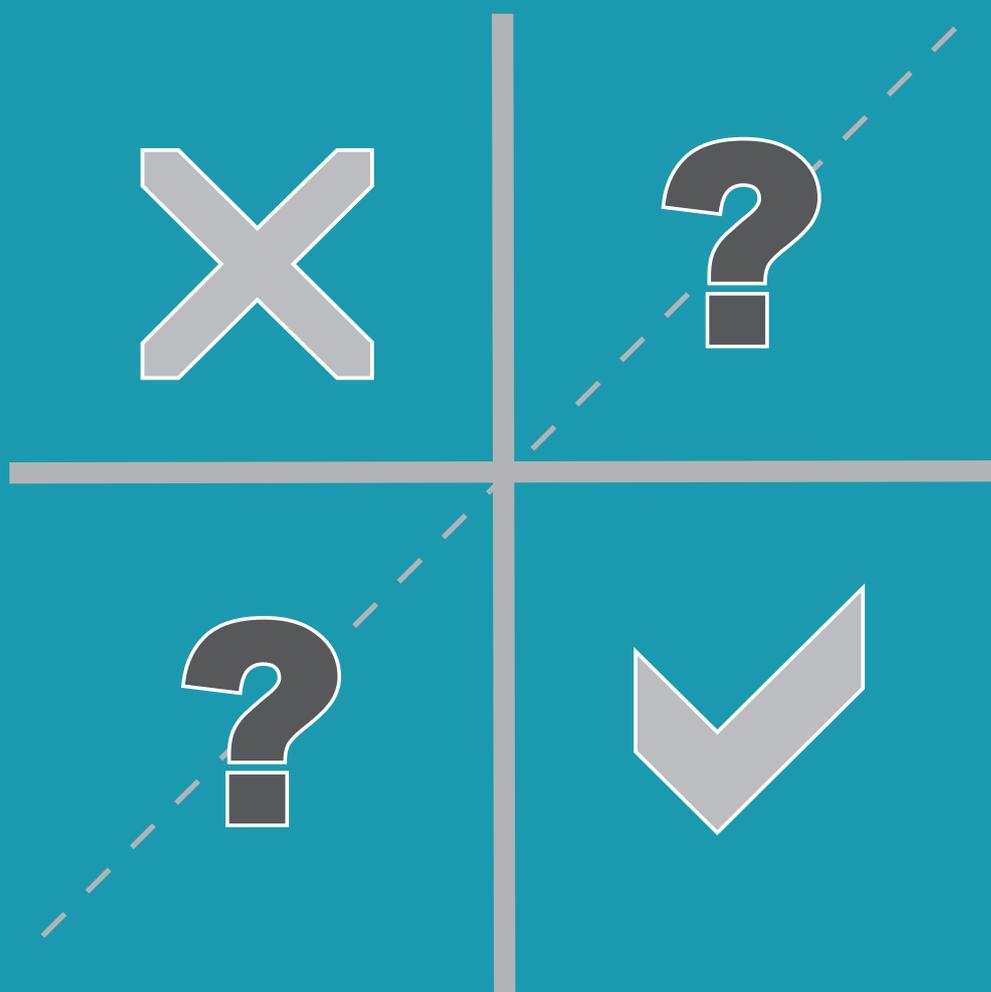


MAKING THE CASE FOR COST-EFFECTIVE WOUND MANAGEMENT



an expert working group review

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This document has been supported by Biomonde Ltd, Kinetic Concepts Inc (KCI), Smith & Nephew, Shire and Tissue Therapies.

How to cite this document:

International consensus. Making the case for cost-effective wound management. Wounds International 2013. Available to download from www.woundsinternational.com

FOREWORD

Clinicians who treat patients with wounds need access to the resources that will enable them to deliver the best and most appropriate treatments. With economic constraints on healthcare budgets, in addition to challenges to prove efficacy, budget holders and payors are increasingly asking for financial justification for the provision of treatment. Clinicians therefore need to know how to provide such justification to ensure continued provision of appropriate wound management services, including the implementation of service improvements and new technologies.

In June 2013, an international group of wound management and health economic experts met in London to explore the concept of cost-effectiveness and to discuss how to make the case for cost-effective wound management.

An initial draft based on the group's discussions underwent extensive review by the expert working group. This was then sent to a wider group for further review. The process has resulted in this finalised consensus. Quotes through the text summarise pertinent points from the discussion. The document aims to help clinicians, healthcare budget holders and payors, and other stakeholders to:

- ① understand what is meant by 'cost-effective wound management'
- ② appreciate the different types of economic analysis used in health care to determine cost-effectiveness
- ③ interpret information on the cost and cost-effectiveness of wound management modalities and protocols
- ④ make an appropriate case for cost-effective wound management in their locality
- ⑤ set up systems to collect the data needed for the analysis of the cost and cost-effectiveness of wound management.

Professor Keith Harding

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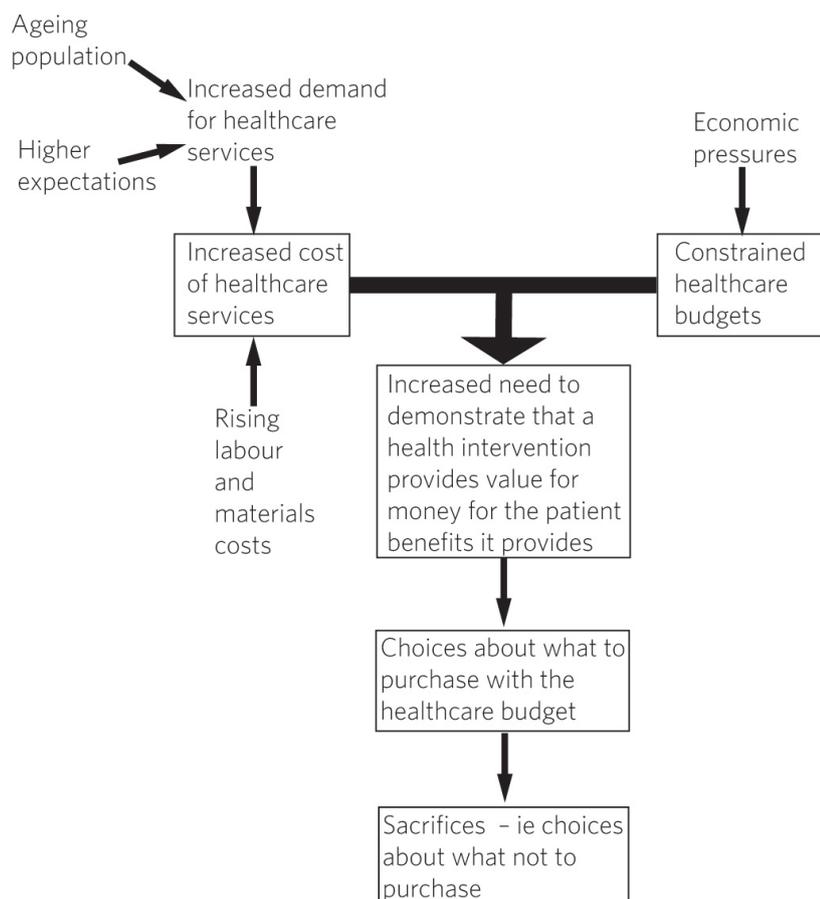
ADDITIONAL EXPERT WORKING GROUP (See Appendix 4, page 18)

Cost-effective healthcare

Our world is one of limited resources, but the tendency of human nature is to want 'more and better'. The tension between resource availability and demand has always been present in healthcare systems worldwide, even during periods of relative economic prosperity. Economic and resource limitations mean that choices have to be made about how money is spent and how resources are allocated for maximum benefit (Figure 1). Making choices inevitably also involves making decisions about what not to spend money on, ie on what sacrifices to make. Health economics has an important role in providing information to those involved in making such complex and often politically charged decisions.

