

# Antimicrobial wound dressings (AWDs) for chronic wounds

Health technology assessment report 13

December 2015



Healthcare Improvement Scotland is committed to equality and diversity. This document, and the research on which it is based, have been assessed for any likely impact on the six equality groups defined by age, gender, race/ethnicity, religion/faith, disability and sexual orientation. For a summary of the equality and diversity impact assessment, please see <http://www.healthcareimprovementscotland.org/>

© Healthcare Improvement Scotland 2015

Published December 2015

Healthcare Improvement Scotland consents to the photocopying, electronic reproduction by 'uploading' or 'downloading' from the website, retransmission, or other copying of this Health Technology Assessment for the purpose of implementation in NHSScotland and educational and 'not-for-profit' purposes. No reproduction by or for commercial organisations is permitted without the express written permission of Healthcare Improvement Scotland.

[www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org)

## Contents

1	Executive summary .....	1
1.1	Introduction .....	1
1.2	A description of the technology .....	1
1.3	Methods .....	1
1.3.1	Clinical effectiveness .....	2
1.3.2	Cost effectiveness .....	2
1.3.3	Patient issues .....	2
1.3.4	Organisational issues .....	2
1.3.5	Recommendations based on the consensus of clinical experts .....	2
1.4	Principal findings .....	3
1.4.1	Clinical effectiveness .....	3
1.4.2	Cost effectiveness .....	3
1.4.3	Patient issues .....	3
1.4.4	Organisational issues .....	4
1.5	Recommendations based on clinical and cost effectiveness evidence, patient issues and organisational issues .....	5
1.6	Recommendations based on the consensus of clinical experts .....	7
1.6.1	Issues for which consensus could not be reached.....	9
2	Introduction .....	10
3	Background on Healthcare Improvement Scotland .....	11
3.1	Health technology assessment .....	11
3.2	An outline of the process.....	11
4	Setting the scene .....	13
4.1	The health problem: chronic wounds.....	13
4.1.1	Venous and arterial leg ulcers .....	14
4.1.2	Foot ulcers in people with diabetes.....	14

4.1.3	Pressure ulcers.....	14
4.1.4	Dehisced surgical wounds/healing by secondary intention.....	14
4.2	Local wound management .....	15
4.3	Chronic wounds: infection .....	15
4.4	A description of the technology: AWDs .....	17
4.5	Clinically relevant endpoints.....	18
4.6	The Scottish context.....	18
4.7	Aims of the HTA .....	19
5	Clinical effectiveness.....	20
5.1	Introduction .....	20
5.2	Methods .....	20
5.2.1	Evidence sources .....	20
5.2.2	Literature search.....	20
5.2.3	Study selection .....	21
5.2.4	Quality assessment .....	24
5.2.5	Data extraction.....	24
5.2.6	Data synthesis .....	25
5.3	Results .....	25
5.3.1	Venous leg ulcers: iodine.....	25
5.3.1.1	Cadexomer-iodine .....	25
5.3.1.2	Povidone-iodine.....	26
5.3.2	Venous leg ulcers: honey .....	26
5.3.3	Venous leg ulcers: silver .....	27
5.3.4	Venous leg ulcers: other AWDs.....	28
5.3.5	Arterial leg ulcers: all AWDs .....	29
5.3.6	Foot ulcers in people with diabetes: iodine .....	29

5.3.7	Foot ulcers in people with diabetes: honey .....	29
5.3.8	Foot ulcers in people with diabetes: silver .....	30
5.3.9	Foot ulcers in people with diabetes: other AWDs .....	31
5.3.10	Pressure ulcers: iodine .....	31
5.3.11	Pressure ulcers: honey.....	32
5.3.12	Pressure ulcers: silver .....	32
5.3.13	Pressure ulcers: other AWDs .....	33
5.3.14	Dehisced surgical wounds and wounds healing by secondary intention: all AWDs .....	33
5.4	Conclusions and discussion .....	34
5.4.1	Conclusions .....	34
5.4.2	Discussion .....	34
5.4.2.1	Quality of the research .....	35
5.4.2.2	Wound healing as an outcome .....	35
5.4.2.3	Wound infection as a primary outcome .....	36
5.4.2.4	Ulcer infection and wound healing.....	36
5.4.2.5	Limitations of this review .....	37
5.5	More information .....	38
6	Cost effectiveness.....	39
6.1	Introduction .....	39
6.2	Methods .....	39
6.2.1	Evidence sources and literature search.....	39
6.2.2	Study selection and data extraction .....	40
6.3	Results .....	40
6.3.1	Venous leg ulcers .....	40
6.3.1.1	Venous leg ulcers summary .....	48
6.3.2	Foot ulcers in people with diabetes.....	48

6.3.3	Pressure ulcers.....	49
6.3.3.1	Foot ulcers in people with diabetes and pressure ulcers summary.....	50
6.4	Conclusions.....	50
7	Patient issues.....	52
7.1	Introduction .....	52
7.2	Methods .....	52
7.2.1	Synthesis of qualitative research .....	52
7.2.2	Primary qualitative research .....	53
7.3	Results .....	54
7.3.1	Synthesis of qualitative research .....	54
7.3.1.1	Description of studies .....	54
7.3.1.2	Results of the framework synthesis.....	55
7.3.1.3	Synthesised themes .....	56
7.3.2	Primary qualitative research .....	72
7.3.2.1	Participants.....	72
7.3.2.2	The thematic framework.....	72
7.3.2.3	Themes .....	73
7.4	Discussion.....	82
7.4.1	Limitations .....	83
7.4.1.1	Synthesis of qualitative research.....	83
7.4.1.2	Primary qualitative research .....	84
7.5	Conclusions.....	85
8	Organisational issues.....	87
8.1	Introduction .....	87
8.2	Methods .....	87
8.2.1	Review of the literature .....	87

