National Clinical Guidelines Centre

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Appendix L

Pressure ulcer prevention and management

Cost effectiveness analysis

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Contents

Appendix L: Cost effectiveness analysis

L.1 Repositioning for the prevention of pressure ulcers

L.1.1 Introduction

Pressure relief is crucial for pressure ulcer prevention, and repositioning can be an effective way to achieve this. Whilst some individuals are able to reposition themselves, and do so regularly without conscious effort, others may require assistance. In clinical practice, the frequency that an individual is repositioned depends on a range of factors, including individual risk factors, a person's clinical condition and the experience and availability of staff. Given the significant benefits associated with repositioning, the GDG felt that it was important to establish a minimum frequency of repositioning for people who are at high risk of developing pressure ulcers. The GDG noted that where assistance is required, repositioning can become resource intensive, as multiple members of staff and/or hoist equipment may be required. Therefore it is important to establish a minimum frequency of repositioning which is clinically and cost-effective.

One relevant economic evaluation was identified in the review undertaken for this topic.[5] The study found repositioning using a 30° tilt (left side, back, right side, back) every 3 hours during the night to be cost effective compared to repositioning every 6 hours at night using 90° lateral rotation. The 3 hourly turning was found to be cheaper than 6 hourly turning, as the turns were smaller (and therefore required less time and fewer staff), and also more effective, leading to a lower incidence of pressure ulcers. Note that at the time the GDG were prioritising topics for original economic analysis, there was no published economic evidence in this topic area. Repositioning was therefore identified by the GDG as a priority for new economic analysis. Economic modelling has been undertaken, comparing the cost-effectiveness of various repositioning regimes, based on the clinical evidence identified in the systematic review of clinical evidence in Chapter 9.

L.1.2 Methods

L.1.2.1 Overview of analysis

The analysis was based on a key randomised controlled trial identified in the systematic review of clinical literature.[11] This approach was taken because the clinical evidence identified in the systematic review for this question was plagued with confounding factors (such as differential use of pressure relieving equipment), and failed to provide clear information on the effectiveness of the various repositioning schedules. None of the studies had common comparators, and the majority had different populations and different follow up times, thus the interventions could not be reliably compared across the trials. The GDG therefore agreed that the most appropriate way forward would be to conduct economic analyses of key trials separately; two trials were selected to be modelled,[6,11] based on the applicability of the populations and the interventions to the UK NHS. Note that an economic evaluation of the study by Moore and colleagues was subsequently published, thus this analysis is based solely on the trial presented by Vanderwee and colleagues. The implication of this approach is that the model does not produce an overall answer of which is the cost-effective repositioning strategy out of all the possible options, but rather identifies the cost-effective strategy within the trial. The results were used to facilitate GDG discussion of the most appropriate repositioning schedules.

Costs were considered from a UK NHS and personal social services perspective and health outcomes expressed as quality adjusted life years (QALYs) in accordance with the NICE reference case.[7] The time horizon of the model was duration of the trial, or until healing of pressure ulcer. Discounting was not undertaken due to the short time horizon.

Population, intervention and comparator were dictated by the trial, a summary of which is presented in Table 1; full details are provided in the evidence table in Appendix G.

Table 1: Overview of clinical trial

	Vanderwee 2007[11]
Setting	84 wards of 16 Belgian elder care nursing homes
Interventions	**Intervention 1**: 4 hours in a semi-Fowler 30° position and 4 hours in a lateral position 30°. The semi-Fowler position consisted of a 30° elevation of the head end and the foot end of the bed. In a lateral position, the position, the patient was rotated 30°, with their back supported with an ordinary pillow. **Intervention 2**: Repositioning was the same as above but with 4 hours spent in the semi-Fowler 30° position, and 2 hours in lateral 30° position. Patients in both groups were lying on a visco-elastic foam overlay mattress
Length of study	5-week study period
Patient characteristics	
• N	235
• Age (mean)	84.4
• % female	83%
• Risk level	All patients had non-blanchable erythema in a pressure area
Outcomes	Incidence of pressure ulcer, severity of pressure ulcer, location of pressure ulcer, time to develop pressure ulcer.

L.1.2.2 Approach to modelling

Patients in the model received intervention 1 or intervention 2. The key clinical outcome was the incidence of pressure ulcers. The proportion of patients developing pressure ulcers in each trial arm determined the magnitude of the incremental QALYs. The costs were calculated based on the cost of the repositioning strategies themselves, plus the cost of treating the number of pressure ulcers which developed.

Uncertainty

Where possible, the model was built probabilistically to take account of the uncertainty around input parameter point estimates. A probability distribution was defined for each model input parameter which was to be modelled in this way. When the model was run, a value for each input was randomly selected simultaneously from its respective probability distribution; mean costs and mean incremental QALYs were calculated using these values. The model was run repeatedly – 10,000 times for the base case, and the results summarised. Sensitivity analyses were run deterministically.

The way in which distributions are defined reflects the nature of the data, so for example the probability of developing a pressure ulcer could be given a beta distribution, which is bounded by zero and one, reflecting that probabilities will not be outside this range. Distributions in the analysis were parameterised using error estimates from data sources. Details of the distributional parameters of variables which were probabilistic are detailed in Table 2.

Table 2: Description of the type and properties of distributions used in the probabilistic sensitivity analysis

Parameter	Type of distribution	Properties of distribution
Utility decrement associated with a pressure ulcer	Normal	Symmetrical around its mean; allows positive and negative values.[a] Derived from mean and variance.
Probability of developing a pressure ulcer	Beta	Bounded between 0 and 1. As the sample size and the number of events were specified alpha and beta values were calculated as follows: Alpha=(number of patients that developed a pressure ulcer) Beta=(Number of patients)-(number of patients that developed a pressure ulcer)

a) Note that negative values imply that an individual with a pressure ulcer has higher utility than an individual without; whilst this seems unlikely, it is not impossible. The mean estimate of the utility decrement is very close to zero, thus the normal distribution was chosen so as to avoid forcing the whole distribution to be one side of zero. The decrement will be negative in only a small number of probabilistic iterations, and is unlikely to have a large impact upon the results.

The following variables were left deterministic (i.e. were not varied in the probabilistic analysis): the cost-effectiveness threshold (which was deemed to be fixed by NICE), resource use (including time and cost of staff) required to implement each strategy (assumed to be fixed according to national pay scales and programme content), and the cost of treating a pressure ulcer, which included an estimate of time to healing of pressure ulcer (no error estimate available).

