than 100 were the most important methodological flaws[60,96-98]. In addition, two studies[96,98] had an unclear duration of the follow-up period and one study[98] had significant missing data. Moreover, patients received preventive measure which influenced the results on predictive validity. In appendix 4 the level of evidence can be found per scale for studies reporting on the area under the receiver operating characteristics curve. The evidence base for all scales has been rated as low to very low quality.

Evidence statements

Sensitivity and specificity are the most commonly used and recommended statistics for evaluating the predictive validity of pressure ulcer risk assessment scales and skin assessment methods, assuming that a good and useful scale or skin assessment should have both high sensitivity and high specificity. There is, however, an important difference between a diagnostic/prognostic screening test and a risk assessment scale or skin assessment method. In contrast with prognostic and diagnostic tests, skin assessment methods (and risk assessment scales) are used to identify patients in need of preventive measures and are intended to contribute to the prevention of pressure ulcer development. In that way, they differ from diagnostic/prognostic screening tests. If preventive measures are used, the probability that a patient will develop a pressure ulcer at the start of the study will not remain constant until its end. The use of effective prevention will alter the sensitivity and specificity of the risk assessment scales and skin assessment methods. The results should therefore be considered with caution.

Subjective nursing assessment of moist skin:

- One study (ICU patients) showed a sensitivity of 76%, a specificity of 65% and a diagnostic odds ratio of 5.9 for the subjective nursing assessment of moist skin as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Subjective nursing assessment of oedematous skin:

- One study (ICU patients) showed a sensitivity of 64%, a specificity of 77% and a diagnostic odds ratio of 5.7 for the subjective nursing assessment of oedematous skin as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Subjective nursing assessment of mottled skin:

- One study (ICU patients) showed a sensitivity of 33%, a specificity of 92% and a diagnostic odds ratio of 5.4 for the subjective nursing assessment of mottled skin as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Subjective nursing assessment of livid skin:

- One study (ICU patients) showed a sensitivity of 31%, a specificity of 92% and a diagnostic odds ratio of 5.0 for the subjective nursing assessment of livid skin as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Subjective nursing assessment of centralised circulation:

- One study (ICU patients) showed a sensitivity of 71%, a specificity of 70% and a diagnostic odds ratio of 5.8 for the subjective nursing assessment of centralised circulation as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Subjective nursing assessment of cyanosis:

- One study (ICU patients) showed a sensitivity of 45%, a specificity of 81% and a diagnostic odds ratio of 3.5 for the subjective nursing assessment of cyanosis as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Subjective nursing assessment of reddened skin:

- One study (ICU patients) showed a sensitivity of 69%, a specificity of 70% and a diagnostic odds ratio of 5.1 for the subjective nursing assessment of reddened skin as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Subjective nursing assessment of hyperaemic skin:

- One study (ICU patients) showed a sensitivity of 21%, a specificity of 91% and a diagnostic odds ratio of 2.9 for the subjective nursing assessment of reddened skin as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[60]

Presence of blanchable erythema assessed by the finger test:

- One study (hospitalized patients) showed a sensitivity of 75%, a specificity of 77% and a diagnostic odds ratio of 9.9 for the assessment of blanchable erythema by the finger test as a predictor for the development of pressure ulcers according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[96]
- Two studies showed a wide range of specificity and diagnostic odds ratios.[96,98] One study showed a sensitivity of 75%, a specificity of 76% and a diagnostic odds ratio of 9.4 for the assessment of blanchable erythema by the finger test as a predictor for the development of PU (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system.[96] The other study showed a sensitivity of 75%, a specificity of 10% and a diagnostic odds ratio of 0.33 for the assessment of blanchable erythema by the finger test as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[98]

Thermography:

- One study (hospitalized patients) showed a sensitivity of 100%, a specificity of 74% and a diagnostic odds ratio of 36.7 for thermography (presence of thermal anomaly – an area of the skin at least 1°C warmer than the surrounding skin) as a predictor for the development of skin breakdown (LOW QUALITY).[97]

Presence of non-blanchable erythema assessed by the finger test:

- One study (surgical in-patients) showed a sensitivity of 73%, a specificity of 74% and a diagnostic odds ratio of 8.0 for the assessment of non-blanching erythema by the finger test as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system (LOW QUALITY).[98]

3.3.3 Conclusion

- **Clinical effectiveness**
  - **One single RCT provided evidence of moderate quality that the time to develop a pressure ulcer was significantly longer when the start of preventive measures was based on a combined approach of risk and skin assessment (i.e. Braden score in combination with daily skin assessment with transparent disk: preventive measures were started when non-blanchable erythema appeared or in case of a Braden-score of ≤17) compared to a decision based on daily skin assessment with transparent disk only (i.e. preventive measures were started when non-blanchable erythema appeared). However, there was no difference in effect on pressure ulcer incidence.**
- **Predictive ability**
  - **No clear conclusions about the prognostic ability of skin assessment methods can be drawn due to large heterogeneity between studies in terms of results, population, reported assessment methods and timing of the performed assessments.**
  - **One study (hospitalized patients) showed a sensitivity of 100% and a specificity of 74% for thermography (presence of thermal anomaly – an area of the skin at least 1°C warmer than the surrounding skin) as a predictor for the development of skin breakdown.**
  - **One study (surgical in-patients) showed a sensitivity of 73% and a specificity of 74% for the assessment of non-blanchable erythema by the finger test as a predictor for the development of pressure ulcers (grades 2-4) according to the European Pressure Ulcer Advisory Panel classification system. Two studies investigating the predictive ability of blanchable erythema by the finger test illustrated similar sensitivity rates (75%) but a wide range in specificity (10% - 76%).**

3.3.4 Recommendation and Best practices for clinical practice

Recommendation	Strength of Recommendation	Level of Evidence
A comprehensive head-to-toe skin assessment with special attention to vulnerable areas (especially bony prominences) should be part of a structured risk assessment approach.	Strong	Low

Best Practices
Skin assessment should be an integral part of routine care and the frequency of inspection may need to be adapted in response to the changes in the individual's condition (improvement or deterioration) and level of risk.
Inspect the skin regularly for signs of redness and non-blanchable erythema. Skin assessment should also include assessment for localized heat, oedema, or induration (hardness).
Observe the skin for pressure damage caused by medical devices.
With individuals with darkly pigmented skin, consider an individual at risk when there are: • purplish/bluish localised areas of skin; • localised heat which, if tissue becomes damaged, is replaced by coolness; • localised oedema; • localised induration.
Any skin changes should be documented, made accessible and communicated to the members of the multidisciplinary team.

3.4 Skin massage

3.4.1 Introduction

One of the practices still widely used to prevent development of pressure ulcers is massage. Although massage is internationally no longer officially recommended as a preventive method, the technique is still practiced in many health care settings.[5] The aim of this review is to study the clinical effectiveness of massage as an intervention to prevent pressure ulcer development.

3.4.2 Review question

What is the clinical effectiveness of skin massage in the prevention of pressure ulcers?

3.4.3 Clinical evidence

One randomized clustered double-blind cross-over clinical trial was included in this review.[99] This trial assessed the effectiveness of massage with dimethyl sulfoxide (DMSO) or Vaseline added to position change in preventing pressure ulcers compared with position change only. Residents of 8 Dutch nursing homes received either position change only or massage with position change. The first product (Vaseline or DMSO) was used during 4 weeks (period 1), and after a wash-out period of 2 weeks, the other product (DMSO or Vaseline) during 4 weeks (period 2). Crossover design was judged to be inappropriate here since authors are reporting the number of patients with pressure ulcers. People who have had the outcome (PU) in period 1 should not be entered in period 2 (because different population compared to the start of period 1 and they have already had the event) and because there may be a time dependence to pressure ulcer development. For these reasons only the data of period 1 are used. Patient acceptability and skin damage as critical outcomes were not covered by the study.

No studies focusing on children were found.

3.4.3.1 Quality of studies

The quality of the included study was poor. The absence of power calculations, correct randomization procedures and blinded assessments were the most important methodological flaws. In addition, analyses were not corrected for clustering. The number of patients included was small (N=79) and analysis were not corrected for clustering. Grades of pressure ulcers developed during the study were not reported. In appendix 5 the level of evidence can be found per outcome after applying the GRADE-methodology. The evidence base for all outcomes has been rated as very low quality.

3.4.3.2 Evidence statements

Proportion of people developing pressure ulcers

- One cross-over study (n= 49) showed that there may be no clinical difference between the group that received massage with indifferent cream (Vaseline) and position change compared to the group that only received position change for reducing the incidence of pressure ulcers, but the direction of effect favoured the position change only (VERY LOW QUALITY).[99]
- One cross-over study (n= 37) showed that position change only is potentially more clinical effective to reduce the incidence of pressure ulcers compared to massage with DMSO cream in combination with position change (VERY LOW QUALITY).[99]
- One cross-over study (n= 60) showed that massage with indifferent cream (Vaseline) in combination with position change is potentially more clinical effective to reduce the incidence of pressure ulcers compared to massage with DMSO cream in combination with position change (VERY LOW QUALITY).[99]

3.4.4 Conclusion

One study was identified that evaluated clinical effectiveness of skin massage for the prevention of pressure ulcers. This study was not sufficiently powered to detect benefit or rule out harm of skin massage in the prevention of pressure ulcers. No evidence could be retrieved on patient acceptability or skin damage.

3.4.5 Recommendation and Best practice for clinical practice

Recommendation	Strength of Recommendation	Level of Evidence
Skin massage and rubbing, particularly over bony prominences, should be avoided to prevent pressure ulcers.	Strong	Very Low

Best Practice

The clinical effectiveness of various types of skin products (e.g. creams, ointments) being intended for other purposes (such as skin hydration, skin protection) was not studied for this guideline. Applying such products requires a gentle application technique; rubbing of the skin should be avoided.

3.5 Repositioning

3.5.1 Introduction

Patient repositioning is considered to be an integral component of a pressure ulcer management strategy. The aim of patient repositioning (or turning) is to relieve pressure and shear on particular body parts being at risk for pressure ulcer development. This pressure can result in sustained deformation of the tissues (skin, muscle, underlying structures) and in ischemia of the affected area. Repositioning may vary in terms of (1) frequency, (2) postures, and (3) methods. In practice, repositioning methods include both small shifts in position undertaken by the patient, and full support for lateral repositioning by healthcare professionals. Literature recommends different postures, the 90° laterally inclined, prone, and 30° tilt position being mentioned mostly [5].

The aim of this review was to guide clinicians in their decision making about (1) frequency, (2) postures, and (3) methods for repositioning to be used for the prevention of pressure ulcers.

3.5.2 Review question

How and at what frequency should repositioning be undertaken for prevention of pressure ulcers?

3.5.3 Clinical evidence

We searched for randomised trials assessing effectiveness of repositioning for the prevention of pressure ulcers in patients of all ages in any setting. Nine randomized controlled trials (three cluster randomised trials[100, 101, 15] and six parallel RCTs[102-107] were included in this review.

Included populations varied from geriatric patients to critically ill infants and children, all assessed in different inpatient hospital settings. Four trials included geriatric patients with a mean age of 80 years, one trial included acute in-patients with a mean age of 70 years and the sixth trial included infants and children. Two studies regarding turning tables were included in the Cochrane Review 'Support surfaces for the prevention of pressure ulcers'[108]. However, these studies were included in this review about repositioning since they were deemed to be more related to repositioning than to redistributing devices.

Studies looked at different reposition techniques applied at different time intervals. For the purpose of this review, the trials have been grouped and analysed in five different comparisons:

- Repositioning (frequent turning with or without the use of pressure reducing mattress) versus no repositioning (standard care without turning);[100]
- Different frequencies of repositioning;[100,15,103]

- Different positions for repositioning – 30° tilt position versus 90° lateral and supine position[101,107] and semi recumbent position (i.e., 45° position of the head and back) versus standard care (supine position)[104];
- Different positions for repositioning – prone/semi recumbent positioning versus control supine positioning;[102]
- Turning tables for repositioning.[105,106]

Trials reported the incidence of pressure ulcers (proportion of participants developing pressure ulcers, Grades I-IV)[15,101,107], the 'time to pressure ulcer development' and patient tolerability.

Included studies had varying time periods (ranging from one night to 5 weeks). Cluster randomised trials and trials including children[102] have been analysed separately.

3.5.3.1 Quality of studies

In general the methodological quality of the included studies was poor. The majority of studies were not blinded[15,101-103,106] and did not use an intention-to-treat analysis[15,100,101,103,105,106]. Four studies had unclear allocation concealment.[15,103,105,106,] In addition, power calculation was only done in four studies[15,100,101,104]. Moreover two of these studies had a sample size lower than the desired power[151,01]. Four of the remaining studies had a small sample size. In appendix 6 the level of evidence can be found per outcome after applying the GRADE-methodology. The evidence base for all outcomes has been rated as being of low or very low quality.

3.5.3.2 Evidence statements

Repositioning compared to no repositioning

Proportion of people developing pressure ulcers

- One study (n=574) showed there is potentially no clinical difference between the group that received frequent turning (2 hourly) compared to the group that received standard care for reducing the incidence of pressure ulcers (Grade 1 - non-blanching erythema), the direction of effect favoured standard care (standard hospital mattress) (VERY LOW QUALITY).[100]
- One study (n=569) showed there is potentially no clinical difference between the group that received frequent turning (3 hourly) and the group that received standard care for reducing the incidence of pressure ulcers (Grade 1 - non-blanching erythema), but the direction of the effect of the estimate could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=577) showed there is potentially no clinical difference between the group that received pressure reducing mattress in combination with less frequent turning (4 hourly) compared to the group that received standard care for the incidence of pressure ulcer (Grade 1 - non-blanching erythema), but the direction of the effect of the estimate could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=578) showed there is potentially no clinical difference between the group that received a pressure-reducing mattress in combination with less frequent turning (6 hourly) and the group that received standard care for the incidence of pressure ulcers (Grade 1 - non-blanching erythema), but the direction of the effect of the estimate could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=574) showed that frequent turning (2 hourly) is clinically more effective at reducing the incidence of pressure ulcers (Grade 2 and above) compared to the group that received standard care (LOW QUALITY).[100]
- One study (n= 569) showed that frequent turning (3 hourly) is potentially clinically more effective at reducing the incidence of pressure ulcers (Grade 2 and above) compared to the group that received standard care (VERY LOW QUALITY).[100]
- One study (n=577) showed that the use of a pressure reducing mattress in combination with less frequent turning (4 hourly) is clinically more effective at reducing the incidence of pressure ulcers (Grade 2 and above) compared to the group that received standard care (LOW QUALITY).[100]

- One study (n=574) showed that the use of a pressure reducing mattress in combination with less frequent turning (6 hourly) is clinically more effective at reducing the incidence of pressure ulcers (Grade 2 and above) compared to the group that received standard care (LOW QUALITY).[100]

Different frequencies of repositioning

Proportion of people developing pressure ulcers

- One study (n=121) showed there may be no clinical difference between the group that received frequent turning (2 hourly) compared to the group that received frequent turning (3 hourly) for the incidence of pressure ulcer (grade 1 - non-blanching erythema), the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=129) showed there is potentially no clinical difference between the group that received frequent turning (2 hourly) compared to the group that used a pressure reducing mattress in combination with less frequent turning (4 hourly) follow up for the incidence of pressure ulcers (Grade I - non-blanching erythema), the direction of the effect favoured the 4 hour turning and pressure-reducing mattress (VERY LOW QUALITY).[100]
- One study (n=126) showed there may be no clinical difference between the group that received frequent turning (2 hourly) compared to the group that used a pressure reducing mattress in combination with less frequent turning (6 hourly) for reducing the incidence of pressure ulcers, the direction of the estimate of effect could favour either intervention (Grade I - non-blanching erythema) (VERY LOW QUALITY).[100]
- One study (n=124) showed there may be no clinical difference between the group that received frequent turning (3 hourly) compared to the group that used a pressure reducing mattress in combination with less frequent turning (4 hourly) for reducing the incidence of pressure ulcers (Grade I - non-blanching erythema), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=121) showed there may be no clinical difference between the group that received frequent turning (3 hourly) compared to the group that used a pressure reducing mattress in combination with less frequent turning (6 hourly) for reducing the incidence of pressure ulcer (Grade I non-blanching erythema), the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=129) showed there may be no clinical difference between the two groups that used a pressure reducing mattress in combination with less frequent turning (4 versus 6 hourly) for reducing the incidence of pressure ulcers (Grade 1 - non-blanching erythema), the direction of effect could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=235) showed there may be no clinical difference between repositioning with unequal time interval (2 hours in a lateral position and 4 hours in a supine position) compared to repositioning with equal time interval (4 hourly) for reducing the incidence of pressure ulcers (Grade 2 and above) but the direction of the estimate off effect could favour the unequal time interval(VERY LOW QUALITY).[15]
- One study (n=19) showed there may be no clinical difference between the group that received repositioning with unequal time interval (small unscheduled shifts) compared to the group that received repositioning with equal time interval (2 hourly) at 2 weeks follow up for the incidence of pressure ulcers (Grade 2 and above), but the direction of the estimate of effect could favour the equal time interval (2 hourly) (VERY LOW QUALITY).[103]
- One study (n=121) showed the 2 hourly turning scheme may be more clinically effective for reducing the incidence of pressure ulcers (Grade 2 and above) when compared to the 3 hourly turning scheme (VERY LOW QUALITY).[100]
- One study (n=129) showed a pressure reducing mattress in combination with less frequent turning (4 hourly) is potentially more clinically effective in reducing pressure ulcers (Grade 2 and above) when compared to frequent turning (2 hourly) (VERY LOW QUALITY).[100]