8.2.2	A staff survey .....	88
8.2.3	An NHS board level survey.....	88
8.2.4	Spend on AWDs in community and acute settings .....	88
8.2.5	Case studies .....	88
8.3	Results .....	89
8.3.1	Review of the literature .....	89
8.3.1.1	Staff training in the use of AWDs.....	89
8.3.1.2	Decision-making and wound management.....	89
8.3.1.3	Decision-making support.....	90
8.3.1.4	The rationale for conducting a staff survey.....	91
8.3.2	Staff survey.....	92
8.3.2.1	Demographics .....	92
8.3.2.2	Current practice.....	94
8.3.2.3	Preferred dressing choice.....	96
8.3.2.4	What influences clinician’s decision-making? .....	97
8.3.2.5	Clinician knowledge.....	99
8.3.2.6	Safety issues/adverse events .....	99
8.3.2.7	Any other comments.....	100
8.3.2.8	Consensus questions for guiding decision-making in areas where the evidence base is insufficient .....	102
8.3.3	NHS board level survey results.....	103
8.3.4	Spend on AWDs in community and acute settings .....	105
8.3.5	Case studies .....	115
8.3.5.1	Case study 1: NHS Lothian .....	115
8.3.5.2	Case study 2: Comrie Medical Centre .....	115
8.4	Discussion.....	116
8.4.1	Limitations .....	117

8.5	Conclusions.....	117
8.5.1	Literature review .....	117
8.5.2	Staff survey.....	118
8.5.3	NHS board level questionnaire .....	119
8.5.4	Spend on AWDs in community and acute settings .....	119
8.5.5	Case studies .....	119
8.6	More information .....	119
9	Principal findings and recommendations.....	120
9.1	Principal findings .....	120
9.1.1	Clinical effectiveness .....	120
9.1.2	Cost effectiveness .....	120
9.1.3	Patient issues .....	120
9.1.4	Organisational issues .....	121
9.2	Recommendations based on HTA .....	122
9.2.1	Previous technologies scoping report on silver dressings .....	124
9.2.2	Upcoming publications of interest from Healthcare Improvement Scotland.....	125
10	Consensus guidelines .....	126
10.1	Introduction .....	126
10.1.1	Justification for developing consensus guidelines .....	126
10.2	Methods .....	126
10.3	Results .....	127
10.3.1	Consensus statements.....	128
10.3.2	Areas where consensus was not achieved.....	129
10.4	Limitations.....	130
11	Acknowledgements .....	132
12	The team.....	133

12.1	Healthcare Improvement Scotland project team .....	133
12.2	Topic proposers .....	133
12.3	HTA topic group membership (as of May 2014).....	133
13	Glossary .....	135
14	References.....	138

### **List of tables**

Table 1:	Average number of visits/contacts per patient.....	42
Table 2:	The scenarios modelled .....	43
Table 3:	Unit costs used in the analysis .....	46
Table 4:	Cost effectiveness results data.....	47
Table 5:	Synthesis of qualitative research: themes and subthemes.....	55
Table 6:	Primary qualitative research: themes and subthemes.....	73
Table 7:	Annual spend on AWDs in community and acute (based on data from April to September 2014).....	106
Table 8:	Total annual community spend on AWDs by NHS board .....	108
Table 9:	Silver, honey and iodine dressings dispensed in community setting, per capita spend for April 2012–March 2015.....	111
Table 10:	Total annual acute spend by NHS board.....	112

### **List of figures**

Figure 1:	Factors to consider in selecting a dressing for a chronic wound .....	64
Figure 2:	In which region do you work?.....	92
Figure 3:	What is your job role?.....	93
Figure 4:	Where do you provide care for patients with chronic wounds? .....	93
Figure 5:	Wound characteristics that prompt use of AWD.....	94
Figure 6:	AWDs you have used most frequently in the past year .....	96

Figure 7: Once you have established that an AWD is required, do you have a preference for certain types? .....	98
Figure 8: If there is training available, who is it provided by? .....	99
Figure 9: The Ropper Lothian Ladder. ....	131

# **1 Executive summary**

## **1.1 Introduction**

The overarching research questions addressed in this Health Technology Assessment (HTA) are:

- What is the clinical and cost effectiveness of different antimicrobial wound dressings (AWDs), and their safety, compared with other dressings and techniques, for treating localised wound infection in chronic wounds in adults?
- What are the patient and organisational issues associated with the use of different AWDs in adult patients with chronic wounds?

## **1.2 A description of the technology**

An AWD is a dressing that carries or delivers an antimicrobial agent. A variety of AWDs are available, and each has different antibacterial and fluid-handling properties. Topical antimicrobials used in NHSScotland include: silver, iodine (povidone-iodine and cadexomer-iodine<sup>2</sup>; honey, alginate gels containing enzymes, octenidine and polyhexanide (PHMB).