Various deterministic sensitivity analyses were undertaken to test the robustness of model assumptions. In these, one or more inputs were changed and the analysis rerun to evaluate the impact on results and whether conclusions on which intervention should be recommended would change. Full details can be found in section L.1.5.

L.1.3 Model inputs

L.1.3.1 Summary table of model inputs

Model inputs were based on clinical evidence identified in the systematic review undertaken for the guideline, supplemented by additional data sources as required. Model inputs were validated with clinical members of the GDG. A summary of the model inputs used in the base-case analyses is provided in Table 3. More details about sources, calculations and rationale for selection can be found in the sections following this summary table.

Table 3: Overview of parameters and parameter distributions used in the model

Parameter description	Point estimate	Probability distribution	Distribution parameters	Source
Cost of pressure ulcer	£5,672	Deterministic sensitivity analysis only		Dealey et al[3]
Utility loss from pressure ulcer	0.026	Normal	μ = 0.026, σ = 0.008	Soares et al[10]
Probability of developing pressure ulcer				
Intervention 1	0.16	Beta	α = 24, β = 89	Vanderwee et al[11]
Intervention 2	0.21	Beta	α = 20, β = 102	Vanderwee et al[11]
Cost per position change				
Intervention 1	£11.67	Deterministic sensitivity analysis only		See Table 4
Intervention 2	£11.67	Deterministic sensitivity analysis only		See Table 4

Parameter description	Point estimate	Probability distribution	Distribution parameters	Source
Position changes per day				
Intervention 1	6	Set by intervention – not varied		Vanderwee et al[11]
Intervention 2	8	Set by intervention – not varied		Vanderwee et al[11]

L.1.3.2 Probabilities

The probability of developing a pressure ulcer under each strategy was taken directly from the trial (see Table 2). Data on the severity of the pressure ulcers that developed was not included in this analysis. This was because the available utility data does not distinguish between different grades of pressure ulcer, and the average cost of pressure ulcers was calculated to reflect the average in the UK, rather than those specifically developed in the trials. Mortality was not considered in the model.

L.1.3.3 Utilities

A review of the pressure ulcer quality of life literature was undertaken. Unfortunately, data on the impact of pressure ulcers on quality of life is limited. Few studies report quality of life outcomes, and where they do there are questions over reliability. This is because factors such as limited mobility, which would cause someone to score low on a quality of life tool, also make them more likely to contract a pressure sore. The implication of this is that individuals with low quality of life may be more likely to develop a pressure sore, and it cannot necessarily be inferred that the pressure sore has caused the decrease in quality of life. No reliable pressure ulcer specific quality of life tools were found, and no mapping studies were found.

Essex and colleagues[4] analyse two studies to identify the impact of pressure ulcers on health related quality of life. The first study includes Short Form-36 (SF-36) data for 218 UK patients with pressure ulcers (grades 1-4), and 2,289 people without ulcers. Essex and colleagues adjust for age, sex and co-morbidities, and find that the presence of a pressure ulcer reduces health related quality of life. However, insufficient detail is provided to allow mapping to a preference based measure for use in economic evaluation (e.g. the SF-12 or the EQ-5D). The second study was a small pilot study, which included 22 patients: 6 patients with pressure ulcers, and 16 patients without pressure ulcers. This study reported SF-36 data, and EQ-5D data, and the presence of a pressure ulcer was found to effect both health related quality of life (measured by the SF-36), and utility (measured by EQ-5D). Unfortunately the results from the pilot study are not adjusted for confounders, and it is noted that patients with pressure ulcers had, on average, twice the number of comorbidities as patients without (p=0.002).

Soares and colleagues[10] conducted a Bayesian linear regression analysis, using the SF-36 data set of UK patients obtained from Essex and colleagues. Age, sex, and comorbidities were adjusted for. Full details of the analysis are not published, but the results are used in a peer-reviewed cost-utility analysis.[10] The authors were contacted and full details were provided. The analysis found a utility decrement of 0.028 (standard deviation: 0.008) associated with a pressure ulcer (note that the results do not distinguish between grades of pressure ulcer). In the base case this figure was modelled probabilistically using a normal distribution, as specified in Table 2.

The GDG were concerned that the value described above may be too low to accurately capture the impact a pressure ulcer would have on an individual's utility. If this is indeed the case, this may cause the results to bias away from the more effective interventions, as the full QALY gain would not be realised. In the absence of better evidence, the GDG agreed that this value should be used, but that the impact of this input on the results should be tested thoroughly.

To calculate QALYs, the utility decrement was multiplied by the average amount of time spent with a pressure ulcer[3] (see Table 5).

L.1.3.4 Resource use and costs

Cost of repositioning strategies

The cost of the repositioning strategies was based on the cost of nurse time. The amount of nurse time required for each position change was estimated by the GDG, and was specific to each strategy. The GDG noted that at least 2 members of staff would be required for each position change. Resource use estimates and costs are documented in Table 4.

Table 4: Resource use for repositioning strategies

Strategy	Staff time required per position change – minutes (A)	Cost of staff per minute (£) (B)	Cost per position change (A*B)
Intervention 1	10 minutes * 2 nurses	0.583[a]	£11.67
Intervention 2	10 minutes * 2 nurses	0.583[a]	£11.67

a) *Based on £35 per hour nurse time from the PSSRU*[1]

Other aspects of preventative care, for example nutritional strategies or pressure redistributing devices, were not included in the analysis. These were assumed to be constant between the groups, and would therefore not impact the incremental analysis.

Cost of pressure ulcer

The cost of a pressure ulcer was taken from a study conducted by Dealey and colleagues (2012).[3] This study was considered to represent the best available UK evidence on this topic. Resource use is derived from a bottom up methodology, based on that required to deliver good clinical practice (based on EPUAP PU treatment guidelines). Resources estimates include nurse time (dressing changes, repositioning, and assessment), dressings, antibiotics, diagnostic tests, support surfaces, debridement, and inpatient days (where appropriate – only for patients who develop complications). Additional costs were included to account for patients who develop critical colonisation, cellulitis and osteomyelitis. It is assumed that patients are cared for in hospital or a long term care setting but are not admitted solely for the PU. The results of the study are presented in Table 5.

Table 5: Cost of pressure ulcers

Category of pressure ulcer	Proportion of pressure ulcers in each category[a]	Expected time to healing[a]	Expected cost[c]
Category 1	37.20%	28 days	£1,214
Category 2	29.10%	94 days	£5,241
Category 3	20.90%	127 days	£9,041
Category 4	12.80%	155 days	£14,108
Weighted average		**84 days**	**£5,672**

(a) *Derived from a review of clinical literature*[3]
(b) *Based on nurse time (dressing changes, repositioning, and assessment), dressings, antibiotics, diagnostic tests, support surfaces, debridement, and inpatient days (where appropriate – only for patients who develop complications).*

The GDG were concerned that the costs for category 3 and 4 ulcers may be too low – but the group agreed these costs should be used as a starting point. Therefore these values were used as minimum values, with sensitivity analyses conducted using higher estimates. The cost of a pressure ulcer was not modelled probabilistically, as no measure of error was reported with the estimate.

