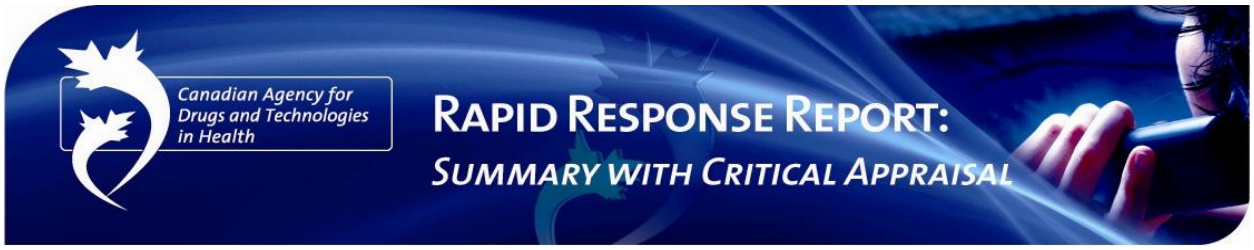

TITLE: Emerging Technologies for the Prevention of Pressure Ulcers in Acute Care Settings: A Review of Clinical and Cost-Effectiveness and Guidelines

DATE: 12 September 2016

CONTEXT AND POLICY ISSUES

Pressure ulcers, commonly referred to as decubitus ulcers or informally as bed sores, are localized injuries to the skin and underlying tissue caused by sustained pressure or rubbing at the weight-bearing, bony parts of the body of immobilized individuals, such as the hips, elbows and heels.[1,2] Pressure sores can develop as a result of pressure alone, or pressure combined with forces of friction and shear, and they can progress across different levels of severity based on depth of damage from mild tissue damage to necrosis.[2]

Skin and tissue damage occurs most frequently among individuals who cannot reposition themselves, among the elderly, those who are acutely ill or malnourished, or among persons with neurological deficits, such as those with spinal cord injury.[1,2] The elderly population is particularly at risk given that the risk of skin tears grows with increasing age as the skin becomes less dense and less vascular.[1,2] The prevalence of pressure ulcers in Canada ranges between 25.1% in acute care hospitals and 29.9% in long-term care facilities.[3] Pressure ulcers can have a negative impact on the quality of life of the affected individuals, and pose a significant financial burden on the healthcare system.[4,5]

A number of interventions are currently being used to prevent the development of pressure ulcers in patients at risk of skin ulceration. Pressure ulcer prevention is achieved most commonly by reducing or redistributing pressure at anatomical sites most susceptible for skin and tissue damage;[1] preventive strategies may include the use of special support surfaces (including special beds, mattresses and overlays) designed to redistribute pressure, heel supports, patient repositioning techniques, wheelchair cushions, nutritional supplementation, among others.[1-3] Despite these established preventive strategies, new and emerging interventions may also be available for efficient pressure ulcer prevention. The purpose of this report is to examine the clinical effectiveness, cost-effectiveness, and evidence-based guidelines regarding the preventive use of emerging technologies in adult patients at risk of developing pressure ulcers in acute care settings.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

2. What is the clinical effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in the operating room?

3. What is the cost-effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

4. What are the evidence-based guidelines regarding the use of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

KEY FINDINGS

One systematic review and one randomized controlled trial were identified regarding the clinical effectiveness of emerging interventions for the prevention of pressure ulcers in acute care settings. Findings of the systematic review which focused on pressure ulcer prevention using electrical stimulation of the muscles in persons with spinal cord injury were inconclusive; however, results of one randomized controlled trials revealed that prophylactic polyurethane film dressings may be effective in preventing pressures sores in individuals without existing skin or tissue damage.

One evidence-based guideline was identified relating to emerging technologies for the prevention of pressure ulcers in acute care settings; recommended practices include microclimate manipulation, prophylactic dressings, silk-like fabrics designed to reduce shear and friction, and electrical stimulation of the muscles in individuals with spinal cord injury.