For wounds that are uninfected, and healing as expected, topical antimicrobial therapy is not normally indicated. There may be a role for topical antimicrobial therapy for wounds that are failing to heal and have some signs and symptoms of localised infection. However, it is not clear from the literature what the evidence is to direct usage of these products.

This HTA is concerned with AWD use in chronic wounds in adults. Chronic wounds are an important health problem, affecting many patients. The chronic wounds eligible for inclusion in this HTA are venous and arterial leg ulcers, foot ulcers in people with diabetes, pressure ulcers and dehisced surgical wounds/wounds healing by secondary intention.

The use of AWDs has increased rapidly in recent years and accounts for a quarter of wound dressings spend. This HTA has been conducted due to concerns that AWDs are being overused in NHSScotland.

## **1.3 Methods**

The HTA process comprises four elements: clinical effectiveness, cost effectiveness, patient issues and organisational issues.

Based on the evidence and information gathered in each of these sections, recommendations for NHSScotland are given (see Section 1.5).

Where the evidence did not allow recommendations to be made, the consensus of clinical experts was sought using a modified Delphi method, and consensus guidelines prepared.

### 1.3.1 Clinical effectiveness

The published literature was systematically reviewed. Searches were run in numerous bibliographic databases (including Medline, Embase, CINAHL, The Cochrane Library and Web of Science) and manufacturers were invited to submit evidence. Good quality systematic reviews and randomised controlled trials (RCTs) were eligible for inclusion. Studies were selected using pre-defined inclusion and exclusion criteria, and critically appraised using methodological checklists. Study selection and critical appraisal was performed independently by two researchers, with disagreements resolved by discussion or, if required, by a third researcher. Evidence tables were created for each type of wound and category of antimicrobial. A narrative of the findings was written up by one researcher and quality assured by a second.

### 1.3.2 Cost effectiveness

The published literature was systematically reviewed. Searches were run in Medline, CINAHL, the Health Economic Evaluations Database (HEED), and NHS Economic Evaluations Database (NHSEED) and manufacturers were invited to submit evidence. Two health economists independently screened the literature search results for relevance, and critically appraised studies eligible for inclusion. A narrative of the findings was written up by one health economist, and quality assured by a second.

### 1.3.3 Patient issues

This section involved two separate pieces of research.

- A synthesis of existing qualitative research on patient experiences of chronic wounds and wound dressings.
- Primary qualitative research with a sample of people with chronic wounds. This involved running a focus group (n=8) and undertaking six telephone interviews.

### 1.3.4 Organisational issues

This section was informed by a review of the literature, a survey of NHSScotland staff, an NHS board level survey, and a review of data on spend from NHS National Procurement and Information Services Division (ISD) Scotland.

### 1.3.5 Recommendations based on the consensus of clinical experts

A call for volunteers to be involved in the development of the consensus guidelines was issued across NHSScotland. Consensus was reached using a modified Delphi approach. This involved three rounds of questioning, conducted via email. Thirty people took part in the first round, 23 in the second, and 21 in the third. The threshold for consensus was 70% of people strongly agreeing or agreeing with a statement.

## 1.4 Principal findings

### 1.4.1 Clinical effectiveness

Several good quality systematic reviews were identified, but the studies that they included were generally methodologically weak.

The main outcomes of interest for this HTA related to treating localised wound infection. However, studies on AWDs in chronic wounds mostly report on outcomes related to wound healing. Conclusions for both outcomes are presented.

Based on a systematic review of the clinical evidence:

- for treating localised wound infection in chronic wounds, the evidence is insufficient in terms of quality and quantity to draw conclusions on the use of AWDs.
- for the healing of chronic wounds, the evidence either:
  - does not support the use of AWDs, or
  - is insufficient in terms of quality and/or quantity to draw conclusions on the use of AWDs.

### 1.4.2 Cost effectiveness

A systematic review of the economic evidence highlighted a small number of relevant studies. However, taken together there is insufficient evidence in terms of quality and quantity to determine the cost effectiveness of AWDs relative to non-AWDs for the treatment of localised wound infection and healing of chronic wounds.

### 1.4.3 Patient issues

The review of qualitative literature and primary qualitative research highlighted the following.

- The impact of chronic wounds on people's lives is considerable. The persistence, recurrence and symptoms of a chronic wound can have severe physical, psychological and social consequences.
- People's knowledge around dressings, and wound care more generally, was good.
- There is often a 'trial and error' approach to dressing selection, and this process can continue until the wound begins to heal. People may then credit a particular dressing type with healing their wound.
- Wound healing was usually the most important outcome to patients, but control of symptoms (in particular pain, odour and exudate), and prevention of infection and wound deterioration were also important. People often report wanting to 'try anything' to achieve these outcomes.
- Patients report that the extent and impact of pain from chronic wounds can be considerable. Reports of pain are not always acknowledged by

healthcare professionals, and it seemed that pain frequently remains uncontrolled.

- The people who took part in the primary research (n=14) were generally positive about AWDs. People felt that they helped (or were helping) to heal their wound(s), and/or they helped with wound symptoms. There was no one favourite AWD, and what worked for one person may not work for another.
- People value care that they feel is personal, and from healthcare professionals who they trust and who are persistent with treating their wounds, even when wound healing is slow.
- The primary research indicated inconsistent access to AWDs across healthcare settings. This led to frustration and inconvenience for some people with chronic wounds, who had to source access to their preferred AWD, often from a particular healthcare professional. This inconsistency can make people feel that the best treatments are being withheld from them because of costs.