L.1.4 Computations

The model was constructed in Microsoft Excel.

Let U_{PU} represent the utility loss associated with a pressure ulcer (see section L.1.3.3), and T_{PU} represent the time spent with a pressure ulcer (see Table 5). $PUs\ avoided$ is the incremental number of pressure ulcers between the two trial arms. Then, incremental QALYs were calculated as follows:

$$Incremental\ QALYs = PUs\ avoided\ \times U_{PU}\ \times T_{PU}$$

For costs, let $staff_i$ represent the total cost of staff time for intervention i (i=1,2), $nurse\ cost$ is the cost of nurse time per minute, and $minutes_i$ is the number of minutes required per day to implement intervention i. $days$ is the number of days in the time horizon. Then:

$$Staff_i\ = nurse\ cost \times\ minutes_i \times days$$

Now let p_i represent the probability of developing a pressure ulcer when receiving intervention i, and let $cost_{PU}$ represent the cost of a pressure ulcer. Then total cost for strategy i is computed as follows:

$$Total\ Cost_i\ = Staff_i\ + (p_i \times cost_{PU})$$

Note that the cost of repositioning the patient was calculated for the duration of the trial, regardless of whether or not an individual develops a pressure ulcer. The implication of this is that, as the cost of treating a pressure ulcer also includes some repositioning, there may be some double counting if the pressure ulcer develops before the end of the trial. This approach was considered to be more accurate than including an estimate of the time point at which each pressure ulcer developed, and was not considered to be a major limitation here, as the GDG had previously noted that treatment cost estimates were low (as discussed previously).

Discounting was not undertaken for costs or QALYs as the time horizon was short.

L.1.5 Sensitivity analyses

Sensitivity analyses were undertaken to explore the effect of different parameter inputs and assumptions on the results of the model. The results of all sensitivity analyses are presented in section L.2.2.

The following sensitivity analyses were conducted:

SA1: Shorter time required for repositioning

This sensitivity analysis was included to test impact of the resource input assumptions provided by the GDG. In this analysis 5 minutes was allowed for each position change, as the GDG felt that in some circumstances the position changes may be carried out faster than indicated in the base case .

SA2: Clinical support workers to change patient's position & SA3: One nurse and one clinical support worker to change patient's position

The GDG noted that in some cases clinical support workers may change a patient's position, or at least assist too. These sensitivity analyses were included to investigate the impact of using difference staff members on the results. The cost of clinical support worker time was £21 per hour.[1]

SA4: Cost of treating pressure ulcers

The GDG felt that the cost of treating pressure ulcers included in the model may be too low. This sensitivity analysis was included to investigate the cost of pressure ulcer at which the more resource intensive interventions became cost-effective. Depending on the base-case results, this could involve increasing or decreasing the cost of pressure ulcer.

L.1.6 Model validation

The model was developed in consultation with the GDG; model structure, inputs and results were presented to and discussed with the GDG for clinical validation and interpretation.

The model was systematically checked by the health economist undertaking the analysis; this included inputting null and extreme values and checking that results were plausible given inputs. The model was peer reviewed by a second experienced health economist from the NCGC; this included systematic checking of the model calculations.

L.1.7 Estimation of cost effectiveness

The widely used cost-effectiveness metric is the incremental cost-effectiveness ratio (ICER). This is calculated by dividing the difference in costs associated with two alternatives by the difference in QALYs. If the ICER falls below a given cost per QALY threshold, the more effective intervention (that which yields the greatest QALY gain) is considered to be cost effective. If both costs are lower and QALYs are higher the option is said to dominate the comparator, and an ICER is not calculated.

$ICER = \frac{Incremental\ Costs}{Incremental\ QALYs}$ Where: Costs/QALYs(X) = total costs/QALYs for option X	• Cost-effective if: ICER < Threshold

It is also possible, for a particular cost-effectiveness threshold, to re-express cost-effectiveness results in terms of incremental net monetary benefit (incremental NB). This is calculated by multiplying the incremental QALYs by the threshold cost per QALY value (for example, £20,000), and then subtracting the incremental costs (formula below). If the incremental net monetary benefit is positive, the more effective intervention is the most cost-effective option at the specified threshold.

$Incremental\ NB = Incrmental\ QALYs\ \times\ \lambda - Incremental\ costs$ *Where: λ = threshold*	• Cost-effective if: Incremental NB > 0

These methods of determining cost effectiveness are equivalent, and will identify exactly the same optimal strategy.

Results are also presented graphically where incremental costs and incremental QALYs are shown. Comparisons not ruled out by dominance or extended dominance are joined by a line on the graph where the slope represents the incremental cost-effectiveness ratio.

L.1.8 Interpreting Results

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money. In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

- The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- The intervention costs less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

Note that this analysis only compares 2 interventions, rather than all relevant alternatives. Consequently, the results were used to facilitate GDG discussion of the most appropriate frequencies of repositioning, rather than to identify and recommend one specific repositioning schedule from within the trial.

L.2 Results

L.2.1 Base case

Table 6 shows the results of the probabilistic base case analysis. Intervention 2 is more costly than intervention 1, and also leads to a greater health benefit. However, the incremental QALY gains are small, and as such, intervention 2 has not been found to be cost-effective at the £20,000 per QALY gained threshold. These results are shown graphically in Figure 1 . Probabilistic sensitivity analysis revealed that intervention 2 has a probability of being cost-effective of just 3.2%, when compared to intervention 1.

Table 7 shows the breakdown of the costs. As expected, more frequent repositioning leads to an increase in the cost of the intervention, but a decrease in treatment costs, as more pressure ulcers are prevented. The increased cost of the intervention substantially outweighs the reduction in treatment costs, leading to an overall increase in cost.

