

Appendix H

Pressure ulcer prevention and management

Economic evidence tables

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*Commissioned by the National Institute for
Health and Care Excellence*

Disclaimer

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Contents

Appendix H: Economic evidence tables	8
H.1 Pressure ulcer prevention	8
H.1.1 Repositioning.....	8
H.1.2 Nutritional supplementation and hydration strategies	9
H.1.3 Pressure redistributing devices	11
H.1.4 Pressure redistributing devices for the prevention of heel ulcers.....	14
H.1.5 Barrier creams	17
H.2 Pressure ulcer management	22
H.2.1 Nutritional supplementation and hydration strategies	22
H.2.2 Pressure redistributing devices	23
H.2.3 Adjunctive therapies	25
H.2.4 Debridement	28
H.2.5 Dressings.....	29
H.2.6 Management of heel pressure ulcers.....	44
H.3 References.....	46

Appendix H: Economic evidence tables

H.1 Pressure ulcer prevention

H.1.1 Repositioning

Table 1: Moore 2013

Z. Moore, S. Cowman, and J. Posnett. An economic analysis of repositioning for the prevention of pressure ulcers. J.Clin.Nurs. 22 (15-16):2354-2360, 2013.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome: incidence of pressure ulcer)</p> <p>Study design: Within trial analysis (RCT)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied</p> <p>Perspective: NR (appears to be Irish healthcare payer)</p> <p>Time horizon/Follow-up: 4 weeks</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p>	<p>Population: Participants from 12 long-term care of the older person hospital settings in the Republic of Ireland</p> <p>Patient characteristics: N: 213 Age: 53% aged between 81-90 years, 13% aged between 91-100 years (mean age NR) Male: 21%</p> <p>Intervention 1: Repositioning every 6 hours at night using 90° lateral rotation.</p> <p>Intervention 2: Repositioning using a 30° tilt (left side, back, right side,</p>	<p>Total costs (mean per patient): Intervention 1: £209 Intervention 2: £170 Incremental (2-1): -£39 (CI NR; p NR)</p> <p>Currency & cost year: (e.g. 2009 Euros (presented here as 2009 UK pounds^(a))</p> <p>Cost components incorporated: Staff costs and dressing costs.</p>	<p>Pressure ulcers developed (mean per patient): Intervention 1: 0.11 Intervention 2: 0.03 Incremental (2-1): -0.08 (CI NR; p = 0.035)</p>	<p>ICER (Intervention 2 versus Intervention 1): Intervention 2 dominates intervention 1</p> <p>Analysis of uncertainty: None.</p>

	back) every 3 hours during the night.			
	Night was considered to be 8pm-8am. Both groups were nursed during the day according to planned care.			
Data sources				
Health outcomes: Taken from within trial. ¹⁹ Quality-of-life weights: n/a. Cost sources: National salary scales and costs collected from within the trial.				
Comments				
Source of funding: Health Research Board of Ireland. Limitations: Short time horizon (especially considering the long term care population), the cost of treating pressure ulcers is not fully accounted for (although this is unlikely to change the results), all resource estimates and effectiveness estimates obtained from within one trial. No analysis of uncertainty.				
Overall applicability^(b): Partially applicable Overall quality^(c): Minor limitations				

Abbreviations: CEA: cost-effectiveness analysis; CI: 95% confidence interval; ICER: incremental cost-effectiveness ratio; NR: not reported

(a) Converted using 2009 purchasing power parities²²

(b) Directly applicable / Partially applicable / Not applicable

(c) Minor limitations / Potentially serious limitations / Very serious limitations

H.1.2 Nutritional supplementation and hydration strategies

Table 2: Rypkema 2004

G. Rypkema, E. Adang, H. Dicke, T. Naber, B. de Swart, L. Disselhorst, G. Goluke-Willemse, and M. Olde Rikkert. Cost-effectiveness of an interdisciplinary intervention in geriatric inpatients to prevent malnutrition. J Nutr Health Aging 8 (2):122-127, 2004.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CCA (health outcome = incidence of pressure ulcers)	Population: Patients admitted to geriatric units (aged over 60), admitted for 3-150 days.	Total costs (mean per patient): Intvn 1: £5,748 Intvn 2: £5,463 Incremental (2-1): -£285 (CI NR; p = NR)	Incidence of pressure ulcer (mean per patient): Intvn 1: 0.21 Intvn 2: 0.16 Incremental (2-1): -0.04 (CI NR; p = 0.37)	Intvn2 dominated intvn1, with lower cost and reduction in incidence of pressure ulcers. Analysis of uncertainty: Length of stay was tested in sensitivity analysis, using the lower and upper confidence interval values. The
Study design: Within	Patient characteristics:			

<p>study analysis (prospective controlled study)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied</p> <p>Perspective: Healthcare provider</p> <p>Time horizon: duration of hospital stay</p> <p>Treatment effect duration: until nutritional status and swallowing was satisfactory</p> <p>Discounting: n/a</p>	<p>Intvn 1 Start age = 83 M = NR</p> <p>Intvn 2 Start age = 81 M = NR</p> <p>Intervention 1: Standard care (this did include some nutritional supplementation, details not provided)</p> <p>Intervention 2: All patients screened for malnutrition, dysphagia and dehydration on admission. Patients with one positive screening test were also assessed by a dietician, a speech/language therapist and a geriatrician, and were treated immediately, for example beginning a high energy diet or protein-energy supplements. Medical interventions were also started.</p>	<p>Currency & cost year: Euros, year NR (presented here as UK pounds£)</p> <p>Cost components incorporated: Staff time (additional time spent on training and screening, monitoring and intervening), materials used (tests and supplements), cost of hospital days.</p>		<p>cost saving was found to vary between - £1,177 and £607 per patient. In-hospital daily costs were excluded, and costs of antibiotics were varied within the limits of the confidence interval: intvn2 had an incremental cost of £58 to £80 per patient.</p>
Data sources				
<p>Health outcomes: Obtained from within study. Quality-of-life weights: n/a. Cost sources: Cost of a nursing day was taken from a standard tariff for general hospitals in The Netherlands, and other costs from tariffs used by the UMC Nijmegen.</p>				
Comments				

Source of funding: Research grant from the joint society of Dutch Universities (VAZ) and Nutricia, Inc. **Limitations:** Effectiveness and resource use estimates based solely on this prospective study, nutritional supplementation not described in detail. Uncertainty is not thoroughly explored. Control and intervention arms were carried out in separate locations, and preventative efforts (other than just the nutritional protocol) differed. For example the use of pressure ulcer prevention beds was higher in the intervention group. Differences in costs and effects may not be completely due to the nutritional intervention.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

H.1.3 Pressure redistributing devices

Table 3: FLEURENCE2005

Ref citation R. L. Fleurence. Cost-effectiveness of pressure-relieving devices for the prevention and treatment of pressure ulcers. <i>Int.J.Technol.Assess.Health Care</i> 21 (3):334-341, 2005.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CUA</p> <p>Study design: Decision analytic model</p> <p>Approach to analysis: Decision tree which models development of superficial or severe PUs (either singular or multiple), death, healing, and discharge with or without PUs</p> <p>Perspective: UK NHS</p> <p>Time horizon: 1 week, 4 weeks and 12 weeks</p>	<p>Population: Patients admitted to hospital without pressure ulcers (additional scenarios were analysed in which patients already had PUs – not relevant to prevention)</p> <p>Cohort settings: Start age = NR M = NR</p> <p>Intervention 1: Alternating pressure overlays (AO)</p> <p>Intervention 2: Alternating pressure mattress replacements (AR)</p>	<p>Total costs (mean per patient) at 1 week: Intvn1: £558.43 Intvn2: £560.16 Intvn3: £581.89 Incremental (2-1): £1.73 Incremental (3-2): £23.46</p> <p>Total costs (mean per patient) at 4 weeks: Intvn1: £766.25 Intvn2: £786.77 Intvn3: £829.98 Incremental (2-1): £20.52 Incremental (3-2): £43.21</p> <p>Currency & cost year: GBP 2003</p>	<p>QALYs (mean per patient) at 1 week: Intvn1: 0.01574 Intvn2: 0.01574 Intvn3: 0.01571 Incremental (2-1): 0.000007 Incremental (3-2): -0.00003</p> <p>QALYs (mean per patient) at 4 weeks: Intvn1: 0.06261 Intvn2: 0.06269 Intvn3: 0.06229 Incremental (2-1): 0.00008 Incremental (3-2): -0.00032</p> <p>Pressure ulcer free days (mean) at 1 week: Intvn1: 6.798 Intvn2: 6.807 Intvn3: 6.760</p>	<p>Cost per QALY gain (1 week horizon): Intvn 3 is dominated by 1 and 2, Intvn2 v Intvn1 = £262,927 Probability cost-effective at £20,000 threshold (estimated from graph): Intvn1 45%, Intvn2 42%, Intvn3 13%</p> <p>Cost per QALY gain (4 week horizon):Intvn 3 is dominated, Intvn 2 v Intvn 1 = £253,367 Probability cost-effective at £20,000 threshold (estimated from graph): Intvn1 47%, Intvn2 37%, Intvn3 16%</p> <p>Intvn1 is reported to be the cost-effective strategy at 1, 4 and 12 weeks.</p> <p>Analysis of uncertainty: Probabilistic sensitivity analyses were conducted and CEACs presented. At a ceiling ratio of</p>

Treatment effect duration: Full time horizon Discounting: n/a	Intervention 3: Standard care: high-specification foam mattress (SC)	Cost components incorporated: Cost of healing superficial and severe ulcers based on daily resources required to deliver care reflecting good clinical practice, cost of pressure relieving device (adjusted for lifetime use), maintenance contract, cleaning cost, additional costs of renting when purchased stock is not enough.	Incremental (2-1): 0.009 Incremental (3-2): -0.047 Pressure ulcer free days (mean) at 4 weeks: Intvn1: 26.714 Intvn2: 26.828 Intvn3: 26.269 Incremental (2-1): 0.114 Incremental (3-2): -0.559 Outcomes at 12 weeks are also reported in the study, but are not included here.	£5,000/QALY the optimal strategy was Intvn3, beyond this value it switches to Intvn1. Scenario analysis revealed that it was less expensive for the hospital to own devices than to rent them.
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Data sources