#### 1.4.4 Organisational issues

The principal findings for this section are as follows.

- Most respondents to the staff survey had used AWDs in the previous year (98%). The ones that they reported using most frequently were iodine dressings (listed by 69% of respondents), followed by honey and silver dressings (55% each).
- There may be benefits in adopting standardised approaches to wound care. Clinicians in NHSScotland reported that they use local guidelines/formularies to guide their decision-making.
- Most respondents (96%) to the staff survey reported that they used AWDs when a chronic wound was showing signs and symptoms of infection. The most frequently listed signs/symptoms of infection were increased exudate, malodour, increased pain, erythema/redness, slough and inflammation/swelling.
- Most respondents (72%) said that they would stop using an AWD if there was an improvement in the wound, or an improvement or resolution in the signs and symptoms of infection. Other reasons for stopping an AWD were if a wound had not changed (25%), or if a wound deteriorated (13%).
- A fifth of the respondents said that they would review a wound after a period of time (most commonly 2 weeks). However, there did not appear to be agreement on what wound characteristics would prompt them to stop using an AWD, or to continue using an AWD.
- The vast majority of respondents felt competent about assessing wounds for suitability to start using an AWD (92%), and felt confident in their decision-making on the appropriate use of AWDs (89%).
- Overall, there was strong support for AWDs, but an acknowledgement that they are often overused or used inappropriately. Three respondents said that they were opposed to their use completely.

- The majority of AWDs used within NHSScotland are dispensed within the community. The highest proportion of spend on AWDs in NHSScotland is on silver dressings. The per capita spend on AWDs, and the types of AWDs being used, varies between NHS boards.
- Six of the seven NHS board respondents indicated that they had reduced the number of different dressings available in their formularies.

### 1.5 Recommendations based on clinical and cost effectiveness evidence, patient issues and organisational issues

*For healing of chronic wounds, the clinical and cost effectiveness evidence was either insufficient to draw conclusions on the use of AWDs, or showed no difference in healing outcomes compared with non-AWDs.*

*Good quality clinical guidelines generally recommend against the use of AWDs in the routine treatment of clinically uninfected chronic wounds.*

**Recommendation 1:**

***The routine use of AWDs to heal chronic wounds is not recommended.***

*There is insufficient clinical evidence to support the use of AWDs to treat local infection in chronic wounds. Despite this, they are currently used for this indication in NHSScotland. This HTA has highlighted that the approach used varies between and within NHS boards. There are no clear starting and stopping rules for AWDs, and the range of AWDs available for clinicians to use varies. This inconsistency is frustrating for staff, and can be an additional burden to patients. There is a need for a more consistent approach until the clinical evidence becomes more informative.*

**Recommendation 2:**

***In the absence of sufficient clinical evidence to guide decision-making, NHSScotland should adopt a consistent approach to guide usage of AWDs in treating localised wound infection in chronic wounds. A national management algorithm should be agreed.***

***Refer to consensus statements.***

Wound healing was usually the most important outcome to patients, but control of signs and symptoms (like odour, exudate and pain), and prevention of infection and wound deterioration were also important. Some patients may also want dressings that are not visible through clothing, or dressings that do not impair their mobility.

**Recommendation 3:**

**When selecting a dressing for people with chronic wounds, alongside holistic clinical assessment, consider the factors of importance to the patient such as odour, pain/discomfort, leakage and mobility as well as healing.**

The use of AWDs varies across NHS boards. There is marked variation in NHS board expenditure, with no clear rationale. In the absence of clinical and cost effectiveness evidence to support use of one AWD over another, the costs of AWDs should guide their use. Reference should be made to local formularies.

**Recommendation 4:**

**Having first taken into account patient and wound-specific factors, the costs of dressings relative to their benefits should guide their use.**

**Refer to consensus statements.**

There is a lack of good quality RCTs in this area, which follow the principles of the CONSORT statement. The clinical experts on this topic group highlighted the need for studies reporting on outcomes relating to the treatment of wound infection, rather than wound healing. However, this may not be feasible unless a valid way to measure localised wound infection is established. The relationship between ulcer infection and wound healing is also unclear. There is currently consensus work being done to establish a list of the minimum outcomes that should be reported in RCTs for the treatment of venous leg ulcers (<http://www.comet-initiative.org/studies/details/680>).

Following from the above, there is a need for good quality economic evaluations. These should conform to the Consolidated Health Economics Evaluation Reporting Standards (CHEERS <http://www.bmj.com/content/346/bmj.f1049>).

**Recommendation 5:**

**There is a need for good quality RCTs on the use of AWDs to treat localised infection in chronic wounds. The subsequent impact of reduced infection on patient outcomes (for example healing, improvement in signs and symptoms) also needs to be explored.**

**There is also a need for good quality economic evaluations.**

*The patient issues section highlighted the importance of consistent and clear messages from healthcare professionals. A patient version of this HTA has been prepared, which can be used to help patients understand the purpose of AWDs, and the issues around lack of evidence. However, there is a need for a national patient leaflet which explains to patients about chronic wounds, how they should manage them, and what their treatment options are. This leaflet should be developed in conjunction with relevant patient organisations.*

**Recommendation 6:**

***A national patient leaflet should be developed, which can be used as an aid to support shared decision-making between patients with chronic wounds and healthcare professionals.***