'In a system with limited resources, health professionals have a duty to establish not only that they are doing good, but that they are doing more good than anything else that could be done with the same resources.' Alan Williams (Professor of Health Economics, University of York, Health Outcomes Conference, 1993)

FIGURE 1 | The challenges facing healthcare provision



Do healthcare services always deliver health benefits?

The intention of healthcare services is to deliver health benefits. However, it has been suggested that up to 25% of all healthcare services provided may be unnecessary¹. Furthermore, it has been estimated that 10-15% of healthcare interventions reduce health status and a similar percentage improve health status. For the remaining 70-80% of healthcare interventions there is insufficient evidence to determine effectiveness².

Challenges in wound management

“
Lack of implementation of best practice in wound management is a significant contributor to the economic and societal burden of wounds

”

The prevalence and incidence of wounds is likely to continue to increase. This is due in part at least to the increase in average age of the population along with ongoing increases in the prevalence of obesity, diabetes and lower extremity arterial disease^{3,4}.

Securing funding for wound management is challenging, especially in the many healthcare systems where wound management is not recognised as a discrete healthcare field. Gaining funding involves competing against other healthcare fields that are also seeking financial support and showing that wound management provides value for money. Demonstrating value for money is reliant on having data showing that the treatment modality or protocol is clinically effective and also necessitates detailing the costs of using the modality or protocol.

Collecting such data in wound management is difficult:

- Data collection is often sporadic or, where collected, poor or inconsistent methodology makes meta-analysis difficult.
- Data demonstrating clinical efficacy and effectiveness may be limited or not available.
- Financial data may be based on measures that do not provide a true indication of cost.

It is clear that when implemented properly wound management that uses appropriate interventions based on accurate diagnosis delivers benefits to patients, healthcare systems and society⁵⁻⁹. However, the combination of low rates of accurate wound diagnosis and patchy implementation of wound management principles unfortunately may result in failed management and wasted resources and so undermine efforts to show wound management to be a good use of healthcare funds (Box 1). A further issue is that reimbursement systems can sometimes disincentivise practitioners by reimbursing products or procedures which are not recommended in best practice guidelines¹⁰.

Even so, there is a positive side to these problems: raising awareness and understanding of the need to show value for money can drive widened implementation of improved wound management.



Wound management protocols or interventions shown to be cost-effective by health economic analysis will only be cost-effective in clinical practice if patients choose and are able and willing to adhere to that protocol or intervention

BOX 1 | Some of the challenges in the provision of cost-effective wound management

There is lack of awareness that wound management extends beyond the use of dressings to include interventions directed at the cause of the wound and there is under usage of established standard wound management principles^{11,12}:

- An audit in England in 2005 found that 26% of leg and foot wounds had no definite diagnosis¹³
- Studies in Denmark and Ireland found that only about half of patients with leg ulcers had undergone investigations to determine aetiology^{14,15}
- Studies have shown that 50–60% of patients with venous leg ulcers had not been treated with compression^{13,15}
- Data from the USA shows that diabetic foot ulcer patients received adequate offloading at only 6% of visits¹⁰
- In the USA, from 2001 to 2010, 2.5 million adult inpatient admissions involved a diabetic foot ulcer¹⁶

Demystifying cost-effectiveness

“
Cheap no good;
good no cheap”

Dr Colin Song

Myth: Cost-effective means cheaper or cost saving

Cost-effectiveness is assessed by analyses that relate costs of an intervention or treatment to the outcomes produced. Cost-effectiveness is relative: an apparently expensive intervention may be cost-effective in comparison with a cheaper alternative if the benefits gained are greater. In general, there is an increased cost for an increased benefit.

Myth: An intervention is either cost-effective or not cost-effective

Some healthcare bodies use thresholds to determine cost-effectiveness, eg in the UK the National Institute for Health and Care Excellence (NICE) uses a threshold of less than £20,000-£30,000/QALY as indicative of cost-effectiveness¹⁷. However, cost-effectiveness is comparative: an intervention can be shown to be more or less cost-effective than another intervention. Nonetheless, extreme care is needed to ensure comparability of analyses of cost-effectiveness because of high variability in the assumptions and methodologies used.

Myth: Evidence of cost-effectiveness in wound management is sparser and more difficult to acquire than in other areas of healthcare

The evidence base for cost-effectiveness in all areas of healthcare is somewhat limited and is no worse in the field of wound management than any other. Reversing the situation will be reliant on improving data collection and understanding of the need for and uses of health economic analyses. It is important that improved data collection is underpinned by wider education of clinicians in implementation of best practice in wound management.

Myth: Analysis of cost-effectiveness is too difficult and time-consuming to undertake

Limited research budgets mean that health economic analyses need to be focused on areas where they will be most beneficial, ie where outcomes are poorest, to see which interventions or diagnostic tools might have the greatest impact.

Improvements in data collection will aid the process of determining the cost-effectiveness of wound management products. Institutions that invest in data collection may find that they reap financial benefits by enabling such analyses.

Involvement of health economists in the planning, execution and analysis of clinical trials is essential to ensure that the potential economic impact of the intervention being explored has been evaluated. Clearly such information is valuable to those who may be the ultimate decision makers on whether the intervention is reimbursed or not.

Myth: A favourable cost-effectiveness analysis will in itself gain the intervention funding or reimbursement and adoption into clinical practice and is the only parameter of interest to payors

In reality, even if an intervention has a favourable cost-effectiveness analysis many other factors influence whether it is adopted into practice. When lobbying for funding or adoption of an intervention, the perspective and needs of each stakeholder or funder involved need to be considered.



Being cost-effective is sometimes equated with being inexpensive or cost-saving, but often this is not the case. Broadly, if a healthcare product works and the cost is reasonable, it is likely to be cost-effective

What is cost-effectiveness?

The phrase 'cost-effective' means that something is "effective or productive in relation to its cost"¹⁸. In healthcare, a cost-effective intervention provides clinical benefits at a reasonable cost, and the benefits provided exceed those that would be gained if the resources were used elsewhere¹⁹.

In health economics, the cost-effectiveness analysis is one of several formal methods of assessing the value for money provided by clinical interventions (Table 1). However, cost-effectiveness is also used as a blanket term for all types of economic evaluation of healthcare²⁰ and as such may be confused with cost itself²¹. All of the analyses described in Table 1 require an assessment of costs of the health condition.