Table 6: Base case results (probabilistic)

Intervention	Total cost	Incremental cost	Incremental QALYs	ICER
Intervention 1	£3,656			
Intervention 2	£4,197	£541	0.000292	£1,854,070

Note: all results are mean (per patient) results

Figure 1: Cost-effectiveness plane

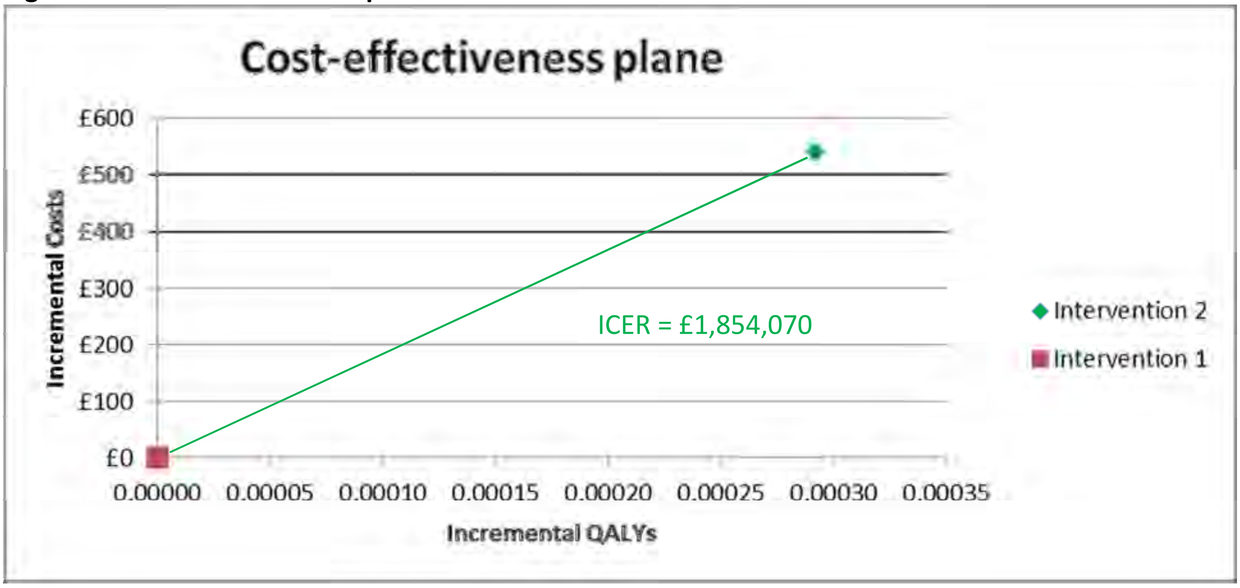

Table 7: Base case results (probabilistic): breakdown

Intervention	Cost of intervention per 24 hours	Total cost of intervention over trial duration	Cost of PUs	PUs avoided
Intervention 1	£70	£2,450	£1,206	
Intervention 2	£93	£3,267	£930	0.049

Note: all results are mean (per patient) results

L.2.2 Sensitivity analyses

Table 8 shows that in all sensitivity analyses intervention 2 was not found to be cost effective compared to intervention 1.

Table 8: Sensitivity analyses results

Intervention	Incremental cost	Incremental QALYs	ICER
SA1: shorter time required for repositioning			
Int 2 vs Int 1	£133	0.000291	£458,776
SA2: 2 x clinical support workers to change patient's position			
Int 2 vs Int 1	£215	0.000291	£739,448
SA3: one clinical support worker and one nurse to change patient's position			
Int 2 vs Int 1	£378	0.000291	£1,300,791

Note: incremental values are calculated as intervention 2- intervention 1.

Threshold sensitivity analyses revealed that intervention 2 would be cost-effective if, ceteris paribus, the cost of treating a pressure ulcer increased to £16,734 (195% increase). The GDG noted that the cost of a pressure ulcer could feasibly reach this value, as high risk patients are likely to develop more severe pressure ulcers which take a long time to heal and could feasibly cost this much to treat. However, in most cases the cost to treat would be below this figure.

From the results in Table 6 we can calculate that a QALY loss of 0.55 would need to be caused by the development of a pressure ulcer in order for intervention 2 to be considered cost-effective. This is not feasible over the expected duration of a pressure ulcer (84.3 days), whatever the utility value used. From this we can infer that, *ceteris paribus*, the utility input data is not a driver of the model.

Overall, the sensitivity analyses demonstrated that the results of this analysis were largely robust to changes in key assumptions and costs.

L.2.3 Discussion

L.2.3.1 Summary of results

This analysis found that 4 hourly repositioning is cost-effective compared to 2 and 4 hourly repositioning in elderly nursing home patients with non-blanchable erythema. This conclusion was robust to a range of sensitivity analyses, demonstrating that although uncertainty surrounds model inputs, variation within reasonable ranges does not change the results.

Areas of particular uncertainty were the utility decrement associated with a pressure ulcer, and the cost of treating a pressure ulcer. However, threshold analyses found that the utility figure was not a driver of the model, and *ceteris paribus*, intervention 2 would not have been cost-effective whatever of the value of this input. Sensitivity analyses revealed that the cost of treating a pressure ulcer would have to be more than double the base case value for intervention 2 to be cost-effective; the GDG noted that this may be plausible in some cases.

L.2.3.2 Limitations and interpretation

The results above are based on one trial, comparing just two possible repositioning strategies. Based on this, we cannot conclude that intervention 1 would be the most cost-effective strategy compared to all relevant alternatives, but rather that it is cost-effective compared to intervention 2. Nevertheless, the finding that a more regular repositioning provides small health gains, but at a substantial additional cost, is useful for informing GDG discussion of the most appropriate repositioning schedules. Ideally, clinical evidence would have allowed a full comparison of all feasible strategies against each other; however this was not possible in this case.

This analysis is subject to several minor limitations. Firstly, the model is constrained by the trial on which it is based. As such, probabilities are based on a 5 week follow up period, despite the patients being long term care residents. In addition, the model does not account for differences in quality of life arising from differences in time until pressure ulcer development, or capture any long term quality of life impact of a pressure ulcer once it has healed. It is unlikely that this has a substantial effect upon the results of the analysis.

Note that it was assumed in the model that all adults required two members of staff to change their position. However, many adults are able to reposition themselves, and in such cases the economic impact will be greatly reduced. For patients who do require staff members to assist repositioning, this serves as a patient contact point, which can have benefits which extend beyond the prevention of pressure ulcers. Such additional benefits are not captured in this analysis.

L.2.3.3 Generalisability to other populations/settings

The population considered in this analysis is high risk long-term care patients (see Table 1). The GDG agreed that repositioning is likely to be of greatest benefit in a high risk population; therefore if 2 and 4 hourly alternate turning is not cost effective in this population (compared to 4 hourly turning), it is unlikely to be cost-effective in a lower risk population. As such, we can infer that the conclusions of this analysis can be applied more generally to a UK adult population.