Health outcomes: Epidemiology data which provided information on proportion of patients admitted to hospital at risk of developing a pressure ulcer and risk of new ulcers per week, as well as data on superficial and severe pressure ulcers, was obtained from a prospective nonrandomised cohort study conducted by Clark and colleagues 2002⁵. No reliable effectiveness data was obtained from the literature so effectiveness was estimated and these estimates validated by a specialist in wound care. **Quality-of-life weights:** Obtained via visual analogue scale from five health professionals with expertise in wounds management. **Cost sources:** Cost of healing pressure ulcers was obtained from Bennett and colleagues 2004.² Prices of SC devices were obtained from a health technology assessment¹⁰ and from a previous NICE guideline.²⁰ Prices of AR and AO devices were obtained from Huntleigh Healthcare Products and from the literature.^{11,26}

Comments

Source of funding: Medical research council PhD Studentship; **Limitations:** Quality of life data is obtained from health care professionals rather than from patients, short time horizon may not capture full economic impact of these devices – not necessarily generalisable to individuals who face lifetime risk. Estimates of health effect estimated rather than obtained from the literature, baseline health outcomes not based on randomised data. **Other:** This paper also included an analysis which looked at devices for management of pressure ulcers; a separate evidence table is presented for this comparison.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CUA = cost-utility analysis; ICER = incremental cost-effectiveness ratio; NR = not reported; QALYs = quality-adjusted life years

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitation

Table 4: LEGOOD2005

Ref citation R. Legood and E. McInnes. Pressure ulcers: guideline development and economic modelling. <i>J.Adv.Nurs.</i> 50 (3):307-314, 2005.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness

<p>Economic analysis: CEA (health outcome = incidence of pressure ulcers)</p> <p>Approach to analysis: Calculation of additional cost of devices net of any saving from reduced incidence of pressure ulcers.</p> <p>Perspective: UK NHS</p> <p>Time horizon: 5 day hospital stay</p> <p>Treatment effect duration: 5 days</p> <p>Discounting: N/A</p>	<p>Population: Patients admitted to hospital. Patients were separated into four risk groups with A the lowest risk and D the highest.</p> <p>Intervention 1: High specification foam mattress</p> <p>Intervention 2: Standard mattress</p>	<p>Total costs (mean per patient):</p> <p>Patient risk group A: Intvn 1: £3.86 Intvn 2: £1.70 Incremental (2-1):- £2.16</p> <p>Patient risk group B: Intvn 1: £37.61 Intvn 2: £11.82 Incremental (2-1): -£25.79</p> <p>Patient risk group C: Intvn 1: £75.11 Intvn 2: £23.07 Incremental (2-1): -£52.04</p> <p>Patient risk group D: Intvn 1: £150.11 Intvn 2: £45.57 Incremental (2-1): -£104.54</p> <p>Currency & cost year: GBP 2000/2001</p> <p>Cost components incorporated: Cost of treating a pressure ulcer (differed by patient risk group), cost of standard mattress and high-specification foam mattress</p>	<p>Incidence of pressure ulcers (mean per patient):</p> <p>Patient risk group A: Intvn 1: 0.005 Intvn 2: 0.0015 Incremental (2-1): -0.0035</p> <p>Patient risk group B: Intvn 1: 0.05 Intvn 2: 0.015 Incremental (2-1): -0.035</p> <p>Patient risk group C: Intvn 1: 0.1 Intvn 2: 0.03 Incremental (2-1): -0.07</p> <p>Patient risk group D: Intvn 1: 0.2 Intvn 2: 0.06 Incremental (2-1):- 0.14</p>	<p>Standard mattress vs. high specification foam: High specification foam dominated standard mattress with a lower incidence of pressure ulcers and lower costs for all patient risk groups.</p> <p>Analysis of uncertainty: Results were recalculated using extreme estimates; when only one in one hundred patients develops a PU, the pressure relieving mattress was still dominant.</p>
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Data sources

Health outcomes: Clinical review conducted for the NICE guideline preventing pressure ulcers using pressure-relieving devices (CG7).²⁰ **Cost sources:** Data from costing papers^{8,9,12,13} identified in the economic review for the guideline, the NHS supplies and purchasing agency and GDG member input. The cost of treating pressure ulcers was based on GDG estimation.

Comments
Source of funding: National Institute of Health and Clinical Excellence; Limitations: QALYs were not calculated, although this will not have had an impact on the conclusion of the study. The calculations only consider 100 5-day patient episodes – people at long term risk of developing a PU are not accounted for. The baseline probability of developing a pressure ulcer is based on GDG estimate, as it the cost of treating pressure ulcers.
Overall applicability*: Partially applicable Overall quality**: Minor limitations
<i>Abbreviations: CCA = cost-consequence analysis; CEA = cost-effectiveness analysis; CI = confidence interval; CUA = cost-utility analysis; d/a deterministic analysis ICER = incremental cost-effectiveness ratio; NR = not reported; pa = probabilistic analysis; QALYs =quality-adjusted life years</i>
<i>Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations</i>

H.1.4 Pressure redistributing devices for the prevention of heel ulcers

Table 5: LYMAN2009

Ref citation V. Lyman. Successful heel pressure ulcer prevention program in a long-term care setting. <i>Journal of Wound Ostomy and Continence Nursing</i> 36 (6):616-621, 2009.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome = pressure ulcer incidence)</p> <p>Study design: Within study analysis (before and after study)</p> <p>Approach to analysis: Cost savings associated with prevented pressure ulcers considered against cost of preventative measures employed within the study</p>	<p>Population: Patients in a nursing home with low Braden scores (≤ 18) and specific comorbidities (either diabetes, peripheral vascular disease, cerebrovascular accident, hemiparesis or weakness, low albumin, hip fracture, total knee replacement, or vasopressor medications).</p> <p>Patient characteristics: Start age = NR M = NR</p> <p>Intervention 1:</p>	<p>Total costs (mean per patient): Intvn 1: NR Intvn 2: NR Incremental (2-1): -£15 (based on cost of treating a pressure ulcer of £1,319) (CI NR; p = NR)</p> <p>Currency & cost year: US dollars (Year NR, presented here as UK pounds£).</p> <p>Cost components incorporated: Wound care time, supply</p>	<p>Incidence of pressure ulcers (mean per patient): Intvn 1: 0.071 Intvn 2: 0.004 Incremental (2-1): 0.067 (CI NR; p = NR)</p>	<p>ICER (Intvn 2 vs Intvn 1): Quality improvement project (use of heel protector) dominates standard care; cost savings result from reduced incidence of pressure ulcers.</p> <p>Analysis of uncertainty: Different estimates for the cost of treating pressure ulcers were employed. If treatment of a pressure ulcer costs £19,787, the cost savings would be £1,257 per person. If treatment of pressure ulcers costs £2,003 per ulcer, cost savings would be £61 per person.</p>

<p>Perspective: Not stated (appears to be nursing home)</p> <p>Time horizon: 3 months at risk of developing pressure ulcer with ongoing treatment costs</p> <p>Discounting: Costs = NR; Outcomes = N/A</p>	<p>Standard care (before implementation of the quality improvement project)</p> <p>Intervention 2: Quality improvement project. This involved the use of heel protectors (Prevalon Heel Protector; Sage Products), in addition to more frequent risk assessments, skin assessments and daily application of a moisturising cream to the heels.</p>	<p>costs for treatment, supply costs for heel protector.</p>		
Data sources				
<p>Health outcomes: Data obtained from within the before-and-after study. Cost sources: Within study with additional information on the cost of treating pressure ulcers obtained from Courtney and colleagues (2006)⁷ and Young and colleagues (2004)²⁷.</p>				
Comments				
<p>Source of funding: Sage product Inc. Limitations: Neither discounting nor QALYs (or any measure of quality of life) appear to be considered, and the time horizon is not made explicit. Limited information is provided on the characteristics of the study patients, and the effectiveness evidence is based on a simple before and after study; no attempt is made to base the analysis on randomised trial data or any systematic search procedure. Little information on the costs used for the treatment of pressure ulcers is provided, thus it is unclear why these figures have been selected for use in the analysis. Limited sensitivity analysis does not adequately explore uncertainty.</p>				
<p>Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations</p>				

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; QALYs = quality-adjusted life years † Converted using 2009 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

Table 6: TORRA2009

<p>Ref citation I. Bou JE Torra, Lopez J. Rueda, G. Camanes, Narvaez E. Herrero, Blanco J. Blanco, Torralba J. Balleste, E. H. Martinez-Esparza, L. S. Garcia, and J. V. Soriano. Preventing pressure ulcers on the heel: a Canadian cost study. <i>Dermatol.Nurs.</i> 21 (5):268-272, 2009.</p>				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis:	Population:	Total costs (mean per	Incidence of pressure ulcers	Incremental cost per pressure ulcer avoided

<p>CEA (health outcome = pressure ulcers avoided)</p> <p>Study design: Within trial analysis</p> <p>Approach to analysis: Costs of applying the interventions over the duration of the trial compared and divided by incremental pressure ulcer incidence</p> <p>Perspective: Not stated (appears to be health care payer)</p> <p>Time horizon: 8 weeks</p> <p>Discounting: Costs = N/A; Outcomes = N/A</p>	<p>Patients in a nursing home or home care programme deemed to be at risk of pressure ulcer according to the Braden scale (no explicit cut off score reported).</p> <p>Patient characteristics: Intvn 1: Start age = 84.8 M = 26%</p> <p>Intvn 2: Start age = 84.8 M = 29.5%</p> <p>Intervention 1: Protective heel bandage (soffban and gauze)</p> <p>Intervention 2: Specially shaped hydrocellular dressing (Allevyn heel). Dressings were fixed with a socket or a net bandage.</p>	<p>patient): Intvn 1: £89 Intvn 2: £95 Incremental (2-1): £6 (CI NR; p = NR)</p> <p>Currency & cost year: Canadian dollars 2006 (presented here as 2006 UK pounds£).</p> <p>Cost components incorporated: Dressing costs, nurse time.</p>	<p>(mean per patient): Intvn 1: 0.44 Intvn 2: 0.033 Pressure ulcers avoided (2-1): 0.407 (CI NR; p = NR)</p>	<p>(Intvn 2 vs Intvn 1): £15</p> <p>Analysis of uncertainty: Two additional scenarios presented: nursing time (for dressing changes and skin inspection) doubled and a decrease in hourly rate for nursing time. Incremental costs per pressure ulcer avoided were £26 and £11 respectively.</p>
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Data sources