- One study (n=126) showed there may be no clinical difference between the group that received frequent turning (2 hourly) compared to the group that used a pressure reducing mattress in combination with less frequent turning (6 hourly) for reducing the incidence of pressure ulcers (grade 2 and above), the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[100]
- One study (n=124) showed a pressure reducing mattress in combination with less frequent turning (4 hourly) is clinically more effective at reducing the incidence of pressure ulcers (Grade 2 and above) when compared to frequent turning (3 hourly) (VERY LOW QUALITY).[100]
- One study (n=121) showed a pressure reducing mattress in combination with less frequent turning (6 hourly) may be clinically more effective at reducing the incidence of pressure ulcers (Grade 2 and above) compared to the 3 hourly turning scheme (VERY LOW QUALITY).[100]
- One study (n=129) showed the use of a pressure reducing mattress in combination with less frequent turning (4 hourly) is potentially more clinically effective at reducing the incidence of pressure ulcers (Grade 2 and above) when compared to the use of a pressure reducing mattress in combination with 6 hourly turning scheme (LOW QUALITY).[100]

Different positions for repositioning

Proportion of people developing pressure ulcers

- One study (n=213) showed that repositioning using the 30° tilt (3 hourly at night) is potentially more clinically effective at reducing pressure ulcers (Grade I - IV) when compared to the 90° lateral position (6 hourly at night) (VERY LOW QUALITY).[101]
- One study (n=46) showed that the 90° lateral position (at night) may be more clinically effective at reducing the incidence of pressure ulcers (Grade 1: non-blanching erythema) when compared to the 30° tilt over one night (VERY LOW QUALITY).[107]
- One study (n=221) showed there may be no clinical difference between the group that received semi recumbent positioning (45° position of the head and back) when compared to the group that received supine positioning (standard care) for reducing the incidence of pressure ulcers (Grade I-IV), the direction of the estimate of effect could favour either intervention (LOW QUALITY).[104]
- One study (n=213) reported evidence of the 30° tilt (3 hourly at night) (26 days, range 3 days) to pressure ulcer development compared to 90° lateral position (6 hourly at night) (17 days, range 24 days) but no other statistics were reported. The clinical importance is unknown (VERY LOW QUALITY).[101]
- One study (n=213) reported that 22% of patients could not tolerate repositioning using the 30° but the results were only given for one arm of the trial. The clinical importance is unknown (VERY LOW QUALITY).[107]

Turning tables

- Two studies (n=151) showed there may be no clinical difference between a kinetic treatment table and standard care for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour the standard care (VERY LOW QUALITY).[106,105]
- One study (n=86) reported evidence for a kinetic treatment table and standard care for the time in hospital. The number of days in hospital was 6.7 for the kinetic treatment table and 11.6 days for standard care. The clinical importance is unknown.[106]

Critically ill infants and children: different positions for repositions (prone positioning) versus control (supine positioning)

Proportion of people developing pressure ulcers

- One study (n=102) showed supine positioning (2 hour cyclic rotation) may be more clinically effective at reducing pressure ulcers (Grade 2 and above) when compared to prone positioning (VERY LOW QUALITY).[102]

3.5.4 Conclusion

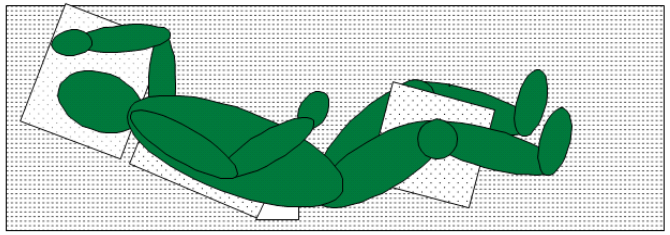
- **There was evidence that repositioning compared to no repositioning is clinically effective.**
- **No sound evidence was found for clear differences between different repositioning schedules. However, to reduce the incidence of pressure ulcers grade 2 or above, there is a potential clinical effectiveness of 4 or 6 hour turning combined with a pressure-reducing mattress compared to 2-3 hour turning on a standard institutional mattress, 4 hour turning combined with a pressure-reducing mattress compared to a 6 hour turning combined with a pressure-reducing mattress.**
- **One study showed that positioning using 30° tilt every 3 hours at night is potentially more effective at reducing all grades of pressure ulcer compared to 90° lateral every 6 hours at night.**
- **These conclusions should be interpreted with caution, because all studies had a low or very low quality.**

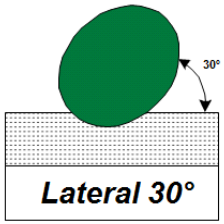
3.5.5 Recommendations and Best practices for clinical practice

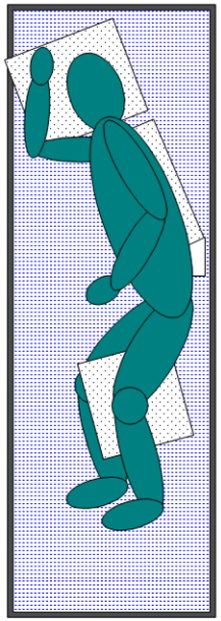
Recommendation	Strength of Recommendation	Level of Evidence
A repositioning protocol (including specifications about posture and frequency) should be established and documented for each person at risk for pressure ulcer development.	Strong	Very Low
Individuals being at risk for pressure ulcer development should be repositioned. The frequency and method for repositioning and the posture should be determined and adapted based on an individual assessment and should take into account: • the level of risk; • the individual's medical condition; • the individual's skin condition; • the individual's level of activity and mobility; • the individual's comfort; • the individual's overall plan of care; • the characteristics of the support surface.	Strong	Very Low

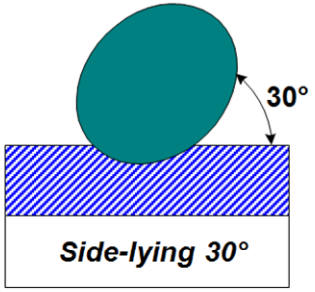
Repositioning – lying position: Strong Very Low

- Repositioning using the 30° tilted side-lying position is recommended if the individual can tolerate it and her/his medical condition allows (back supported and sacrum free).





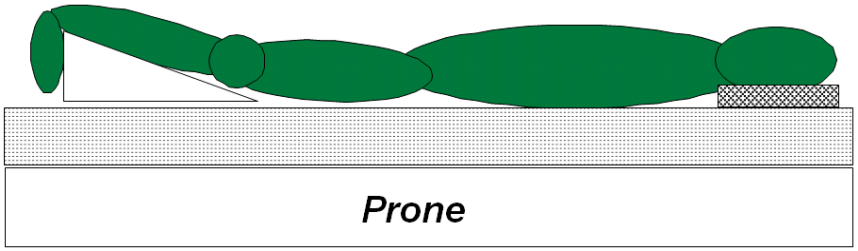




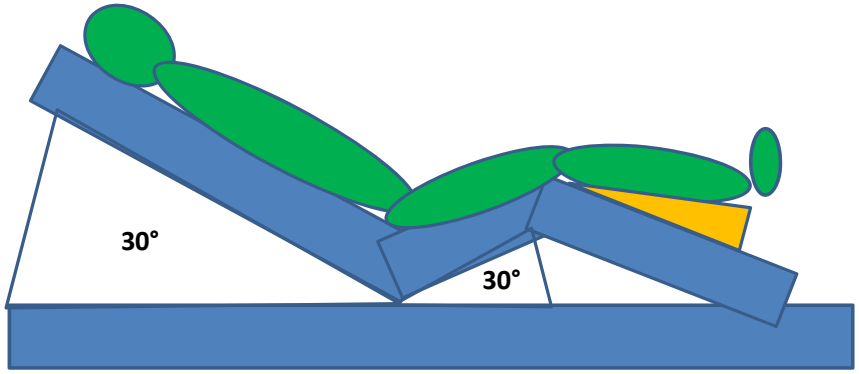
Best Practices

Repositioning technique:

- Repositioning should be undertaken (alternately, right side, back, left side) if the individual can tolerate this and her/his medical condition allows. Also the prone position can be considered. Avoid postures that increase pressure, such as the 90-degree side-lying position, or the semi-recumbent position.



- Increase the contact surface between the individual and the support surface to redistribute and reduce the pressure maximally on the individual's skin and underlying tissue.
- Avoid the skin being exposed to pressure or shearing forces.
- Avoid positioning the individual on a bony prominence, especially if non-blanchable erythema is present.
- Manual handling devices should be used correctly (Lift – don't drag – the individual) in order to minimise shear and friction damage. After manipulation of the individual, any slings, hoists, sleeves or other parts of the handling equipment being used should be removed immediately if they can damage the skin (a slide sheet can be tolerated and helps to prevent shear forces in combination with a good posture).
- If sitting in a more upright position in bed is needed, a head-of-bed elevation of more than 30° and (a subsequent) slouched position (increasing pressure and shear on the sacrum and coccyx) should be avoided. A **Semi-Fowler's** position (the head of the bed at approximately 30° and the knees in 30° flexion) should be used if the individual is lying in a supine position.



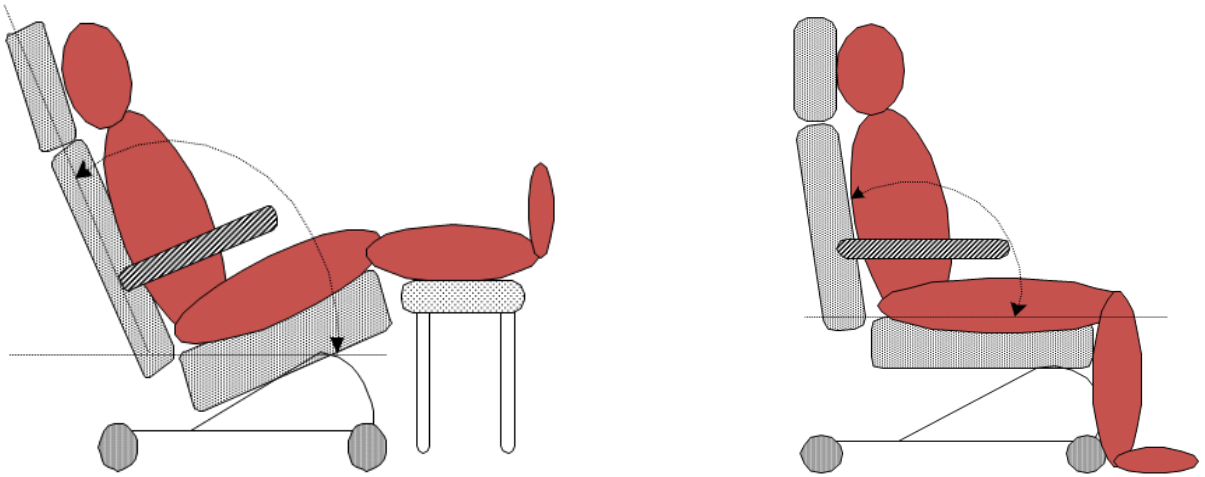
- Avoid pressure of medical devices or other materials directly on the skin and underlying tissue (e.g. tubes, drainage systems, syringes, caps….).

Repositioning schedule:

- Assess the individual's skin condition and general comfort on a regular basis. If the individual is not responding to the repositioning regimen as being expected (e.g. if a not-preexisting category I pressure ulcer occurs), the frequency, method, and applied postures for repositioning should be reconsidered, documented and made accessible to all members of the multidisciplinary team.

Repositioning seating:

- Position the individual so as to maintain his/her full range of normal activities. Make sure that everything he/she needs is in reach;
- The time that individuals at risk for pressure ulcer development are seated in a chair should be limited. The time an individual is seated in a chair should be determined and continuously adapted based on an individual assessment and should take into account comfort/dignity, the overall plan of care, the medical condition, and the characteristics of the pressure relieving devices used;
- Position a seated individual in a posture so as to maintain his/her usual range of activities with minimum pressure and shear forces exerted on the skin and soft tissues. When sitting upright ensure the individual's lower limbs are supported in optimal alignment (e.g. 90º at hip, knee and foot). Avoid positioning hips at an ankle greater than 90º, to minimise pressure on ischial tuberosities. Place the feet of the individual on the ground or on a footstool or footrest when the feet do not reach the floor. When sitting back in an armchair, position the individual with the feet up and heels offloaded.



Repositioning - operating room:

In addition to the use of overlays on the operating table, other general preventive measures should be undertaken during surgery:

- Position the individual in such a way as to reduce the risk of pressure ulcer development, especially by avoiding shear forces.
- Elevate the heels completely (offload them) in such a way to redistribute the weight of the leg along the calf without putting all the pressure on the Achilles tendon. The knee should be in flexion and supported.

Repositioning – Patient education:

- Individuals (or informal carers assisting the individual) who are willing and able should be taught the principles of weight re-distribution and how to achieve this (if possible combined with active exercises).

3.6 Redistributing devices

3.6.1 Introduction

Pressure-relieving devices (e.g. mattresses/overlays, beds, seat cushions and sheepskins) are commonly used to help prevent ulcer development. They are used with the aim to reduce/redistribute the pressure between an individual and the support surface, to reduce shearing forces and to control for the local microclimate. Redistributing devices are often used in combination with repositioning.[5,108,109] There are many different types of redistributing devices available. Therefore, we have conducted a systematic review with the aim to guide clinicians in their decision making in daily practice about which redistributing devices to use in the prevention of pressure ulcers.

3.6.2 Review question

What are the most clinically effective pressure redistributing devices for the prevention of pressure ulcers?

3.6.3 Clinical evidence

We identified a recent Cochrane review by McInnes et al. (2011)[108] that was adapted and updated for the current review. We quality assured the Cochrane review[108,109] and it was of very high quality. Since it matched the majority of our protocol we used the information within it to populate our review for the summary of studies table, forest plots and for the quality assessment of studies (see Appendix 7).

Changes or additions were made based on differences in the protocol or for the purposes of GRADE. We removed 7 of the 53 studies that were included in the Cochrane review. Four studies[110-113] were removed from this review as they included only heel ulcers and will be covered in the heel ulcer prevention review (see 0). One other study (Economides, 1995)[114] was excluded as it looked at wound breakdown rather than incidence of pressure ulcers. Two other studies (Gentilello, 1988[105] and Summer, 1989[106]) were excluded from this review as they were deemed more relevant to the repositioning review.

Five additional studies[17,115-118] were identified in our search, which were not included in the review, and have been extracted (see Appendix 7).

Fifty-one studies in total were included in this review.[17,26,51,114-161]

This review identified studies in different settings: operating theatre[119,129,146,149], intensive care units[117,137,141,153,155,157,160], orthopaedic ward[54,126,128,131,136,144,148,152], accident and emergency ward[134], extended care facilities[123-125,127,143], nursing homes[17,118,130,142,145], different types of hospital wards.[26,115,120,121,133,139,150,161] Several studies did not specify the study setting.[51,122,132,135,136,138,140,147,151,156,158,159]

Evidence from these studies is summarised in the clinical GRADE evidence profiles (see Appendix 7). See also the study selection, flow chart, forest plots, study evidence tables and exclusion list in Appendix 7.