*Despite most respondents to the staff survey saying that they felt competent and confident in their decision-making around AWDs, there was also an acknowledgement that they can be used inappropriately and/or are overused. Healthcare professionals need training in order to support evidence-informed discussions about courses of treatment with patients. Respondents said that time/resource issues, as well as travel, might make attending training difficult for them. This HTA should be used to inform training material.*

**Recommendation 7:**

***There is a need for accessible and evidence-based education and training on the appropriate use of AWDs in chronic wounds.***

*There is a need for a national group to take this work forward; otherwise it is unlikely that the goal of a consistent approach will be achieved.*

**Recommendation 8:**

***The Therapeutics Branch in the Pharmacy and Medicines Division at Scottish Government would be well placed to take forward the implementation of the recommendations in this HTA.***

## **1.6 Recommendations based on the consensus of clinical experts**

For chronic wounds, the evidence is insufficient in terms of quality and quantity to draw conclusions on the use of AWDs to treat localised wound infection. These dressings are being used for this indication in NHSScotland. While this HTA has been unable to guide the use of AWDs in chronic wounds with local infection, it has identified the importance of a more consistent approach across NHSScotland. Therefore, until the evidence becomes more compelling, guidance on AWD use based on the consensus of clinical experts was sought.

Consensus was achieved on the following statements.

1.
  - a. ***When treating a patient with a chronic wound, symptoms of localised infection must be present before use of an AWD is commenced.***
  - b. ***However, in certain patients with underlying health conditions, some of the signs and symptoms of localised infection might be masked.***
  
2.
  - a. ***Clinical experts agreed that the most commonly observed signs and symptoms of localised infection, which might prompt use of AWDs, include:***
    - ***pain/increased pain***
    - ***erythema/redness***
    - ***heat***
    - ***wound deteriorating/getting bigger***
    - ***exudate: thick, haemopurulent or purulent and/or high volumes***
    - ***inflammation/swelling/oedema***
    - ***delayed or stalled healing***
    - ***malodour***
  
    - ***Positive wound swab***

Consensus was achieved on this statement in round 2 of the process (21/23 people strongly agreed or agreed). While there was agreement on the list of signs and symptoms, the addition of 'positive wound swab' was questioned by members of the consensus group and during peer review. It is not a 'symptom', and is not practical in certain settings (for example community). It was also argued that this could increase inappropriate swabbing of wounds. The HTA topic group, following further discussion, agreed that this criterion should not be on the list.

  - b. ***Some of the above signs and symptoms can be caused by patient factors other than localised wound infection. Therefore, a holistic assessment of the patient is required to rule out causes other than localised infection.***
  
3. ***After 2 weeks of using an AWD, if the symptoms of localised infection have ceased entirely, stop using the AWD and dress wound as per formulary recommendation.***

- 4. After 2 weeks of using an AWD, if the symptoms of localised infection have improved, but not ceased entirely, consider continued use of the AWD, but review at weekly intervals.**
- 5. If, after 2 weeks of using an AWD, the symptoms of localised infection have not changed or have become worse, follow the guidance given in stage 3 of 'The Ropper Lothian Ladder' in tandem with your local policies and procedures.**

It should be noted that swabbing would not be supported by some NHS boards for localised infection. The HTA topic group advised that wound swabbing is not appropriate for localised infection.

- 6. Do not use an AWD for longer than 2 weeks without reassessing wound progress.**
- 7. AWDs should not normally be used for longer than recommended by the product information, or as documented within local policies or procedures.**
- 8. Having taken into account patient and wound specific factors, the costs of dressings relative to their benefits should guide their use.**

#### 1.6.1 Issues for which consensus could not be reached.

- Consensus could not be reached on which type of AWD to use in different wound types. Therefore, when selecting AWDs, clinicians should be guided by their local formularies and guidelines.
- It was not possible to obtain consensus on how long to use AWDs in chronic wounds in which signs and symptoms of infection were improving, but not clearing entirely (other than to review at weekly intervals, as Statement 4 suggests). In such cases, AWDs could theoretically be used for extended periods of time. This is an area for which more consensus work is needed, as AWDs should not be used for indefinite periods of time.

## **2 Introduction**

This report presents the recommendations arising from the Healthcare Improvement Scotland HTA on AWDs for chronic wounds.

Section 3 of the document provides information on Healthcare Improvement Scotland and on the HTA process. A description of AWDs, chronic wounds and the rationale for undertaking this work are presented in Section 4. A review of the clinical effectiveness evidence is presented in Section 5 and a review of the cost effectiveness evidence is detailed in Section 6. Patient's views and perspectives are considered in Section 7 and issues around the organisation, provision and delivery of care are explored in Section 8. Section 9 discusses the HTA findings, including its limitations and uncertainties, and presents the recommendations. Consensus recommendations, developed with clinical experts, are presented in Section 10.

### **3 Background on Healthcare Improvement Scotland**

Healthcare Improvement Scotland is a public body and the national healthcare improvement organisation for Scotland. We work with staff who provide care in hospitals, GP practices, clinics, NHS boards and with patients, carers, communities and the public. Our work drives improvements in the quality of healthcare people receive by:

- supporting and empowering people to have an informed voice in managing their own care and shaping how services are designed and delivered
- delivering scrutiny activity which is fair but challenging and leads to improvements for patients
- providing quality improvement support to healthcare providers, and
- providing clinical standards, guidelines and advice based upon the best available evidence.