Some of the terms used in health economics may have multiple meanings in everyday language. Therefore, it is important that the meanings of the terms in use are explained clearly to avoid misinterpretation

TABLE 1 | Types of health economic analysis²²⁻²⁶

Type of analysis	Details	Measure of analysis	Comments
Cost or burden of illness	Determines how much a particular disease costs individuals, the healthcare system, the economy and society	Total cost	<ul style="list-style-type: none"> Only gives an indication of the magnitude of financial impact of the condition being investigated Does not indicate 'value for money'
Cost-minimisation	Measures the costs of treatments with identical outcomes	Cost of the treatments; the difference in costs between different treatments can be calculated	<ul style="list-style-type: none"> Assumes that the outcomes of each treatment are exactly identical The lowest cost is the cheapest way of achieving the outcome Not often used as outcomes are rarely truly equivalent
Cost-effectiveness*	Measures the costs of achieving a defined unit of outcome, eg cost per wound healed or amputation avoided or life year gained	Cost-effectiveness = cost/per unit of outcome Incremental cost-effectiveness ratio (ICER) = the difference in the cost of treatments/difference in benefits between treatments	<ul style="list-style-type: none"> The lowest CE generally indicates the most efficient use of resources The ICER indicates how much more (or less) than an existing treatment a new more effective treatment would cost for additional benefits The most widely used form of analysis Can be used to compare interventions within a disease type, eg to compare dressings for treating a diabetic foot ulcer
Cost-utility	Measures costs in terms of survival and quality of life	Cost per quality-adjusted life year (QALY) A QALY is a measure that combines quality and quantity of life	<ul style="list-style-type: none"> Use of the QALY allows comparisons to be made between different areas of healthcare, eg between a treatment for diabetic foot ulcers and a treatment for cancer Required form of analysis in some countries because it can be used for wider comparisons Discouraged by law in the USA because of the political difficulties of making choices between different patient groups and the fear of healthcare rationing
Cost-benefit	Measures both costs and benefits in monetary terms	Comparison of costs, eg if cost of treatment is less than the monetary value of the benefit, then the treatment is acceptable	<ul style="list-style-type: none"> Allows for comparisons across all areas of healthcare and with other areas such as education or transport Infrequently used because of the practical and ethical problems of assigning monetary value to health outcomes
Cost-consequences	All outcomes are quantified and related to the costs for each of a range of alternative courses of action	Comparison of costs across a range of outcomes that may arise from different courses of action	<ul style="list-style-type: none"> Gaining support from health economists Extension of cost-effectiveness analysis Does not restrict the outcomes to a single measure Easier to understand by decision makers than cost-utility

*Sometimes also known as a cost-benefit study - see definition of cost-benefit study.



Assessing the cost-effectiveness of a health intervention is about examining the balance between cost and benefit

Understanding costs

Costs can be divided into:

- **Direct costs** — those costs that are incurred by the healthcare system and/or the patient as a direct result of the disease, eg a wound, and its associated treatment (Table 2).
- **Indirect costs** — less immediately obvious and include the losses to society caused by the disease and its treatment, eg inability to work or to engage in social activities.

Definitions of direct and indirect costs may vary and it is prudent to check what costs are included in an individual analysis^{25,26}.



Direct costs are easier to collect than are indirect costs, but analyses including just direct costs may not be fully representative of the economic impact of a wound or its treatment

TABLE 2 | Examples of direct and indirect costs in wound management

Direct costs	Indirect costs
<ul style="list-style-type: none"> ■ Diagnostic tests ■ Primary and secondary dressings, tape, cleansers, bandages, support stockings, medication and other materials costs ■ Clinician time (eg nursing and medical) ■ Hospital/clinic overheads (eg administration services, building costs, heating, lighting, cleaning etc) ■ Costs of transporting the patient to the health service 	<ul style="list-style-type: none"> ■ Loss of income by patients and/or their carers due to reduced time at or ability to work ■ Costs due to reduced ability to undertake domestic responsibilities, eg cleaning or caring for others ■ Welfare, social security or disability payments by government or insurance company

Cost perspective

The costs used in an analysis will depend on the perspective or viewpoint of the analysis. For example, if the perspective is that of a health system, only the costs incurred by the health system in the treatment of the disease or condition will be included, ie mainly direct costs. If the perspective is that of society, costs will include those incurred by the health system plus the costs incurred by society, ie direct and indirect costs. Some analyses use a very selective perspective, eg that of a clinic or a hospital. In such cases, the analysis may fail to recognise costs that are incurred by other sections of the healthcare system, eg costs that occur in the community as a result of early hospital discharge. Therefore, reports of economic analyses should clearly specify the perspective and objectives of the analyses.



In wound management, distinguishing costs arising from the treatment of a wound may be difficult because wound management may form part of the treatment for an overall condition, eg a diabetic foot ulcer may be treated in a clinic attended by the patient for management of diabetes

To aid study comparisons, economic analyses of wound management interventions should specify amounts for each resource analysed, eg number of hours of clinician time and number of dressings used, in addition to the monetary costs and the date and source of the valuation for each

Economic analyses of wound management interventions need to clearly define the costs used and how they are derived to ensure valid interpretation and comparison with other studies.

Opportunity costs

Cost analyses may also examine opportunity costs. These are the costs of a treatment that would not be possible if a particular sum of money was spent on something else. For example, funding of one sort of dressing may be at the cost of discontinuing funding for another dressing or intervention.

Cost sources

Comparisons of cost analyses between studies and countries may be complicated by differences in cost sources, resource usage, exchange rates and local practices²⁷. For example, costs may be based on reimbursement values rather than on actual costs, and labour costs may vary considerably between countries. Therefore, direct application of a cost analysis from one situation or country to another may not always be appropriate.

Outcome measures for wounds

The outcome measure used in an economic analysis should be appropriate for the disease or condition and intervention being studied, and ideally should be meaningful to patients^{23,28}.

A few examples of the many outcome measures that have been used in wound management studies include:

- proportion of wounds healed
- time to complete healing
- percentage wound area reduction
- proportion of wounds infected
- number needed to treat
- number of ulcer days averted
- proportion of lower extremity amputations
- change in wound rating score.



The wide variety of outcome measures used in wound management research hinders comparisons of interventions and progress. There is an urgent need to develop patient-centred outcomes that look at function and quality of life and to obtain international agreement on which outcome measures should be used

During analysis the outcome measure may be stratified according to the severity of the wound using a wound-appropriate recognised classification system. An economic analysis calculates the cost to achieve the chosen outcome measure.

Using consistent outcome measures

Outcome measures used to compare different interventions should have the same units. The outcome measures should also have an appropriate time horizon, ie data on the outcome should be collected for a suitable length of time. For example, if examining the effect of an intervention on rates of wound infection, follow up of a few weeks may be appropriate. However, a study examining effect on amputation rates or death may need a follow up that extends for years. If time horizons are sufficient for positive outcomes to develop (should they exist), the cost-effectiveness analysis is more likely to produce a favourable result²⁵.



The outcome measures and benefits used in economic analyses of wound management should be clearly defined and explained

Utilities and indicators of quality of life

Cost-utility analyses are of increasing interest in some countries because they enable comparisons to be made between interventions in different healthcare fields. The comparability of these studies stems from their use of utilities which provide a measure of the preference for a specific health state. However, the potential political problems of overtly using such studies to make choices on healthcare spending have led to restrictions on the development or use of cost per quality-adjusted life year (QALY) thresholds by the Patient-Centred Outcomes Research Institute (PCORI) in the USA^{29,30} and concerns in Europe³¹.