Various types of redistributing devices are used, and the Cochrane review[108] categorised them as:

- Low-tech (non-powered) constant low pressure support surfaces;
- High-tech support surfaces;
- Other support surfaces (e.g. operating table overlay, turning beds/frames, wheelchair cushions and limb protectors).

We adopted this classification to structure the current review. As pre-specified in our protocol we looked at grades 2 pressure ulcers and above as well as all grades of ulcer. This deviates from the Cochrane review since it included studies regardless of whether grade 1 ulcers were described separately. However they stated that studies comparing the incidence of pressure ulcers of grade 2 or greater were more likely to be reliable.[109] Grading systems are variable but from the studies which reported grades 2 and above separately the EPUAP or NPUAP classification system[5] was most commonly used. For those studies that did not use the EPUAP/NPUAP and reported grades of ulcer separately the distinction was usually a break in the skin or worse.

The Cochrane review also found that methods for measuring outcomes such as comfort, durability, reliability and acceptability were not well developed. Where data were presented they did give details in the characteristics of included studies table, but did not incorporate into their analysis. As these were critical outcomes for this review, we have included these outcomes in the GRADE evidence tables.

The Cochrane review meta-analysed studies where there was more than one trial for an outcome which compared similar devices. The results were

pooled using a fixed effect model, but if heterogeneity (I^2 = 50% or above and the p value was less than 0.10) was found they used a random-effect model. Authors stated that they assumed that the risk ratio remained constant for different lengths of follow-up and so were pooled if participants were followed-up for different lengths of time.[109]

3.6.3.1 Quality of studies

The Cochrane review indicated that the included primary studies suffered from major methodological problems such as allocation bias (unclear randomisation method in 51% of the studies; only 30% of studies detailed allocation concealment), blinding (blinded for outcome assessment in only 15% of RCTs), incomplete outcome data (unclear or inappropriately addressed in 52% of the included studies).[108] The authors noted that blinding was not always possible (e.g. difficult to disguise the support surface, patients were too ill to be removed from their beds to assess for pressure ulcers) but that means to minimise bias were considered (e.g. using a second assessor and presenting inter-rater reliability; independent assessment of photographic evidence of the pressure ulcer status).[108]

Several of these methodological problems were also present in the 5 additional studies. None of these studies blinded the outcome assessors. Grisell et al. (2008)[116] and Malbrain et al. (2010)[117] reported single-blinding (patients not aware about type of redistributing device). Insufficient details about randomization (i.e. sequence generation and allocation concealment) were reported in three studies.[116-118] Incomplete outcome data were adequately addressed in all 5 studies but very high dropout rates (303 of the 610 randomized patients) were reported by Demarre et al. (2012)[115]. In addition baseline-differences (in 30% of studies included in the Cochrane review) between the intervention and control group were reported by Brienza et al. (2010)[17]; (Malbrain et al. 2010)[117] and Van Leen et al. (2011)[118]. Van Leen et al. (2011)[118] reported more pressure ulcer prone patients (high risk based on Norton) in the intervention group, Malbrain et al. (2010)[117] reported significant differences in per-albumin and age and Brienza et al. (2010)[17] reported slightly fewer males in the segment foam cushion Group compared to the skin protection cushion Group.

3.6.3.2 Evidence statements Low-tech (non-powered) constant low pressure surfaces

Low tech constant low pressure support surfaces are conforming support surfaces that mould around the shape of the patient to distribute the body weight over a large area and include constant low-pressure devices.[108,109] They include:

- Alternative foam mattresses/overlays: these are comfortable and aim to redistribute pressure over a larger contact area;
- Gel-filled mattresses/overlays: mode of action as above;
- Fibre-filled mattresses/overlays: mode of action as above;
- Air-filled mattresses/overlays: mode of action as above;
- Water-filled mattresses/overlays: mode of action as above;
- Bead-filled mattresses/overlays: mode of action as above;
- Sheepskins: mode of action unclear.

Standard foam hospital mattresses are not considered as CLP for the purpose of this review. The Cochrane review compared standard foam hospital mattresses with low specification (low-tech), constant low-pressure (CLP) supports. However, it is important to note that there is not an international definition of what a standard foam mattress is, and it can change over time, within countries, and even within hospitals.[108]

Constant low-pressure supports (CLP) versus standard foam mattresses (SFM) for pressure ulcer prevention:

- One study (n=36) showed a cubed foam mattress (COMFORTEX DECUBE) is potentially more clinically effective at reducing the incidence of pressure ulcers (grades 2-4) when compared to a standard foam mattress (standard polypropylene SG40) (VERY LOW QUALITY).[136]
- One study (n=170) showed a softform mattress is more clinically effective at reducing the incidence of pressure ulcers (grades 2-4) when compared to a standard foam mattress (LOW QUALITY).[133]

- One study (n=36) showed a cubed foam mattress (COMFORTEX DECUBE) is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (standard polypropylene SG40) (VERY LOW QUALITY).[136]
- One study (n=75) showed a bead-filled mattress (BEAUFORT) is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (VERY LOW QUALITY).[131]
- One study (n=316) suggested a water-filled mattress is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (VERY LOW QUALITY).[51]
- Two studies (n=644) showed alternative foam pressure-reducing mattresses (CLINIFLOAT, OMNIFOAM, SOFTFORM, STM5, THERAREST, VAPOURLUX) are more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to standard foam mattresses (LOW QUALITY).[122,152]
- One study (n=1 166) showed there is potentially no clinical difference between a hi-spec foam mattress/cushion (visco-polymer energy absorbing foam mattress (CONFORM-ED)) and a standard foam mattress (KING's FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING's FUND MATTRESS with a speNco OR PROPAD mattress overlay) for reducing the incidence of pressure ulcers (all grades), the direction of effect favoured the hi-spec foam mattress/cushion (VERY LOW QUALITY).[162]
- One study (n=170) showed there is no clinical difference between a softform mattress (SOFTFOAM) and a standard foam mattress (130 mm NHS foam mattress) for scoring the mattress as very uncomfortable (LOW QUALITY).[133]
- One study (n=170) showed there may be no clinical difference between a softform mattress (SOFTFOAM) and a standard foam mattress (130 mm NHS foam mattress) for scoring the mattress as uncomfortable, but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[133]
- One study (n=170) showed a softform mattress (SOFTFOAM) is more likely to be scored as adequate for comfort when compared to a standard foam mattress (130 mm NHS foam mattress) (LOW QUALITY).[133]
- One study (n=170) showed a softform mattress (SOFTFOAM) is more likely to be scored as comfortable when compared to a standard foam mattress (130 mm NHS foam mattress) (LOW QUALITY).[133]
- One study (n=170) showed a softform mattress (SOFTFOAM) is potentially more likely to be scored as very comfortable when compared to a standard foam mattress (130 mm NHS foam mattress), however there is uncertainty in the size of effect (VERY LOW QUALITY).[133]
- One study (n=706) showed there is no clinical difference between a hi-spec mattress (visco-polymer energy absorbing foam mattress (CONFORM-ED)) for comfort rating when compared to a standard foam mattress (KING's FUND, LINKNURSE, SOFTFOAM, TRANSFOAM, KING's FUND MATTRESS with a speNco OR PROPAD mattress overlay) (LOW QUALITY).[162]
- One study (n=36) reported medians for cubed-mattress (COMFORTEX DECUBE) vs. standard mattress (standard polypropylene SG40) for the length of stay in hospital. Median differences ranged from 4-120 days, no estimate of effect or precision could be derived (VERY LOW QUALITY).[136]

Alternative foam mattress vs. standard foam mattress for pressure ulcer prevention:

- Five studies (n=2 016) showed there is potentially a clinical benefit for various alternatives of mattresses when compared to standard mattresses, however there was considerable heterogeneity in results (VERY LOW QUALITY).[122,133,136,152,162]
- Two studies (n=206) showed alternative foam mattresses (SOFTFOAM) are more clinically effective at reducing the incidence of pressure ulcers (grades 2-4) when compared to a standard foam mattress (130 mm NHS foam mattress) (LOW QUALITY).[133,136]

Comparisons between alternative foam supports for pressure ulcer prevention:

- One study (n=505) showed an alternative foam mattress (CLINIFLOAT, OMNIFOAM, SOFTFORM, STM5, THERAREST, VAPOURLUX) is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to standard NHS foam mattress (REYLON 150mm) (LOW QUALITY).[152]
- One study (n=40) showed a foam mattress (MAXIFLOAT) is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to an foam mattress overlay (IRIS 3000) (VERY LOW QUALITY).[158]
- One study (n=84) showed a solid foam mattress overlay is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a convoluted foam mattress overlay (LOW QUALITY).[139]
- One study (n=100) showed there may be no clinical difference between a pressure-reducing foam mattress (TRANSFOAM) and a pressure-reducing foam mattress (TRANSFOAMWAVE) at reducing the incidence of pressure ulcers (all grades), the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[132]
- One study (n=40) showed a foam mattress replacement (MAXIFLOAT) is potentially more clinically effective at reducing the incidence of pressure ulcers (grades 2 and above) when compared to an foam overlay mattress (IRIS 300) (VERY LOW QUALITY).[158]
- One study (n=40) reported evidence for foam mattress replacement (MAXIFLOAT) vs. foam overlay mattress (IRIS 300) for the time to pressure ulcer development. A value favouring maxifloat was the only reported statistic (not statistically significant).[158]

Comparisons between "low-tech" constant low-pressure supports:

- One study (n=40) showed an constant low pressure mattress (CARITAL OPTIMA) is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (10cm tick foam density 35kg/m³) (VERY LOW QUALITY).[155]
- One study (n=84) showed there may be no clinical difference between dry flotation mattress (SOFLEX) and dry flotation mattress (ROHO) for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favours the dry flotation mattress (ROHO) (VERY LOW QUALITY).[126]
- One study (n=84) showed there may be no clinical difference between dry flotation mattress (SOFLEX) and dry flotation mattress (ROHO) for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of the estimate of effect could favours the dry flotation mattress (ROHO) (VERY LOW).[126]
- One study (n=66) showed there may be no clinical difference between a gel mattress and an air-filled overlay (SOFCARE) (all grades of ulcer), but the direction of the estimate of effect could favour the gel mattress (VERY LOW QUALITY).[142]
- One study (n=66) showed there may be no clinical difference between a gel mattress and an air-filled mattress (SOFCARE) for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of the estimate of effect could favour the gel mattress (VERY LOW QUALITY).[142]
- One study (n=37) showed a static air mattress (GAY MAR SOFCARE) may be more clinically effective for reducing the incidence of pressure ulcers (all grades) compared to a water mattress (LOTUS PXM 3666) (VERY LOW QUALITY).[153]
- One study (n=68) showed there may be no clinical difference between foam overlay and a silicore overlay (SPENCO) for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of the estimate of effect could favour the silicore overlay (SPENCO) (VERY LOW QUALITY).[154]

- Three studies (n=1 281) showed that Australian medical sheepskin is clinically more effective than no sheepskin for reducing the incidence of pressure ulcers (all grades) (VERY LOW QUALITY).[138,144,145]
- Three studies (n=1 281) showed that Australian medical sheepskin is potentially clinically more effective than no sheepskin for reducing the incidence of pressure ulcers (grades 2 and above) (VERY LOW QUALITY).[138,144,145]
- One study (n=74) showed a static air overlay is potentially more clinically effective at reducing the incidence of pressure ulcers (grades 2 and above) when compared to a cold foam mattress (VERY LOW QUALITY).[118]
- One study (n=441) reported evidence for Australian medical sheepskin for comfort ratings. Results were only reported for the Australian medical sheepskin arm of the group, the clinical importance is unknown (VERY LOW QUALITY).[138]
- One study (n=297) reported evidence for Australian medical sheepskin and withdrawal from the study due to discomfort. Results were only reported for the Australian medical sheepskin arm of the group, the clinical importance is unknown (VERY LOW QUALITY).[144]
- One study (n=84) showed there is no clinical difference between dry flotation mattress (SOFLEX) and dry flotation mattress (ROHO) for comfort scoring of very uncomfortable (MODERATE QUALITY).[126]
- One study (n=84) showed there is potentially no clinical difference between dry flotation mattress (SOFLEX) and dry flotation mattress (ROHO) for comfort scoring of uncomfortable, the direction of effect favoured dry flotation mattress (ROHO) (LOW QUALITY).[126]
- One study (n=84) showed there may be no clinical difference between dry flotation mattress (SOFLEX) and dry flotation mattress (ROHO) for comfort scoring of adequate, but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[126]
- One study (n=84) showed there may be no clinical difference between dry flotation mattress (SOFLEX) and dry flotation mattress (ROHO) for comfort scoring of comfortable, but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[126]
- One study (n=84) showed there may be no clinical difference between dry flotation mattress (SOFLEX) and dry flotation mattress (ROHO) for comfort scoring of very comfortable, but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[126]
- One study (n=297) reported that a Australian medical sheepskin is potentially more effective at increasing time to onset of first ulcer when compared to no Australian medical sheepskin, the clinical effect was unknown. (VERY LOW QUALITY).[138]
- One study (n=543) reported evidence for Australian medical sheepskin vs. no sheepskin. Number of days to time of onset of first ulcer was reported but no other results were given, the clinical importance is unknown (VERY LOW QUALITY).[145]

3.6.3.3 Evidence Statements "High-tech" pressure supports

"High-tech" pressure supports include:

- Alternating-pressure mattresses/overlays: patient lies on air-filled sacs that inflate and deflate sequentially to relieve pressure at different anatomical sites for short periods; these may incorporate a pressure sensor;
- Air-fluidised beds: warmed air circulates through fine ceramic beads covered by a permeable sheet; allowing support over a larger contact area (CLP);
- Low-air-loss beds: patients are supported on a series of air sacs through which warmed air passes (CLP).

This section outlines these three main groups of support.