Our work programme supports the healthcare priorities of the Scottish Government, in particular those of NHSScotland's Healthcare Quality Strategy and the 2020 Vision.

#### **3.1 Health technology assessment**

The HTA process normally comprises four elements: clinical effectiveness, cost effectiveness, patient issues and organisational issues. The clinical effectiveness section mainly uses published literature to establish the clinical benefits and harms associated with the technology. This focuses on outcome measures of importance to patients evaluated in standard clinical settings. The cost effectiveness element seeks to assess the relative costs and consequences associated with using the technology compared with standard alternative treatments. The patient issues section can include a review of the literature, and may also entail primary research to understand patients' experience of the technology, and their needs and preferences. The organisational issues element may involve primary research to assess the infrastructure requirements of NHSScotland, and any issues arising in service delivery in different settings and areas. It can also include a literature review, and consideration of relevant policy documents.

#### **3.2 An outline of the process**

This HTA has considered each of the four elements described above.

The topic was referred to the Scottish Health Technologies Group (SHTG) in August 2013, who agreed that Healthcare Improvement Scotland should conduct an HTA.

An HTA topic group was convened to oversee the work, and to give advice and input at various stages in its development. The topic group comprised of experts on AWDs and/or chronic wounds (details in Section 12.3).

A protocol was prepared by the internal project team in early 2014. Advice and input was sought from the topic group. The draft protocol was subject to an open consultation, and a final version was published in May 2014. The protocol lists all the research questions and sub-questions to be addressed in the HTA, and can be downloaded from the Healthcare Improvement Scotland website.

The EUNETHTA core model was used to inform the research questions and sub-questions ([http://mekat.thl.fi/htacore/model/AE-tables\\_intervention.pdf](http://mekat.thl.fi/htacore/model/AE-tables_intervention.pdf)).

The team at Healthcare Improvement Scotland worked on the four elements of the HTA from May 2014 to October 2015. The topic group was kept informed of progress and provided comments on draft sections.

The draft HTA was subject to peer review and an open consultation.

## 4 Setting the scene

### 4.1 The health problem: chronic wounds

Chronic wounds are an important health problem, affecting many patients. They cause considerable morbidity and are detrimental to quality of life. They consume significant healthcare resources, in terms of both the costs of the products used for treatment and also staff time (particularly nursing). The long-lasting nature of chronic wounds further amplifies the impact on patients' lives, and the resources required for treating them.

The healing of a skin wound normally involves four sequential phases: haemostasis (stopping of blood flow), inflammation, repair and remodelling (scar tissue formation)<sup>1</sup>. Sometimes, an acute wound will become 'stuck' at one of these four stages, and this can cause a wound to become chronic<sup>1</sup>. All wounds have the potential to become chronic<sup>1</sup>. There is no clearly defined length of time after which an acute wound becomes chronic, and varying times are given in the literature (most commonly 3 months). Typically, a chronic wound develops when an acute wound fails to heal within the expected period for that type of wound, which might be anything from a couple of weeks to several weeks<sup>2</sup>.

The healing process is complex, as it is dependent on numerous patient-related and wound-related factors, and on the treatment received<sup>3</sup>. Healing may be impaired by a number of local and systemic factors, including: poor nutrition, reduced blood supply, circulatory disorders, medication, chemotherapy, radiotherapy, psychological stress, lack of sleep, obesity, infection, reduced wound temperature, underlying disease, maceration, inappropriate wound management, patient compliance with treatment, unrelieved pressure, immobility, substance abuse (including alcohol and tobacco), and older age<sup>3, 4</sup>. Furthermore, healing can be impacted by wound size, wound duration, or wounds in particular anatomical locations<sup>3, 5</sup>.

The chronic wound environment is different to the acute wound environment. The clinical signs of a chronic wound include: non-viable wound tissue (slough and/or necrosis), lack of healthy granulation tissue, no reduction in wound size over time, and recurrent wound breakdown<sup>4</sup>.

More than 90% of chronic wounds can be classified into three major types: foot ulcers in people with diabetes, pressure ulcers, and venous/arterial leg ulcers<sup>6</sup>. These three types of wounds are especially prone to recurrence. This may often be because the patients' underlying and wound-provoking factors have not been adequately addressed. Reported recurrence rates range from 23% to 40% for pressure ulcers, 24% to 57% for venous ulcers, and upward of 60% for foot ulcers in people with diabetes<sup>7</sup>.

For the purpose of this HTA, the main wounds of interest are venous and arterial leg ulcers, foot ulcers in people with diabetes, pressure ulcers, and dehisced surgical wounds/wounds healing by secondary intention. These were chosen as NHSScotland clinical experts advised that they encompass most

chronic wound types that they see in their clinical practice. They are briefly described below.

#### 4.1.1 Venous and arterial leg ulcers

These wounds occur most commonly in older people, and can be lymphovenous, venous, arterial, or both venous and arterial in origin. Approximately 1% of the population will suffer from leg ulceration at some point in their lives<sup>8</sup>.

Venous ulcers account for the majority of leg ulcer cases. They are the consequence of dysfunctional valves in the veins, which causes blood and fluid to pool in the lower extremities. This results in poor circulation, congestion and chronic inflammation at the site, with the tissue eventually breaking down and forming an ulcer<sup>2,9</sup>. The application of graduated compression in the form of stockings or bandages is a proven treatment for healing venous leg ulceration<sup>5</sup>.