No published literature was identified relating to the cost-effectiveness of emerging interventions for the prevention of pressure ulcers in acute care setting or regarding the clinical effectiveness of emerging preventive strategies in the operating room.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including Medline, PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomised controlled trials, economic studies, and guidelines. The search was also limited to English language documents published between January 1, 2011 and August 12, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Q1, Q3, Q4: Adult patients in hospital at high risk of developing PrUs Q2: Adult patients undergoing surgery longer than 2.5 hours, bariatric patients
Intervention	Emerging interventions for the PrU prevention (alone or in combination with established PrU preventive techniques), including: - microclimate control techniques - prophylactic dressings (e.g., polyurethane) - silk or silk-like fabrics - electrical muscle stimulation (for spinal cord injuries) - decision support systems/tools included in EHRs, monitoring alarms and systems (e.g., Leaf patient monitoring system)
Comparator	• Established interventions for PrU prevention, including: - mattresses and beds - patient repositioning - nutrition - heel supports and other support surfaces - wheelchair cushions - silicone foam dressings - Australian sheepskin - pads for incontinence - general skin care and maintenance; • No comparator
Outcomes	Q1, Q2: Clinical effectiveness, safety, patient preferences, ease of use Q3: Cost-effectiveness Q4: Evidence-based guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, economic evaluations, evidence-based guidelines

EHR = electronic health record; PrU = pressure ulcer

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2011. Health technology assessment reports, systematic reviews (SRs) and meta-analyses were excluded if there was incomplete reporting of methods or if they were superseded by an updated review or a more recent rigorous review. Randomized controlled trials (RCTs) were excluded if they were described within a SR selected for inclusion in this report. Furthermore, health economic studies which reported only direct

costs that were not cost-effectiveness, cost-utility, cost-comparison, or cost-benefit analyses were excluded. Guidelines were excluded if they did not clearly indicate a formal literature search and an assessment of the quality of the evidence upon which the recommendations were based.

Critical Appraisal of Individual Studies

The quality of included studies was assessed based on their study design. SRs were critically appraised using the AMSTAR tool,[6] while the methodological quality of RCTs was assessed using the SIGN-50 checklist,[7] and evidence-based guidelines using the AGREE II instrument.[8] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study was performed and described narratively.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 525 citations were identified in the literature search. Following screening of titles and abstracts, 481 citations were excluded and 44 potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search. Of these potentially relevant articles, 42 publications were excluded for various reasons, while 3 publications met the inclusion criteria and were included in this report. Appendix 1 presents the PRISMA flow diagram of the study selection process, including reasons for exclusion of full-text publications.

Summary of Study Characteristics

A brief overview of the studies selected for inclusion is presented in Appendix 2.

Study Design

One SR[9] and one RCT[10] were identified regarding the clinical effectiveness of emerging technologies for the prevention of pressure ulcers in acute care settings. In addition, one evidence-based guideline met the inclusion criteria for this review.[11] This guideline was developed using a systematic review methodology and an evidence grading approach adapted from Sackett et al.;[12] a web-based consensus voting process was used to assign a strength to each recommendation.

Country of Origin

The SR and RCT were conducted in the United Kingdom[9] and Brazil[10], respectively.

The identified evidence-based guideline[11] was the product of collaboration between three international organizations, including the National Pressure Ulcer Advisory Panel (NPUAP) in the United States, the United Kingdom-based European Pressure Ulcer Advisory Panel (EPUAP), and the Pan Pacific Pressure Injury Alliance (PPPIA), consisting of the Australian Wound Management Society, New Zealand Wound Care Society, Hong Kong Enterostomal Therapists Association, and Wound Healing Society (Singapore).

Patient Population

The target population within the SR[9] comprised individuals with a spinal cord injury who were at risk of, or had an existing pressure ulcer; conversely, the patient population in the identified RCT comprised adult patients who were at risk of developing a pressure ulcer.[10]

The intended users of the evidence-based guideline[11] were described as qualified health professionals who are involved in the care of individuals who are at risk of developing pressure ulcers, or those with an existing pressure ulcer; the guideline may also be used as a resource among individuals who are at risk of, or have an existing pressure ulcer.

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Interventions and Comparators

The intervention of interest considered by the SR[9] was any type of intervention using electrical stimulation (ES), including functional ES (surface or implant), neuromuscular ES, or nerve root stimulation. Conversely, the identified RCT[10] assessed the prophylactic use of a polyurethane film dressing versus a hydrocolloid dressing, each applied bilaterally to the trochanteric and sacral regions of individuals at risk of developing pressure ulcers.

The included evidence-based guideline[11] assessed a range of new and emerging therapies for preventing pressure ulcers in adults, including microclimate manipulation, prophylactic dressings, fabrics designed to reduce shear and friction, and electrical stimulation of the muscles in individuals with spinal cord injury.

Outcomes

Clinical outcomes of the SR[9] comprised pressure ulcer (PrU) incidence, seating pressure, muscle thickness, skin blood flow, tissue oxygenation, and adverse events. Similarly, the included RCT[10] also assessed the incidence of PrUs, as well as reasons for prophylactic dressing changes, the mean number of dressing changes per body region, and the total number of dressing changes during the study period.