Alternating-pressure compared with constant low pressure

Alternating-pressure versus standard foam mattress

- Two studies (n=409) showed that an alternating air mattress/overlay is more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam mattress (LOW QUALITY).[51,151]
- One study (n=82) showed that an alternating air mattress/overlay is potentially more clinically effective at reducing the incidence of pressure ulcers (grades 2 and above) when compared to a standard foam mattress (VERY LOW QUALITY).[151]

Alternating-pressure versus constant low-pressure

- Eleven studies (n=1 622) showed there is potentially no clinical difference between various alternating pressure mattresses and various low-pressure mattresses for reducing the incidence of pressure ulcers (all grades), the direction of effect favoured alternating-pressure mattresses (VERY LOW QUALITY).[51,117,120,123,127,148,153,154,159-161,]
- One study (n=230) showed that various alternating pressure mattresses were clinically more effective at reducing the incidence of pressure ulcers (all grades) when compared to various constant low pressure mattresses (LOW QUALITY).[117,148,160]
- Four studies (n=331) showed there is potentially no clinical difference between alternating pressure overlay and silicore or foam overlay for reducing the incidence of pressure ulcers (all grades and all types of patients), the direction of effect favoured the alternating pressure overlay (VERY LOW QUALITY).[123,127,154,159]
- Three studies (n=458) showed there may be no clinical difference between alternating pressure and water or static air mattress for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[51,148,153]
- One study (n=140) showed there may be no clinical difference between alternating pressure setting in mattress (DUO 2) and constant low pressure mattress setting on mattress (DUO 2) for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[120]
- One study (n=447) showed there may be no clinical difference between alternating pressure air mattress (ALPHA-X-CELL) and visco-elastic foam mattress (TEMPUR) for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[161]
- One study (n=16) showed there may be no clinical difference between alternating pressure (NIMBUS 3) vs. dry flotation mattress overlay (ROHO) for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[117]
- Two studies (n=151) showed there may be no clinical difference between alternating pressure and silicore for reducing the incidence of pressure ulcers (all grades of ulcers) in patients without chronic neurological conditions, but the direction of the estimate of effect could favour the alternating pressure (VERY LOW QUALITY).[154,159]
- Two studies (n=180) showed there may be no clinical difference between alternating pressure and silicore for reducing the incidence of pressure ulcers (all grades of ulcers) in patients with chronic neurological conditions, the direction of effect favoured alternating pressure (VERY LOW QUALITY).[123,127]
- Six studies (n=826) showed there is potentially no clinical difference between alternating pressure and silicore for reducing the incidence of pressure ulcers (grades 2 and above), the direction of effect favoured alternating pressure (VERY LOW QUALITY).[117,148,154,160,161]
- One study (n=187) showed there may be no clinical difference between alternating pressure overlay and silicore overlay for drop out due to discomfort, but the direction of the estimate of effect could favour the silicore (VERY LOW QUALITY).[123]
- One study (n=50) showed there may be no clinical difference between a dynamic flotation mattress (NIMBUS 2) and alternating pressure overlay cushion and low pressure inflatable mattress (REPOSE SYSTEM) and cushion for comfort rating, the direction of estimate of

effect could favour the dynamic flotation mattress (NIMBUS 2) and alternating pressure overlay cushion (VERY LOW QUALITY).[148]

- One study (n=140) reported there is no difference in length of stay between alternating pressure setting on mattress (DUO 2) and constant low pressure mattress setting on mattress (DUO 2) but no results were given to estimate the clinical effect (VERY LOW QUALITY).[120]

Alternating pressure and constant low pressure in intensive care units/post intensive care units (factorial design) for pressure ulcer prevention

- One study (n=160) showed there is potentially a clinical difference between standard mattress in ICU/standard foam mattress post-ICU and alternating pressure mattress (NIMBUS) in ICU/Standard foam mattress post-ICU for reducing the incidence of pressure ulcers (all grades), the direction of effect favoured the standard mattress in ICU/standard foam mattress post-ICU (VERY LOW QUALITY).[141]
- One study (n=155) showed there may be no clinical difference between a standard mattress in ICU/standard foam mattress post-ICU and standard ICU/constant low pressure mattress (TEMPUR) post-ICU for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour the standard ICU/constant low pressure mattress (TEMPUR) post-ICU (VERY LOW QUALITY).[141]
- One study (n=155) showed there may be no clinical difference between an alternating pressure (NIMBUS) ICU/SFM post-ICU and a standard ICU/constant low pressure mattress (TEMPUR) post-ICU for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour the alternating pressure (NIMBUS) ICU/SFM post-ICU (VERY LOW QUALITY).[141]
- One study (n=157) showed there may be no clinical difference between a standard ICU/SFM post-ICU and an alternating pressure (NIMBUS) ICU/SFM post-ICU for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[141]
- One study (n=157) showed there may be no clinical difference between an alternating pressure (NIMBUS) ICU/SFM post-ICU and an alternating pressure mattress (NIMBUS) ICU/Constant low pressure mattress (TEMPUR)CLP post-ICUU for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[141]
- One study (n=157) showed there may be no clinical difference between standard ICU/constant low pressure mattress (TEMPUR) post-ICU and alternating pressure (NIMBUS) ICU/SFM post-ICU for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour alternating pressure (NIMBUS) ICU/SFM post-ICU (VERY LOW QUALITY).[141]

Comparisons between different alternating pressure devices

- One study (n=44) showed there may be no clinical difference between alternating-pressure mattress (TRINOVA) and control for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[156]
- One study (n=610) showed there is potentially a clinical difference between alternating low pressure air mattress with multi-stage inflation and deflation of air cells and standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells for reducing the incidence of pressure ulcers (all grades), the direction of effect favoured alternating low pressure air mattress with multi-stage inflation and deflation of air cells (VERY LOW QUALITY).[115]
- One study (n=62) showed an alternating-pressure mattress with two layers of air cells (PEGASUS AIRWAVE SYSTEM) is potentially more clinically effective at reducing the incidence of pressure ulcers (grades 2 and above) when compared to an alternating-pressure large cell ripple mattress (VERY LOW QUALITY).[128]
- One study (n=75) showed no difference between an alternating-pressure mattress (PEGASUS AIRWAVE SYSTEM)and alternating-pressure mattress (PEGASUS CAREWAVE SYSTEM) for reducing the incidence of pressure ulcers (grade 2 and above) (LOW QUALITY).[135]

- One study (n=44) showed there may be no difference between an alternating-pressure mattress (TRINOVA) and control for reducing the incidence of pressure ulcers (grade 2 and above), but the direction of the estimate of effect could favour alternating-pressure mattress (TRINOVA) (VERY LOW QUALITY, forest plot missing).[156]
- One study (n=1 971) showed there is potentially no clinical difference between an alternating pressure overlay and an alternating-pressure mattress for reducing the incidence of pressure ulcer (grade 2 and above), the direction of effect favoured the alternating pressure mattress (VERY LOW QUALITY).[147]
- One study (n=62) showed there may be no clinical difference between an alternating pressure bed (THERAPULSE) and alternating pressure mattress (HILL-ROM DUO) for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of the estimate effect could favour the an alternating pressure bed (THERAPULSE) (VERY LOW QUALITY).[157]
- One study (n=610) showed there may be no clinical difference between alternating low pressure air mattress with multi-stage inflation and deflation of air cells and standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[115]
- One study (n=610) showed there may be no clinical difference between alternating low pressure air mattress with multi-stage inflation and deflation of air cells and standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells for withdrawal due to discomfort, but the direction of the estimate of effect could favour the alternating low pressure air mattress with multi-stage inflation and deflation of air cells (VERY LOW QUALITY).[115]
- One study (n=18) reported evidence for alternating-pressure mattress (TRINOVA) versus control but data was only reported for the alternating-pressure mattress (TRINOVA)arm. The clinical importance is unknown (VERY LOW QUALITY).[156]
- One study (n=50) reported evidence for an alternating pressure bed (THERAPULSE) versus duo but data was only given for mean and range for the length of stay in hospital for those who developed a pressure ulcer. The clinical importance is unknown (VERY LOW QUALITY).[157]
- One study (n=38) reported evidence for an alternating pressure bed (THERAPULSE) versus duo but data was only given for mean and range for the length of stay in hospital for those who did not develop a pressure ulcer. The clinical importance is unknown (VERY LOW QUALITY).[157]
- One study (n=610) reported evidence for alternating low pressure air mattress with multi-stage inflation and deflation of air cells vs. standard (CLINACTIV, HILLROM) alternating low pressure air mattress with single-stage inflation and deflation of air cells for time to develop a new pressure ulcer. The mean and interquartile ranges were given and a p value showing no significant difference. The clinical importance is unknown (VERY LOW QUALITY).[115]

Low-air loss beds

Three studies[26,121,137] evaluated the use of low-air-loss beds. Such devices provide a flow of air that assists in controlling the microclimate of the patient's skin.[5]

- One study (n=123) showed a low-air-loss bed (KINAIR) is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to other static air mattress overlay (EHOB WAFFLE) (VERY LOW QUALITY).[121]
- Three studies (n=319) showed a low-air-loss bed (KINAIR/CLENSICAIR) is more clinically effective at reducing the incidence of pressure ulcers (grades 2 and above) when compared to static air mattress overlay (EHOB WAFFLE) or standard ICU bed or standard care (standard bed or foam, air alternating pressure mattress) (LOW QUALITY).[26,121,137]
- Two studies (n=221) showed a low-air-loss bed (KINAIR) is more clinically effective at reducing the incidence of pressure ulcers (grades 2 and above) when compared to static air mattress overlay (EHOB WAFFLE) or standard ICU bed (LOW QUALITY).[26,121,137]

- One study (n=10) reported evidence between low air loss hydrotherapy (CLENSICAIR) and standard care (standard bed or foam, air alternating pressure mattress) but only reported the comfort for one arm, which was mixed for comfortable and uncomfortable. The clinical importance is unknown (VERY LOW QUALITY).[26]
- One study (n=106) reported evidence that there was more discomfort with the low air loss hydrotherapy (CLENSICAIR) than the standard care (standard bed or foam, air alternating pressure mattress). The clinical importance is unknown (VEFY LOW QUALITY).[26]

3.6.3.4 Evidence Statements Other Support Surfaces

The other support surfaces included:

- Operating table overlays: mode of action as above;
- Limb protectors: pads and cushions of different forms to protect bony prominences;
- Turning beds/frames: these work by aiding manual repositioning of the patient, or by motor driven turning and tilting;
- Wheelchair cushions: either conforming cushions that reduce contact pressures by increasing surface area in contact, or mechanical cushions e.g. alternating pressure.

Operating table overlay:

- Operating room foam mattress (indentation load deflection (IDL) 25% (density 1.3 cubic feet, IDL 30lb)) versus usual care
  - One study (n=413) showed usual care is potentially more effective than indentation load deflection operating mattresses for reducing the incidence of pressure ulcers (all grades) (LOW QUALITY).[163]
  - One study (n=413) showed usual care may be more effective than indentation load deflection operating mattresses for reducing the incidence of pressure ulcers (grade II and above) (LOW QUALITY).[163]
  - One study (n=413) reported evidence for patient acceptability. Patients on the indentation load deflection operating mattress were significantly more likely to have skin changes than those on the usual care operating room table, no further information is provided (VERY LOW QUALITY).[163]
- Operating table overlay versus no overlay
  - One study (n=416) showed a visco-elastic polymer pad operating table overlay is potentially more effective than no overlay for reducing the incidence of pressure ulcers (all grades) (LOW QUALITY).[146]
  - One study (n=175) showed there may be no clinical difference between a visco-elastic foam operating table overlay and no overlay for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate favours no overlay (VERY LOW QUALITY).[129]
  - One study (n=175) showed there may be no clinical difference between a visco-elastic foam operating table overlay and no overlay for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of the estimate of effect could favour either intervention (VERY LOW QUALITY).[129]

Schultz (1999)[163] compared an operating theatre mattress with usual care. The Cochrane authors stated that they contacted the author for details on stage of ulcer by group and the name of the product and had no response. Due to the lack of data for each group the findings could not be reported in this review.

Face pillows in operating theatre

- Disposable polyurethane foam prone head positioner (OSI) vs neoprene air filled bladder (dry flotation) (ROHO) face pillow
  - One study (n=44) showed a ROHO face pillow is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to an OSI face pillow, although there is uncertainty in the estimate of effect (VERY LOW QUALITY).[116]
  - One study (n=44) showed a ROHO face pillow may be more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to an OSI face pillow, although there is uncertainty in the estimate of effect (VERY LOW QUALITY).[116]
- Disposable polyurethane foam prone head positioner (OSI) vs. prone view protective helmet system with a disposable polyurethane foam prone head positioner (DUPACO)
  - One study (n=44) showed a Dupaco face pillow is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to an OSI face pillow, although there is uncertainty in the estimate of effect (VERY LOW QUALITY).[116]
  - One study (n=44) showed a Dupaco face pillow may be more clinically effective at reducing the incidence of pressure ulcers (grade 2 and above) when compared to an OSI face pillow, although there is uncertainty in the estimate of effect (VERY LOW QUALITY).[116]
- Neoprene air filled bladder (dry flotation) (ROHO) face pillow vs prone view protective helmet system with a disposable polyurethane foam prone head positioner (DUPACO)
  - One study (n=44) showed there is no clinical difference between ROHO face pillow and Dupaco face pillow for reducing incidence of pressure ulcers (all grades) (LOW QUALITY).[116]
  - One study (n=44) showed there is no clinical difference between ROHO face pillow and Dupaco face pillow for reducing incidence of pressure ulcers (grades 2 and above) (LOW QUALITY).[116]

Multi-cell pulsating dynamic mattress system (MICROPULSE) vs. standard mattress for surgical patients

- Two studies (n=368) showed that a micropulse system is clinically more effective than standard mattress for reducing the incidence of pressure ulcers (all grades) (LOW QUALITY)[119,149]
- One study (n=170) showed there is a potentially clinical difference between micropulse system and standard mattress for reducing the incidence pressure ulcers (grade 2 and above) (VERY LOW QUALITY).[119]
- One study (n=8) reported evidence between micropulse system and standard mattress for length of stay in hospital for those who developed ulcers. The clinical importance is unknown (VERY LOW QUALITY).[119]

Visco-elastic foam (TEMPUR-PEDIC) Accident &Emergency (A&E) overlay and ward mattress vs. standard A &E overlay and ward mattress

- One study (n=101) showed there may be no clinical difference between visco-elastic foam (TEMPUR-PEDIC) A&E overlay and ward mattress and standard A&E overlay and ward mattress for reducing the incidence of pressure ulcers (grade 2 and above), the direction of effect could favour either intervention (VERY LOW QUALITY).[134]
- One study (n=101) showed there may be no clinical difference between visco-elastic foam (TEMPUR-PEDIC) A&E overlay and ward mattress and standard A&E overlay and ward mattress for reducing the incidence of pressure ulcers (all grades), the direction of effect could favour the visco-elastic foam (TEMPUR-PEDIC) (VERY LOW QUALITY).[134]

Comparison between profiling bed and flat-based bed

- One study (n=70) showed there is no clinical difference between a profiling bed with a pressure-reducing foam mattress and a flat-based bed with a pressure-reducing mattress (LOW QUALITY).[140]

Seat cushions

Seat cushions for pressure ulcer prevention

- Two studies (n=300) showed there is no clinical difference between a slab foam cushion and a bespoke contoured foam cushion for reducing the incidence of pressure ulcers (all grades) (LOW QUALITY).[124,143]
- One study (n=141) showed gel cushion with foam base (JAY) is potentially more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to foam cushion (LOW QUALITY).[124]
- One study (n=32) showed a pressure-reducing cushion may be more clinically effective at reducing the incidence of pressure ulcers (all grades) when compared to a standard foam cushion (3inch convoluted foam cushion) (EGGRATE) (VERY LOW QUALITY).[130]
- One study (n=232) showed a skin protection cushion is potentially clinically more effective than a segmented foam cushion for reducing the incidence of pressure ulcers (for all grades for sitting related ischial tuberosities) (VERY LOW QUALITY).[17]
- One study (n=232) showed a skin protection cushion is potentially more effective than a segmented foam cushion for reducing the incidence of pressure ulcers (for all grades for ischial tuberosities and sacral/coccyx) (VERY LOW QUALITY).[17]
- One study (n=163) showed there may be no clinical difference between a gel cushion with foam base (JAY) and a foam cushion for withdrawal due to discomfort, the direction of effect could favour a jay gel cushion (VERY LOW QUALITY).[125]

3.6.4 Conclusion

Conclusion

- **Both constant low-pressure devices as well as alternating (high-tech) pressure devices were clinically more effective than standard foam mattresses to prevent the development of pressure ulcers.**
- **The evidence about competing continuously low-pressure devices did not show clear differences in effectiveness. Neither did the comparisons between alternating devices with constant-low pressure devices or comparisons between competing types of alternating pressure devices showed clear differences. Two studies showed a low-air-loss bed is more clinically effective at reducing the incidence of pressure ulcers (grades 2 and above) when compared to other support surfaces. However, there is evidence from one study that there was more discomfort with the low air loss bed than the standard bed. The clinical importance of this finding is unclear.**
- **Three trials showed that sheepskin is potentially clinically more effective than no sheepskin for reducing the incidence of pressure ulcers (grades 2 and above).**
- **One large trial showed that a visco-elastic polymer pad operating table overlay is potentially more effective than no overlay for reducing the incidence of pressure ulcers (all grades). In addition, two studies showed a micropulse overlay system is clinically more effective than standard treatment (gel pad in operating room and a replacement mattress postoperatively)).**
- **One small study compared a profiling bed with a pressure-reducing foam mattress and found no clinical difference between both devices.**
- **There is insufficient evidence to determine the value of seat cushions and various types of face pillows as pressure ulcer prevention strategies.**
- **All conclusions from the included studies were weakened due to major limitations: the poor methodological quality of the trials, the lack of replication of most comparisons and the fact that "standard mattresses" are often not clearly defined.**

3.6.5 Recommendations and Best practices for clinical practice

Recommendations	Strength of Recommendation	Level of Evidence
The use of pressure redistributing devices (low-tech constant low pressure surfaces or high-tech support surfaces) is recommended for individuals at risk of pressure ulcers development. As clinical studies did not demonstrate the superiority of one pressure redistributing device over another, decisions about which pressure redistributing device to use should be based on an overall assessment of the individual including level of risk, comfort and general health state. Appropriateness of each device in different care settings, and other considerations (e.g. cleaning, type of mattress cover, Cardiopulmonary resuscitation-function, disinfection and cost) can contribute to guide the choice.	Strong	Very Low
Mattresses without pressure redistributing or relieving characteristics should be avoided to prevent ulcers development in at risk individuals.	Strong	Very Low
Pressure redistributing overlays are recommended on the operating table. Consider the use of a visco elastic polymer support surface on the operating table. Several devices to redistribute pressure (e.g. face pillows for individuals in a prone position on the operating table) are available but no devices have shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.	Strong	Low

Best Practices
Verify the functioning of the pressure redistributing device on a regular basis.
Use a pressure redistributing seat cushion for an individual at risk of pressure ulcer development when in a seated position: • No seat cushion with specific pressure redistributing devices showed to out-perform another, therefore no recommendation can be made about which specific type of cushion to use for pressure redistribution purposes. The decision on which type of pressure redistributing seat cushion to use should be adapted to the individual's needs and context.