Arterial insufficiency ulcers are the direct result of blocked blood flow to small vascular beds in the body, for example the dorsum (top) of the foot. If a wound occurs in this area, it is unable to heal itself due to lack of blood flow<sup>2,9</sup>.

#### 4.1.2 Foot ulcers in people with diabetes

People with diabetes (type 1 and 2) are at increased risk of peripheral vascular disease and neuropathy, as well as having a higher risk of developing infections and a decreased immune response. People with diabetes can develop ulcers on their feet because of neuropathy, ischaemia or both. The initial injury may be from acute or thermal trauma, or from repetitively or continuously applied mechanical stress<sup>10</sup>.

#### 4.1.3 Pressure ulcers

These occur most commonly around bony prominences (for example the coccyx, heels and ankles), and are the consequence of prolonged, unrelieved pressure. This constant pressure causes damage to the skin by decreasing blood supply, which is made worse by other factors such as friction and excess moisture<sup>11</sup>. Anyone with limited mobility is at risk of developing a pressure ulcer. Poor nutrition and incontinence may also increase risk<sup>11</sup>.

#### 4.1.4 Dehisced surgical wounds/healing by secondary intention

A dehisced surgical wound is a surgical wound where the suture line has failed to heal so that the wound re-opens when the sutures are removed. A wound heals by 'secondary intention' if it is left to heal on its own, rather than being stitched closed. The clinical experts asked that this group was also considered, as they regularly encountered people with such wounds in their own clinical practice.

## 4.2 Local wound management

As already described, the factors that contribute to wound formation and their chronicity are multifactorial<sup>6</sup>. Therefore, ongoing wound and patient assessment is important in order to identify and address compounding factors that may impede wound healing.

However, regardless of the wound type, general local wound management principles exist for a wide variety of chronic wounds. In 2003, the Wound Bed Preparation and TIME acronym was developed to help in the treatment of chronic wounds. The aim was to help clinicians to identify the key barriers to healing, taking into account co-morbidity, patient-centred issues and wound bed diagnosis (TIME) to design a wound management plan. The individual elements of TIME are:

- **T-issue:** This relates to the debridement or removal of devitalised or non-functional tissue, which is not optimal repair tissue. Debridement also plays an important role in reducing the levels of bacterial biofilms. Debridement (mechanical or surgical) of devitalised tissues and bacterial biofilms has become a 'must-do' component of wound bed preparation<sup>1, 12</sup>.
- **I-nfection/Inflammation:** Infection and inflammation may impair wound healing.
- **M-oisture balance:** This relates to achieving the optimal balance of moisture in the wound bed, which can impact considerably on the healing of wounds<sup>1</sup>. Exudate needs to be controlled to create the optimal moist environment for wound healing, and also to protect the surrounding skin from the risks of maceration and excoriation<sup>12</sup>. High levels of exudate are associated with a number of factors, including bacterial colonisation of a wound<sup>12</sup>. However, a wound can still be infected even in the absence of thick or discoloured exudate<sup>12</sup>. Low levels of exudate may delay epithelialisation.
- **E-dge of the wound/epithelial migration:** An indicator that the three other components of the TIME acronym have been adequately addressed is if there is a healthy sheet of epithelial cells migrating from the edge of a chronic wound<sup>1</sup>. Lack of improvement in wound dimensions and non-progression of the wound edge indicate failure to heal<sup>12</sup>.

## 4.3 Chronic wounds: infection

All open wounds are colonised with microorganisms, but this usually has no clinical consequences<sup>13</sup>. The World Union of Wound Healing Societies (WUWHS) states that the presence of microbes in a wound can result in the following.

- **Contamination:** the microbial burden does not increase or cause clinical problems (no host response).
- **Colonisation:** the microbes multiply, but wound tissues are not damaged (no host response).

- **Critical colonisation or localised infection:** microbes multiply and the wound moves from benign colonisation to an infected state with impaired healing, but without tissue invasion or host immunological response. There is currently no consensus on how to define or identify critical colonisation.
- **Infection (spreading or systemic):** bacteria multiply, healing is disrupted and deep tissues are damaged. Bacteria might produce localised problems or cause systemic illness<sup>14</sup> (host response).

It has been suggested that infection and excessive inflammation might impair wound healing<sup>1, 12</sup>. One proposed mechanism by which might impair healing is that inflammation and infection lead to elevated levels of proteases in chronic wounds<sup>1</sup>. These proteases are part of the inflammatory response of the host to fight the infection<sup>12</sup>. However, persistently elevated levels of proteolytic activity in chronic wound fluids are linked to the destruction of essential growth factors, their receptors and extracellular matrix proteins<sup>1</sup>.

Opinions differ on which clinical signs and symptoms define wound infection<sup>13</sup>. There is no one test to diagnose wound infection, so clinical judgement and sound clinical assessment skills are needed to interpret signs and symptoms<sup>12</sup>. Some wounds are clearly infected, with purulent secretions or some of the manifestations associated with inflammation (erythema, warmth, pain or tenderness, or induration)<sup>13</sup>. When wounds occur in people with neuropathy (which can obscure or cause pain), ischaemia (which may reduce erythema, warmth or induration), or venous insufficiency (which can mask warmth or cause induration), the expression of inflammation can be limited<sup>13</sup>. In such cases, some define infection by 'secondary' signs and symptoms of local infection, for example nonpurulent exudate, discoloured or friable (easily bleeding) granulation tissue, breakdown or pocketing at the wound base, or an abnormally foul odour. More criteria for identifying wound infection are listed in the European Wound Management Association (EWMA) position document<sup>15</sup>.