The included evidence-based guideline[11] focused on PrU risk assessment and strategies for PrU healing and prevention; in addition, consideration was given to special populations as well as facilitators and barriers to guideline implementation. The underlying evidence base for the therapeutic and preventive strategies considered in this guideline was rated using an evidence classification system adapted from Sackett et al.,[12] and a consensus voting process (GRADE) involving all stakeholders engaged in the development of the guideline was used to assign a strength of recommendations to each guideline statement; assigned strengths indicate the confidence that health professionals can have that a recommended practice will improve patient outcomes.

Summary of Critical Appraisal

A detailed overview of the strengths and limitations of each study selected for inclusion can be found in Appendix 3.

What is the clinical effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

Systematic Reviews and Meta-Analyses

The included SR[9] appeared well designed. Namely, the review authors developed a study protocol outlining research questions and study selection criteria before the conduct of the review, utilized a comprehensive literature search across several electronic databases, performed data extraction using two independent reviewers and assessed the scientific quality of included studies. In addition, the decision to not statistically combine results of individual studies was well justified, the scientific quality of included studies was considered in formulating the review conclusions, and the authors disclosed no potential conflicts of interest. Nevertheless, it was unclear whether article screening was performed using two independent reviewers, the likelihood of publication was not formally assessed, and sources of funding of studies included in the review were not described.

Randomized Controlled Trials

The included RCT[10] was generally well conducted. Specifically, the study authors addressed an appropriate and focused question, utilized a randomization procedure to assign study subjects to treatment groups and ensured that treatment groups were sufficiently similar at the start of the trial (i.e. main confounding variables were well balanced at baseline). Moreover, relevant outcomes were measured in a standard, valid and reliable manner, and study subjects were analyzed in the groups to which they were randomly assigned. Notwithstanding the application of best practices in the conduct of this trial, it remains unclear whether an adequate concealment method was used during the randomization procedure and whether the analysis adjusted for participants' potential differences in length of follow-up. In addition, it is unclear whether the specialist nurses involved in the application of the intervention were blinded to the treatment; however, blinding in a wound care unit may not be possible due to the highly visible nature of the interventions. Furthermore, estimation of the sample size was not described or justified, and there were statistically significant differences between groups at baseline in terms of ethnicity, psychomotor agitation, level of consciousness, and nutritional state; as a result, the generalizability of findings may be limited.

What is the clinical effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in the operating room?

No published literature was identified.

What is the cost-effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

No published literature was identified.

What are the evidence-based guidelines regarding the use of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

The scientific quality of the included evidence-based guideline was strengthened by a number of factors. These include a clear description of the guideline scope and purpose, involvement of appropriate stakeholders and consideration for the views and preferences of the target population, as well as the use of rigorous methods in the guideline development process,

including a systematic search for identifying published evidence to support recommendations, use of an appropriate evidence-grading approach, and consideration for health benefits, adverse effects, and risks in formulating recommendations. This guideline also described facilitators and barriers to its implementation, provided guidance on how the recommendations can be put into practice, and described a procedure for updating the recommended practices. Nevertheless, it remains unclear whether recommended practices were externally reviewed by experts prior to its publication and the potential resource implications of applying the published recommendations did not appear to have been considered.

Summary of Findings

A detailed synthesis of the results of each included study is presented in Appendix 4.

What is the clinical effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

Electrical stimulation of the muscles

In the SR by Liu et al.[9] which examined the dynamic effect of ES on preventing PrU development in patients with spinal cord injury, the authors found that eight of 11 preventive studies showed a significant decrease in pressure under the ischial tuberosities following ES, and that three of five studies which assessed local tissue oxygenation or blood flow reported a significant increase in these parameters during ES, while two studies reported an increase in tissue oxygenation in a subset of participants; however, it was unclear whether observed differences between groups reached statistical significance A reduction in seating pressure or incidence of PrUs was observed in four of five studies examining long-term effects of ES; these studies also reported increased muscle thickness, ischial tissue oxygenation, and sitting tolerance following ES, while one study reported no change in gluteal thickness or pressure distribution after 12 weeks of prophylactic treatment. No adverse events were experienced by any participants in four studies which reported on this outcome. Despite the potential for ES to prevent the development of PrUs among individuals with spinal cord injury, the authors concluded that the evidence base originating from preventive studies was methodologically poor, and that one standard approach for PrU prevention could not be encouraged owing to the variability in ES parameters, stimulating locations, and outcome measures across the identified studies.