Health outcomes: Data obtained from within the trial. **Cost sources:** Material costs were based on the manufacturer's 2006 price list for Canada. Where costs were not available for the specific materials used within the trial, costs for similar products were used instead. Labour costs were calculated based on information from the Nurse Union (2006).¹⁶

Comments

Source of funding: Allevyn heel provided by Smith & Nephew. In addition Torra is an employee of Smith & Nephew. **Limitations:** QALYs are not included in the analysis and quality of life is not considered. Costs savings associated with avoided pressure ulcers are not included (thus the analysis does not include all relevant cost components) and the analysis is based on a short trial of only 8 weeks. Limited sensitivity analysis does not adequately explore uncertainty.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; QALYs = quality-adjusted life years † Converted using 2006 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

H.1.5 Barrier creams

Table 11: Bale 2004

Bale, Tebble, Jones, and Price. The benefits of implementing a new skin care protocol in nursing homes. <i>J Tissue Viability</i> 14 (2):44-50, 2004.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA (health outcome=incidence of incontinence dermatitis (ID) and pressure ulcers)</p> <p>Study design: Within study analysis (pre and post intervention study)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied.</p> <p>Perspective: NHS</p> <p>Study duration: Unclear (post intervention 3 months)</p>	<p>Population: Nursing home patients with incontinence (included patients with ID as well, not just those with intact skin)</p> <p>Patient characteristics: Mean age =83.4 years M =29.9%</p> <p>Intervention 1: Standard care (skin care was undertaken, and sometimes included use of barrier creams)</p> <p>Intervention 2: Skin care protocol. This consisted of a spray cleanser (Cavilon srpay cleanser) and</p>	<p>Total cost (per patient): Intvn 1:NR Intvn 2: NR Incremental(2-1): -£9 (CI NR; p NR)</p> <p>Currency & cost year: UK pounds, cost year NR</p> <p>Cost components incorporated: Staff time and product costs.</p>	<p>Incidence of pressure ulcers (grade 1): Fewer developed once intervention 2 was in place (p=0.042)</p> <p>Incidence of ID: There was a significantly lower incidence of ID once intervention 2 was in place. Mild, moderate and severe incontinence decreased. (p=0.021)</p>	<p>Intervention 2 dominates intervention 1, with reduced costs and a reduction in ID and pressure ulcers.</p> <p>Analysis of uncertainty: Lower costs of staff time were included to reflect unqualified nurse costs; intervention 2 remained cost saving (£3 cost saving).</p>

Discounting: N/a	a barrier cream (Cavilon double barrier cream) for patients with intact skin or mild ID, and pray cleanser (Cavilon srpay cleanser) and a barrier film (Cavilon no sting barrier film) for those with more severe ID.			
Data sources				
Health outcomes: obtained from within the study Quality-of-life weights: NR Cost sources: NR.				
Comments				
Source of funding: NR Limitations: The effectiveness data and resource use were collected from this small single study. The study design and methodology is not adequately described. Study doesn't include the costs of treating the incontinence dermatitis or pressure ulcers. Only the costs of staff time and products are included, the educational programme and other aspects of the skin care protocol are omitted. Cost sources are not reported.				
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations				

Abbreviations: CCA = cost-consequence analysis; CI – 95% confidence interval; NR = not reported;

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

Table 7: Pham 2011A

B. Pham, A. Stern, W. Chen, B. Sander, A. John-Baptiste, H. H. Thein, T. Gomes, W. P. Wodchis, A. Bayoumi, M. Machado, S. Carcone, and M. Krahn. Preventing pressure ulcers in long-term care: a cost-effectiveness analysis. Arch.Intern.Med. 171 (20):1839-1847, 2011.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CUA Study design: Decision analytic model Approach to analysis: The markov model utilises a one week cycle length and considers patients of both high and low risk.	Population: Long term care residents. Cohort settings: Start age = 83 M = NR Intervention 1: Current practice (45.5% use	Total costs (mean per patient): Intvn 1: £81,938 Intvn 2: £81,875 Intvn 3: £82,340 Intvn 4: £81,951 Intvn 5: £81,840 Incremental(2-1): -£63	QALYs (mean per patient): Intvn 1: 1.2421 Intvn 2: 1.2429 Intvn 3: 1.2422 Intvn 4: 1.2424 Intvn 5: 1.2426 Incremental(2-1): 0.00085	ICER (Intvn 2 vs Intvn 1): Intvn 2 dominates. ICER (Intvn 3 vs Intvn 1): £4,303,278 per QALY gained ICER (Intvn 4 vs Intvn 1): £43,054 per QALY gained ICER (Intvn 5 vs Intvn 1): Intvn 5 dominates. Probability cost-effective (compared to intervention 1) at willingness to pay of

<p>The model considers stage 1-4 pressure ulcers (as defined by the NPUAP), and healing.</p> <p>Perspective: A single health care payer</p> <p>Time horizon: Lifetime</p> <p>Discounting: Costs = 3%; Outcomes = 3%</p>	<p>of pressure redistribution mattresses, 50% use of soap and water for incontinence care, 50% use of skin care products)</p> <p>Intervention 2: Replace all standard mattresses in long-term care facilities with pressure redistribution mattresses</p> <p>Intervention 3: Provide daily oral nutritional supplements to high-risk residents with recent weight loss</p> <p>Intervention 4: Apply a skin emollient daily to dry skin of high-risk residents</p> <p>Intervention 5: Replace soap and water with a foam cleanser (containing an emollient, a water-repellent barrier and a water deodorant) for high-risk residents requiring incontinence care.</p>	<p>Incremental(3-1): £402 Incremental(4-1): £13 Incremental(5-1): -£98 (CI NR; p NR)</p> <p>Currency & cost year: 2009 Canadian dollars (presented here as 2009 UK pounds£)</p> <p>Cost components incorporated: Nursing and personal care, food, basic accommodation (assumed to differ by risk category and stage of pressure ulcer), labour costs and supply cost of moisturiser.</p>	<p>Incremental(3-1): 0.00008 Incremental(4-1): 0.00030 Incremental(5-1): 0.00055 (reported as quality adjusted life days gained, presented here as QALYs) (CI NR; p NR)</p>	<p>\$50,000 (£27,498) per QALY: Intvn 2: 82% Intvn 3: 1% Intvn 4: 43% Intvn 5: 94%</p> <p>Analysis of uncertainty:</p> <p>Intervention 2: Remained dominant when analysis conducted from a long-term care perspective, ICER of £48,629 when excess all-cause mortality attributable to pressure ulcers included.</p> <p>Intervention 3: Not cost-effective at £20,000 threshold in any scenario.</p> <p>Intervention 4: Remained not cost-effective at £20,000 threshold when approached from long term care perspective and when excess all-cause mortality attributable to pressure ulcers was included. Became dominant when only supply costs were included.</p> <p>Intervention 5: Remained dominant when analysis conducted from a long-term care perspective, and when only supply costs included. ICER of £30,370 when excess all-cause mortality attributable to pressure ulcers included.</p>
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Data sources

Health outcomes: Effectiveness data was taken from a Cochrane systematic review of RCTs by McInnes and colleagues (2008),¹⁷ for intervention2, from a systematic review and meta-analysis presented by Stratton and colleagues (2005)²⁴ for intervention3, from Torra 2005³ for intervention 4, and from Cooper (2001)⁶ for intervention 5. **Quality-of-life weights:** Based on the Minimum Data Set-Health Status Index which predicts HUI scores from RAI-MDS scores. RAI-MDS from all residents from 89 long-term facilities in Ontario were included.²⁵ **Cost sources:** Costs of nursing, food, accommodation etc. from minimum data set, Ontario Ministry of Health and Long-Term care. Supply, staff time costs and unit costs were obtained from the literature. The cost of the pressure redistributing devices was calculated per resident by amortizing the cost of upgrading the mattress over the mattress lifetime.

Comments

Source of funding: The Ontario Ministry of Health and Long-Term care provided funding to the Toronto Health Economics and Technology Assessment Collaborative.
Limitations: Whilst based on published systematic reviews, the effectiveness data for two of the comparisons are based on one study alone. Utility data is not calculated from EQ-5D or SF-36 data. Baseline health estimates and progression of pressure ulcers through the various stages are estimated from RAI-MDS instead of obtained via a systematic procedure. **Other:** All interventions are compared to standard care, rather than to each other.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CUA = cost-utility analysis; CI = 95% confidence interval; EQ-5D = Euroqol five dimensions (scale: 0.0 [death] to 1.0 [full health]; <0.0 = worse than death); ICER = incremental cost-effectiveness ratio; NR = not reported; QALYs = quality-adjusted life years

‡ Converted using 2009 purchasing power parities²²

** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations*

H.2 Pressure ulcer management

H.2.1 Nutritional supplementation and hydration strategies

Table 8: HISASHIGE2012

Hisashige, A. and T. Ohura. "Cost-effectiveness of nutritional intervention on healing of pressure ulcers." <i>Clinical Nutrition</i> 31.6 (2012): 868-74.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome = pressure ulcer days)</p> <p>Study design: Economic evaluation based on single RCT plus post trial extrapolation</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied. 4 week follow up period was added for economic analysis to 12 week in trial observation.</p> <p>Perspective: Japanese health care provider†</p> <p>Time horizon: 16 weeks</p> <p>Discounting: n/a</p>	<p>Population: Tube-fed, bed-ridden patients with Stage III-IV PU (NPUAP staging system. Hospitalised in long-term care facilities.</p> <p>Patient Characteristics:</p> <p>Intvn 1 N=29 Mean age=80.6 (SD:8.9) Male=34.5%</p> <p>Intvn 2 N=21 Mean age=81.4 (SD:8.1) Male= 28.6%</p> <p>Intervention 1: Conventional care</p> <p>Intervention 2: Nutritional intervention Racol feeding formula with an energy goal in the range calculated by Basal Energy Expenditure*active</p>	<p>Total costs (mean per patient): 16 weeks Intvn 1: £3,062 Intvn 2: £2,473 Incremental (2-1):-£586 (CI NR; p < 0.05)</p> <p>Currency & cost year: Calculated in Japanese Yen; presented in US dollars (\$1=¥111, based on 2010 purchasing power parities). Cost year NR. Costs presented here as 2010 UK pounds£</p> <p>Cost components incorporated: Direct medical care costs e.g. tests, nutrition, drugs, health care personnel, dressing materials pressure redistribution mattresses and consumables.</p>	<p>Pressure ulcer days (mean per patient): Intvn 1: 100.8 Intvn 2: 84.6 Incremental (2-1): -16.2 (CI -8.7, -23.7; p = NR)</p>	<p>ICER (Intvn 2 vs Intvn 1): Intvn 2 dominates intvn 1 (cost saving and fewer days spent with pressure ulcer)</p> <p>Analysis of uncertainty: Sensitivity analyses were undertaken, but the results are only presented in "cost-effectiveness ratios". It is unclear how these have been calculated.</p>