3.7 Heel ulcer prevention (devices)

3.7.1 Introduction

The heels are particularly vulnerable to pressure ulcer development as the calcaneum (heel bone) is subject to high levels of pressure and shear on a small surface area, only minimally being protected by a thin covering of subcutaneous fat[5]. Prevention should aim to remove pressure and shear totally from the heels. Specific devices should be placed to elevate the heel (offload them) as to distribute the weight of the leg along the calf without putting pressure on the Achilles tendon. A plethora of different devices and features is currently available to prevent heel pressure ulcers[5].

The aim of this review was to describe the current evidence about the effectiveness of different devices for heel pressure ulcer prevention and to provide recommendations for clinical practice.

3.7.2 Review question

What is the clinical effectiveness of pressure-redistributing devices for the prevention of heel ulcers?

3.7.3 Clinical evidence

Five randomized controlled trials were included in the review.[110,112,113,115,119,127,147,149,151,155,160,161,164-167]

3.7.3.1 Quality of Studies

In general the methodological quality of the included studies was poor. The majority of studies were not blinded[110,112,113,164-167] and did not report on allocation concealment.[112,113,119,167] One study did not report on sequence generation[167] and three studies did not use an intention-to-treat analysis.[112,113,167] Two studies had no a priory sample size calculation,[110,167] and two additional studies[112,164] had a sample size lower than calculated. In appendix 8 the level of evidence can be found per outcome after applying the GRADE-methodology. The evidence base for all outcomes has been rated as moderate to very low quality.

3.7.3.2 Evidence statements

- One study (n=164) showed there may be no clinical difference between a bunny boot fleece cushion heel protector and an egg crate heel lift positioner for reducing the incidence of heel pressure ulcers, but the direction of the estimate of effect favoured the bunny boot fleece cushion heel protector (VERY LOW QUALITY).[112]
- One study (n=153) showed there may be a clinical difference for a bunny boot fleece cushion heel protector compared to foot waffle air cushion for reducing the incidence of heel pressure ulcers (VERY LOW QUALITY).[112]
- One study (n=163) showed there may be a clinical difference for an egg crate heel lift positioner compared a foot waffle air cushion for reducing the incidence of heel pressure ulcers (VERY LOW QUALITY).[112]
- One study (n=52) showed there may be a clinical difference for a foot waffle heel elevation device compared to a heel elevation pillow for reducing the incidence of heel pressure ulcers (VERY LOW QUALITY).[113]
- One study (n=52) reported a significant difference between a foot waffle heel elevation device (10 days) and a heel elevation pillow (13 days) for time to heel pressure ulcer (VERY LOW QUALITY).[113]
- One study (n=239) showed an eggcrate suspension boot heel elevation device plus a pressure-reducing support surface is more clinically effective at reducing the incidence of heel pressure ulcers when compared to a pressure-redistributing surface alone (MODERATE QUALITY).[164]
- One study (n=240) reported themed analysis for the opinions of patients on the comfort of an eggcrate suspension boot heel elevation device. 32% of patients felt the boots interfered with sleep, 41% felt it adversely affected movement in bed, 59% rated them as comfortable overall. Poor concordance reasons were given as the weight and bulk of the boot (36%), heat (particularly at night) (31%) and discomfort (24%). The clinical importance is not known (VERY LOW QUALITY).[164]

- One study (n=70) showed a foam body support (perpendicular foam blocks covered with jersey) is more clinically effective at reducing the incidence of pressure ulcers when compared to usual care (MODERATE QUALITY).[110]
- One study (n=70) showed a significant difference between a foam body support (perpendicular foam blocks covered with jersey) (5.6 days) and usual care (2.8 days) for the mean time without a heel pressure ulcer (VERY LOW QUALITY).[110]
- One study (n=unclear) showed a polyurethane hydrocellular foam dressing may be more clinically effective when compared to a protective bandage for reducing the incidence of heel pressure ulcers (VERY LOW QUALITY).[167]

3.7.4 Conclusion

- **There is evidence of moderate quality that using a pressure relieving device for heel off-loading, combined with the use of a pressure redistributing mattress, is clinically more effective than the use of a pressure redistributing mattress alone to prevent pressure ulcer development. However, there is no clear evidence about which heel ulcer prevention device is clinically most effective.**

3.7.5 Recommendations and Best practices for clinical practice

Recommendation	Strength of Recommendation	Level of Evidence
The use of devices that ensure that heels are free of the surface of the bed in combination with a mattress with pressure-relieving characteristics is recommended for individuals at risk for pressure ulcers development. No device had been shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.	Strong	Very Low

Best Practices
The use of devices that ensure that heels are free of the surface of the bed in combination with a mattress with pressure-relieving characteristics is recommended for individuals at risk for pressure ulcers development. No device had been shown to out-perform another, therefore no recommendation can be made about which type to use for pressure redistribution purposes.
For bedridden individuals or individuals sitting in a chair in backward position with the feet up, heel-protection devices should offload the heel completely. This can be done by distributing the weight of the leg along the calf without putting pressure on the Achilles tendon. The knee should be in slight flexion and supported.
Inspect the skin of the heels regularly.

3.8 Nutrition/hydration

3.8.1 Introduction

One of the international proposed approaches to prevent pressure ulcers is to optimise hydrational and nutritional status of patient.[5] The rationale is that decreased calorie intake and dehydration may decrease the tolerance of the skin and underlying tissue to pressure, friction and shearing force, increasing the risk of skin breakdown.[168] This is supported by the fact that several studies showed associations between poor nutritional status and related factors (e.g. low body weight, insufficient oral food intake, low BMI) and pressure ulcers.[169,170] In clinical practice the standard hospital diet is therefore often complemented with nutritional supplements (oral or parenteral nutrition) or a special diet. Therefore it was considered important to clinical practice to conduct a systematic review to summarize the best available evidence about nutritional interventions such as oral nutritional supplements and/or tube feeding in the prevention of pressure ulcers.

3.8.2 Review question

What are the most clinically effective nutritional interventions for the prevention of pressure ulcers?

3.8.3 Clinical evidence

No studies were found for hydrational interventions to prevent the occurrence of pressure ulcers. A Cochrane Review by Langer (2003)[168] including four RCTs about the effect of nutritional interventions to prevent pressure ulcers was found. We updated the Cochrane review with four other studies, Dennis et al. (2005)[171], Craig et al. (1998)[172], Theilla et al. (2007)[173] and Oloffson et al. (2007)[174]. Dennis et al. (2005)[171], Craig et al. (1998)[172] and Oloffson et al. (2007)[174] were not looking at pressure ulcers, but rather pressure ulcers were an event or complication that occurred during these trials.

The literature search and Cochrane reviewers identified five RCTs comparing participants who received nutritional supplementation in addition to their standard diet (which was the hospital standard diet) to those who received only the standard hospital diet.[171,175-178] These studies all included older people who were in hospital. Houwing et al. (2003)[177] and Hartgrink et al. (1998)[178] included patients with hip fracture, Delmi et al. (1990)[176] included patients with fractured neck of the femur, Bourdel-Marchasson et al. (2000)[175] included critically ill patients and Dennis et al. (2005)[171] included stroke patients. Hartgrink et al. (1998)[178] gave patients a supplement of energy and protein by nasogastric tube compared to the standard hospital diet. Studies follow-up period ranged from 2 weeks to 6 months. The supplements included various compositions of protein, carbohydrate, vitamins and minerals.

One study[172] included long-term patients with type 2 diabetes. Researchers gave the patients a disease-specific (reduced-carbohydrate and modified fat) formula compared to the standard high carbohydrate formula. Patients were followed up for 3 months.

Another study[173] gave patients suffering from lung injury a macronutrient diet plus lipids and vitamins compared to a macronutrient diet alone. These patients were followed up for 7 days.

One RCT[174] with femoral neck fracture patients who were given protein-enriched meals compared to normal postoperative care and followed them up for 4 months.

We have meta-analysed the results in contrast to the original Cochrane review[168] to lump the studies together aiming to gain a greater confidence in the evidence and then report on heterogeneity of studies if this exists. We meta-analysed studies together that looked at nutritional supplements in addition to standard hospital diet (which mainly included energy and protein) versus the standard hospital diet.[171,175-178] We conducted another meta-analysis of these studies of nutritional supplements and also included a study (Oloffson et al., 2007)[174] with a protein diet compared to the standard hospital diet since all of the interventions had a high proportion of protein.

Some of the studies gave the results separately by grade of pressure ulcer that occurred as well as all grades of ulcers that occurred. We have split the results (see appendix 9) to show data for all pressure ulcers and for those with grade 2-4 ulcers (with details of the classification system of grading).

3.8.3.1 *Quality of studies*

In general the methodological quality of the included studies was poor. The majority of studies were not blinded[171,173-176,178], had unclear sequence allocation[172,173,175-178] and allocation concealment[172,173,175-178]. In addition, power calculation was only done in one study[171], baseline differences between intervention and control group were observed in 4 studies[173-176] and pressure ulcers were not defined in 4 studies[171,172,174,176]. In Appendix 9 the level of evidence can be found per outcome after applying the GRADE-methodology. The evidence base for all outcomes has been rated as being of low or very low quality.

3.8.3.2 *Evidence statements*

In this paragraph we describe the clinical statements that result from the evidence review (see Appendix 9 for details).

- One study (n=672) (critically ill older people) showed there is potentially no clinical difference between a supplement containing protein, fat, carbohydrates, minerals and vitamins and standard diet for reducing the incidence of pressure ulcers, the direction of effect favoured the supplement (VERY LOW QUALITY).[175]
- One study (n=672) (critically ill older people) reported compliance of 60% for the first week and 99% for the 2nd week for the supplements group. The clinical importance is unknown (VERY LOW QUALITY).[175]
- One study (n=103) (older people with a hip fracture) showed there may be no clinical difference between a supplement containing high amounts of protein, arginine, zinc and antioxidants and a standard diet for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of the estimate of effect could favour the supplement (VERY LOW QUALITY).[177]
- One study (n=103) (older people with a hip fracture) showed there may be no clinical difference between a supplement containing high amounts of protein, arginine, zinc and antioxidants and a standard diet for reducing the incidence of pressure ulcers (all grades), but the direction of the estimate of effect could favour the supplement (VERY LOW QUALITY).[177]
- One study (n=103) (older people with a hip fracture) reported compliance of 70% for a supplement containing high amounts of protein, arginine, zinc and antioxidants. The clinical importance is unknown (VERY LOW QUALITY).[177]
- One study (n=52) (older people with a fractured neck of the femur) showed there may be no clinical difference between a supplement containing protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals and standard diet for reducing the incidence of pressure ulcers, but the direction of the estimate of effect could favour the supplement (VERY LOW QUALITY).[176]
- One study (n=52) (older people with a fractured neck of the femur) reported a supplement containing protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals was said to be well-tolerated and completely ingested and no side-effects were observed. The clinical importance is unknown (VERY LOW QUALITY).[176]
- One study (n=52) (older people with a fractured neck of the femur) reported medians for a supplement containing protein, carbohydrate, lipid, calcium, vitamin A, vitamin D, vitamins E, B1, B2, B6, B12, C, nicotinamide, folate, calcium pantothenate, biotin, and minerals and the standard diet for time in hospital. The median for the supplement was 24 days (range 13-157) and 40 days (range 10-259) for the standard diet. No estimate of effect or precision could be derived (VERY LOW QUALITY).[176]
- One study (n=4 023) (older hospitalized patients with a stroke) showed there is potentially no difference between a nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) and standard hospital diet for reducing the incidence of pressure ulcers, but the direction of the estimate favoured the supplement (VERY LOW QUALITY).[171]
- One study (n=4 023) (older hospitalized patients with a stroke) reported evidence between nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) and standard hospital diet. A crude compliance rate of 96% and 48% of those who were supposed to only

receive the normal diet had some supplements, crude compliance of 98%. The clinical importance is unknown (VERY LOW QUALITY).[171]

- One study (n=4 023) (older hospitalized patients with a stroke) showed there is potentially no clinical difference between a nutritional supplement (360mL at 6.27kJmL and 62.5gL in protein) and standard hospital diet in length of time in the hospital, but the direction of effect favoured the standard hospital diet (LOW QUALITY).[171]
- One study (n=101) (older people with a hip fracture) showed there may be no clinical difference between a supplement of tube fed energy and protein and standard diet for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of effect could favour the supplement (VERY LOW QUALITY).[178]
- One study (n=101) (older people with a hip fracture) showed there may be no clinical difference between a supplement of tube fed energy and protein and standard diet for reducing the incidence of pressure ulcers (all grades), but the direction of effect could favour the supplement (VERY LOW QUALITY).[178]
- One study (n=32) (long-term care residents with diabetes mellitus type II) showed there may be no clinical difference between a disease-specific supplement (reduced-carbohydrate, modified-fat formula) and a standard high-carbohydrate formula for reducing the incidence of pressure ulcers, but the direction of effect could favour the disease specific supplement (VERY LOW QUALITY).[172]
- One study (n=32) (long-term care residents with diabetes mellitus type II) reported no differences for number of adverse events reported. The clinical importance is unknown (VERY LOW QUALITY).[172]
- One study (n=95) (critically ill, mechanically ventilated patients suffering from an acute lung injury) showed there may be no clinical difference between a macronutrient diet plus lipids (elcosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) and a macronutrient diet (high fat, low carbohydrate, enteral formula) in mechanically ventilated critically ill patient for reducing the incidence of pressure ulcers (all grades), but the direction of effect could favour macronutrient diet plus lipids (VERY LOW QUALITY).[173]
- One study (n=95) (critically ill, mechanically ventilated patients suffering from an acute lung injury) showed there may be no clinical difference between a macronutrient diet plus lipids (elcosapentanoic acid, gamma-linolenic acid, vitamins A, C and E) and a macronutrient diet (high fat, low carbohydrate, enteral formula) in mechanically ventilated critically ill patient for reducing the incidence of pressure ulcers (grades 2 and above), but the direction of effect could favour macronutrient diet plus lipids (VERY LOW QUALITY).[173]
- One study (n=157) (patients with a fractured femoral neck) showed a protein-enriched meal is potentially more clinically effective at reducing the incidence of pressure ulcers when compared to normal postoperative care (VERY LOW QUALITY).[174]
- One study (n=157) (patients with a fractured femoral neck) showed there is potentially no clinical difference between a protein-enriched meal and normal postoperative care for time in hospital, the direction of effect favoured the protein-enriched meal (LOW QUALITY).[174]
- Five studies pooled (n=4 951) (older people with a hip fracture or a stroke) showed there is potentially no clinical difference between oral supplements and normal hospital diet for reducing the incidence of pressure ulcers, the direction of effect favoured the oral supplements (VERY LOW QUALITY).[171,175-178]
- Six studies pooled (n=5 108) (older people with a hip fracture or a stroke and patients with a fractured femoral neck) showed there is potentially no clinical difference between nutritional supplementation and normal hospital diet for reducing the incidence of pressure ulcers, the direction of effect favoured the oral supplements (VERY LOW QUALITY).[171,174 175-178]

3.8.4 Conclusion

- **Pooled study results of 6 randomized trials showed that nutritional supplements had a favourable effect on the incidence of pressure ulcers compared to standard hospital diet but this effect is potentially not clinically important. The clinical importance of the evidence about patient acceptability (compliance) and length-of-time in hospital is unclear.**

3.8.5 Recommendations and Best practices for clinical practice

Best Practices
Best practice includes monitoring the nutritional status of individuals as part of a general assessment procedure and as an ongoing process throughout an individual's episode of care. Initially, this assessment should include documentation and monitoring of the following factors: • current weight and height; • recent weight loss; • usual eating habits; • recent changes in eating habits and intake.
If nutritional risk is suspected, practitioners should undertake more detailed screening. A formal nutritional risk assessment scale may be preferred to help with this and nutritionally compromised individuals should be discussed multidisciplinary.