Prophylactic dressings

In the RCT by Dutra et al.[10] which examined the comparative clinical effectiveness of polyurethane film dressings (PF) versus hydrocolloid dressings (HD) for PrU prevention among 160 hospitalized adults, findings showed that the incidence of PrUs was significantly lower in the PF group than in the HD group (8.7% versus 15%, respectively). In addition, individuals who were prophylactically treated with PF had a lower mean number of dressing changes in the sacral region and required overall fewer dressing changes than those who received HD, and the total number of dressing changes during the study period was significantly lower in the PF group. Based on these findings, the authors concluded that PF performed better and was more effective in preventing the development of PrUs in acute care setting.

What is the clinical effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in the operating room?

No published literature was identified.

What is the cost-effectiveness of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

No published literature was identified.

What are the evidence-based guidelines regarding the use of emerging technologies when used alone, or in combination with established interventions, for the prevention of pressure ulcers in acute care settings?

The evidence-based guideline developed by the NPUAP, EPUAP, and PPPIA made a number of recommendations relating to the use of emerging therapies for preventing pressure ulcers in acute care settings. Recommended prophylactic practices include management of microclimate by selecting support surfaces or support surface covers based on their ability to control moisture and temperature at the body/support surface interface. Moreover, prevention of PrUs may be done by applying a polyurethane foam dressing to an individual's bony prominences, or by using silk-like fabrics instead of cotton or cotton-blends to reduce shear and friction. Finally, for patients with spinal cord injury, guideline authors recommended the use of electrical stimulation for parts of the body that are at risk of PrU development. On the whole, these recommendations were made based on indirect evidence and/or expert opinion, with few recommendations supported by direct scientific evidence from properly designed and implemented clinical studies. The majority of recommendations received a weak positive recommendation grade, as determined through a formal consensus process.

Limitations

The SR and RCT included in this report appeared well designed and addressed the research questions posed. However, certain factors related to these publications may limit a clear interpretation of the results and their applicability to the Canadian setting. In particular, the large number of non-randomized (cohort, case series and case report) studies included within the identified SR brings into question the validity and reliability of study findings. Moreover, the lack of reporting of statistical significance related to observed effects prevents a clear interpretation of the results. Admittedly, the authors acknowledged that the scientific quality of the evidence base was poor, effectively limiting the utility of the review to inform preventive strategies in persons with spinal cord injury. Moreover, given that the focus of this review was on individuals with spinal cord injury, the applicability of the results is restricted to this special population and may not extend to a broader population at risk of developing PrUs. In contrast to the SR, the included RCT assessed prevention of PrUs in a broader, non-specific population; yet, the reliability of study findings remains limited owing to uncertainty related to the adequacy of the sample size, short follow-up period, and a residual baseline imbalance on a number of patient characteristics despite the application of a randomization procedure.

The selected guideline recommendations were developed using a scientifically sound process; however, the applicability of this guideline to clinical practice, particularly in the Canadian context, may be limited owing to the lack of direct evidence from high-quality studies supporting the specified recommendations and the weak strengths assigned to each recommendation during a formal consensus voting procedure.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

One SR and one RCT were identified regarding the clinical effectiveness of emerging interventions for the prevention of pressure ulcers in acute care settings. Based on the identified published literature, results of a review of studies relating to the use of electrical stimulation of the muscles in persons with spinal cord injury were inconclusive, and findings of one randomized study revealed that prophylactic polyurethane film dressings may be effective in preventing pressure sores in individuals without existing skin or tissue damage. The applicability of these studies may be limited due to a number of methodological shortcomings.

One evidence-based guideline was identified and recommends several emerging technologies for the prevention of pressure ulcers in acute care settings, including microclimate manipulation, prophylactic dressings, fabrics designed to reduce shear and friction, and electrical stimulation of the muscles in individuals with spinal cord injury; yet, the applicability of the recommended practices remains limited owing to insufficient direct evidence from high-quality studies and weak confidence associated with each recommendation.

No published literature was identified relating to the cost-effectiveness of emerging interventions for the prevention of pressure ulcers in acute care setting or regarding the clinical effectiveness of emerging preventive strategies in the operating room.