The results of this analysis are not intended to be generalisable to people under the age of 18. Recommendations for repositioning in this population have been informed by the Delphi consensus panel, with consideration given to relevant economic implications.

L.2.3.4 Comparisons with published studies

One economic evaluation was identified in this area. Moore and colleagues[5] found repositioning using a 30° tilt (left side, back, right side, back) every 3 hours during the night to be cost effective compared to repositioning every 6 hours at night using 90° lateral rotation. The 3 hourly turning was found to be cheaper than 6 hourly turning, as the turns were smaller (and therefore required less time and fewer staff), and also more effective, leading to a lower incidence of pressure ulcers. This economic evaluation considered different interventions to those included in our analysis, and therefore the results of the two studies cannot be compared directly. As with our analysis, the published study identifies the cost-effective option out of just two strategies, thus is useful to inform discussion of appropriate repositioning schedules, rather than pinpoint one single cost-effective repositioning strategy.

L.2.4 Conclusion/evidence statement

One cost-utility analysis found that repositioning every 4 and 2 hours (alternatively) was not cost-effective compared to repositioning every 4 hours (ICER = £1,854,070)) in long term care patients with non-blanchable erythema. This analysis was assessed as directly applicable with minor limitations.

L.2.5 Implications for future research

The analysis was constrained by the limitations of the clinical data identified in this area. High quality research into comparisons of repositioning at several different time intervals would be beneficial, as this would provide additional clinical data to inform a full cost-utility analysis. This would serve to reduce any remaining uncertainty around the cost-effectiveness of repositioning for the prevention of pressure ulcers, and assist in the identifying the efficient allocation of resources in this area.

L.3 Negative pressure wound therapy

L.3.1 Introduction

This analysis compares the cost of negative pressure (NPWT) wound therapy to a standard dressing regimen for the management of pressure ulcers that exhibit high levels of exudate and require regular dressing changes.

A systematic review was undertaken to identify economic evaluations of NPWT; one relevant UK cost-utility analysis was identified.[9] The analysis compared NPWT to various individual types of dressings, and, using inputs obtained from existing literature, found NPWT was not cost-effective (at a willingness to pay threshold of £20,000 per QALY) for the treatment of pressure ulcers. NPWT was however found to be cost-effective an alternative scenario, when evidence from other sources (pilot trial and expert opinion) was also included (for full details see the economic evidence profile in Chapter 6, and the full evidence table in Appendix G). However, the GDG had concerns about using this study on which to base decisions of cost-effectiveness for several reasons. Firstly, the GDG felt that the comparator to NPWT should be a dressing regimen, which includes several dressing components, and this is not captured in the published study (only individual types of dressings are considered). Secondly, the available clinical data is weak, and the GDG did not consider it sufficiently reliable on which to base a cost-effectiveness or cost-utility analysis. The published analysis aims to overcome this by presenting scenarios in which data from the existing literature is supplemented with pilot trial data and expert opinion; however the GDG wished to avoid placing too much reliance on expert elicited data. In the absence of evidence to suggest otherwise, Soares and colleagues assume a constant rate of healing of pressure ulcers, which the GDG did not believe to be an accurate assumption. Finally, the GDG noted that the cost of NPWT has reduced since the paper was written, and therefore the conclusions may no longer be applicable. Therefore, whilst this study is a full economic evaluation conducted to a high standard, the conclusions must be treated with caution; for this reason NPWT was considered a priority for original economic analysis.

A cost comparison was chosen as the most appropriate form of analysis here because the clinical data on the comparative effectiveness of NPWT is weak, and was considered not sufficiently reliable on which to base a cost-effectiveness or cost-utility analysis. The GDG therefore decided to focus on NPWT for the on-going management of pressure ulcers which are exhibiting high exudate levels and require regular dressing changes, rather than to look at differential effects on healing. It was felt that cost-savings could potentially be realised through fewer dressing changes required with NPWT than with a standard dressing regimen. The aim of this analysis is to explore this hypothesis further.

L.3.2 Methods

L.3.2.1 Model overview

A cost-comparison was undertaken where costs were considered from a UK NHS and personal social services perspective; health outcomes were not considered. The model was developed in Excel.

L.3.2.2 Comparators

Two management strategies were considered:

- NPWT (foam or gauze)
- A standard care dressing regimen.

The standard care dressing regimen was based on advice from the GDG members, and included a combination of alginates, cavity Fillers, absorbent dressings and a film membrane in various quantities, depending on size of pressure ulcer. The dressing regimen was chosen to reflect a fairly high cost dressing combination, in order to compare the cost of NPWT against the maximum cost of dressings. Full details are provided in Table 9.

L.3.2.3 Population

Adults with pressure ulcers that are exhibiting high exudate levels that require regular dressing changes.

L.3.2.4 Time horizon

The time horizon of the model was 2 weeks in the base case, as the GDG felt that this would be a reasonable time frame over which cost differences could be estimated. This is an arbitrary cut off as the model does not consider healing, and is not intended to reflect time to healing.

L.3.3 Approach to modelling

Patients in the model are allocated to either NPWT or the standard care dressing regimen. Costs of managing the pressure ulcer using each of these techniques is calculated over the 2 week time horizon. Costs include staff time and materials needed for dressing changes, but do not include adjunct management methods such as pressure relieving devices, as these are assumed constant between the two arms of the model. Mortality is not considered in the model, as this is also assumed constant between the two arms.

The model considers three separate scenarios, management of small pressure ulcers (requiring dressings approximately 10cmx8cm), medium pressure ulcers (requiring dressings approximately 18cmx12cm) and large pressure ulcers (requiring dressings approximately 25cmx15cm). All scenarios only considered pressure ulcers exhibiting high exudate levels and requiring regular dressing changes.

L.3.3.1 Uncertainty

Various sensitivity analyses were undertaken to test the robustness of model assumptions and data sources. In these analyses, one or more inputs were changed in order to evaluate the impact of these changes on the results of the model. Key parameters for sensitivity analysis were unit costs, frequency of dressing change, and staff time.

None of the inputs were reported with an associated measure of uncertainty, therefore probabilistic analysis was not undertaken.

L.3.4 Model Inputs

Model inputs were based on national cost sources and GDG assumptions. All inputs were checked for face validity by the clinical members of the GDG.

Resource use

Estimates of the frequency of dressing change and the time taken to change the dressings were required. It was decided that these should not be extracted from clinical papers, as such factors were likely to be set in trial protocols, and/or depend on the nature and setting of the trial. The GDG felt that GDG estimation would be more representative of current practice in the UK.