Recommendation	Strength of Recommendation	Level of Evidence
As clinical studies did not demonstrate the superiority of one nutritional intervention such as oral nutritional supplements and/or tube feeding on another, no specific complementary diet with nutritional supplements can be recommended to prevent the development of pressure ulcers.	Strong	Very Low

4 DISCUSSION

4.1 Pressure ulcers: an important health problem hampered by a lack of high-quality research on how to prevent them

Pressure ulcer prevalence rates remain high and are associated with considerable discomfort, comorbidity and costs. As a consequence pressure ulcer prevention is one of the most frequently applied healthcare interventions in different settings (hospitals, nursing homes and homecare). Some interventions often require a lot of nursing resources (e.g. repositioning of patients) and can be costly (e.g. high tech redistributing mattresses). There is however a large discrepancy between the relevance of this topic and the availability of methodologically sound clinical studies that focused on the risk assessment and prevention of pressure ulcers.

The limitations have been described extensively in recent reviews[40,108,109,168,179,180] and are confirmed in this study. In general, the included RCTs are largely under-powered and have common methodological flaws such as: lack of allocation concealment; lack of baseline comparability; lack of blind – or independently verified – outcome assessment; failing to report whether or not participants were free from pressure ulcers (especially for GRADE 1 pressure ulcers) on study entry; lack of adequate definition for pressure ulcer status; a poor description of standard care and co-interventions (e.g. repositioning in case of re-distributing devices). In addition, the different follow-up times, the various types of interventions (e.g. in case of pressure relieving devices many different types are tested) and the different patient populations contributed to substantial clinical heterogeneity. Furthermore, there is a lack of replication studies in large samples.

It is also important to highlight some topic specific methodological limitations. First, risk assessment tools aim to stratify patients likely to develop pressure ulcers. However, the published studies are not well designed to evaluate the predictive validity of risk assessment tools. After all, the patients in validity studies are usually subject to pressure prevention strategies and so intrinsic risk is not being assessed. Predictive validity cannot be properly determined when the probability of the outcomes reduces as a result of the prediction.[181,182] Second, evaluating the clinical effectiveness of skin massage is difficult since it is impossible to disentangle the skin massage technique from the potential effects of the products used during the massage on the prevention of pressure ulcer incidence. Third, re-distributing devices are often compared with a "standard" mattress. However, most studies lack a clear definition of what is a "standard" mattress. In addition, the lack of standard turning regimen on different types of mattresses hinders the isolation of the effects of different mattresses in the reduction of pressure ulcer incidence because of an interaction with the turning regimen.[109]

4.2 Summary of results and coherence with other recent reviews

Given the major methodological limitations of the available studies for each topic, all results obtained should be interpreted with caution. Below we summarize the findings as follows:

- None of the risk assessment tools being studied and none of their thresholds outperform the others in assessing the risk of pressure ulcer development. The conclusion of Pancorbo-Hidalgo et al. (2006)[39] that the Braden scale provided the best balance between sensitivity and specificity and that the Braden and Norton scales better predict pressure ulcer risk than nurses clinical judgment are slightly toned down by the current review. On the other hand, the current review confirms the lack of evidence to support superior clinical effectiveness of one risk assessment approach over another in the prevention of pressure ulcer development (Body of evidence: very low quality).[39,40]
- No clear conclusions about the prognostic ability of skin assessment methods can be drawn due to the methodological limitations mentioned above. Yet, there are indications that the balance between specificity and sensitivity is better for thermography (presence of thermal anomaly – an area of the skin at least 1°C warmer than the surrounding skin) and non-blanchable erythema by the finger test than for blanchable erythema by the fingertest (Body of evidence: low quality). In addition, one single RCT provided evidence of moderate quality that the time to develop a pressure ulcer was significantly longer when the start of preventive measures was based on a combined approach of risk and skin assessment (i.e. Braden score in

combination with daily skin assessment with transparent disk: preventive measures were started when non-blanchable erythema appeared or in case of a Braden-score of ≤17) compared to a decision based on daily skin assessment with transparent disk only (i.e. preventive measures were started when non-blanchable erythema appeared). However, there was no difference in effect on pressure ulcer incidence.

- No evidence for clinical effectiveness (or harm) of skin massage in the prevention of pressure ulcers was found. (Body of evidence: very low quality).
- There is evidence that repositioning compared to no repositioning is clinically effective which confirms results of an earlier review[180]. Yet, no sound evidence was found for clear differences between different repositioning regimens (frequency and posture) (Body of evidence: very low quality).
- There is evidence illustrating that both constant low-pressure devices as well as alternating (high-tech) pressure devices were clinically more effective than standard foam mattresses to prevent the development of pressure ulcers (Body of evidence: very low quality). As in a previous review[109] the evidence about competing constant low-pressure devices did not show clear differences in effectiveness (Body of evidence: very low quality). Neither did the comparisons between alternating devices with constant-low pressure devices or comparisons between competing types of alternating pressure devices showed clear differences (Body of evidence: very low quality). Yet, there are indications that a low-air-loss bed is more effective at reducing the incidence of pressure ulcers when compared to other support surfaces, potentially causing more discomfort (Body of evidence: low quality). In addition, as indicated before by McInnes (2012)[109] there are indications that specific medical sheepskin is more effective than no sheepskin for reducing the incidence of pressure ulcers (Body of evidence: very low quality).
- There are indications from a large trial that a visco-elastic polymer pad operating table overlay is potentially more effective than no overlay for reducing the incidence of pressure ulcers (Body of evidence: low quality). In addition, a micropulse overlay system is clinically more effective than a gel pad in operating room and a replacement mattress postoperatively (Body of evidence: low quality).
- There is insufficient evidence to determine the clinical effectiveness of profiling beds, seat cushions and various types of face pillows as pressure ulcer prevention strategies.
- There is evidence of moderate quality that using a pressure relieving device for heel off-loading, combined with the use of a pressure redistributing mattress, is clinically more effective than the use of a pressure redistributing mattress alone to prevent heel pressure ulcer development. However, there is no clear evidence about which heel ulcer prevention device is clinically most effective.
- Pooled study results of 6 randomized trials showed that nutritional supplements in addition to a standard diet had a favourable effect on the incidence of pressure ulcers compared to standard hospital diet alone. But this effect is potentially not clinically important which is in line with the conclusions of previous reviews (Body of evidence: very low quality).[168,180]

4.3 Absence of evidence is not the same as evidence of absence

Based on the evidence reviews we cannot formulate specific recommendations on, for instance, how frequent a patient should be repositioned and what type of mattresses should be used. However, it should be stressed that **absence of evidence is not the same as evidence for absence of clinical effectiveness**.[183] In general, the topics of this guideline are largely understudied and the (few) published studies are generally underpowered to illustrate clinical effectiveness (or rule out harm). The lack of pre-market evaluation of medical devices is well-known. A previous KCE-report showed the lack of research in the pre-market phase of innovative high-risk medical devices (e.g. pacemakers; coronary stents) (Hulstaert et al., 2011). In this study this lack of evidence is confirmed for devices (not classified as being “high risk” devices) used

for the prevention of pressure ulcer development such as mattresses, seat cushions, heel protectors, etc.

4.4 Quality improvement

4.4.1 Comprehensive programs for preventing pressure ulcers

Studies report large variation in pressure ulcer rates across organizations[184,185] and the prevention of pressure ulcers is seen to be a key quality improvement goal[186] Despite the lack of evidence on the effectiveness of specific interventions there is a growing literature evaluating multi-facetted multidisciplinary interventions to prevent pressure ulcers as part of comprehensive quality improvement programs. These interventions include the implementation of 'bundles of best practices', awareness campaigns, staff education, clinical monitoring and feedback, skin care champions/ resource nurse, clinical decision aids. There are indications that organizations that use such comprehensive programs are successful in reducing the incidence of pressure ulcers.[187-189]

4.4.2 Quality indicators

Pressure ulcer incidence has been included in international quality indicators sets.[190,191] Also in Belgium, the incidence of pressure ulcers has been included in the Belgian Health system Performance Report 2012. Besides monitoring the outcome it is also recommended to develop process indicators based on this guideline. This should be aligned with the existing efforts undertaken by the Federal Council of Nursing Care Quality.

4.5 Suggestions for further research

It is clear that vigorous research efforts are needed to improve the body of knowledge concerning assessment of risk for pressure ulcer development and the effectiveness of preventive strategies. For each of the topics under study there is a need for more independent, well designed multi-centre studies. Some suggestions can be made for priority setting:

- Design studies that allow evaluating the predictive validity of risk and skin assessment methods. This would ideally require an inception cohort without risk reduction strategies and with individuals free of pressure ulcers.[182] An alternative is to better document the combination of risk and preventive measures to enable a more accurate calculation of the predictive validity.[181] Consecutively these risk and skin assessment methods should be evaluated as part of a complex intervention to prevent pressure ulcers by means of high quality RCTs.
- There is a need for studies that compare "high tech" alternating pressure mattresses with the "low tech" constant low pressure ones. In the same way, there is a need for research on the optimal frequency (also in combination with other measures such as the use of redistributing devices), in order to allocate the workforce in the most efficient way. Besides comparing the clinical effectiveness these studies should therefore also incorporate the evaluation of cost-effectiveness.

4.6 How to use this guideline

This guideline should be considered as a starting point to develop a broad awareness campaign and develop quality improvement programs that targets all caregivers concerned.

On one hand it can be used as a tool to support health policies to improve the quality of care: support of actions to increase caregivers' awareness and to improve their practice, development (or revision) of sets of process and outcome quality indicators. These indicators might be integrated into larger sets used in ambulatory or institutional settings.

On the other hand the scientific material of this guideline is intended to be disseminated by scientific and professional organisations. They can transform this material into attractive and user-friendly tools tailored to caregivers groups. They will also play a key role by a dissemination that makes use of diverse channels such as websites or sessions of continuing education.[192]

REFERENCES

1. Gawlitta D, Oomens CW, Bader DL, Baaijens FP, Bouten CV. Temporal differences in the influence of ischemic factors and deformation on the metabolism of engineered skeletal muscle. J Appl Physiol. 2007;103(2):464-73.
2. Loerakker S, Stekelenburg A, Strijkers GJ, Rijpkema JJ, Baaijens FP, Bader DL, et al. Temporal effects of mechanical loading on deformation-induced damage in skeletal muscle tissue. Ann Biomed Eng. 2010;38(8):2577-87.
3. Vanderwee K, Defloor T, Beeckman D, Demarre L, Verhaeghe S, Van DT, et al. Assessing the adequacy of pressure ulcer prevention in hospitals: a nationwide prevalence survey. BMJ Qual Saf. 2011;20(3):260-7.
4. Black JM, Cuddigan JE, Walko MA, Didier LA, Lander MJ, Kelpe MR. Medical device related pressure ulcers in hospitalized patients. Int Wound J. 2010;7(5):358-65.
5. European Pressure Ulcer Advisory Panel, National Pressure Ulcer Advisory Panel. Prevention and treatment of pressure ulcers: Clinical Practice Guideline. Washington (DC): 2009.
6. Beeckman D, Schoonhoven L, Fletcher J, Furtado K, Gunningberg L, Heyman H, et al. EPUAP classification system for pressure ulcers: European reliability study. J Adv Nurs. 2007;60(6):682-91.
7. Dealy C, Lindholm C. Pressure Ulcer Classification. London: European Pressure Ulcer Advisory Panel & Springler-Verlag; 2012.
8. Barrois B, Labalette C, Rousseau P, Corbin A, Colin D, Allaert F, et al. A national prevalence study of pressure ulcers in French hospital inpatients. J Wound Care. 2008;17(9):373-9.
9. Capon A, Pavoni N, Mastromattei A, Di LD. Pressure ulcer risk in long-term units: prevalence and associated factors. J Adv Nurs. 2007;58(3):263-72.
10. Gunningberg L, Hommel A, Baath C, Idvall E. The first national pressure ulcer prevalence survey in county council and municipality settings in Sweden. J Eval Clin Pract. 2012.
11. Tannen A, Dassen T, Halfens R. Differences in prevalence of pressure ulcers between the Netherlands and Germany--associations between risk, prevention and occurrence of pressure

ulcers in hospitals and nursing homes. J Clin Nurs. 2008;17(9):1237-44.

12. Alderden J, Whitney JD, Taylor SM, Zaratkiewicz S. Risk profile characteristics associated with outcomes of hospital-acquired pressure ulcers: a retrospective review. Crit Care Nurse. 2011;31(4):30-43.
13. Kottner J, Gefen A, Lahmann N. Weight and pressure ulcer occurrence: a secondary data analysis. Int J Nurs Stud. 2011;48(11):1339-48.
14. Shahin ES, Dassen T, Halfens RJ. Pressure ulcer prevalence and incidence in intensive care patients: a literature review. Nurs Crit Care. 2008;13(2):71-9.
15. Vanderwee K, Clark M, Dealey C, Gunningberg L, Defloor T. Pressure ulcer prevalence in Europe: a pilot study. J Eval Clin Pract. 2007;13(2):227-35.
16. Maida V, Corbo M, Dolzhykov M, Ennis M, Irani S, Trozzolo L. Wounds in advanced illness: a prevalence and incidence study based on a prospective case series. Int Wound J. 2008;5(2):305-14.
17. Brienza D, Kelsey S, Karg P, Allegretti A, Olson M, Schmeler M, et al. A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions. J Am Geriatr Soc. 2010;58(12):2308-14.
18. Gorecki C, Closs SJ, Nixon J, Briggs M. Patient-reported pressure ulcer pain: a mixed-methods systematic review. J Pain Symptom Manage. 2011;42(3):443-59.
19. Hopkins A, Dealey C, Bale S, Defloor T, Worboys F. Patient stories of living with a pressure ulcer. J Adv Nurs. 2006;56(4):345-53.
20. Allman RM, Goode PS, Burst N, Bartolucci AA, Thomas DR. Pressure ulcers, hospital complications, and disease severity: impact on hospital costs and length of stay. Adv Wound Care. 1999;12(1):22-30.
21. Graves N, Birrell F, Whitby M. Effect of pressure ulcers on length of hospital stay. Infect Control Hosp Epidemiol. 2005;26(3):293-7.
22. Theisen S, Drabik A, Stock S. Pressure ulcers in older hospitalised patients and its impact on length of stay: a retrospective observational study. J Clin Nurs. 2012;21(3-4):380-7.
23. Bo M, Massaia M, Raspo S, Bosco F, Cena P, Molaschi M, et al. Predictive factors of in-hospital mortality in older patients admitted to a medical intensive care unit. J Am Geriatr Soc. 2003;51(4):529-33.
24. Redelings MD, Lee NE, Sorvillo F. Pressure ulcers: more lethal than we thought? Adv Skin Wound Care. 2005;18(7):367-72.
25. Severens JL, Habraken JM, Duivenvoorden S, Frederiks CM. The cost of illness of pressure ulcers in The Netherlands. Adv Skin Wound Care. 2002;15(2):72-7.
26. Bennett RG, Baran PJ, DeVone LV, Bacetti H, Kristo B, Tayback M, et al. Low airloss hydrotherapy versus standard care for incontinent hospitalized patients. J Am Geriatr Soc. 1998;46(5):569-76.
27. Gray M, Beeckman D, Bliss DZ, Fader M, Logan S, Junkin J, et al. Incontinence-associated dermatitis: a comprehensive review and update. J Wound Ostomy Continence Nurs. 2012;39(1):61-74.
28. National Institute for Health Clinical Excellence. Inherited Clinical Guideline B. Pressure Ulcer Risk Assessment and Prevention. London: National Institute for Clinical Excellence; 2001.
29. National Institute for Health Clinical Excellence. Pressure ulcer prevention: pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. London: National Institute for Clinical Excellence; 2003.
30. National Institute for Health Clinical Excellence. Pressure ulcers: The management of pressure ulcers in primary and secondary care. London: National Institute for Clinical Excellence; 2005.
31. National Institute for Health Clinical Excellence. The guidelines manual. London: National Institute for Health and Clinical Excellence; 2009. Available from: http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp