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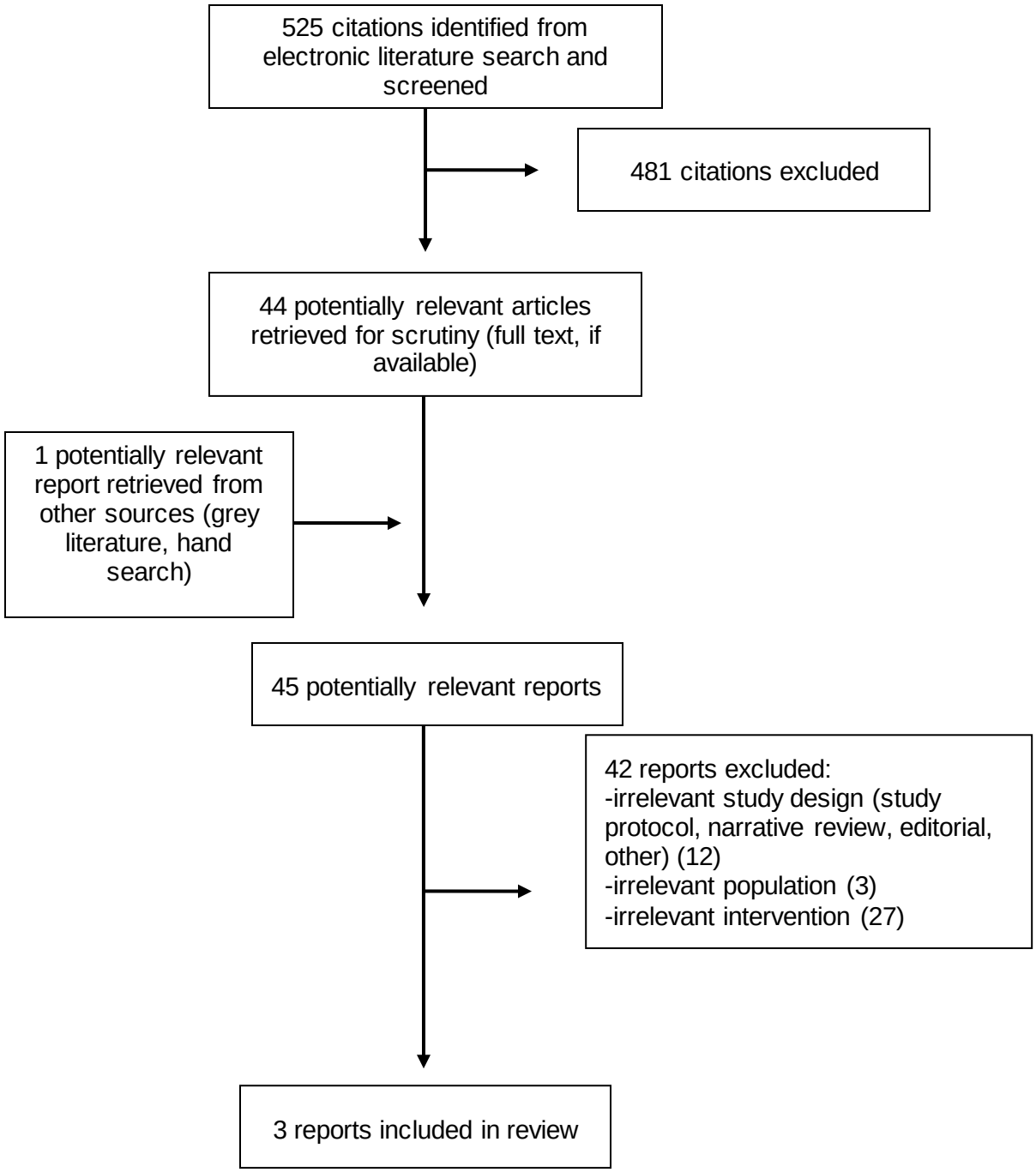
APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Publications

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Types and numbers of primary studies included	Population Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes, Length of Follow-Up
Liu, 2014[9] United Kingdom	27 included studies: 16 preventive studies (i.e. 3 RCTs, 1 cohort study, 9 case series, 3 case reports) 11 therapeutic studies	Persons with SCI irrespective of their age, sex, and degree of severity of traumatic or non-traumatic SCI	Any type of intervention using electrical stimulation (ES), including functional electric stimulation (surface/implant), neuromuscular electric stimulation (NMES), and nerve root stimulation.	None specified.	Prevention outcomes: - PrU incidence (direct) - seating pressure - muscle bulk - skin blood flow - transcutaneous oximetry ($TcPO_2$) (indirect) Length of follow-up: - 5 years (1 study) - 24 months (1 study) - 1 year (1 study) - 12 weeks (1 study) - 8 weeks (1 study) - On time (9 studies) - Dynamic (2 studies)