factor*stress factor. Racol contains 4.38g protein, 2.23g fat, and 15.62g carbohydrate per 100ml of product.			
Data sources			
Health outcomes: The economic evaluation used evidence from a single RCT. ²¹ Using patients data the prevalence rate of PUs was estimated by the Kaplan-Meier method up to 16 weeks from the start of trial. Quality-of-life weights: n/a Cost sources: Acquisition prices were used as unit costs. Drug costs were sourced from the NHI reimbursement list. Wages per hour were estimated by the basic survey on wage structure in Japan.			
Comments			
Source of funding: The study was partly supported by the Institute of Healthcare Technology Assessment, Tokushima, Japan. Limitations: The effectiveness estimates are based on the results of a single RCT set in Japan, rather than a systematic procedure. It is unclear how the cost-effectiveness ratios have been calculated; many of these are negative. Analysis of uncertainty unclear. Other: QALYs are also reported but mean QALYs for both groups are negative; this does not fit with the reported positive utility values. Therefore the QALYs are not reported here.			
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations			

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported; QALYs = quality-adjusted life years

†Stated as societal but only direct medical costs included and all patients were hospitalised, therefore the societal perspective in this case aligns closely with that of the health care provider

‡Converted using 2010 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

H.2.2 Pressure redistributing devices

Table 9: FLEURENCE2005

R. L. Fleurence. Cost-effectiveness of pressure-relieving devices for the prevention and treatment of pressure ulcers. <i>Int.J.Technol.Assess.Health Care</i> 21 (3):334-341, 2005.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CUA Study design: Decision analytic model	Population: Patients admitted to hospital with superficial or severe pressure ulcers; results are presented separately for	Superficial ulcers - Total costs (mean per patient) at 4 weeks: Intvn1: £206 Intvn2: £185 Intvn3: £286	Superficial ulcers - QALYs (mean per patient) at 4 weeks: Intvn1: 0.06242 Intvn2: 0.06247 Intvn3: 0.06220	Superficial ulcers - Primary ICER at 4 weeks: ICER: Intvn 2 dominates both Intvn 1 and Intvn 3 Probability cost-effective at threshold of £20,000: Intvn1 36%, Intvn2 64%, Intvn3

<p>Approach to analysis: Decision tree which models development of superficial or severe PUs (either singular or multiple), death, healing, and discharge with or without PUs</p> <p>Perspective: UK NHS</p> <p>Time horizon: 1 week, 4 weeks and 12 weeks</p> <p>Treatment effect duration: Full time horizon</p> <p>Discounting: n/a</p>	<p>these two patient groups (prevention was also analysed in a separate scenario– not relevant to management)</p> <p>Cohort settings: Start age = NR M = NR</p> <p>Intervention 1: Alternating pressure overlays (AO)</p> <p>Intervention 2: Alternating pressure mattress replacements (AR)</p> <p>Intervention 3: Standard care: high-specification foam mattress (SC)</p>	<p>Incremental (2-1): -£20 Incremental (3-2): £100</p> <p>Severe ulcers - Total costs (mean per patient) at 4 weeks: Intvn1: £168.58 Intvn2: £157.81 Intvn3: £213.92 Incremental (2-1): -£11 Incremental (3-2): £56</p> <p>Currency & cost year: GBP 2003</p> <p>Cost components incorporated: Cost of healing superficial and severe ulcers based on daily resources required to deliver care reflecting good clinical practice, cost of pressure relieving device (adjusted for lifetime use, maintenance contract, and an annuity factor), cleaning cost, additional costs of renting when purchased stock is not enough.</p>	<p>Incremental (2-1): 0.00005 Incremental (3-2): -0.00027</p> <p>Severe ulcers - QALYs (mean per patient) at 4 weeks: Intvn1: 0.06276 Intvn2: 0.06278 Intvn3: 0.06267 Incremental (2-1): 0.00002 Incremental (3-2): -0.00011</p> <p>Outcomes at 1 week similar to 4 weeks. Outcomes at 12 weeks not reported.</p>	<p>0%</p> <p>Intvn2 is reported to be the cost-effective strategy at 1, 4 and 12 weeks.</p> <p>Severe ulcers - Primary ICER at 4 weeks: ICER: Intvn 2 dominates both Intvn 1 and Intvn 3. Probability cost-effective between thresholds of £5,000 to £100,000: Intvn1 39-40%, Intvn2 61-62%, Intvn3 1%</p> <p>Intvn2 is reported to be the cost-effective strategy at 1, 4 and 12 weeks.</p> <p>Analysis of uncertainty: Probabilistic sensitivity analyses were conducted and CEACs presented. The optimal strategy was Intvn 2 between thresholds of £5,000 per QALY and £100,000 per QALY.</p>
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Data sources

Health outcomes: Epidemiology data which provided information on proportion of patients admitted to hospital at risk of developing a pressure ulcer and risk of new ulcers per week, as well as data on superficial and severe pressure ulcers, was obtained from a prospective nonrandomised cohort study conducted by Clark and colleagues 2002.⁵ No reliable effectiveness data was obtained from the literature so effectiveness was estimated and these estimates validated by a specialist in wound care. **Quality-of-life weights:** Obtained via visual analogue scale from five health professionals with expertise in wounds management. **Cost sources:** Cost of healing pressure ulcers was obtained from Bennett and colleagues 2004.² Prices of SC devices were obtained from a health technology assessment¹⁰ and from a previous NICE guideline.²⁰ Prices of AR and AO devices were obtained from Huntleigh Healthcare Products and from the literature.^{11,26}

Comments

Source of funding: Medical research council PhD Studentship; **Limitations:** Quality of life data is obtained from health care professionals rather than from patients, short time horizon may not capture full economic impact of these devices – not necessarily generalise able to individuals who face lifetime risk. Estimates of health effect estimated by experts rather than obtained from the literature (the estimates do not align with the evidence identified by our clinical review), baseline health outcomes not based on randomised data. **Other:** This paper also included an analysis which looked at devices for prevention of pressure ulcers; a separate evidence table is presented for this comparison.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CEA = cost-effectiveness analysis; ICER = incremental cost-effectiveness ratio; NR = not reported; QALYs = quality adjusted life years

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

H.2.3 Adjunctive therapies

Table 10: Soares 2013

Soares, Marta O., et al. "Methods to assess cost-effectiveness and value of further research when data are sparse: negative-pressure wound therapy for severe pressure ulcers." *Medical Decision Making* 33.3 (2013): 415-36.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CUA</p> <p>Study design: Probabilistic decision analytic model</p> <p>Approach to analysis: Markov model of pressure ulcer healing based on 3 states: unhealed, healed, and dead. Cycle length is 4 weeks. Rate of healing differs by intervention, based on a network meta-analysis. Three scenarios are</p>	<p>Population: UK patients with severe pressure ulcers</p> <p>Cohort settings: Start age = NR M =NR</p> <p>Intervention 1: Alginate</p> <p>Intervention 2: Spun hydrocolloid</p> <p>Intervention 3: Foam</p> <p>Intervention 4: Negative pressure wound therapy (NPWT)</p>	<p>Total costs (mean per patient): Intvn1: £15,249 Intvn2: £15,054 Intvn3: £14,178 Intvn4: £17,521</p> <p>Note all costs have been estimated from a graph using Grab It!</p> <p>Currency & cost year: UK pound 2008-2009</p> <p>Cost components incorporated: Cost of treatments eg.</p>	<p>QALYs (mean per patient): Intvn1: 1.2662 Intvn2: 1.2676 Intvn3: 1.2681 Intvn4: 1.2701</p> <p>Note all health outcomes have been estimated from a graph using Grab It!</p>	<p>ICER: Foam dressings had the highest expected net benefit (at the £20,000 threshold). NPWT has lowest expected net health benefit of all four treatments.</p> <p>Probability cost-effective (£20,000 threshold): Foam 32% Spun hydrocolloid 16% Alginate 30% NPWT 22%</p> <p>Analysis of uncertainty: Analysis based on existing and elicited expert data suggested that spun hydrocolloid dressing had the highest expect net benefit.</p>

<p>presented, using different combinations of published data, expert elicited information and results from a pilot trial. Base case results presented here are based on existing evidence only.</p> <p>Perspective: UK NHS</p> <p>Time horizon: 2 years</p> <p>Discounting: Costs = 3.5%; Outcomes = 3.5%</p>		<p>Machine and canister for NPWT, dressing changes, additional dressing costs, cost of closure(surgery)</p>		<p>NPWT was most clinically effective. The probability of NPWT being cost-effective was found to be 0.29, spun hydrocolloid 0.37, and alginate 0.32. Foam was very unlikely to be cost effective (probability of 2% at threshold of £20,000 per QALY gained).</p> <p>Analysis based on existing, expert elicited and pilot data combined found that NPWT had the highest expect net benefit. NPWT was more effective and less costly than all other treatments. The probability of NPWT being cost-effective was found to be 0.45, spun hydrocolloid 0.30, and alginate 0.23. Foam was very unlikely to be cost effective (probability of 2% at threshold of £20,000 per QALY gained).</p>
Data sources				
<p>Health outcomes: Data from literature using Indirect and Mixed Treatment comparisons was used to estimate relative treatment effects in the absence of relevant head-to-head trials. Elicited data involved systematic capture of expert (23 wound care and tissue viability nurses) knowledge around the treatment and progression of severe pressure ulcers. The third source was a pilot RCT set in 1 UK community health care trust and 1 hospital: 12 patients were randomised to receive NPWT or standard care. The study used a 6 month follow-up. Bayesian updating was used to collate and combine the three sources of data. Here the base case results are those based on existing evidence only, with other scenarios reported as sensitivity analyses. Quality-of-life weights: 1 study reporting SF-36 data from 218 people with and 2289 without pressure ulcers (all grades) in the UK was identified. Patient-level data from this study was used to calculate utility data via SF-6D. EQ-5D data was collected in the pilot trial. Cost sources: Costs and resource use data were derived from the literature.</p>				
Comments				
<p>Source of funding: Medical Research Council. Limitations: The costs of NPWT used in this analysis were not considered to be representative of current costs of this therapy, a limitation which is likely to have a significant impact on the results. In addition, the GDG felt that the comparator should be a dressing regimen rather than individual dressings. Finally, the absolute healing hazard is assumed to be constant over time; this assumption was not considered to be realistic by the GDG. Clinical evidence on the effectiveness of NPWT for the treatment of pressure ulcers is considered to be weak. Other: The primary purpose of this analysis was to demonstrate an approach to decision making when robust evidence is lacking. Cost effectiveness and uncertainty was considered with existing evidence, existing and elicited evidence combined, and finally existing, elicited and trial data. Base case results reported above are based on existing evidence alone, as selected by the GDG.</p>				
<p>Overall applicability*: Directly Applicable Overall quality**: Potentially serious limitations</p>				