Resource use was therefore estimated by clinical members of the GDG. Dressing components for NPWT and the standard care dressing routine are documented in Table 9 and Table 10 for each scenario. The GDG identified the key NPWT systems which are most commonly used in the UK (V.A.C, RENASYS GO, and Avance), for inclusion in the model. For these systems, each dressing change requires 1 primary contact dressing, 1 foam/gauze dressing, and 1 canister. One pump is also required, per person, for the duration of the therapy. The GDG acknowledge that other dressings and NPWT systems are available, other than those specified in Table 9 and Table 10, however it was decided that the analysis should focus on the NPWT systems most commonly used in the UK.

In the base case it was assumed that the first NPWT dressing change is required after 2 days, and subsequent dressing changes take place every 3 days, while the standard dressing regimen is changed every 2 days throughout the time horizon. It was assumed that half an hour of Band 5 nurse time is required for each dressing change, regardless of the management strategy.

The GDG noted that the NPWT regimen may require supervision from a more senior nurse, although not for every dressing change. 30 minutes of specialist nurse (Band 7) time was included to account for this (only once in the two week period).

Costs

The cost of staff time was taken from the PSSRU[2]); Band 5 staff nurse (patient contact) time costs £85 per hour, therefore each dressing change (NPWT and standard care dressing regimen) costs £42.5 in staff costs; Band 7 time costs £43 per hour (lower than the staff nurse cost because this is not patient contact time), therefore each half hour supervision costs £21.50.

Standard care dressing costs were collected from the NHS drug tariff[8] and are documented in Table 9. The costs of the NPWT dressings, primary contact dressings (small £3.19; medium £6.45; large

£17.38), and canisters were also taken from the NHS drug tariff, with the costs of the pumps obtained directly from the manufacturers (Table 10). NPWT pumps are typically rented rather than purchased, therefore only rental costs are considered in the analysis. Rental costs vary greatly across the UK; list prices provided by the manufacturers are used in the base case, with estimates reflecting local pricing used employed in sensitivity analyses. The price of the NPWT pump is subject to particular uncertainty, and was therefore varied extensively within the analysis.

The total cost per dressing change for the dressing regimen and for NPWT can be found in Table 11. The total cost per dressing change for the dressing regimen includes the cost of the dressing materials and the cost of staff time. The total cost per dressing change for NPWT includes the NPWT dressing materials, primary contact dressings, canisters, and staff time changing the dressing. Note that the cost of the pump and the cost of the fortnightly supervision by the specialist nurse are not included. The costs of the various NPWT systems are brought together to calculate an unweighted mean cost per dressing change. The accompanying range shows the highest and lowest costs per dressing change out of the included NPWT systems.

Table 9: Resource use and unit costs – Dressings regimen

Dressing component	Size	Quantity per dressing change[a]	Unit cost[b]	Total material cost per dressing change
Small ulcers				
Sorbsan Flat	10x10	1	£1.71	£1.71
Allevyn Cavity Filler	10x10	1	£9.80	£9.80
Sorbsan Packing	-	1	£3.47	£3.47
Sorbsan Plus	10x15	1	£3.07	£3.07
C-View	15x20	1	£2.36	£2.36
Total				**£20.41**
Medium ulcers				
Sorbsan Flat	10x20	1	£3.20	£3.20
Allevyn Cavity Filler	5x5	1	£4.11	£4.11
Allevyn Cavity Filler	10x10	1	£9.80	£9.80
Sorbsan Packing	-	2	£3.47	£6.94
Sorbsan Plus	15x20	1	£5.43	£5.43
C-View	15x20	1	£2.36	£2.36
Total				**£31.84**
Large ulcers				
Sorbsan Flat	10x20	1	£3.20	£3.20
Allevyn Cavity Filler	10x10	2	£9.80	£19.60
Sorbsan Packing	-	4	£3.47	£13.88
Sorbsan Plus	10x15	1	£3.07	£6.14
C-View	20x30	1	£2.36[c]	£2.36
Total				**£45.18**

(a) GDG expert opinion
(b) Drug Tariff[8]
(c) The price for the 20x30 C-view is not available from the drug tariff; the price of the 15x20 C-view is included here.

Table 10: Unit costs - NPWT

Dressing component	Cost of NPWT components per dressing change[a]				
	Avance	Avance	RENASYS Go	RENASYS Go	**Average[b]**

Dressing component	Cost of NPWT components per dressing change[a]				
	(gauze)	(foam)	(foam)	(gauze)	
Small dressing	£19.37	£15.80	£19.87	£16.93	£17.99
Medium dressing	£22.43	£19.88	£23.08	£21.23	£21.66
Large dressing	£26.51	£25.49	£27.38	£26.94	£26.58
Canister	£19.37	£19.37	£19.10	£19.10	£19.24
Pump (rental per day)	£20.00	£20.00	£20.00	£20.00	£20.00

(a) *Source: Dressing and canister costs are obtained from the drug tariff.[8] Rental charges are example costs provided by the manufacturers. Local prices vary.*
(b) *This is the unweighted mean of the material costs from the other four columns.*

Table 11: Mean cost per dressing change (range)

Ulcer size	Standard care dressing regimen	NPWT[a,b]
Small	£63	£83 (£81 – £85)
Medium	£74	£90 (£88 – £91)
Large	£88	£106 (£105 – £106)

(a) *Note these costs do not include the cost of the pump or the fortnightly supervision by the specialist nurse.*
(b) *The range is included in parenthesis to shows the minimum and maximum totals based on the different NPWT systems included in this analysis*

L.3.5 Computations

To compute total costs, the cost per dressing change (including staff costs and material costs – see Table 11) was multiplied by the number of dressing changes required over the two week time horizon (see section L.3.4). For the NPWT arm, the total rental cost of the pump (cost per day multiplied by time horizon), and the cost of fortnightly nurse supervision was also added to this.

L.3.6 Sensitivity analyses

Sensitivity analyses were undertaken to explore the effect of different parameter inputs and assumptions on the results of the model. The results of all sensitivity analyses are presented in section L.3.9.2. None of the inputs were reported with an associated measure of uncertainty, and therefore they were not modelled probabilistically.

The following sensitivity analyses were conducted:

SA1: 45 minutes for NPWT dressing change

The GDG felt that in some cases the NPWT dressing change may take marginally more time than the standard care dressing change, thus this sensitivity analysis was included the investigate the effect of this. Standard care dressing time remained at 30 minutes.

SA2: Specialist nurse (Band 7) conducting all dressing changes

This increased the staff time cost component of the dressing change, from £85 per hour to £105 per hour.[2] The cost of the fortnightly Band 7 supervision was removed.