A QALY provides an indication of the impact of an intervention on quantity and quality of life. The benefit of an intervention is expressed as a utility with a score usually between 0 (death) and 1 (perfect health)²⁶. The number of life years gained by the treatment is multiplied by the utility to give the number of QALYs produced by that intervention. For example, if a treatment has a utility score of 0.5 and produces 10 additional years of life, it would produce $0.5 \times 10 = 5$ QALYs. Once the benefit of an intervention has been expressed in QALYs it is then possible to calculate the cost of generating a QALY and to use that to compare interventions.

The EQ-5D (www.euroqol.org/) is a quality of life tool that is often required by assessment agencies. However, there is some doubt over whether it is sufficiently sensitive for conditions such as chronic wounds. There are tools available to map quality of life or clinical measures to EQ-5D³². There is increasing interest in developing wound specific patient-reported outcome measures (PROMS) that include measures of quality of life³³.

Interpreting cost studies

Studies examining the costs of wound management vary in complexity, eg from calculation of dressing costs and nursing time incurred during wound management to studies that calculate cost-effectiveness ratios or cost-utilities.

There are no universally accepted specific reporting criteria for studies of cost and benefit²⁵, although some guidelines have been published³⁴⁻³⁶. Interpretation of cost studies requires care; Box 2 provides a list of questions to ask when evaluating an economic analysis of a wound management intervention.



Cost studies are very variable in approach and quality. Great care is required when assessing the value of studies and their generalisability to other healthcare settings

A common misinterpretation of cost analysis in healthcare is that a cost-effective intervention is always the cheapest intervention³⁷. If the outcomes of the intervention are absolutely identical then this is valid (ie in cost-minimisation studies). However, if there are additional benefits then there may be an additional cost that is worth paying in order to receive those benefits.

BOX 2 | Questions to ask when evaluating an economic analysis (adapted from³⁴)

Study design

- Is the research question stated clearly?
- Is the research question economically important?
- What is the perspective of the study — ie has the study been conducted from the perspective of the payor or society, and exactly which costs have been included?
- Is the type of economic evaluation chosen stated and is it appropriate?
- When, where, how and by whom was the study conducted and how was it funded?

Data collection

- Sources of the cost and clinical data:
 - Is the data source stated? Were they collected as part of an audit or were data extrapolated from data collected for previous studies?
 - Was prevalence or incidence used, how was the measure used defined, and was it appropriate to the time horizon of the clinical pathway under consideration?
 - Are any assumptions stated and reasonable?
- Clinical or quality of life outcomes:
 - Is the patient group representative of patients as a whole — ie what were the inclusion/exclusion criteria, and how generalisable is the study?
 - Are the clinical outcomes clearly defined and relevant?
 - Where data are drawn from different studies to compare interventions, are the criteria for the clinical outcomes and follow up periods the same?
 - Was the protocol within which the intervention under investigation was used specified?
 - Was the study a suitable length for the outcome(s) being investigated?
 - Have any quality of life data used a validated and suitable quality of life instrument for data collection, and have all relevant aspects of quality of life been included?
 - Where utilities are used, have they been collected using a recognised instrument, and do the utility scores seem reasonable?
- Cost data:
 - Is resource usage specified separately to the cost of the resources used?
 - How were costs calculated — eg are they based on a reimbursement or fee tariff, or on national/regional health system reference costs?
 - What is the currency and calculation date of the costs used?
- Has discounting been used for costs and benefits?
- Has a sensitivity analysis been conducted — ie has any analysis been performed to check the effect of varying the assumptions made and to see how robust are the results? Have the variables been stated and justified, and the range over which the variables have been varied stated?

Analysis and interpretation of results

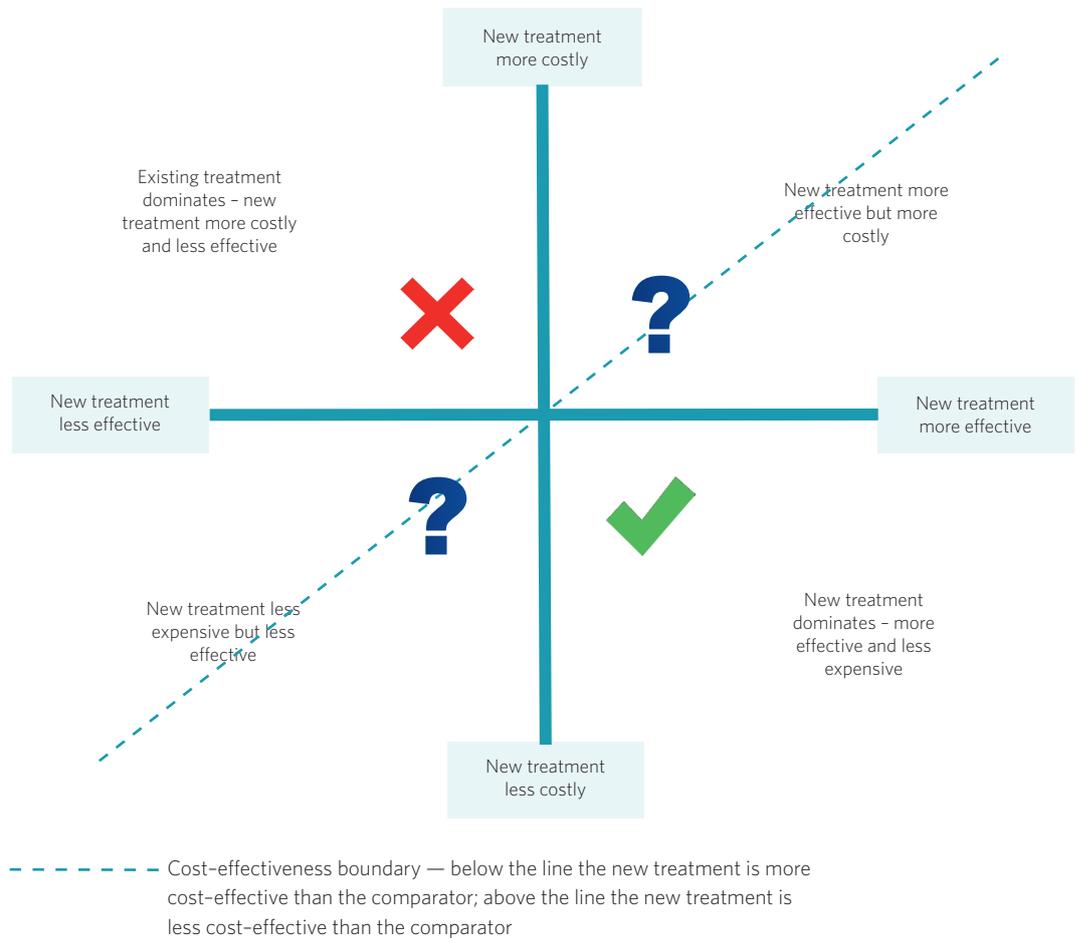
- Do the results stated answer the study question?
- Are the results in line with similar studies? If they are contradictory, are potential reasons discussed?
- Do the conclusions follow on from the results reported?
- Is there an analysis of study strengths/weaknesses?
- If the study is restricted to a specific healthcare setting, eg a hospital, has generalisability to other settings, eg the community, been explored?