Abbreviations: CI = 95% confidence interval; CUA = cost-utility analysis; EQ-5D = Euroqol five dimensions (scale: 0.0 [death] to 1.0 [full health]); <0.0 = worse than death); ICER = incremental cost-effectiveness ratio; NR = not reported; QALYs = quality-adjusted life years; SF36 = Short Form 26

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

Table 11: Mittmann 2011

N. Mittmann, B. C. Chan, B. C. Craven, P. K. Isogai, and P. Houghton. Evaluation of the cost-effectiveness of electrical stimulation therapy for pressure ulcers in spinal cord injury. <i>Arch Phys Med Rehabil.</i> 92 (6):866-872, 2011.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome = pressure ulcers healed)</p> <p>Study design: Decision analytic model</p> <p>Approach to analysis: Decision tree based on effectiveness data and resource use from Houghton 2010¹⁵. Model allows for healing of pressure ulcer, complications and new pressure ulcers.</p> <p>Perspective: Canadian public health care payer</p> <p>Time horizon: 1 year</p> <p>Discounting: N/A</p>	<p>Population: Community dwelling spinal cord injury patients with stage 3-4 pressure ulcers</p> <p>Cohort settings: NR</p> <p>Intervention 1: SWC for one year. SWC was tailored to the patient including nutritional intervention, optimal wound dressing and continence management.</p> <p>Intervention 2: Electrical stimulation (ES) + standard wound care (SWC). ES was delivered daily for 3 months, with SWC continuing for one year. SWC was tailored to the patient including nutritional intervention, optimal wound dressing and continence</p>	<p>Mean total cost per patient: Intvn 1: £16,374 Intvn 2: £16,251 Incremental (2-1): -£123</p> <p>Currency & cost year: 2009 Canadian dollars (presented here as 2009 UK pounds£)</p> <p>Cost components incorporated: Treatment costs of ES and SWC, surgical repair costs of cutaneous flap repair and muscle flap repair (including hospitalisation, assessments, surgeon costs, anaesthesiologist cost, subsequent visits and discharge) and complications (including hospitalisation, emergency department admission, consultation, physician visits, antibiotics and discharge).</p>	<p>Primary outcome measure: Average overall pressure ulcers healed per year (healed minus relapsed) Intvn 1: 0.045 Intvn 2: 0.208 Incremental (2-1): 0.164</p>	<p>Primary ICER (Intvn 2 vs Intvn 1): ES + SWC dominates SWC Probability cost-effective: 96% at a threshold of \$50,000 (£27,198) per ulcer healed</p> <p>Analysis of uncertainty: A series of one way sensitivity analyses were carried out in which costs and probabilities were varied by 25%. This d/a revealed that the percentage of pressure ulcers healed was the largest driver of the model. ES+SWC remained the dominant strategy as long as the percentage of individuals with pressure ulcers healed remained above 29%. In the p/a, 61.5% of the iterations resulted in ES+SWC dominating SWC, with a further 35% of iterations resulting in ICERs below a threshold of \$50,000 (£27,250) per ulcer healed.</p>

management.			
Data sources			
<p>Health outcomes: Clinical data was obtained from a literature review. Specifically; effectiveness data was obtained from Houghton 2010,¹⁵ with relapse data taken from Bates-Jensen 2009¹, and complications data from Cardenas 2004⁴ and Hitzig 2008¹⁴; of these evidence sources only Houghton is randomised. The percentage of individuals requiring skin or muscle flap repair, or with skin or muscle flap complications was taken from Schryvers 2000²³. Cost sources: Costs were obtained from Houghton 2010¹⁵ and the Ontario Ministry of Health and Long Term Care.</p>			
Comments			
<p>Source of funding: The Ontario neurotrauma Foundation and Réseau provincial de recherché en adaptation-réadaptation; Limitations: Clinical inputs are obtained from a literature review but it is not clear whether this review was systematic. In addition important assumptions have been made about the data, for example the 12 month healing rate utilised in the model is the 3 month healing rate from Houghton 2010,¹⁵ whereas the relapse rate is a 9 month rate taken from Bates-Jensen.¹ The time horizon is only one year and not all wounds had healed so costs which would have continued past the one year mark have not been accounted for. Resource use is calculated from the Houghton trial rather than identified through a systematic review, and whilst sources are provided for unit costs it is unclear how the overall cost figures have been calculated. Finally, the diagram of the model does not fully the pathway described in the text.</p>			
<p>Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations</p>			

Abbreviations: CEA = cost-effectiveness analysis; d/a deterministic analysis; ES = electrical stimulation; NR = not reported; pa = probabilistic analysis; QALYs = quality-adjusted life years; SWC = standard wound care

‡ Converted using 2009 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

H.2.4 Debridement

Table 12: Mosher 1999

B. A. Mosher, J. Cuddigan, D. R. Thomas, and D. M. Boudreau. Outcomes of 4 methods of debridement using a decision analysis methodology. Adv.Wound Care 12 (2):81-88, 1999.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CC (no health outcome)</p> <p>Study design: Deterministic decision model</p> <p>Approach to analysis: A decision tree including branches for</p>	<p>Population: Female residents of a long term care facility. Pressure ulcer on trochanter (7x6x4 cm) with approximately 50% necrotic tissue covering the pressure ulcer.</p> <p>Cohort settings: Mean age = 78 M = 0%</p>	<p>Total costs:</p> <p>Intvn 1: £591 Intvn 2: £648 Intvn 3: £392 Intvn 4: £633</p> <p>Currency & cost year:</p>	<p>No health outcome reported.</p>	<p>Collagenase had the lowest cost of the four methods of debridement.</p> <p>Analysis of uncertainty: All inputs were varied by +/-10%. Collagenase remained the least expensive option.</p>

<p>complete/incomplete debridement, infection, and an option for switching method of debridement. Patients could only die if they had an unresolved infection. Model structure was based on a literature review.</p> <p>Perspective: Medicare</p> <p>Time horizon: 28 days</p> <p>Treatment effect duration: 28 days</p> <p>Discounting: Costs = n/a; Outcomes = n/a</p>	<p>Intervention 1: Autolysis</p> <p>Intervention 2: Wet-to-dry saline dressings (mechanical debridement)</p> <p>Intervention 3: Collagenase (enzymatic debridement)</p> <p>Intervention 4: Fibrinolysin and desoxyribonuclease combined (enzymatic debridement)</p>	<p>1995 US dollars (presented here as 1995 UK pounds£)</p> <p>Cost components incorporated: Physician and nurse time, drug costs, dressings, costs associated with inpatient stay ancillary costs.</p>		
<p>Data sources</p>				
<p>Health outcomes: Based on expert opinion – a modified Delphi approach was used to elicit estimates from 9 experts. Quality-of-life weights: n/a. Cost sources: Drug costs were obtained from the 1995 Red book (ref); dressing costs were obtained from wholesalers; physician costs, ancillary costs and inpatient days were calculated from reimbursement rates in 1995 in Rhode Island; the cost of nurse time was based on responses from the expert panel.</p>				
<p>Comments</p>				
<p>Source of funding: Funded in part through a contract with Knoll Pharmaceutical Company. Limitations: no consideration of quality of life or health outcomes, unclear whether unit costs are nationally representative, efficacy is based on expert opinion (small sample of only 9 experts), the time horizon is short and therefore the model may not capture the full cost impact between the different strategies.</p>				
<p>Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations</p>				

Abbreviations: CC = cost-comparison

‡ Converted using 1995 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

H.2.5 Dressings

Table 13: Bergerman 1999

R. Bergemann, K. W. Lauterbach, W. Vanscheidt, K. Neander, and R. Engst. Economic evaluation of the treatment of chronic wounds: hydroactive wound dressings in combination with enzymatic ointment versus gauze dressings in patients with pressure ulcer and venous leg ulcer in Germany. <i>Pharmacoeconomics</i> 16 (4):367-377, 1999.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CC (no health outcome)</p> <p>Study design: Probabilistic decision model</p> <p>Approach to analysis: Calculation of resource use, using data from four hospitals and an expert panel. Four sizes of PU considered: 5cm x 8 cm, 8cm x 12 cm, 10cm x 15cm, 12cm x 20cm.</p> <p>Perspective: German hospital administrator</p> <p>Time horizon: 22- 50 days depending on size of wound/type of treatment</p> <p>Discounting: n/a</p>	<p>Population: Inpatients with pressure ulcers</p> <p>Cohort settings: Mean age = NR M = NR</p> <p>Intervention 1: Gauze</p> <p>Intervention 2: Ointment impregnated gauze</p> <p>Intervention 3: Calcium alginate</p> <p>Intervention 4: Hydroactive 1 (hydroactive wound dressing in combination with enzymatic wound cleaning (collagenase))</p>	<p>Total costs (per patient, median) for 12x20cm ulcer: Intvn 1: £3,813 Intvn 2: £1,501 Intvn 3: £1,677 Intvn 4: £592</p> <p>Intvn 4 had the lowest cost across all wound sizes.</p> <p>Currency & cost year: 1997 German Deutschmarks (presented here as 1997 UK pounds£)</p> <p>Cost components incorporated: Dressings used, ancillary supplies, nursing time.</p>	<p>Equal efficacy assumed, aside from a decrease in the length of hospital stay of 10% for Intvn 4.</p>	<p>Intervention 4 has the lowest cost.</p> <p>Analysis of uncertainty: Results were not sensitive to changes in personnel cost per minute, time required for changing a wound dressing or total number of wound dressing changes.</p>
Data sources				
<p>Health outcomes: none (frequency of dressing change etc. taken from observational level evidence). Quality-of-life weights: n/a. Cost sources: Material costs were taken from list prices, staff costs based on German data.</p>				
Comments				
<p>Source of funding: Beiersdorf AG and Knoll AG, Germany. Limitations: no consideration of quality of life, unclear whether unit costs are nationally representative, efficacy is assumed the same which is unlikely to be a reasonable assumption. It is assumed (not based on evidence) that treatment with hydroactive wound dressing reduces inpatient stay by 10% - this is likely to have a substantial impact on costs. Limited information is given on the population considered in the model.</p>				
<p>Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations</p>				