PrU = pressure ulcer; RCT = randomized controlled trial; SCI = spinal cord injury

Table A2: Characteristics of Included Clinical Studies

First Author, Publication Year, Country	Study Design	Patient Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes, Length of Follow-Up
Dutra, 2015[10] Brazil	RCT	Adult patients, without PrUs, hospitalized in the adult ICU, CCU or medical clinic, at moderate or high risk of PrUs (according to Braden scale) **Total n = 160;** n= 80 PF group; n= 80 HD group. PF group: Mean age = 64.13±17.49 years No. males (%) = 47 (58.8) HD group: Mean age = 65.25±17.99 years No. males (%) = 44 (55.0)	Polyurethane film (PF) dressing, applied bilaterally to the trochanteric and sacral regions	Hydrocolloid dressing (HD) , applied bilaterally to the trochanteric and sacral regions	- Incidence of PrUs - Reasons for dressing changes - Mean number of dressing changes per body region - Total number of dressing changes during the study period Length of follow-up: 30 days or until the patient was discharged, transferred, or died.

CCU = coronary care unit; HD = hydrocolloid dressing; ICU = intensive care unit; PF = polyurethane film; PrU = pressure ulcer; RCT = randomized controlled trial

Table A3: Characteristics of Included Guidelines						
Objectives			**Methodology**			
Intended users/ Target population	**Intervention and Practice Considered**	**Major Outcomes Considered**	**Evidence collection, Selection and Synthesis**	**Evidence Quality and Strength**	**Recommendations development and Evaluation**	**Guideline Validation**
Haesler (Ed.), 2014[11] – National Pressure Ulcer Advisory Panel (NPUAP) European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA)						
Intended users: All health professionals who are involved in the care of individuals who are at risk of developing PrUs, or those with an existing PrU. Target population: Individuals who are at risk of, or have an existing PrU.	Strategies to promote PrU healing or to prevent the development of PrUs.	Risk factors and Risk assessment; Therapeutic and preventive strategies for PrU healing and prevention; Special populations; Facilitators, barriers and implementation strategy.	Comprehensive review of the literature on PrU prevention and treatment in several electronic databases using a sensitive search strategy; evidence summarized narratively.	SWG members conducted critical appraisals of the identified evidence, assigned a level of evidence to each study using a classification system adapted from Sackett (1997), and refined the evidence tables.	Each SWG formulated conclusions about the body of available evidence and developed recommendations that emerged from the evidence. The SWGs summarized the evidence supporting each recommendation. Recommendations and evidence summaries were reviewed by the GDG and international stakeholders with final drafts approved by the GDG.	Individuals involved in the guideline development process were invited to review every recommendation and participate in a web-based consensus voting process in which strength of recommendations were assigned.

GDG = guideline development group; PrU = pressure ulcer; SWG = small working group
Note: GDG and SWG consisted of representative of the three development organizations (i.e. NPUAP, EPUAP, and PPPIA)

APPENDIX 3: Critical Appraisal of Included Publications

Table A4: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR[6]

Strengths	Limitations
Liu, 2014[9]	
• Research questions posed and inclusion criteria used were established *a priori* through a published study protocol • Data extraction was performed by two independent reviewers, and any disagreements were adjudicated by a third reviewer • A comprehensive search of the literature (electronic databases) was performed, including a search of grey literature • A list of included studies and study characteristics was provided. • Methodological quality assessment of included studies was performed and documented • Rationale for the decision to not meta-analyze the results was described. • The scientific quality of included studies was considered in formulating conclusions of the review. • Review authors disclosed no potential conflicts of interest.	• Unclear whether duplicate article screening was performed • List of excluded studies was not provided nor referenced (only reasons for exclusion are provided) • Likelihood of publication was mentioned, but no evidence of formal assessment using statistical methods or visual inspection • Sources of funding of included studies were not described.