Cost-effectiveness studies

Figure 2 illustrates the potential results of comparing the cost-effectiveness ratios of an existing and a new intervention. A new intervention that falls into the bottom right section should be implemented because it brings additional benefits at lower cost when compared to an existing treatment. An intervention in the top left section should be disregarded because this intervention is more costly and less effective than the comparator treatment.

The situation is less clear for the two remaining sections — top right and bottom left — because in the first case the new treatment is more effective but more costly, and in the second, the new treatment is less expensive but also less effective. Which intervention is deemed to be more cost-effective will depend on where the cost-effectiveness boundary has been set.

FIGURE 2 |
Comparing cost-effectiveness ratios (adapted from^{24,25,38})



Cost-utility studies

Cost-utility studies use the common denominator of the QALY (page 6) and as a result allow comparisons between different areas of healthcare. Some agencies, eg NICE in the UK, weight QALY gains at the end of life more highly than QALY gains at other stages of life.

What do we know about cost-effectiveness in wound management?

“
There is no
consistency in
what we measure
and what data we
collect

”

In common with many other fields of healthcare, there is limited information on cost and cost-effectiveness for wound management, and what is available varies considerably between countries³⁹. Part of the limitation arises from the wide variety of outcomes used, but also because many studies have relatively short time horizons (eg 12 weeks or less), even though the cost impact of chronic and hard-to-heal wounds can occur over many months or years.

The generalisability of the studies that have been performed is variable as many are highly specific to the setting and healthcare system in which they were performed and also to the study population involved. As a result, use of existing studies to justify the use of a particular wound intervention locally requires great attention to detail to ensure that the study data are applicable to the local situation and local population.



In general, and in common with other areas of health care, cost analyses of wound management result in underestimates because measurement and valuation of all costs in monetary terms is not usually possible

Major contributors to the cost of treating a wound include management of wound complications (eg delayed healing, pain, infection, and amputation, with associated medication and diagnostic and therapeutic procedures), hospital admission and delayed hospital discharge^{13,40,41}. Dressings represent a relatively small proportion of total cost even though with appropriate use within a wound management protocol they have the potential to improve outcomes^{42,43}.



Cost-effective wound management will include treatment of the underlying cause of the wound in addition to the use of appropriate interventions directed at the wound itself, eg dressings

Appendix 1 (pages 15–16) summarises some of the studies of cost and cost-effectiveness in chronic wound management. These vary in type from reviews summarising studies of cost of illness to analyses of cost-utility.

There is a need to develop models to improve the accuracy and applicability of economic evaluations of wound management. Models are able to embrace longer time periods than most clinical studies are able, and can allow for comparisons between sub-groups within the study population. Such models may use discrete-event simulation and Markov modelling⁴⁴. The limitations of such models need to be recognised, however, and the models should include a series of sensitivity analyses to provide an indication of the extent that treatment represents value for money^{24,45}.

Data collection for economic analysis

Many economic analyses of the effect of interventions in wound management rely on estimates of incidence and prevalence, data on wound outcomes and on resource usage, and costs derived from the literature, and on modelling. This use of previously published information is driven by the paucity of data in wound management. However, using data from other sources and relying on modelling are fraught with methodological difficulties that may compromise the validity and generalisability of the results.



Given the significant costs and logistical issues involved in formal clinical trials, using data collected as part of routine clinical contact provides opportunities for accumulating data that can be used for economic analyses

Routinely collected data, ie data that are collected in the course of clinical contact and not specifically for the purpose of a research study, have the advantage of being 'in the real world'. This is in contrast to data acquired from the often highly controlled environment of a clinical trial where the patients selected may not be representative of the general population. Such data collection also has the potential to allow for the longer time horizons that are more suited to investigating prevention.

“
It is not the case
that there is an
abundance of high
quality studies of
cost-effectiveness
in wound
management ”

Box 3 lists some of the attributes that a routine data collection system would have ideally to aid analysis of cost-effectiveness. As electronic health records become more widespread, it should become easier to collect such data. However, it may be necessary for incentive schemes to be implemented, such as linking data collection to reimbursement and payment. Implementing such a data collection system is likely to be expensive and difficult.

The use of an electronic data collection system may deliver patient benefits by:

- providing an opportunity for standardising practice
- encouraging use of accepted diagnostic and clinical management pathways, and prompting referral where appropriate
- enabling tracking of patients between healthcare sectors and specialties.

BOX 3 | Ideal properties of a system for collecting routine data for cost-effectiveness analysis of wound management

- Part of an electronic health record scheme used at the point of management that is patient centric and collected real time
- Straightforward to use, has intuitive interfaces, minimal training requirements and is backed up automatically to prevent data loss
- Checks the integrity of data
- Holds data securely and transmits it periodically to a central repository
- Is able to provide appropriate point of care reminders based on accepted diagnostic and clinical management pathways
- Uses an agreed structured language and terminology, eg SNOMED (<http://www.ihtsdo.org/snomed-ct/>), to facilitate data exchange
- Records resource usage, ie patient contact time and dressings used, rather than costs alone
- Completion is incentivised, eg through legal requirements or links to reimbursement
- Data extracted for analysis is anonymised and open source (ie available to anyone)

Box 4 (page 11) lists some practical tips for clinicians to consider when embarking on data collection for economic analyses of wound management products.

“
Cost studies rely too heavily on assumption-driven modelling
 ”

BOX 4 | Practical considerations — collecting the data

- Know what you are measuring and why
- Develop uniform methods for collecting data
- Involve a statistician and health economist
- Educate colleagues on why data collection is important
- Consider quality of life data, ie measure benefits felt by patients
- Tailor your cost-effectiveness study to the reimbursement system in your locality
- Consider starting on a small scale and then scale up to involve more centres to allow larger amounts of data to be collected over a wider area
- **Remember** - if a product works, and has a reasonable cost, it is likely to be cost-effective

Data for different types of analysis

Different types of economic analysis require different types of data. Table 3 gives a broad outline of the types required for each analysis. The table in Appendix 2 (page 17) lists items of resource utilisation to consider. Clinicians are advised to involve a statistician and health economist in any analysis.

TABLE 3 | Data needed for the different sorts of economic analysis

See Table 1 (page 4) for definitions of each of these analyses. This table gives a broad outline of the sorts of data required and is indicative only.