32. NCGC. Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing, Clinical Guideline, Methods, evidence and recommendations. London: Royal College of Physicians; 2009.
33. Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 2011;64(4):401-6.
34. National Institute for Health Clinical Excellence. Guidelines on pressure ulcer risk management and prevention - guideline. London: National Institute for Clinical Excellence; 2001.
35. National Institute for Health Clinical Excellence. Pressure relieving devices: the use of pressure relieving devices for the prevention of pressure ulcers in primary and secondary care. London: National Institute for Clinical Excellence; 2003.
36. National Institute for Health Clinical Excellence. The prevention and treatment of pressure ulcers. London: National Institute for Clinical Excellence; 2005.
37. Papanikolaou P, Lyne P, Anthony D. Risk assessment scales for pressure ulcers: a methodological review. Int J Nurs Stud. 2007;44(2):285-96.
38. Nixon J, McGough A. Principles of patient assessment: screening for pressure ulcers and potential risk. In: Morison M, editor. The prevention and treatment of pressure ulcers. London: Mosby; 2001. p. 55-74.
39. Pancorbo-Hidalgo PL, Garcia-Fernandez FP, Lopez-Medina IM, Alvarez-Nieto C. Risk assessment scales for pressure ulcer prevention: a systematic review. J Adv Nurs. 2006;54(1):94-110.
40. Moore ZEH, Cowman S. Risk assessment tools for the prevention of pressure ulcers. Cochrane Database Syst Rev. 2008(3).
41. Cullum N, Deeks JJ, Fletcher AW, Sheldon TA, Song F. Preventing and treating pressure sores. BMJ Group. 1995;4(4):289.
42. McGough A. A systematic review of the effectiveness of risk assessment tools in the prevention and treatment of pressure sores. York: University of York; 1999.
43. Moore ZE, Cowman S. Repositioning for the prevention of pressure ulcers. Wound Repair Regen. 2010;18(2):A14.
44. Saleh M, Anthony D, Parboteeah S. The impact of pressure ulcer risk assessment on patient outcomes among hospitalised patients. J Clin Nurs. 2009;18(13):1923-9.
45. Webster J, Coleman K, Mudge A, Marquart L, Gardner G, Stankiewicz M, et al. Pressure ulcers: effectiveness of risk-assessment tools. A randomised controlled trial (the ULCER trial). BMJ Quality and Safety. 2011;20(4):297-306.
46. Bergquist S, Frantz R. Braden scale: Validity in community-based older adults receiving home health care. Elsevier. 2001;14(1):36-43.
47. Fuentelsaz GC. Validación de la escala EMINA: un instrumento de valoración del riesgo de desarrollar úlceras por presión en pacientes hospitalizados. Enerferia Clinica. 2001;11(3):97-103.
48. Boyle M, Green M. 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. 2001;14(1):24-30.
49. Gunningberg L, Lindholm C, Carlsson M, Sjödén PO. Implementation of risk assessment and classification of pressure ulcers as quality indicators for patients with hip fractures. Wiley Online Library. 1999;8(4):396-406.
50. Hagisawa S, Barbenel J. The limits of pressure sore prevention. Royal Society of Medicine Press. 1999;92(11):576-8.
51. Andersen KE, Jensen O, Kvorning SA, Bach E. Prevention of pressure sores by identifying patients at risk. Bmj. 1982;284(6326):1370-1.
52. Anthony D, Reynolds T, Russell L. A regression analysis of the Waterlow score in pressure ulcer risk assessment. England. 2003;17(2):216-23.
53. Barnes D, Payton RG. Clinical application of the Braden Scale in the acute-care setting. Dermatol Nurs. 1993;5(5):386-8.

54. Bergstrom N, Demuth PJ, Braden BJ. A clinical trial of the Braden Scale for Predicting Pressure Sore Risk. The Nursing Clinics of North America. 1987;22(2):417-29.
55. Bergstrom N, Braden BJ, Laguzza A, Holman V. The Braden Scale for Predicting Pressure Sore Risk. Nurs Res. 1987;36(4):205-10.
56. Bergstrom N, Braden B, Kemp M, Champagne M, Ruby E. Predicting pressure ulcer risk: a multisite study of the predictive validity of the Braden Scale. Nurs Res. 1998;47(5):261-9.
57. Braden BJ, Bergstrom N. Predictive validity of the Braden Scale for pressure sore risk in a nursing home population. Wiley Online Library. 1994;17(6):459-70.
58. Capobianco ML, McDonald DD. Factors affecting the predictive validity of the Braden Scale. Adv Wound Care. 1996;9(6):32-6.
59. Chan WS, Pang SM, Kwong EW. Assessing predictive validity of the modified Braden scale for prediction of pressure ulcer risk of orthopaedic patients in an acute care setting. England. 2009;18(11):1565-73.
60. Compton F, Hoffmann F, Hortig T, Strauss M, Frey J, Zidek W, et al. Pressure ulcer predictors in ICU patients: nursing skin assessment versus objective parameters. Erratum appears in J Wound Care. 2008 Nov;17(11):493. England. 2008;17(10):417-24.
61. Curley MAQ, Razmus IS, Roberts KE, Wypij D. Predicting pressure ulcer risk in pediatric patients: the Braden Q Scale. Nurs Res. 2003;52(1):22-33.
62. de Souza DM, Santos VL, Iri HK, Sadasue Oguri MY. Predictive validity of the Braden Scale for Pressure Ulcer Risk in elderly residents of long-term care facilities. United States. 2010;31(2):95-104.
63. Edwards M. The levels of reliability and validity of the Waterlow pressure sore risk calculator. J Wound Care. 1995;4(8):373-8.
64. Feuchtinger J, Halfens R, Dassen T. Pressure ulcer risk assessment immediately after cardiac surgery--does it make a difference? A comparison of three pressure ulcer risk assessment instruments within a cardiac surgery population. England. 2007;12(1):42-9.
65. Goodridge DM, Sloan JA, LeDoyen YM, McKenzie JA, Knight WE, Gayari M. Risk-assessment scores, prevention strategies, and the incidence of pressure ulcers among the elderly in four Canadian health-care facilities. The Canadian Journal of Nursing. 1998;30(2):23-34.
66. Halfens RJG, Van Achterberg T, Bal RM. Validity and reliability of the Braden scale and the influence of other risk factors: a multi-centre prospective study. Elsevier. 2000;37(4):313-9.
67. Hatanaka N, Yamamoto Y, Ichihara K, Mastuo S, Nakamura Y, Watanabe M, et al. A new predictive indicator for development of pressure ulcers in bedridden patients based on common laboratory tests results. England. 2008;61(4):514-8.
68. Jalali R, Rezaie M. Predicting pressure ulcer risk: comparing the predictive validity of 4 scales. United States. 2005;18(2):92-7.
69. Kim E, Lee S, Lee E, Eom M. Comparison of the predictive validity among pressure ulcer risk assessment scales for surgical ICU patients. Aust J Adv Nurs. 2009;26(4):87-94.
70. Kwong E, Pang S, Wong T, Ho J, Shao-ling X, Li-jun T. Predicting pressure ulcer risk with the modified Braden, Braden, and Norton scales in acute care hospitals in Mainland China. Appl Nurs Res. 2005;18(2):122-8.
71. Langemo DK, Olson B, Hunter S, Hanson D, Burd C, Cathcart-Silberberg T. Incidence and prediction of pressure ulcers in five patient care settings. Decubitus. 1991;4(3):25-36.
72. Lewicki LJ, Mion LC, Secic M. Sensitivity and specificity of the Braden Scale in the cardiac surgical population. Journal of Wound Ostomy & Continence Nursing. 2000;27(1):36-41.
73. Lincoln R, Roberts R, Maddox A, Levine S, Patterson C. Use of the norton pressure sore risk assessment scoring system with elderly patients in acute care. J Enterostomal Ther. 1986;13:132-8.
74. Lindgren M, Unosson M, Krantz AM, Ek AC. A risk assessment scale for the prediction of pressure sore development: reliability and validity. Wiley Online Library. 2002;38(2):190-9.
75. Lothian P. Identifying and protecting patients who may get pressure sores. Nurs Stand. 1989;18(4):26-9.

76. Lyder CH, Yu C, Emerling J, Mangat R, Stevenson D, Empleo-Frazier O, et al. The Braden Scale for pressure ulcer risk: evaluating the predictive validity in Black and Latino/Hispanic elders. Elsevier. 1999;12(2):60-8.
77. Ongoma C, Schmollgruber S, Langley GC. Predictive validity of pressure risk assessment scales in a private sector trauma intensive care unit. Southern African Journal of Critical Care. 2005;21(2):78-86.
78. Page KN, Barker AL, Kamar J. Development and validation of a pressure ulcer risk assessment tool for acute hospital patients. United States. 2011;19(1):31-7.
79. Pang SM, Wong TK. Predicting pressure sore risk with the Norton, Braden, and Waterlow scales in a Hong Kong rehabilitation hospital. Nurs Res. 1998;47(3):147-53.
80. Perneger TV, Rae AC, Gaspoz JM, Borst F, Vitek O, Heliot C. Screening for pressure ulcer risk in an acute care hospital: development of a brief bedside scale. J Clin Epidemiol. 2002;55(5):498-504.
81. Ramundo JM. Reliability and validity of the Braden Scale in the home care setting. Journal of Wound Ostomy & Continence Nursing. 1995;22(3):128-34.
82. Salvadalena GD, Snyder ML, Brogdon KE. Clinical trial of the Braden Scale on an acute care medical unit. Journal of Enterostomal Therapy Nursing. 1992;19(5):160-5.
83. Schoonhoven L, Haalboom JRE, Bousema MT, Algra A, Grobbee DE, Grypdonck MH, et al. Prospective cohort study of routine use of risk assessment scales for prediction of pressure ulcers. British Medical Journal Publishing Group. 2002;325(7368):797.
84. Seongsook RNJ, Ihnsook RNJ, Younghee RNL. Validity of pressure ulcer risk assessment scales; Cubbin and Jackson, Braden, and Douglas scale. Int J Nurs Stud. 2004;41(2):199-204.
85. Serpa LF, de Gouveia Santos VL, Gomboski G, Rosado SM. Predictive validity of Waterlow Scale for pressure ulcer development risk in hospitalized patients. United States. 2009;36(6):640-6.
86. Smith I. Waterlow/Norton scoring system: a ward view. CARE-Science and Practice. 1989;7(4):93-5.
87. Stotts NA. Predicting pressure ulcer development in surgical patients. Heart & Lung. 1988;17(6 Pt 1):641-7.
88. Suriadi, Sanada H, Sugama J, Thigpen B, Kitagawa A, Kinosita S, et al. A new instrument for predicting pressure ulcer risk in an intensive care unit. J Tissue Viability. 2006;16(3):21-6.
89. Suriadi, Sanada H, Sugama J, Thigpen B, Subuh M. Development of a new risk assessment scale for predicting pressure ulcers in an intensive care unit. England. 2008;13(1):34-43.
90. Towey AP, Erland SM. Validity and reliability of an assessment tool for pressure ulcer risk. Decubitus. 1988;1(2):40-8.
91. VandenBosch T, Montoye C, Satwicz M, Durkee-Leonard K, Boylan-Lewis B. Predictive validity of the Braden Scale and nurse perception in identifying pressure ulcer risk. Elsevier. 1996;9(2):80-6.
92. Wai-Han C, Kit-Wai C, French P, Yim-Sheung L, Lai-Kwan T. Which pressure sore risk calculator? A study of the effectiveness of the Norton scale in Hong Kong. Elsevier. 1997;34(2):165-9.
93. Weststrate JT, Hop WC, Aalbers AG, Vreeling AW, Bruining HA. The clinical relevance of the Waterlow pressure sore risk scale in the ICU. Intensive Care Med. 1998;24(8):815-20.
94. Serpa LF, Santos VL, Campanili TC, Queiroz M. Predictive validity of the Braden scale for pressure ulcer risk in critical care patients. Brazil. 2011;19(1):50-7.
95. Vanderwee K, Grypdonck M, Defloor T. Non-blanchable erythema as an indicator for the need for pressure ulcer prevention: a randomized-controlled trial. J Clin Nurs. 2007;16(2):325-35.
96. Konishi C, Sugama J, Sanada H, Okuwa M, Konya C, Nishizawa T, et al. A prospective study of blanchable erythema among university hospital patients. Int Wound J. 2008;5:470-5.
97. Newman P, Davis NH. Thermography as a predictor of sacral pressure sores. Age Ageing. 1981;10:14-8.

98. Nixon J, Cranny G, Bond S. Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: a cohort study. Int J Nurs Stud. 2007;44:655-63.
99. Duimel-Peeters IG, Halfens JG, Ambergen AW, Houwing RH, Berger PF, Snoeckx LH. The effectiveness of massage with and without dimethyl sulfoxide in preventing pressure ulcers: a randomized, double-blind cross-over trial in patients prone to pressure ulcers. Int J Nurs Stud. 2007;44(8):1285-95.
100. Defloor T, De BD, Grypdonck MH. The effect of various combinations of turning and pressure reducing devices on the incidence of pressure ulcers. Int J Nurs Stud. 2005;42(1):37-46.
101. Moore Z, Cowman S, Conroy RM. A randomised controlled clinical trial of repositioning, using the 30degrees tilt, for the prevention of pressure ulcers. J Clin Nurs. 2011;20(17-18):2633-44.
102. Fineman LD, LaBrecque MA, Shih MC, Curley MAQ. Prone positioning can be safely performed in critically ill infants and children. Pediatr Crit Care Med. 2006;7(5):413-22.
103. Smith AM, Malone JA. Preventing pressure ulcers in institutionalized elders: assessing the effects of small, unscheduled shifts in body position. Decubitus. 1990;3(4):20-4.
104. van Nieuwenhoven CA, Vandenbroucke-Grauls C, van Tiel FH, Joore HC, van Schijndel RJ, van d T, et al. Feasibility and effects of the semirecumbent position to prevent ventilator-associated pneumonia: a randomized study. Crit Care Med. 2006;34(2):396-402.
105. Gentilello L, Thompson DA, Tonnesen AS, Hernandez D, Kapadia AS, Allen SJ, et al. Effect of a rotating bed on the incidence of pulmonary complications in critically ill patients. Crit Care Med. 1988;16(8):783-6.
106. Summer WR, Curry P, Haponikm EF, Nelson S, Elston R. Continuous mechanical turning of intensive care unit patients shortens length of stay in some diagnostic-related groups. J Crit Care. 1989;4:45-53.
107. Young T. The 30 degree tilt position vs the 90 degree lateral and supine positions in reducing the incidence of non-blanching erythema in a hospital inpatient population: a randomised controlled trial. J Tissue Viability. 2004;14(3):88, 90, 2-88, 90, 6.
108. McInnes E, Jammali-Blasi A, Bell-Syer Sally EM, Dumville JC, Cullum N. Support surfaces for pressure ulcer prevention. Cochrane Database Syst Rev. 2011;Issue 4:CD001735.
109. McInnes E, Jammali-Blasi A, Bell-Syer S, Dumville J, Cullum N. Preventing pressure ulcers-Are pressure-redistributing support surfaces effective? A Cochrane systematic review and meta-analysis. Int J Nurs Stud. 2012;49(3):345-59.
110. Cadue JF, Karolewicz S, Tardy C, Barrault C, Robert R, Pourrat O. Prevention of heel pressure sores with a foam body-support device. A randomized controlled trial in a medical intensive care unit. Presse Med. 2008;37(1 Pt 1):30-6.
111. Ewing MR, Garrow C, Presley TA, Ashley C, Kisella NM. Further experiences in the use of sheep skins as an aid in nursing. Aust Nurses J. 1964:215-9.
112. Gilcreast DM, Warren JB, Yoder LH, Clark JJ, Wilson JA, Mays MZ. Research comparing three heel ulcer-prevention devices. Journal of Wound Ostomy and Continence Nursing. 2005;32(2):112-20.
113. Tymec AC, Pieper B, Vollman K. A comparison of two pressure-relieving devices on the prevention of heel pressure ulcers. Adv Wound Care. 1997;10(1):39-44.
114. Economides NG, Skoutakis VA, Carter CA, Smith VH. Evaluation of the effectiveness of two support surfaces following myocutaneous flap surgery. Adv Wound Care. 1995;8(1):49-53.
115. Demarre L, Beeckman D, Vanderwee K, Defloor T, Grypdonck M, Verhaeghe S. Multi-stage versus single-stage inflation and deflation cycle for alternating low pressure air mattresses to prevent pressure ulcers in hospitalised patients: A randomised-controlled clinical trial. Int J Nurs Stud. 2012;49(4):416-26.
116. Grisell M, Place HM. Face tissue pressure in prone positioning: a comparison of three face pillows while in the prone position for spinal surgery. Spine. 2008;33(26):2938-41.
117. Malbrain M, Hendriks B, Wijnands P, Denie D, Jans A, Vanpellicom J, et al. A pilot randomised controlled trial comparing reactive air and

active alternating pressure mattresses in the prevention and treatment of pressure ulcers among medical ICU patients. J Tissue Viability. 2010;19(1):7-15.