Abbreviations: CC = cost-comparison; CI = 95% confidence interval; NR = not reported

‡ Converted using 1997 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

Table 14: Burgos 2000

A. Burgos, J. Gimenez, E. Moreno, E. Lamberto, M. Utrera, E. M. Urraca, F. J. Velez, E. Lopez, M. A. Martinez, M. J. Gomez, and L. Garcia. Cost, efficacy, efficiency and tolerability of collagenase ointment versus hydrocolloid occlusive dressing in the treatment of pressure ulcers: a comparative, randomised, multicentre study. Clinical Drug Investigation 19(5):357-365, 2000.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA (various health outcomes)</p> <p>Study design: Within trial analysis (RCT)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied</p> <p>Perspective: NR – appears to be Spanish hospital</p> <p>Time horizon: 12 weeks or until healing of the ulcer, whichever occurred first</p> <p>Treatment effect duration: 12 weeks or until healing of the ulcer, whichever occurred first</p> <p>Discounting: n/a</p>	<p>Population: Patients aged ≥ 55 with a grade III PU for <1 year</p> <p>Patient characteristics: Mean age = 80 M = 46%</p> <p>Intervention 1: Collagenase ointment (Irujol® Mono, Laboratorios Knoll, SA)</p> <p>Intervention 2: Hydrocolloid dressing (Varihesive®, Convatec, SA)</p>	<p>Total costs (mean per patient): Intvn 1: £224 Intvn 2: £178 Incremental (2-1): -£46 (CI NR; p < 0.0001)</p> <p>Currency & cost year: 1998 Spanish Pesetas (presented here as 1998 UK pounds‡)</p> <p>Cost components incorporated: Dressings used, ancillary supplies (saline solution, gauzes, tapes, bandages) and nursing time</p>	<p>Patients healed: RR 0.95 (CI 0.22-4.10)</p> <p>Mean percentage reduction in ulcer area MD -9.6 (CI -69.17-49.97)</p> <p>Mean cm² reduction in ulcer area MD -2.9 (CI -10.24 – 4.44)</p>	<p>Collagen is more expensive per patient, but produces favourable results across all three reported health outcomes</p> <p>Analysis of uncertainty: No sensitivity analysis reported</p>
Data sources				
<p>Health outcomes: obtained from within trial. Quality-of-life weights: n/a. Cost sources: unit costs were based on public selling price (for example for a patient in a pharmacy) and labour cost was taken from the Agency for Health Care Policy and Research.</p>				
Comments				

Source of funding: Laboratorios Knoll, SA, Madrid. **Limitations:** no consideration of quality of life, no analysis of uncertainty reported, unit costs are based on prices faced by patients and could be substantially different to those faced by hospitals. Differential costs past 12 weeks not included due to time horizon restriction.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = 95% confidence interval; MD = mean difference; NR = not reported; RR = risk ratio

‡ Converted using 1998 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

Table 15: Graumlich 2003

J. F. Graumlich, L. S. Blough, R. G. McLaughlin, J. C. Milbrandt, C. L. Calderon, S. A. Agha, and L. W. Scheibel. Healing pressure ulcers with collagen or hydrocolloid: a randomized, controlled trial. J.Am.Geriatr.Soc. 51 (2):147-154, 2003.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA (various health outcomes)</p> <p>Study design: Within trial analysis (RCT)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied</p> <p>Perspective: US nursing home provider</p> <p>Time horizon: 8 weeks</p> <p>Treatment effect duration: 8 weeks</p> <p>Discounting: Costs = n/a; Outcomes = n/a</p>	<p>Population: Patients ≥ 18 years with a stage II or III pressure ulcer</p> <p>Patient characteristics: Mean age = 83 M = 27%</p> <p>Intervention 1: Collagen dressing (Medifil®, Kollagen, BioCore, Topeka, KS) covered with dry gauze.</p> <p>Intervention 2: Hydrocolloid (DuoDerm®, ConvaTec, ER Squibb & Sons, Inc. Princeton, NJ), perimeter rimmed with tape.</p>	<p>Total costs (mean per patient): Intvn 1: £402 Intvn 2: £142 Incremental (2-1): -£260 (CI NR; p NR)</p> <p>Currency & cost year: US Dollars, year NR (presented here as UK pounds‡)</p> <p>Cost components incorporated: Dressings used, ancillary supplies and nursing time</p>	<p>Patients healed: RR 0.97 (CI 0.60-1.57)</p> <p>Mean percentage reduction in ulcer area MD -24.00 (CI -60.08-12.08)</p> <p>Mean time to healing (weeks) MD 1.00 (CI -0.36-2.36)</p> <p>Mean healing speed (mm²/day) MD 0.00 (CI -8.23-8.23)</p>	<p>Collagen is more expensive per patient, but produces favourable results across most health outcomes</p> <p>Analysis of uncertainty: It is stated that sensitivity analyses did not reveal likely conditions under which collagen would be cheaper than hydrocolloid; results are not presented.</p>

Data sources

Health outcomes: obtained from within trial. **Quality-of-life weights:** n/a. **Cost sources:** prices were obtained from a Midwestern wholesaler

Comments

Source of funding: Grant from the Retirement Research Foundation. Collagen product donated by BioCore Medical Technologies. **Limitations:** no consideration of quality of life, analysis of uncertainty results are not reported, it is not clear whether unit costs are nationally representative. Differential costs past 8 weeks not included due to time horizon restriction.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CCA = cost-consequence analysis; CI = 95% confidence interval; MD = mean difference; NR = not reported; RR = risk ratio

‡ Converted using 2003 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

Table 16: Kerstein 2001

M. D. Kerstein, E. Gemmen, Rijswijk L. van, C. H. Lyder, T. Phillips, G. Xakellis, K. Golden, and C. Harrington. Cost and cost effectiveness of venous and pressure ulcer protocols of care. Disease Management and Health Outcomes 9 (11):651-663, 2001.

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome = pressure ulcers healed)</p> <p>Study design: Decision analytic model</p> <p>Approach to analysis: Model includes proportion of patients healed, and the probability of debridement (both surgical and non-surgical) and/or infection.</p> <p>Perspective: NR – appears to be US health care provider</p> <p>Time horizon: 12 weeks</p> <p>Treatment effect duration: 12 weeks</p> <p>Discounting: Costs = n/a; Outcomes = n/a</p>	<p>Population: Patients with pressure ulcers</p> <p>Patient characteristics: Mean age = NR M = NR</p> <p>Intervention 1: Saline gauze</p> <p>Intervention 2: Hydrocolloid Comfeel® dressing</p> <p>Intervention 3: Hydrocolloid DuoDERM® dressing</p>	<p>Total costs (mean per patient): Intvn 1: £703 Intvn 2: £384 Intvn 3: £353</p> <p>Incremental (2-1): -£319 (CI NR; p NR) Incremental (3-2): -£31 (CI NR; p NR)</p> <p>Currency & cost year: 2000 US\$ (presented here as 2000 UK pounds‡)</p> <p>Cost components incorporated: Dressing materials and products to absorb excess wound exudate, physician costs and nurse costs.</p>	<p>Proportion of patients healed at 12 weeks: Intvn 1: 51% Intvn 2: 48% Intvn 3: 61%</p> <p>Incremental (2-1): -3% (CI NR; p NR) Incremental (3-2): 13% (CI NR; p NR)</p>	<p>DuoDERM dressing dominates Comfeel dressing and saline gauze. Saline gauze is slightly more effective than Comfeel dressing, but is substantially more expensive.</p> <p>Analysis of uncertainty: No sensitivity analysis reported</p>
Data sources				

Health outcomes: obtained from a meta-analysis of 15 trials, 12 of which were included in the clinical review for this question. **Quality-of-life weights:** n/a. **Cost sources:** Dressing costs obtained from the 2000 Drug Topics Red Book, physicians costs from the 2000 Medicare Physician Fee schedule, and nursing costs calculated from the 1996 National Sample survey of registered Nurses.

Comments

Source of funding: ConvaTec: A Bristol-Myers Squibb Company, USA. **Limitations:** no consideration of quality of life, no analysis of uncertainty reported, discussion of results based on average ratios (not a useful measure of cost-effectiveness), no cohort characteristics given. Differential costs past 12 weeks not included due to time horizon restriction.