Table A5: Strengths and Limitations of Randomized Controlled Trials using SIGN-50[7]

Strengths	Limitations
Dutra, 2015[10]	
• The study addressed an appropriate and clearly focused question • The assignment of subjects to treatment groups was randomized • Treatment and control groups were sufficiently similar at the start of the trial • All relevant outcomes were measured in a standard, valid, and reliable way • There were no losses to follow-up. • Study subjects were analyzed in the groups to which they were randomly allocated (i.e. intention-to-treat analysis) • No conflicts of interest or sources of funding were declared	• Unclear whether the concealment method used was adequate due to limited reporting (i.e. lottery randomization via drawing from a sealed envelope) • Unclear whether subjects and investigators/assessors were blinded to treatment allocation • There were significant differences between groups at baseline in terms of ethnicity, psychomotor agitation, level of consciousness, and nutritional state • Sample size estimation was not described • Unclear whether analysis adjusted for participants' different lengths of follow-up • Generalizability of findings is uncertain

Table A6: Strengths and Limitations of Guidelines using AGREE II[8]	
Strengths	**Limitations**
Haesler (Ed.), 2014[11]	
Scope and Purpose • The overall objective of the guideline is specifically described • The key clinical questions covered by the guideline are specifically described (in a document separate from the guideline) • The population to whom the guideline is meant to apply is specifically described *Stakeholder Involvement* • The guideline development group included individuals from all relevant professional groups (including the NPUAP, EPUAP, and PPPIA) • The views and preferences of the target population were sought (i.e. patient representative organizations were invited to participate in the stakeholder review process to provide a consumer perspective). • The target users of the guideline are clearly described. *Rigour of Development* • Systematic methods were used to search for evidence • Criteria for selection the evidence are clearly described • Strengths and limitations of the body of evidence are clearly described (in a separate supporting technical document) • Methods for formulating recommendations are clearly described (i.e. web-based consensus voting process) • Health benefits, side effects, and risks were considered in formulating the recommendations (when available) • There is an explicit link between the recommendations and the supporting evidence (sources are referenced in full guidance document and supporting documents) • A procedure for updating the guidelines is provided (i.e. another revision is planned for 2019 or sooner, if ongoing literature reveals major advances in pressure ulcer prevention and treatment prior to 2019) *Clarity of Presentation* • Recommendations are specific and unambiguous • Different options for management (and prevention) of the condition are clearly	*Scope and Purpose* • No concerns regarding scope and purpose *Stakeholder Involvement* • No concerns regarding stakeholder involvement *Rigour of Development* • Unclear whether the guideline has been externally reviewed by experts prior to its publication *Clarity of Presentation* • No concerns regarding clarity of presentation *Applicability* • The potential resource implications of applying the recommendations do not appear to have been considered *Editorial independence* • No concerns regarding editorial independence

Table A6: Strengths and Limitations of Guidelines using AGREE II[8]	
Strengths	**Limitations**
presented. • Key recommendations are easily identifiable *Applicability* • Guideline described facilitators and barriers to its implementation • Guideline provides guidance on how the recommendations can be put into practice (i.e. implementation strategy included) • Guideline presents monitoring and/or auditing criteria (i.e. includes quality indicators) *Editorial Independence* • The views of the funding body have not influenced the content of the guideline (i.e. all financial contributions by sponsors were made after the guideline development phase) • Competing interests of guideline development group member have been recorded and addressed.	

EPUAP = European Pressure Ulcer Advisory Panel; NPUAP = National Pressure Ulcer Advisory Panel; PPPIA = Pan Pacific Pressure Injury Alliance

APPENDIX 4: Main Study Findings and Author's Conclusions

Table A7: Summary of Findings of Included Studies

Main Study Findings	Author's Conclusions
Systematic review	
Liu, 2014[9]	
Preventive studies (n=16): • 4 types of ES devices were identified: conventional surface electrodes (10 studies); custom-made garment with built-in electrodes (one study); electrical current delivered through a sacral anterior nerve root stimulator (SARS) implant (2 studies); and electrical current delivered via implanted intramuscular electrodes (3 studies). • Of 11 studies examining dynamic effect of ES, 8 studies demonstrated a reduction of pressure under the ischial tuberosities; 3 of 5 studies which measured local tissue oxygenation or blood flow reported an increase in regional tissue oxygenation or blood flow during the stimulation, and 2 studies reported an increase of tissue oxygenation in some participants (unclear if observed differences reached statistical significance). • Of 5 studies examining long-term effects of ES, 4 studies demonstrated positive changes including reduced seating pressure or incidence of PrUs, increased muscle thickness, ischial tissue oxygenation, and sitting tolerance; one study reported no change in gluteal thickness or pressure distribution after a 12-week follow-up • Of 4 studies which reported on adverse events (two studies delivered ES using surface electrodes and two studies sued a SARS implant), no adverse events were experienced by the participants.	• "The methodological quality of the studies was poor, in particular for prevention studies. A significant effect of ES on enhancement of PU healing is shown in limited Grade I [strong] evidence. The great variability in ES parameters, stimulating locations, and outcome measure leads to an inability to advocate any one standard approach for PU therapy or prevention." (p.703)
Randomized controlled trials	
Dutra, 2015[10]	
Incidence of PrUs • Incidence of PrUs was significantly lower (*P* = 0.038) in the PF group (8.7%) than in the HD group (15%).	• "The results suggest that the transparent polyurethane film had a better performance and was more effective than the hydrocolloid dressing in preventing PU development." (p.268)