118. van Leen M, Hovius S, Neyens J, Halfens R, Schols J. Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home. J Tissue Viability. 2011;20(1):30-4.
119. Aronovitch SA, Wilber M, Slezak S, Martin T, Utter D. A comparative study of an alternating air mattress for the prevention of pressure ulcers in surgical patients. Ostomy Wound Manage. 1999;45(3):34-.
120. Cavicchioli A, Carella G. Clinical effectiveness of a low-tech versus high-tech pressure-redistributing mattress. J Wound Care. 2007;16(7):285-9.
121. Cobb GA, Yoder LH, Warren JB. Pressure ulcers: patient outcomes on a KinAir bed or EHOB waffle mattress. Bethesda, Maryland, USA: TriService Nursing Research Program (TSNRP); 1997. Available from: http://www.ntis.gov/search/product.aspx?ABBR=PB2002107655
122. Collier ME. Pressure-reducing mattresses. J Wound Care. 1996;5(5):207-11.
123. Conine TA, Daechsel D, Lau MS. The role of alternating air and Silicore overlays in preventing decubitus ulcers. Int J Rehabil Res. 1990;13(1):57-65.
124. Conine TA, Daechsel D, Hershler C. Pressure sore prophylaxis in elderly patients using slab foam or customised contoured foam wheelchair cushions. Occupational Therapy Journal of Research. 1993;13(2):101-16.
125. Conine TA, Hershler C, Daechsel D, Peel C, Pearson A. Pressure ulcer prophylaxis in elderly patients using polyurethane foam or Jay wheelchair cushions. Int J Rehabil Res. 1994;17(2):123-37.
126. Cooper PJ, Gray DG, Mollison J. A randomised controlled trial of two pressure-reducing surfaces. J Wound Care. 1998;7(8):374-6.
127. Daechsel D, Conine TA. Special mattresses: effectiveness in preventing decubitus ulcers in chronic neurologic patients. Arch Phys Med Rehabil. 1985;66(4):246-8.
128. Exton-Smith AN, Overstall PW, Wedgwood J, Wallace G. Use of the 'air wave system' to prevent pressure sores in hospital. Lancet. 1982;1(8284):1288-90.
129. Feuchtinger J, de BR, Dassen T, Halfens R. A 4-cm thermoactive viscoelastic foam pad on the operating room table to prevent pressure ulcer during cardiac surgery. J Clin Nurs. 2006;15(2):162-7.
130. Geyer MJ, Brienza DM, Karg P, Trefler E, Kelsey S. A randomized control trial to evaluate pressure-reducing seat cushions for elderly wheelchair users. Adv Skin Wound Care. 2001;14(3):120-9.
131. Goldstone LA, Norris M, O'Reilly M, White J. A clinical trial of a bead bed system for the prevention of pressure sores in elderly orthopaedic patients. J Adv Nurs. 1982;7(6):545-8.
132. Gray D, Smith M. A randomized controlled trial of two pressure-reducing foam mattresses. European Wound Management Association Conference; Harrogate, UK. 1998.
133. Gray DG, Campbell M. A randomized clinical trial of two types of foam mattresses. J Tissue Viability. 1994;4(4):128-32.
134. Gunningberg L, Lindholm C, Carlsson M, Sjoden PO. Effect of visco-elastic foam mattresses on the development of pressure ulcers in patients with hip fractures. J Wound Care. 2000;9(10):455-60.
135. Hampton S. Evaluation of the new Cairwave Therapy System in one hospital trust. Br J Nurs. 1997;6(3):167-70.
136. Hofman A, Geelkerken RH, Wille J, Hamming JJ, Hermans J, Breslau PJ. Pressure sores and pressure-decreasing mattresses: controlled clinical trial. Lancet. 1994;343(8897):568-71.
137. Inman KJ, Sibbald WJ, Rutledge FS. Clinical utility and cost-effectiveness of an air suspension bed in the prevention of pressure ulcers. JAMA. 1993;269:1139-43.
138. Jolley DJ, Wright R, McGowan S, Hickey MB, Campbell DA, Sinclair RD, et al. Preventing pressure ulcers with the Australian Medical Sheepskin: an open-label randomised controlled trial. Med J Aust. 2004;180(7):324-7.

139. Kemp MG, Kopanke D, Tordecilla L, Fogg L, Shott S, Matthiesen V, et al. The role of support surfaces and patient attributes in preventing pressure ulcers in elderly patients. Res Nurs Health. 1993;16(2):89-96.
140. Keogh A, Dealey C. Profiling beds versus standard hospital beds: effects on pressure ulcer incidence outcomes. J Wound Care. 2001;10(2):15-9.
141. Laurent S. Effectiveness of pressure decreasing mattresses in cardiovascular surgery patients: a controlled clinical trial. 3rd European Conference for Nurse Managers; Brussels, Belgium. 1998.
142. Lazzara DJ, Buschmann MT. Prevention of pressure ulcers in elderly nursing home residents: are special support surfaces the answer? Decubitus. 1991;4(4):42-4, 6, 8.
143. Lim R, Sirett R, Conine TA, Daechsel D. Clinical trial of foam cushions in the prevention of decubitis ulcers in elderly patients. J Rehabil Res Dev. 1988;25(2):19-26.
144. McGowan S, Montgomery K, Jolley D, Wright R. The role of sheepskins in preventing pressure ulcers in elderly orthopaedic patients. Primary Intention. 2000;8(4):1-8.
145. Mistiaen P, Achterberg W, Ament A, Halfens R, Huizinga J, Montgomery K, et al. The effectiveness of the Australian Medical Sheepskin for the prevention of pressure ulcers in somatic nursing home patients: A prospective multicenter randomized-controlled trial (ISRCTN17553857). Wound Repair Regen. 2010;18(6):572-9.
146. Nixon J, McElvenny D, Mason S, Brown J, Bond S. A sequential randomised controlled trial comparing a dry visco-elastic polymer pad and standard operating table mattress in the prevention of post-operative pressure sores. Int J Nurs Stud. 1998;35(4):193-203.
147. Nixon J, Cranny G, Iglesias C, Nelson EA, Hawkins K, Phillips A, et al. Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial. BMJ. 2006;332(7555):1413.
148. Price P, Bale S, Newcombe R, Harding K. Challenging the pressure sore paradigm. J Wound Care. 1999;8(4):187-90.
149. Russell JA, Lichtenstein SL. Randomized controlled trial to determine the safety and efficacy of a multi-cell pulsating dynamic mattress system in the prevention of pressure ulcers in patients undergoing cardiovascular surgery. Ostomy Wound Manage. 2000;46(2):46-5.
150. Russell L, Reynolds TM, Carr J, Evans A, Holmes M. Randomised controlled trial of two pressure-relieving systems. J Wound Care. 2000;9(2):52-5.
151. Sanada H, Sugama J, Matsui Y, Konya C, Kitagawa A, Okuwa M, et al. Randomised controlled trial to evaluate a new double-layer air-cell overlay for elderly patients requiring head elevation. J Tissue Viability. 2003;13(3):112-4, 6, 8.
152. Santy JE, Butler MK, Whyman JD. A comparison study of 6 types of hospital mattress to determine which most effectively reduces the incidence of pressure sores in elderly patients with hip fractures in a District General Hospital. Report to Northern & Yorkshire Regional Health Authority. 1994.
153. Sideranko S, Quinn A, Burns K, Froman RD. Effects of position and mattress overlay on sacral and heel pressures in a clinical population. Res Nurs Health. 1992;15(4):245-51.
154. Stapleton M. Preventing pressure sores--an evaluation of three products. Geriatr Nur (Lond). 1986;6(2):23-5.
155. Takala J, Varmavuo S, Soppi E. Prevention of pressure sores in acute respiratory failure: a randomised controlled trial. Clin Intensive Care. 1996;7(5):228-35.
156. Taylor L. Evaluating the Pegasus Trinova: a data hierarchy approach. Br J Nurs. 1999;8(12):771-8.
157. Theaker C, Kuper M, Soni N. Pressure ulcer prevention in intensive care - a randomised control trial of two pressure-relieving devices. Anaesthesia. 2005;60(4):395-9.
158. Vyhlidal SK, Moxness D, Bosak KS, Van Meter FG, Bergstrom N. Mattress replacement or foam overlay? A prospective study on the incidence of pressure ulcers. Appl Nurs Res. 1997;10(3):111-20.

159. Whitney JD, Fellows BJ, Larson E. Do mattresses make a difference? J Gerontol Nurs. 1984;10(9):20-5.
160. Gebhardt KS, Bliss MR, Winwright PL, Thomas J. Pressure-relieving supports in an ICU. J Wound Care. 1996;5(3):116-21.
161. Vanderwee K, Grypdonck MH, Defloor T. Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers. Age Ageing. 2005;34(3):261-7.
162. Russell LJ, Reynolds TM, Park C, Rithalia S, Gonsalkorale M, Birch J, et al. Randomized clinical trial comparing 2 support surfaces: results of the Prevention of Pressure Ulcers Study. Adv Skin Wound Care. 2003;16(6):317-27.
163. Schultz A, Bien M, Dumond K, Brown K, Myers A. Etiology and incidence of pressure ulcers in surgical patients. Aorn J. 1999;70(3):434, 7-40, 43-49.
164. Donnelly J, Winder J, Kernohan WG, Stevenson M. An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture. J Wound Care. 2011;20(7):309-8.
165. Gray DG, Smith M. Comparison of a new foam mattress with the standard hospital mattress. J Wound Care. 2000;9(1):29-31.
166. Jesurum J, Joseph K, Davis JM, Suki R. Balloons, beds, and breakdown. Effects of low-air loss therapy on the development of pressure ulcers in cardiovascular surgical patients with intra-aortic balloon pump support. Crit Care Nurs Clin North Am. 1996;8(4):423-40.
167. Torra IBJ, Rueda LJ, Camanes G, Herrero NE, Blanco BJ, Balleste TJ, et al. Preventing pressure ulcers on the heel: a Canadian cost study. Dermatol Nurs. 2009;21(5):268-72.
168. Langer G, Schloemer G, Knerr A, Kuss O, Behrens J. Nutritional interventions for preventing and treating pressure ulcers. Cochrane database of systematic reviews (Online). 2003;Issue 4:CD003216.
169. Banks M, Bauer J, Graves N, Ash S. Malnutrition and pressure ulcer risk in adults in Australian health care facilities. Nutrition. 2010;26(9):896-901.
170. Shahin ES, Meijers JM, Schols JM, Tannen A, Halfens RJG, Dassen T. The relationship between malnutrition parameters and pressure ulcers in hospitals and nursing homes. Nutrition. 2010;26(9):886-9.
171. Dennis MS, Lewis SC, Warlow C. Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicentre randomised controlled trial. Lancet. 2005;365(755):763.
172. Craig LD, Nicholson S, Silverstone FA, Kennedy RD. Use of a reduced-carbohydrate,modified-fat enteral formula for improving metabolic control and clinical outcomes in long-term care residents with type 2 diabetes: results of a pilot trial. Nutrition. 1998;14(6):529-34.
173. Theilla M, Singer P, Cohen J, Dekeyser F. A diet enriched in eicosapentanoic acid, gamma-linolenic acid and antioxidants in the prevention of new pressure ulcer formation in critically ill patients with acute lung injury: A randomized, prospective, controlled study. Clin Nutr. 2007;26(6):752-7.
174. Olofsson B, Stenvall M, Lundstrom M, Svensson O, Gustafson Y. Malnutrition in hip fracture patients: An intervention study. J Clin Nurs. 2007;16(11):2027-38.
175. Bourdel-Marchasson I, Barateau M, Rondeau V, Dequae-Merchadou L, Salles-Montaudon N, Emeriau JP, et al. A multi-center trial of the effects of oral nutritional supplementation in critically ill older inpatients. GAGE Group. Groupe Aquitain Geriatrique d'Evaluation. Nutrition. 2000;16(1):1-5.
176. Delmi M, Rapin CH, Bengoa JM, Delmas PD, Vasey H, Bonjour JP. Dietary supplementation in elderly patients with fractured neck of the femur. Lancet. 1990;335(8696):1013-6.
177. Houwing RH, Rozendaal M, Wouters-Wesseling W, Beulens JWJ, Buskens E, Haalboom JR. A randomised, double-blind assessment of the effect of nutritional supplementation on the prevention of pressure ulcers in hip-fracture patients. Clin Nutr. 2003;22(4):401-5.
178. Hartgrink HH, Wille J, Konig P, Hermans J, Breslau PJ. Pressure sores and tube feeding in patients with a fracture of the hip: a randomized clinical trial. Clin Nutr. 1998;17(6):287-92.

179. McInnes E, Bell-Syer SE, Dumville JC, Legood R, Cullum NA. Support surfaces for pressure ulcer prevention. Cochrane Database Syst Rev. 2008;Issue 4:CD001735.
180. Reddy M, Gill SS, Rochon PA. Preventing pressure ulcers: a systematic review. JAMA. 2006;296(8):974-84.
181. Defloor T, Grypdonck MF. Validation of pressure ulcer risk assessment scales: a critique. J Adv Nurs. 2004;48(6):613-21.
182. Jull A, Griffiths P. Is pressure sore prevention a sensitive indicator of the quality of nursing care? A cautionary note. Int J Nurs Stud. 2010;47(5):531-3.
183. Altman DG, Bland JM. Absence of evidence is not evidence of absence. Aust Vet J. 1996;74(4):311.
184. Tannen A, Dietz E, Dassen T, Halfens R. Explaining the national differences in pressure ulcer prevalence between the Netherlands and Germany--adjusted for personal risk factors and institutional quality indicators. J Eval Clin Pract. 2009;15(1):85-90.
185. Van den Heede K, Sermeus W, Diya L, Lesaffre E, Vleugels A. Adverse outcomes in Belgian acute hospitals: retrospective analysis of the national hospital discharge dataset. Int J Qual Health Care. 2006;18(3):211-9.
186. McGlynn EA, Cassel CK, Leatherman ST, DeCristofaro A, Smits HL. Establishing national goals for quality improvement. Med Care. 2003;41(1 Suppl):I16-I29.
187. Niederhauser A, VanDeusen LC, Parker V, Ayello EA, Zulkowski K, Berlowitz D. Comprehensive programs for preventing pressure ulcers: a review of the literature. Adv Skin Wound Care. 2012;25(4):167-88.
188. Soban LM, Hempel S, Munjas BA, Miles J, Rubenstein LV. Preventing pressure ulcers in hospitals: A systematic review of nurse-focused quality improvement interventions. Jt Comm J Qual Patient Saf. 2011;37(6):245-52.
189. van Gaal BG, Schoonhoven L, Mintjes JA, Borm GF, Hulscher ME, Defloor T, et al. Fewer adverse events as a result of the SAFE or SORRY? programme in hospitals and nursing homes. part i: primary outcome of a cluster randomised trial. Int J Nurs Stud. 2011;48(9):1040-8.
190. AHRQ. Guide to patient safety indicators. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ). 2007.
191. Van den Heede K, Clarke SP, Sermeus W, Vleugels A, Aiken LH. International experts' perspectives on the state of the nurse staffing and patient outcomes literature. J Nurs Scholarsh. 2007;39(4):290-7.
192. Registered Nurses' Association of Ontario. Risk Assessment & Prevention of Pressure Ulcers. Ontario: RNAO; 2005.