SA3: Removing the requirement for supervision of NPWT dressing changes by a specialist nurse (Band 7)

This was removed to investigate the impact of no supervision, as this would not be required in all cases.

SA4: Community nursing costs

This was a scenario analysis included to extend the model to look at use of NPWT in the community. Resource use and unit costs were assumed to be the same as in the base case, with the exception of the cost of nurse time: the cost of community nurse time (£61 per hour of home visiting, including travel[2]) was included instead of ward nurse time.

SA5: Local costs

Sometimes NHS trusts face lower prices for dressings and NPWT materials than those quoted in national sources (such as the drug tariff used above). Therefore this sensitivity analysis was included to investigate the effective of such a departure from list prices. GDG members provided costs which represent those experienced by their NHS Trusts (see Table 12 and Table 13).

Table 12: Resource use and unit costs (local costs) – Dressings regimen

Dressing component	Size	Quantity	Unit cost	Subtotal
Small ulcers				
Sorbsan Flat	10x10	1	£1.57	£1.57
Allevyn Cavity Filler	10x10	1	£6.00	£6.00
Sorbsan Packing	-	1	£3.31	£3.31
Sorbsan Plus	10x15	1	£2.99	£2.99
C-View	15x20	1	£1.66	£1.66
Total				**£15.53**
Medium ulcers				
Sorbsan Flat	10x20	1	£3.22	£3.22
Allevyn Cavity Filler	5X5	1	£4.52	£4.52
Allevyn Cavity Filler	10x10	1	£6.00	£6.00
Sorbsan Packing	-	2	£3.31	£6.62
Sorbsan Plus	15x20	1	£5.18	£5.18
C-View	15x20	1	£3.32	£3.32
Total				**£28.86**
Large ulcers				
Sorbsan Flat	10x20	1	£6.44	£6.44
Allevyn Cavity Filler	10x10	2	£6.00	£12.00
Sorbsan Packing	-	4	£3.31	£13.24
Sorbsan Plus	10x15	2	£2.99	£5.98
C-View	20x30	1	£2.08	£2.08
Total				**£39.74**

** The price for the 20x30 C-view is not available from the drug tariff; the price of the 15x20 C-view is included here*

Table 13: Resource use and unit costs (local costs) – negative pressure wound therapy

Dressing component	NPWT system

Dressing component	NPWT system		
	Foam	Gauze	Average[a]
Small dressing	£22.30	£16.28	£19.29
Medium dressing	£26.90	£20.48	£23.69
Large dressing	£29.70	£26.25	£27.98
Canister	£28.30	£19.95	£24.13
Pump (rental per day)	£30.00	£20.00	£25.00

(a) This is the unweighted mean of the material costs from the previous two columns.

SA6: Frequency of NPWT dressing change

The purpose of this sensitivity analysis was to identify how frequently the NPWT could be changed per week to be cost saving compared to the dressing regimen. Depending on the base case results this could involve increasing or decreasing the frequency of dressing change.

SA7: Rental cost of NPWT pump

The purpose of this sensitivity analysis was to investigate how much the rental cost of the NPWT pump would need to be in order to be cost saving compared to the dressing regimen. Depending on the base case results, this could involve increasing or decreasing the rental cost.

L.3.7 Model validation

The model was developed in consultation with the GDG; inputs and results were presented to and discussed with the GDG for validation and interpretation.

The model was systematically checked by the health economist undertaking the analysis; this included inputting null and extreme values and checking that results were plausible given inputs. The model was peer reviewed by an experienced health economist who had not been involved in the guideline; this included systematic checking of the model calculations.

L.3.8 Interpreting results

In the absence of reliable evidence to suggest a clear clinical benefit of NPWT, the GDG agreed that NPWT was only likely to represent an efficient use of resources if it was cost-saving (or cost-neutral) for the management of pressure ulcers.

The GDG did not look at individual products to make recommendations, but rather looked at the more general comparison of standard care dressings compared to NPWT. The focus on specific dressings and NPWT systems used within this analysis should not be interpreted as a recommendation in favour these particular products.

L.3.9 Results

Detailed results are presented in the following sections for the base case analysis and various sensitivity analyses.

L.3.9.1 Base case

Table 14 shows the base case results of the analysis; these results include all the costs detailed in the previous sections, over the two week time horizon. It is clear from the table that, even though fewer dressing changes are required with NPWT, the standard care dressing regimen is still less costly than all of the included negative pressure wound therapy systems, for small, medium and large pressure ulcers.

Table 14: Mean (range) base case results – costs over two week time horizon

Ulcer size	Standard care dressing regimen	NPWT[a]	Incremental cost
Small	£440	£716 (£706 – £725)	£276
Medium	£520	£751 (£743 – £757)	£230
Large	£614	£830 (£825 – £833)	£216

(a) The range shows the minimum and maximum totals based on the different NPWT systems included in this analysis

L.3.9.2 Sensitivity analyses

In the majority of sensitivity analyses the cost of the dressing regimen was less than the NPWT systems (Table 15 and Table 16), including when used in community settings. Threshold sensitivity analyses revealed that NPWT would only be cost saving or cost neutral for large pressure ulcers if the NPWT dressing only had to be changed every 7 days, would only be cost saving for medium pressure ulcers if the NPWT dressing only had to be changed every 9 days, and would only be cost saving for small ulcers if the dressing did not have to be changed at all within the 2 week time horizon (after the initial dressing change at 48 hours) (Table 17). Alternatively, NPWT would be cost saving for the management of large and medium pressure ulcers if the rental cost per day of the pump reduced to £4, and cost saving for small pressure ulcers if the rental cost per day decreased to £1 (Table 18). Overall, the sensitivity analyses demonstrated that the results of this analysis were robust to changes in key assumptions, costs, and frequency of dressing change.