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; NR = not reported;

‡ Converted using 2000 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

Table 17: Meaume2002

S. Meaume and E. Gemmen. Cost-effectiveness of wound management in France: pressure ulcers and venous leg ulcers. <i>J.Wound Care</i> 11 (6):219-224, 2002.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome = pressure ulcers healed)</p> <p>Study design: Decision analytic model</p> <p>Approach to analysis: Model includes proportion of patients healed, and the probability of debridement and/or infection.</p> <p>Perspective: NR – appears to be US health care provider</p> <p>Time horizon: 12 weeks</p> <p>Treatment effect</p>	<p>Population: Patients with grade 2-3 pressure ulcers</p> <p>Patient characteristics: Mean age = NR M = NR</p> <p>Intervention 1: Saline gauze</p> <p>Intervention 2: Hydrocolloid Comfeel® dressing</p> <p>Intervention 3: Hydrocolloid DuoDERM® dressing</p>	<p>Total costs (mean per patient in European model[†]): Intvn 1: £1,651 Intvn 2: £516 Intvn 3: £500</p> <p>Incremental (2-1): -£1,135 (CI NR; p NR) Incremental (3-2): -£16 (CI NR; p NR)</p> <p>Currency & cost year: Euros, year NR (presented here as UK pounds‡)</p>	<p>Proportion of patients healed at 12 weeks (in European model[†]): Intvn 1: 51% Intvn 2: 48% Intvn 3: 61%</p> <p>Incremental (2-1): -3% (CI NR; p NR) Incremental (3-2): 13% (CI NR; p NR)</p>	<p>DuoDERM dressing dominates Comfeel dressing and saline gauze. Saline gauze is slightly more effective than Comfeel dressing, but is substantially more expensive.</p> <p>Analysis of uncertainty: No sensitivity analysis reported</p>

duration: 12 weeks Discounting: Costs = n/a; Outcomes = n/a	Cost components incorporated: Dressing materials and products required to treat infection, physician costs and nurse costs.
Data sources	
Health outcomes: based on meta-analysis of 15 studies; 11 of which were included in the clinical review for this question. Quality-of-life weights: n/a. Cost sources: Costs for European model were based on national averages from the UK (Drug tariff and BNF prices for dressing costs and PSSRU for labour cost), and Germany (Rote Liste for dressing costs, Einheitlicher Bewertungs Massstab (EBM) for physician costs, and Allgemein Orts Krankenkasse for nursing costs).	
Comments	
Source of funding: NR. Limitations: no consideration of quality of life, no analysis of uncertainty reported, average ratios presented (not a useful measure of cost-effectiveness), no cohort characteristics given. Differential costs past 12 weeks not included due to time horizon restriction.	
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations	

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; NR = not reported

[†] Results for a French model were also presented- the conclusions did not differ

[‡] Converted using 2002 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

Table 18: MOTTA1999

G. Motta, L. Dunham, T. Dye, J. Mentz, E. O'Connell-Gifford, and E. Smith. Clinical efficacy and cost-effectiveness of a new synthetic polymer sheet wound dressing. Ostomy.Wound Manage. 45 (10):41-49, 1999.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CCA (various health outcomes) Study design: Within trial analysis (RCT) Approach to analysis: Analysis of individual level resource use, with unit costs applied Perspective: NR – appears	Population: Home care patients with stage II or III PUs Patient characteristics: Mean age = 60 M = 50% Intervention 1: Hydrocolloid dressing (AcryDerm [®] ,	Total costs (mean per patient): Intvn 1: £60 Intvn 2: £38 Incremental (2-1): -£22 (CI NR; p = NR) Currency & cost year: US dollars, year NR (presented)	Patients healed: RR 1 (CI 0.22-4.56) Mean healing rate (cm/day) MD 0.2 (CI -0.22-0.62)	No difference in number of patients healed, so lower cost of hydrogel indicates hydrogel is cost-effective. However the healing rate favours hydrocolloid. Analysis of uncertainty: Statistical analysis to compare costs and effects but tests used were not

to be US healthcare provider Time horizon: 8 weeks Treatment effect duration: 8 weeks Discounting: Costs = n/a; Outcomes = n/a	AcrylMed, Portland, Ore – now known as Flexigel®, Smith & Nephew, Largo, Fla) Intervention 2: Polymer hydrogel dressing (DuoDermCGF®, ConvaTec, Skillman, NJ)	here as UK pounds£) Cost components incorporated: Number of dressings used, ancillary supplies and nursing time	reported
Data sources			
Health outcomes: obtained from within trial. Quality-of-life weights: n/a. Cost sources: costs collected alongside trial – no specific source reported.			
Comments			
Source of funding: Educational grant from AcryMed, Portland. Limitations: small pilot study with only ten patients, no unit cost source reported. Differential costs past 8 weeks not included due to time horizon restriction. no consideration of quality of life, no analysis of uncertainty reported			
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations			

Abbreviations: CCA = cost-consequence analysis; CI = 95% confidence interval; MD = mean difference; NR = not reported; RR = risk ratio

‡ Converted using 1999 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

Table 19: MÜLLER2001

E. Muller, M. W. F. van Leen, and R. Bergemann. Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers. Pharmacoeconomics 19 (12):1209-1216, 2001.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CEA (health outcome = proportion of patients healed) Study design: Within trial analysis (RCT) Approach to analysis: Analysis of individual level resource use, with unit costs applied	Population: Female inpatients with a grade IV heel PU Patient characteristics: Mean age group 1 = 74.6 Mean age group 2 = 72.4 M = 0% Intervention 1:	Total costs (mean per patient): Intvn 1: £522 Intvn 2: £547 Incremental (2-1): £25 (CI NR; p = NR) Currency & cost year: 1998 Dutch guilders	Proportion of patients healed: Intvn 1: 92% Intvn 2: 63% Incremental (2-1): -29% (CI NR; p <0.005)	Incremental cost per healed patient: Intvn 1 dominates Intvn 2 Analysis of uncertainty: DA and PSA of cost-related variables using maximum and minimum values. Average ratios are presented rather than incremental ratios, these are not informative.

Perspective: Netherlands hospital Time horizon: NR - maximum 16 weeks Treatment effect duration: until healing (maximum 16 weeks) Discounting: Costs = n/a; Outcomes = n/a	Intervention 1: Collagenase dressing (Novuxol®) Intervention 2: Hydrocolloid dressing (DuoDerm®)	(presented here as 1998 UK pounds‡) Cost components incorporated: All material and staff costs (including dressings and ancillary supplies)		
Data sources				
Health outcomes: obtained from within trial. Quality-of-life weights: n/a. Cost sources: costs collected alongside trial – no specific source reported although costs are reported to be representative of those faced by the hospital				
Comments				
Source of funding: Grant from Knoll AG, Ludwigshafen, Germany. Limitations: small study with only 23 patients, no unit cost source reported, no consideration of quality of life, average cost-effectiveness ratios are presented, no useful analysis of uncertainty reported				
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations				

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; DA = deterministic analysis; NLG = Dutch guilders; NR = not reported; PSA = probabilistic sensitivity analysis; ‡ Converted using 1998 purchasing power parities²²
* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

Table 20: Ohura 2004

T. Ohura, H. Sanada, and Y. Mino. Clinical activity-based cost effectiveness of traditional versus modern wound management in patients with pressure ulcers. Wounds 16 (5):157-163, 2004.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CEA (health outcome = PSST score) Study design: Within study analysis (prospective cohort study) Approach to analysis:	Population: Patients with grade II or III pressure ulcers Patient characteristics: Mean age = 77 M = 58% Intervention 1:	Total costs (mean per patient): Intvn 1: £7.08 Intvn 2: £6.76 Incremental (2-1): -£0.32 (CI NR; p NR)	Reduction in PSST score: Intvn 1: 6.9 Intvn 2: 11.1 Incremental (2-1): 4.2 (CI NR; p = 0.046)	Modern dressings dominate traditional wound care (reduced costs and greater reduction in PSST score). Analysis of uncertainty: No sensitivity analysis reported

<p>Analysis of individual level resource use, with unit costs applied</p> <p>Perspective: NR – appears to be Japanese hospital</p> <p>Time horizon: maximum 12 weeks</p> <p>Treatment effect duration: maximum 12 weeks</p> <p>Discounting: Costs = n/a; Outcomes = n/a</p>	<p>Traditional care of ointment (including tretinoin tocoferil, alprostadiol ointment, bucladesine sodium and alprostadiol ointments) and gauze with a standardized wound management algorithm</p> <p>Intervention 2: Modern dressings (including DuoDERM®, DuoDERM® CGF®, DuoDERM® Extra Thin, DuoDERM® Hydroactive Gel (GRANUGEL), and AQUACEL® - all ConvaTec) with a standardized wound management algorithm</p> <p>Traditional care without the standardized wound management algorithm was included as a third comparator; results are not presented here.</p>	<p>Currency & cost year: 2001 Japanese Yen (presented here as UK pounds‡)</p> <p>Cost components incorporated: Dressings used, ancillary supplies (including those needed for the wound management algorithm), nursing and physician time.</p>		
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Data sources

Health outcomes: obtained from within trial. **Quality-of-life weights:** n/a. **Cost sources:** Supply purchase prices and representative market prices were used (no specific source stated). Labour costs were based on the Basic Survey on Wage Structure.

Comments

Source of funding: Supported by ConvaTec, New Jersey. **Limitations:** no consideration of quality of life, no analysis of uncertainty reported, it is not clear whether unit costs are nationally representative. Differential costs past 12 weeks not included due to time horizon restriction (healing is not recorded and effectiveness is based on PSST score only), patients were not randomised to treatment groups (although there were no significant differences in age, size of ulcer or PSST score at baseline).

Overall applicability*: Partially applicable **Overall quality**:** Potentially serious limitations

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; NR = not reported; PSST = Pressure sore status tool (score between 65 and 13; a score of 13 represents no ulcer)
‡ Converted using 2001 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations / Potentially serious limitations / Very serious limitations

Table 21: Payne 2009

W. G. Payne, J. Posnett, O. Alvarez, M. Brown-Etris, G. Jameson, R. Wolcott, H. Dharma, S. Hartwell, and D. Ochs. A prospective, randomized clinical trial to assess the cost-effectiveness of a modern foam dressing versus a traditional saline gauze dressing in the treatment of stage II pressure ulcers. <i>Ostomy.Wound Manage.</i> 55 (2):50-55, 2009.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome = ulcers healed)</p> <p>Study design: Within trial analysis (RCT)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied</p> <p>Perspective: US healthcare provider</p> <p>Time horizon: 28 days or until healing (whichever occurred first)</p> <p>Treatment effect duration: 28 days or until healing (whichever occurred first)</p> <p>Discounting: Costs = n/a; outcomes = n/a</p>	<p>Population: Patients 18 years and older with a stage II PU (according to the NPUAP classification)</p> <p>Patient Characteristics: N = 36 Mean age = 72.8 (SD: 13.3) Male = 61.1%</p> <p>Intervention 1: Saline-soaked gauze dressing. Ulcers were cleansed, dried and dressed. A second dry sterile gauze pad was applied. Frequency of dressing change was determined by clinician.</p> <p>Intervention 2: Polyurethane self-adhesive foam dressing (Allevyn® Thin, Smith & Nephew). Ulcers were cleansed, dried and dressed. Frequency of dressing change was determined by clinician.</p>	<p>Total costs (mean per patient): Intvn 1: £504 Intvn 2: £203 Incremental (2-1): -£301</p> <p>Currency & cost year: 2007 US dollars (presented here as 2007 UK pounds£)</p> <p>Cost components incorporated: Dressings, other materials (eg tape, gloves, syringes) and nurse time to dress the ulcer</p>	<p>Pressure ulcer free days (mean per patient): Intvn 1: 6.9 Intvn 2: 9.3 Incremental (2-1): 2.4</p> <p>Ulcers healed by day 28: Intvn 1: 38% Intvn 2: 50% Incremental (2-1): 12%</p>	<p>Incremental cost per pressure ulcer free day (Intvn 2 vs Intvn 1): Intvn 2 dominates Intvn 1 with more pressure ulcer free days at a lower cost</p> <p>Incremental cost per pressure ulcer healed (Intvn 2 vs Intvn 1): Intvn 2 dominates Intvn 1 with a greater proportion of ulcers healed at a lower cost</p> <p>Analysis of uncertainty: Costs for patients who dropped out were included in a deterministic sensitivity analysis. Intvn 2 remained dominant compared to Intvn 1.</p>
Data sources				
<p>Health outcomes: Health outcomes from within RCT. Quality-of-life weights: n/a. Cost sources: Resource use from within RCT; US unit costs applied. Cost of nurse time was taken from the US Bureau of Labour statistics, the foam dressing cost was the average US retail price, and prices of other materials were taken from a web-based surgical supplies company.</p>				