Type of economic analysis	Data required
Cost or burden of illness	Incidence (or prevalence) of disease; target population size; duration of disease; costs of treatment (direct or direct+indirect or direct+indirect+opportunity)
Cost-minimisation	Data confirming equivalence of outcomes of the interventions under investigation; costs of treatment (direct or direct+indirect or direct+indirect+opportunity)
Cost-effectiveness	Clinical outcomes data; costs of treatment (direct or direct+indirect or direct+indirect+opportunity)
Cost-utility	Clinical outcomes data (life years gained); costs of treatment (direct or direct+indirect or direct+indirect+opportunity); utility scores
Cost-benefit	Clinical outcomes expressed in monetary terms; willingness-to-pay
Cost-consequences	Clinical outcomes data — healing rate, time to healing, recurrence rate, adverse effects, utility and quality of life all separately related to cost

Making a case for cost-effective wound management

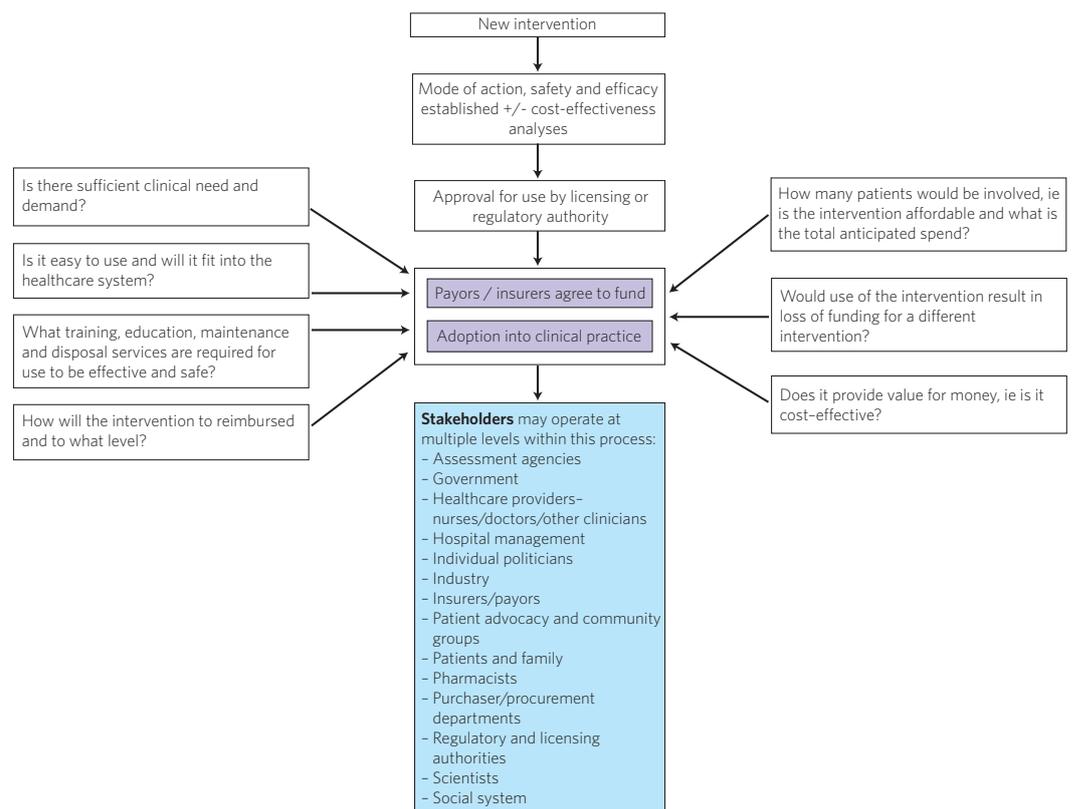
“ It is important that we use limited resources effectively — the right product, on the right wound, at the right time, in the right patient ”

Although showing that an intervention is cost-effective should have a positive effect on prospects for approval for reimbursement and funding, in reality, numerous factors affect whether and when a new intervention is adopted into clinical practice.

Figure 3 is a simplification of the complex process that a new intervention will go through before being adopted. The first stages involve proving efficacy and gaining regulatory approval for use. Demonstration of cost-effectiveness may be required for regulatory approval in some healthcare systems.

Once through these stages, adoption into practice will be determined largely by funding or reimbursement agreements, and ease of use and 'fit' in the local healthcare system. This stage itself is subject to numerous influences including clinical need and the benefits to patients, demand, whether the intervention is practicable in the healthcare setting it is intended for, and level of training required.

FIGURE 3 | The role of cost-effectiveness analysis in the adoption of a new intervention into clinical practice



Expectations and budget impact

When considering cost, payors will be interested in cost-effectiveness, and also in the total expected impact on their budget. For example, an expensive intervention that is used on only a few patients in extreme situations may be funded because the total cost is acceptable and affordable. However, relatively inexpensive interventions that are used on large numbers of patients may be expected to demonstrate particular clinical benefits, and to be cost-neutral or even to be cost-saving to be considered for reimbursement. This will be especially so if an established alternative already exists.

Which type of analysis?

It is likely that more than one type of analysis will be needed when making the case for a new intervention, eg cost of illness and cost-effectiveness ratios. The types used need to be tailored to the target audience. For example, process-orientated analyses, such as of a wound management protocol, may not be relevant where budgets are highly compartmentalised. The controller of a budget that pays for dressings may not be interested that a more expensive dressing saves money overall by reducing the frequency of dressing changes and nurse contact time, because they do not want to pay for benefits accrued elsewhere. In contrast, stakeholders with responsibility for or interest in a broader view of the healthcare system will be interested to know the impact of a change of intervention on the whole patient journey.



When approaching payors and stakeholders ensure that their roles are understood and that the information presented is tailored to be relevant and understandable

Practical considerations

Once the key stakeholder to lobby has been identified, a useful starting point may be to demonstrate the scale of the problem in terms of numbers of patients affected and overall costs of treatment before focusing on key messages on effectiveness and cost. Issues around how the intervention relates to key performance indicators, patient safety, prevention of adverse events and complications may also be usefully presented and discussed (Box 5). If reimbursement has already been agreed, explanation of how this would work and assistance with practicalities such as coding for reimbursement claims may be welcomed.

BOX 5 | What decision makers and stakeholders may need to know

This box lists examples of the types of information that might be used to make the case for an intervention. The information should be tailored to the audience and may not need to include all of the examples mentioned here

- What is the scale of the problem — globally, nationally, locally?
- What is the target group of the intervention — ie which patients will benefit and how many?
- What is the evidence base for the intervention and how does it compare with other interventions?
- Are there examples from the 'real world' if the intervention is already in use elsewhere?
- How long is the intervention required?
- What is the payment/reimbursement mechanism (if already agreed)?
- Is the intervention affordable?
- What costs are involved (direct, indirect, opportunity) and how cost-effective is the intervention?
- What are the benefits to staff and the organisation/healthcare setting or system?
- How will the new intervention fit into the current system of healthcare delivery?
- What education and training costs and additional resources would be needed, eg hospitalisation or special disposal facilities?
- What are the risks associated with adopting the intervention?

“
Support your evidence to non-healthcare professionals with practical examples that show what good wound care can achieve
”

The involvement of individual patients and patient advocacy groups, and physical demonstration of products may also aid understanding by stakeholders (Box 6, page 14).

There is some suspicion of health economic analyses. Some people believe that health economic studies always show interventions to be too expensive, stimulate healthcare rationing and may potentially cause loss of jobs. Others are wary because of the way budgets are structured in some healthcare systems. For example, in some settings if cost savings occur budgets are reduced accordingly and so there may be resistance to implementation of cost-saving measures (Box 6, page 14).