L.3.9.3 Sensitivity analyses

Table 15: Mean (range) sensitivity analysis results

Ulcer size	Standard care dressing regimen	NPWT[a]	Incremental cost
SA1: 45 minutes for NPWT dressing change			
Small	£440	£833 (£823 – £842)	£393
Medium	£520	£868 (£860 – £874)	£347
Large	£614	£947 (£942 – £950)	£333
SA2: Specialist nurse (Band 7) conducting all dressing changes			
Small	£510	£745 (£734 – £753)	£234
Medium	£590	£779 (£771 – £786)	£189
Large	£684	£858 (£854 – £862)	£175
SA3: No supervision of NPWT dressing changes by specialist nurse (Band 7)			
Small	£440	£695 (£684 – £703)	£254
Medium	£520	£729 (£721 – £736)	£209
Large	£614	£808 (£804 – £812)	£195
SA4: Community nursing costs			
Small	£356	£656 (£646 – £665)	£300
Medium	£436	£691 (£683 – £697)	£254
Large	£530	£770 (£765 – £773)	£240

(a) The range shows the minimum and maximum totals based on the different NPWT systems included in this analysis

Table 16: SA5 results: Local costs

Ulcer size	Standard care dressing regimen	NPWT[a]	Incremental cost
Small	£406	£817 (£711 - £923)	£411
Medium	£500	£855 (£748 - £962)	£355
Large	£576	£928 (£828 - £1,027)	£352

(a) The range shows the minimum and maximum totals based on the different NPWT systems included in this analysis

Table 17: SA6 results: Frequency of NPWT dressing change

Frequency of NPWT dressing change[a]	Ulcer size	Optimal strategy
3-6 days[b]	Small	Dressings
	Medium	Dressings
	Large	Dressings
7-8 days	Small	Dressings
	Medium	Dressings
	Large	NPWT
9-14 days	Small	Dressings
	Medium	NPWT
	Large	NPWT

(a) This is frequency after the first change at 48 hours
(b) Base case frequency of NPWT dressing change was every 3 days; frequency of dressing change of the standard care dressings remained at the base case setting of every 2 days throughout this analysis

Table 18: SA7 results: Rental cost of NPWT pump

Rental cost of NPWT pump (per day)	Ulcer size	Optimal strategy
£20-£5[a]	Small	Dressings
	Medium	Dressings
	Large	Dressings
£4-£2	Small	Dressings
	Medium	NPWT
	Large	NPWT
£1-£0	Small	NPWT
	Medium	NPWT
	Large	NPWT

(a) Base case cost per day was £20.

L.3.10 Discussion

L.3.10.1 Summary of results

This analysis found that a standard care dressing regimen is less costly than NPWT for the management of pressure ulcers exhibiting high fluid secretion. This conclusion was robust to a wide range of sensitivity analyses, demonstrating that although uncertainty surrounds model inputs, variation within reasonable ranges does not change the results. Note the analysis did not consider any differential impact on clinical outcomes, or quality of life.

An area of particular uncertainty was the rental cost of the NPWT pump, yet sensitivity analyses revealed that the model is fairly robust to changes in costs. Ceteris paribus, the cost of the pump would have to decrease by 80% for NPWT to be less costly than standard care dressing regimens for management of large and medium pressure ulcers, and by 95% for NPWT to be less costly than standard care dressing regimens for management of small pressure ulcers.

L.3.10.2 Limitations and interpretation

The major drawback to this analysis is the lack of consideration of differential time to healing between the treatment strategies, and the impact on quality of life. As explained above, this decision was taken because the systematic review of the clinical data in this area found little evidence, and the GDG felt it was not strong enough upon which to base a full cost-utility analysis. This analysis has therefore investigated whether NPWT is cost-saving for the management of pressure ulcers exhibiting high fluid secretion over a two week treatment period, without looking at healing, and has found it to be more costly than a standard care dressing regimen. As the existing clinical evidence does not identify any clear benefit of NPWT, the GDG agreed that it is unlikely that NPWT is cost-effective compared to standard care dressings for the treatment of pressure ulcers.

The standard care dressing regimen included in this analysis is just one of many possible dressing combinations. The dressing regimen was chosen to reflect a fairly high cost dressing combination, in order to compare the cost of NPWT against the maximum cost of dressings. As NPWT has been found to be more expensive than the costly dressing regimen, it is clear that it would also be more costly than simpler dressing regimens.

The GDG acknowledged that whilst this analysis only considers the use of NPWT for use with pressure ulcers which are exhibiting high fluid secretion, there are other occasions in which NPWT could be beneficial. For example, NPWT is also sometimes used when other treatment options have failed to have any effect on the pressure ulcer, or when the pressure ulcer has a strong odour. This analysis does not explicitly consider these other scenarios, although it is likely that the conclusion that NPWT is more costly than standard care dressings still applies.

This analysis does not explicitly consider that NPWT pumps are occasionally purchased rather than rented. The purchase prices of the various pumps included in this analysis range from £5,456 to £6,250 (prices obtained from manufacturers), plus additional maintenance costs on top of these prices. The results of the sensitivity analysis on the rental cost of the pump can be applied to the purchase price: the equivalent per day cost over the lifespan of the pump would need to be less than £4 (£1) in order for NPWT to be less costly than standard care dressing regimens for the management of medium and large (small) pressure ulcers.

L.3.10.3 Generalisability to other populations / settings

The conclusions of this analysis are expected to apply to UK adults with pressure ulcers. The GDG felt that as NPWT was not cost-saving for individuals with pressure ulcers that are exhibiting high fluid secretion, it is unlikely to be cost-saving for the management of pressure ulcers generally. Scenario analysis revealed that NPWT is also more costly than standard care dressings when used in the community, taking into account travel costs of nursing staff.

The results of this analysis are not intended to be generalisable to people under the age of 18. Recommendations for NPWT in this population have been informed by the Delphi consensus panel.

L.3.10.4 Comparisons with published studies

Soares and colleagues[10] present the only existing UK cost-utility analysis of negative pressure wound therapy for the treatment of pressure ulcers. Three scenarios are analysed:1) analysis based on existing literature, 2) existing evidence combined with information elicited from experts, 3) existing evidence, expert elicitation and pilot trial data combined (note that this pilot trial data was included in the systematic review of clinical evidence for this guideline). NPWT was found to be cost effective in scenarios 2 and 3, but not when the analysis was based only on exiting literature. Note that the GDG wished to avoid placing too much reliance on expert elicited data, and discussed further limitations of the Soares study (as noted in section L.3). The finding that NPWT is not cost effective when the analysis is based only on existing literature aligns with the conclusions of our analysis.

L.3.10.5 Conclusion = evidence statement

This cost-comparison found NPWT to be more costly than standard care dressings for the management of pressure ulcers exhibiting high fluid secretion. This analysis is considered to be partially applicable, with minor limitations.

L.3.10.6 Implications for future research

This analysis has not included data on the clinical effectiveness of negative pressure wound therapy, as the existing evidence was considered not to be reliable enough on which to base a full economic model. If a clear benefit (or harm) could be identified through high quality research, ideally including data on time to healing of pressure ulcer and quality of life, a complete cost-utility analysis could be carried out. This would serve to reduce any remaining uncertainty around the cost-effectiveness of NPWT in the treatment of pressure ulcers.

L.4 References

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