Comments

Source of funding: Smith & Nephew. **Limitations:** All resource use and health outcomes are obtained from within the trial rather than via a systematic procedure. In addition it is not clear whether the costs for the 'other materials' are nationally representative unit costs as they are obtained from one supplier. Exploration of uncertainty is inadequate. There is also a potential conflict of interest as the study is carried out by manufacturer of the foam dressing. Differential costs past 28 days not included due to time horizon restriction.

Overall applicability*: Partially applicable **Overall quality**:** Minor limitations

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; SD = standard deviation

‡ Converted using 2007 purchasing power parities²²

** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations*

Table 23: Foglia 2012

Foglia, E., et al. "Pressure ulcers management: an economic evaluation." <i>Journal of preventive medicine and hygiene</i> 53.1 (2012): 30-36.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA (health outcome = reduction in ulcer size)</p> <p>Study design: Observational study</p> <p>Approach to analysis: Analysis of individual level resource use with unit costs applied.</p> <p>Perspective: Italian Health care provider</p> <p>Time horizon: 30 days</p> <p>Treatment effect duration: time to heal or reduce in size within 30 days</p> <p>Discounting: none</p>	<p>Population: Community-residing patients with PUs receiving home care</p> <p>Patient characteristics</p> <p>Intvn 1: N=150 Age >80: 47.7% M =34.7%</p> <p>Intvn 2: N= 201 Age >80: 58% M =31.3%</p> <p>Intervention 1: simple and saline dressings (usual care)</p> <p>Intervention 2: advanced dressings</p>	<p>Total costs (mean monthly per patient): Intvn 1:£ 293 Intvn 2:£215 Incremental (2-1): -£78 (CI NR; p = NR)</p> <p>Currency & cost year: 2010 Euros (2008 Euros inflated to 2010 values using Italian inflation rates) (presented here as 2010 UK pounds£)</p> <p>Cost components incorporated: Medications, devices, personnel and transport costs</p>	<p>Health outcomes (mean per patient): Reduction in ulcer size Intvn 1: 34.34% Intvn 2: 40.34% Incremental (2-1): 6% (CI NR; p = 0.05)</p>	<p>ICER (Intvn 2 vs Intvn 1): The use of advanced dressings is dominant compared to simple dressings: lower costs and greater reduction in ulcer area.</p> <p>Probability Intvn 2 cost-effective (£20K/30K threshold): NR</p> <p>Analysis of uncertainty: Deterministic analyses revealed that when using minimum and maximum values for personnel costs, transport expenses and material costs, cost savings from the use of advanced dressings were between 27-29%. Bootstrapping methods and Monte Carlo simulation were also carried out; the use of advanced dressings was cost saving in all scenarios.</p>
Data sources				
<p>Health outcomes: Data collected within trial from care report forms Quality-of-life weights: n/a Cost sources: Resource use collected alongside trial. Unit costs of materials were based on provider supplier records; source of personnel costs not reported; transport costs were calculated based on distance travelled, type of vehicle, related fuel consumption.</p>				
Comments				
<p>Source of funding: NR Limitations: Based on single observation study. The study does not fully describe the interventions, or the cost sources. No consideration is given to quality of life. Only costs were subject to sensitivity analysis. Differential costs past 30 days not included due to time horizon restriction.</p>				
<p>Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations</p>				

Abbreviations: CCA = cost-consequence analysis; CI = 95% confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported

‡ Converted using 2010 purchasing power parities²²

** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations*

Table 23: Waycaster 2013

C. Waycaster and C. T. Milne. Clinical and economic benefit of enzymatic debridement of pressure ulcers compared to autolytic debridement with a hydrogel dressing. J Med Econ 16 (7):976-986, 2013.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CCA (health outcome = days spent with non-healed pressure ulcer)</p> <p>Study design: Non-probabilistic decision analytic model (outcomes based on single RCT)</p> <p>Approach to analysis: Markov model based on 3 states: Inflamed wound, healing wound, and healed wound. Cycle length one day.</p> <p>Perspective: US healthcare system</p> <p>Time horizon: 1 year</p> <p>Discounting: None</p>	<p>Population: Nursing home residents with stage 3-4 pressure ulcers that had ≥ 85% necrotic non-viable tissue.</p> <p>Cohort settings Age = NR M = NR</p> <p>Intervention 1: Collagenase dressing</p> <p>Intervention 2: Hydrogel dressing</p>	<p>Total costs (mean monthly per patient): Intvn 1: £1,323 Intvn 2: £3,620 Incremental (2-1): £2,297 (CI NR; p = NR)</p> <p>Currency & cost year: 2012 US dollars (presented here as 2012 UK pounds£)</p> <p>Cost components incorporated: Nursing time, collagenase ointment, hydrogel dressing, secondary dressings, wound irrigation and wound care kits.</p>	<p>Health outcomes (mean per patient): Days spent with non-healed pressure ulcer Intvn 1: 48 Intvn 2: 147 Incremental (2-1): 99 (CI NR; p NR)</p>	<p>ICER (Intvn 2 vs Intvn 1): The use of collagenase dressings is dominant compared to hydrogel dressings: lower costs and fewer days spent with non-healed pressure ulcer.</p> <p>Analysis of uncertainty: Deterministic analyses were undertaken: all parameters (apart from frequency of dressing change) were varied by +/- 20%. Collagenase dressings remained dominant in all scenarios. Frequency of dressing change was varied from twice daily to every 3 days – this variable had the greatest influence on the results.</p>
Data sources				
<p>Health outcomes: Taken from single RCT¹⁸ Quality-of-life weights: n/a Cost sources: Resource use collected alongside trial¹⁸, from existing literature and the opinion of the lead investigator. Unit costs were based on “standard cost references” (no further detail given).</p>				

Comments
Source of funding: Healthpoint Biotherapeutics, USA. Limitations: Based on single RCT. The study does not fully describe the cost sources or resource usage. No consideration is given to quality of life. Analysis of uncertainty is incomplete.
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations
<i>Abbreviations: CCA = cost-consequence analysis; CI = 95% confidence interval; ICER = incremental cost-effectiveness ratio; NR = not reported</i>
<i>‡ Converted using 2010 purchasing power parities²²</i>
<i>* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations</i>

H.2.6 Management of heel pressure ulcers

Table 22: MÜLLER2001

E. Muller, M. W. F. van Leen, and R. Bergemann. Economic evaluation of collagenase-containing ointment and hydrocolloid dressing in the treatment of pressure ulcers. <i>Pharmacoeconomics</i> 19 (12):1209-1216, 2001.				
Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
<p>Economic analysis: CEA (health outcome = proportion of patients healed)</p> <p>Study design: Within trial analysis (RCT)</p> <p>Approach to analysis: Analysis of individual level resource use, with unit costs applied</p> <p>Perspective: Netherlands hospital</p> <p>Time horizon: NR - maximum 16 weeks</p> <p>Treatment effect duration: until healing (maximum 16 weeks)</p> <p>Discounting: Costs = n/a; Outcomes = n/a</p>	<p>Population: Female inpatients with a grade IV heel PU</p> <p>Patient characteristics: Mean age group 1 = 74.6 Mean age group 2 = 72.4 M = 0%</p> <p>Intervention 1: Collagenase dressing (Novuxol®)</p> <p>Intervention 2: Hydrocolloid dressing (DuoDerm®)</p>	<p>Total costs (mean per patient): Intvn 1: £522 Intvn 2: £547 Incremental (2-1): £25 (CI NR; p = NR)</p> <p>Currency & cost year: 1998 Dutch guilders (presented here as 1998 UK pounds‡)</p> <p>Cost components incorporated: All material and staff costs (including dressings and ancillary supplies)</p>	<p>Pressure ulcers healed (mean per patient): Intvn 1: 0.92 Intvn 2: 0.63 Incremental (2-1): -0.29 (CI NR; p <0.005)</p>	<p>Incremental cost per healed patient: Intvn 1 dominates Intvn 2</p> <p>Analysis of uncertainty: DA and PSA of cost-related variables using maximum and minimum values. Average ratios are presented rather than incremental ratios, these are not informative.</p>

Data sources
Health outcomes: obtained from within trial. Quality-of-life weights: n/a. Cost sources: costs collected alongside trial – no specific source reported although costs are reported to be representative of those faced by the hospital
Comments
Source of funding: Grant from Knoll AG, Ludwigshafen, Germany. Limitations: small study with only 23 patients, no unit cost source reported, no consideration of quality of life, average cost-effectiveness ratios are presented, no useful analysis of uncertainty reported
Overall applicability*: Partially applicable Overall quality**: Potentially serious limitations

Abbreviations: CEA = cost-effectiveness analysis; CI = 95% confidence interval; DA = deterministic analysis; NLG = Dutch guilders; NR = not reported; PSA = probabilistic sensitivity analysis; ‡ Converted using 1998 purchasing power parities²²

* Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious limitations / Very serious limitations

H.3 References

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