Table A7: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
<u>Mean number of dressing changes per body region</u> • Significant between-group differences were found in mean number of dressing changes in the sacral region (HD 2.50±0.871 changes; PF 2.05±0.825; *P* = 0.001), with PF requiring significantly fewer changes than the HD group. <u>Total number of dressing changes during the study period</u> • Significant between-group differences were found in the mean total number of dressing changes (HD 6.09±1.66 chnages; PF 5.59±2.04 changes; *P* = 0.010) <u>Reasons for dressing changes</u> • Most common reasons for changing dressings in both groups were moisture (PF 51.1%; HD 47.9%) and shear (HD 43%; PF 38.9%), with a significant between-group difference in shear (*P* = 0.048).	

ES = electrical stimulation; HD = hydrocolloid dressing; PF = polyurethane film;

Table A8: Summary of Recommendations in Included Guidelines	
Findings and Recommendations	**Grade/Strength of Recommendation**
Haesler (Ed.), 2014[11] – National Pressure Ulcer Advisory Panel (NPUAP) European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA)	
<u>Microclimate control</u> 1. Consider the need for additional features such as ability to control moisture and temperature when selecting a support surface or support surface cover. 2. Do not apply heating devices (e.g., hot water bottles, heating pads, built-in bed warmers) directly on skin surfaces or pressure ulcers. <u>Prophylactic dressings</u> 1. Consider applying a polyurethane foam dressing to bony prominences (e.g., heels, sacrum) for the prevention of pressure ulcers in anatomical areas frequently subjected to friction and shear. 2. When selecting a prophylactic dressing consider: • ability of the dressing to manage microclimate;	<u>Microclimate control</u> 1. Strength of Evidence = **C**; Strength of Recommendation = Weak positive recommendation (probably do it) 2. Strength of Evidence = **C**; Strength of Recommendation = Weak positive recommendation (probably do it) <u>Prophylactic dressings</u> 1. Strength of Evidence = **B**; Strength of Recommendation = Weak positive recommendation (probably do it) 2. Strength of Evidence = **C**; Strength of Recommendation = Weak positive recommendation (probably do it) 3. Strength of Evidence = **C**; Strength of Recommendation = Weak positive recommendation (probably do it) 4. Strength of Evidence = **C**; Strength of Recommendation = Weak positive

Table A8: Summary of Recommendations in Included Guidelines	
Findings and Recommendations	**Grade/Strength of Recommendation**
• ease of application and removal; • ability to regularly assess the skin; • anatomical location where the dressing will be applied; and • the correct dressing size. 3. Continue to use all other preventive measures necessary when using prophylactic dressings. 4. Assess the skin for signs of pressure ulcer development at each dressing change or at least daily, and confirm the appropriateness of the current prophylactic dressing regimen. 5. Replace the prophylactic dressing if it becomes damaged, displaced, loosened or excessively moist. <u>Fabrics and textiles</u> 1. Consider using silk-like fabrics rather than cotton or cotton-blend fabrics to reduce shear and friction. <u>Electrical Stimulation of the Muscles</u> 1. Consider the use of electrical stimulation for anatomical locations at risk of pressure ulcer development in spinal cord injury patients.	recommendation (probably do it) 5. Strength of Evidence = **C**; Strength of Recommendation = Strong positive recommendation (definitely do it) <u>Fabrics and textiles</u> 1. Strength of Evidence = **B**; Strength of Recommendation = Weak positive recommendation (probably do it) <u>Electrical Stimulation of the Muscles</u> 1. Strength of Evidence = **C**; Strength of Recommendation = No specific recommendation

Note: A = the recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at risk for pressure ulcers), providing statistical results that consistently support the recommendation (Level 1 studies required); B = the recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at risk for pressure ulcers) providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies); C = the recommendation is supported by indirect evidence (e.g., studies in healthy humans, humans with other types of chronic wounds, animal models) and/or expert opinion.