BOX 6 | Practical considerations — presenting your case

- Identify and engage with key stakeholders and understand their different perspectives: clinicians will focus on good clinical outcomes, and procurement on the best financial outcomes
- Keep your arguments short and straightforward; avoid technical language
- Use your clinical expertise to provide stakeholders with a deeper knowledge of wound management
- Demonstrate what good wound management can achieve — use simple measures such as clinical photographs
- Educate stakeholders to look at the 'big picture' — cost savings in one area may increase resource usage elsewhere
- Your data are powerful — develop your arguments carefully and be aware of any unintentional consequences (eg might a reduction in nursing time needed lead to staff cuts?)
- Remember — you are the catalyst for improving patient management globally



Cost-effectiveness analyses need to be conducted and presented with care and sensitivity

In the UK, NICE has published guidance on technology appraisal and the types of information and data they require through an example called 'The reference case' (Appendix 3, page 17)⁴⁶.

Issues for further research

- Internationally agreed reporting criteria for studies of cost and benefit
- Agreement and definition of which outcomes and outcome measures should be used
- Development of patient-related outcome measures
- Agreement and definition of which direct and indirect costs should be included in economic evaluations
- Guidance on how to distinguish costs arising from the management of a wound in a patient with multiple morbidities
- Development of models to improve the accuracy and applicability of economic evaluations of wound management
- Is it possible to define an increase in wound healing rates that equate to cost-effectiveness or cost-saving?

APPENDIX 1 | Studies of cost in chronic wound management

This table provides summaries of some examples of different types of cost analysis studies in the most common chronic wound types and is not intended to be an exhaustive list or to be definitive.

	Citation	Study type and location	Results
Chronic wounds	Posnett & Franks, 2007 ⁴⁷	Cost of illness for chronic wounds; UK	<ul style="list-style-type: none"> ■ Cost of caring for patients with chronic wounds in the UK is £2.3-3.1bn per year (2005/6 prices), about 3% of total estimated expenditure for health: <ul style="list-style-type: none"> — VLU - £168-198m per year — PU - £1.8-2.6bn per year — DFU - £300m per year ■ Authors state these are conservative estimates ■ Estimated from direct costs and incidence/prevalence rates in the literature
	Harding et al, 2000 ⁴⁸	Cost-effectiveness of different dressings for leg ulcers and PUs; UK	<ul style="list-style-type: none"> ■ Based on published European clinical trial data: PUs - 519 wounds; leg ulcers - 843 wounds; used 1999 UK costs ■ Compared direct cost per healed wound of hydrocolloid dressings (Granuflex® (DuoDerm® - ConvaTec) and Comfeel® (Coloplast)), traditional saline dressings and a skin replacement (Apligraf® (Organogenesis)) ■ For pressure ulcers - cost per healed wound: <ul style="list-style-type: none"> — Granuflex® - £422 — Comfeel® - £643 — saline gauze - £2548 ■ For leg ulcers - cost per healed wound: <ul style="list-style-type: none"> — Granuflex® - £342 — saline gauze - £541 — Apligraf® - £6741
	Meaume & Gemmen, 2002 ⁴⁹	Cost-effectiveness of different dressings for VLUs and PUs; Europe and France	<ul style="list-style-type: none"> ■ Based on published European clinical trial data as for Harding et al, 2000 ■ Although absolute values differed between the European and French analyses, the results were consistent for: <ul style="list-style-type: none"> — PUs - cost per ulcer healed = saline gauze > Comfeel® > DuoDerm® — VLUs - cost per ulcer healed = Apligraf® > saline gauze > DuoDerm®
	Fife et al, 2012 ⁵⁰	Analysis of US Wound registry data to determine actual cost of outpatient wound management; USA	<ul style="list-style-type: none"> ■ 5,240 patients with 7,099 wounds; 119,786 outpatient visits ■ Average 16.8 visits per wound ■ Average cost to heal per wound (all types) = US\$3,927 ■ DFU average cost per patient US\$5,391 ■ Cost increased with time in service ■ Patients with management >2 years had costs > US\$18,000/patient ■ 31% of patients never healed; non-healing wounds were the most expensive ■ "Cost to heal" increased with number of co-morbid conditions ■ Registries created from linked, de-identified electronic health records may represent a way to determine the real world effectiveness ■ Despite focus on in-patient costs in the USA, these costs were contained under a diagnosis-related group system; outpatient costs have not been explored and may be far greater
Venous leg ulcers (VLUs)	Öien & Ragnarson Tennvall, 2006 ⁵¹	Cost of illness for leg ulcers tracked over 11 years; Sweden	<ul style="list-style-type: none"> ■ Based on questionnaires about prevalence and time spent on wound management that were sent to district and community nurses in one county in Sweden in 1994, 1998, 2004 and 2005 ■ Costs were estimated using a mean weekly cost for treating VLUs in Sweden of €100 per patient ■ Estimated weekly cost for leg and foot ulcer management dropped from SEK808 in 1994 to SEK612 in 2005 ■ Prevalence of leg and foot ulcers decreased from 0.22% to 0.15% from 1994 to 2005 ■ Treatment time per patient fell from 1.7 hours to 1.3 hours over the same time
	Franks & Posnett, 2003 ⁵²	Cost-effectiveness of compression therapy in the community; Europe	<ul style="list-style-type: none"> ■ Markov* model based on published literature ■ Cost per patient was €1205 for systematic management with high compression and €2135 for usual management based on prices in 2000
	Iglesias et al, 2004 ⁵³	Cost-effectiveness and cost-utility of compression bandaging in VLUs; UK	<ul style="list-style-type: none"> ■ Compared four layer and short-stretch bandages ■ Data were collected alongside the VenUS I study ■ Time horizon 1 year; outcomes ulcer free days and QALYs ■ Mean time for healing was 10.9 days less for four layer bandages than for short stretch ■ Mean cost of four layer bandages was £227.32 less per patient per year than short stretch ■ Mean average difference in QALYs was -0.02
	Gordon et al, 2006 ⁵⁴	Cost-effectiveness analysis of community models of management for VLUs; Australia	<ul style="list-style-type: none"> ■ Comparison of costs of traditional home nursing with a community Leg Club model ■ Data were collected on resources used and costs incurred by the service provider, clients, carers and community ■ ICER (Leg Club: community management) from the perspective of the service provider, clients, carers and community was AU\$515 (€318) per healed ulcer and AU\$322 (€199) per reduced pain score ■ For the service provider, the leg club resulted in cost savings and better health effects than did home nursing

Diabetic foot ulcers (DFUs)	Ragnarson Tennvall & Apelqvist, 2004 ⁵⁵	Review of cost of illness studies for treatment of infected DFUs and lower extremity amputation	<ul style="list-style-type: none"> Review of health economic studies from different countries concluded that total direct costs in 1998 US dollars for: <ul style="list-style-type: none"> healing of infected ulcers were approximately US\$17,500 lower extremity amputation were approximately US\$30,000-33,500
	Van Acker et al, 2000 ⁵⁶	Cost of illness for DFUs; Belgium	<ul style="list-style-type: none"> Costs of caring for 151 diabetic patients over one year were analysed according to severity of foot problems Using 1993 costs: <ul style="list-style-type: none"> preventive management of patients who did not have a DFU as the start of the study cost US\$880 per year treatment cost US\$5227 per ulcer management of severe wounds including hospitalisation and amputation cost US\$31176 per ulcer
	Rezende et al, 2009 ⁵⁷	Cost of hospitalisation for patients with DFUs; Brazil	<ul style="list-style-type: none"> The costs of treating a cohort of patients hospitalised with infected DFUs until death or discharge were gathered 39% were discharged with primary healing; 48% received amputation; 13% died in hospital; 4.6% received reconstructive vascular procedures Direct cost per patient varied between US\$324.3 and US\$5628
	Apelqvist et al, 2008 ⁵⁸	Resource utilisation and direct costs for negative wound pressure therapy in diabetic foot ulcers; USA	<ul style="list-style-type: none"> Based on a multicentre UK randomised controlled trial of 162 diabetic patients randomised to NPWT or to standard moist wound therapy There was no difference between groups for hospital stay length More surgical procedures and dressing changes were performed on the moist wound therapy group Average direct cost per patient treated for 8 weeks or longer was US\$27720 for NPWT and US\$36096 for moist wound therapy, irrespective of clinical outcome Average cost to achieve healing was US\$36096 for NPWT group and US\$38806 for the moist wound therapy group
	Ragnarson Tennvall & Apelqvist, 2001 ⁵⁹	Cost-utility analysis of prevention of diabetic foot ulcers and amputation; Sweden	<ul style="list-style-type: none"> Used a Markov* model to estimate cost-utility over 5 years based on data from 1677 diabetic patients and quality of life data from the literature Outcomes included cumulative incidence of foot ulcers, amputations and deaths, costs, cost-effectiveness and quality-adjusted life years The model found that if the risk of foot ulcers and lower extremity amputation could be reduced by 25%, an intensified prevention strategy including patient education, foot care and footwear is cost-effective (<Euros100,000/QALY) or cost-saving (lower costs and higher QALYs) for all patients except those with no specific risk factors
Pressure ulcers (PUs)	Iglesias et al, 2006 ⁶⁰	Cost-effectiveness analysis of alternating pressure mattresses in the prevention of PUs; UK	<ul style="list-style-type: none"> Based on a multicentre UK randomised controlled trial involving 1971 patients; patients received either an alternating pressure mattress or an alternating pressure overlay When compared with the overlays, alternating pressure mattresses were associated with overall lower costs (£283.6 per patient; 95% CI -£377.59-£976.79) due to reduced length of hospital stay and a delay in time to ulceration The mattresses were associated with an 80% probability of being cost saving
	Makai et al, 2010 ⁶¹	Cost-effectiveness evaluation of a PU prevention strategy in long-term care settings; The Netherlands	<ul style="list-style-type: none"> Introduction of a quality improvement collaborative in Dutch long-term care facilities resulted in: <ul style="list-style-type: none"> incidence of PUs dropping from 15% to 4.5%; prevalence decreasing from 38.6% to 22.7% average quality of life increased by 0.02 QALYs healthcare costs increased by €2000 per patient an ICER of 78,500-131,000 (the Dutch cost-effectiveness limit at the time of the study was €80,000/QALY) A sensitivity analysis showed no clear indication that the collaborative would be cost-effective after two years
	Fleurence, 2005 ⁶²	Cost-utility model; UK	<ul style="list-style-type: none"> A decision-analytic model was used to evaluate the prevention and treatment of PUs Expert opinion was used to rate quality of life Using £30,000/QALY as the cut-off: <ul style="list-style-type: none"> mattress overlays were cost-effective for prevention mattress replacement was cost-effective for treatment of superficial and deep PUs A sensitivity analysis, however, indicated a high degree of uncertainty
	Moore et al, 2013 ⁸	Economic analysis of repositioning for the prevention of pressure ulcers; Ireland	<ul style="list-style-type: none"> Comparison of costs of pressure ulcer prevention between two different repositioning regimes The incidence of patients with a new pressure ulcer was significantly lower in the experimental group: 3% compared with 11% in the control group (p = 0.035; 95% CI 0.031-0.038; ICC = 0.001) Cost per patient free of ulcer was €213.9 (experimental group), compared with €287.3 (control) giving an incremental cost of -€73.4 per patient free of ulcer The difference in cost per patient between the groups was statistically significant (p M 0.0001; ICC = 0.000). Because the more frequent repositioning regime appears to offer better outcomes and lower nurse time costs, this is a dominant intervention The more frequent repositioning regime reduced the incidence of pressure ulceration by 8 per 100 patients (11%-3%) Total nurse cost of the two repositioning regimes per 100 patients would be €20,660 (experimental) and €25,310 (control), giving an incremental cost per pressure ulcer avoided of -€547.

*Markov model - a computer modelling system based on probabilities of outcomes.

APPENDIX 2 | Items of resource utilisation to consider for health economic studies of wound management⁴²

Initial patient and wound assessment	<ul style="list-style-type: none"> ■ Clinician time ■ Facility cost (eg outpatient clinic visit) ■ Diagnostic tests (eg X-ray) ■ Laboratory tests (eg microbiology) ■ Dressings, drugs and other disposables ■ Patient and carer travel time* ■ Patient out of pocket payments* ■ Patient/carer lost work time*
Wound treatments	<ul style="list-style-type: none"> ■ Clinician time for dressing changes ■ Facility cost (clinic or outpatient setting) ■ Clinician travel time (to patient's home) ■ Dressings, drugs and other disposables ■ Antibiotics ■ Diagnostic and laboratory tests ■ Special equipment (eg orthotic insoles) ■ Patient and carer travel time* ■ Patient out of pocket payments* ■ Patient/carer lost work time*
Inpatient costs	<ul style="list-style-type: none"> ■ Inpatient bed-days ■ Dressings, drugs and other disposables ■ Antibiotics ■ Diagnostic and laboratory tests ■ Surgical procedures (theatre time, clinician time, disposables) ■ Rehabilitation costs ■ Outpatient follow-up visits ■ Special equipment (eg orthotic insoles) ■ Patient out of pocket payments* ■ Patient/carer lost work time*
*Depending on the perspective of the analysis (patient/carer costs; social costs)	

APPENDIX 3 | Summary of the reference case⁴⁶

Element of health technology assessment	Reference case
Defining the decision problem	The scope developed by NICE
Comparator(s)	As listed in the scope developed by NICE
Perspective on outcomes	All direct health effects, whether for patients or, when relevant, carers
Perspective on costs	National Health Service (NHS) and Personal and Social Services (PSS)
Type of economic evaluation	Cost-utility analysis with fully incremental analysis
Time horizon	Long enough to reflect all important differences in costs or outcomes between the technologies being compared
Synthesis of evidence on health effects	Based on systematic review
Measuring and valuing health effects	Health effects should be expressed in QALYs. The EQ-5D is the preferred measure of health-related quality of life in adults
Source of data for measurement of health-related quality of life	Reported directly by patients and/or carers
Source of preference data for valuation of changes in health-related quality of life	Representative sample of the UK population
Equity considerations	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit
Evidence on resource use and costs	Costs should relate to NHS and PSS resources and should be valued using the prices relevant to the NHS and PSS
Discounting	The same annual rate for both costs and health effects (currently 3.5%)

APPENDIX 4 | Additional expert working group

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