In the literature, infection is sometimes defined microbiologically, suggesting that apparently uninfected, but non-healing wounds, may demonstrate either 'critical colonisation' with certain virulent species or a heavy bacterial bioburden. However, other research suggests it is not the density of organisms, but the presence of specific bacterial species, the diversity of bacteria, or patients' individual response to the colonisation, that might delay wound healing in apparently uninfected, but non-healing wounds<sup>13</sup>. There appears to be uncertainty in this area in the literature.

Infected wounds (spreading or systemic) normally require systemic antibacterial therapy, whereas clinically uninfected wounds that are healing as expected do not require antimicrobials. There is uncertainty surrounding how to treat poorly healing wounds with signs and symptoms of localised infection, and whether these would benefit from any topical antimicrobial agent<sup>13</sup>.

#### 4.4 A description of the technology: AWDs

An antimicrobial is any agent that kills or prevents the multiplication of microorganisms, for example bacteria or fungi. For the purpose of this HTA, studies were eligible for inclusion if the intervention involved an antimicrobial being in contact with a wound for a period of time. This included dressings that are impregnated with the antimicrobials of interest; and also topical application of antimicrobials that are held in place with a non-impregnated dressing.

Antimicrobials may be antibacterials, antiseptics or disinfectants.

- **Antibacterials:** agents that act selectively against bacteria and may be administered systemically or sometimes topically. They usually have one specific target or disruptive activity in bacterial cells and act against a narrower range of bacteria than antiseptics. The development of resistance to antibacterial drugs is an increasing problem<sup>16</sup>.
- **Antiseptics:** chemical agents that can be applied topically to skin or wounds. They are relatively non-selective agents that inhibit multiplication of, or kill, microorganisms. They have multiple sites of antimicrobial action on cells. This means that there is less risk of bacterial resistance than antibacterial drugs<sup>17</sup>. They may also have toxic effects on tissue cells. Antiseptics are often referred to as 'topical antimicrobials' even though the term also applies to topical antibacterials<sup>16</sup>.
- **Disinfectants:** relatively non-selective agents often with multiple sites of action that kill a wide range of microorganisms, including bacteria and fungi. Disinfectants are generally not suitable for use on body tissues because they are toxic to human cells<sup>16</sup>.

For wounds that are uninfected, and healing as expected, topical antimicrobial therapy is not normally indicated. There may be a role for topical antimicrobial therapy for wounds that are failing to heal and have some signs and symptoms of localised infection<sup>13</sup>. However, it is not clear from the literature what the evidence is to direct use of these products.

Antimicrobials have traditionally been applied topically in mediums like creams and ointments. More recently, antimicrobials have been impregnated into dressings such as alginates, foams and sponges. This allows controlled release at the wound surface. Different AWDs have different antibacterial and fluid-handling properties. These different characteristics make them more or less suitable for different types of wounds: "choice of an appropriate antibacterial dressing should be based on the wound type and condition and on clinically applicable measures, such as antibacterial, healing, and exudate handling effects, and not on any single laboratory parameter"<sup>18</sup>.

Topical antimicrobials used in the United Kingdom (UK) include: silver, iodine (povidone-iodine and cadexomer-iodine), honey, alginate gels containing enzymes, octenidine and polyhexanide (PHMB).

According to the British National Formulary (BNF)68 (antimicrobial dressings section; Appendix A5.3), spreading infection at the wound site requires treatment with systemic antibacterials. However, it states that for local wound infection, an AWD might be used to reduce the level of bacteria at the wound surface (but it will not eliminate spreading infection).

The BNF goes on to list various AWDs (Appendix A5.3 of the BNF: <https://www.medicinescomplete.com/mc/bnf/current/PHP9654-antimicrobial-dressings.htm>). These were all eligible for inclusion in the HTA. Even though these are all listed in the BNF, this does not imply that they are all available or currently approved for use in NHSScotland.

The information from Appendix A5.3 of the BNF68, mostly relates to dressings that are impregnated with an antimicrobial. There are also other topical agents elsewhere in the BNF that were considered eligible for inclusion in this HTA, if they were held in contact with the wound for a period of time. These include silver sulfadiazine creams and povidone-iodine powder. The AWDs eligible for inclusion in this HTA are outlined in section 5.2.3.

#### **4.5 Clinically relevant endpoints**

Most studies evaluating the use of AWDs in chronic wounds have endpoints relating to healing. However, there is some disagreement in the literature about how appropriate this is, given that chronic wounds are difficult to heal<sup>19</sup>. It is argued that the primary purpose of AWDs is to reduce wound bioburden and treat local infection: the promotion of wound healing is seen as a secondary outcome resulting from the primary purpose<sup>19</sup>. Therefore, some experts feel more appropriate endpoints might relate to measurement of wound bioburden and assessment of the clinical indicators of infection<sup>12, 16</sup>. However, there is no agreed definition of wound infection given in the literature, which makes it a challenging endpoint to use.

Many clinical experts consulted for this HTA supported the argument that the purpose of AWDs is to reduce bioburden. Therefore, for this HTA, the following primary outcomes of interest were considered: resolution of localised wound infection, improvement in signs and symptoms of wound infection, and reduction of bioburden.

Secondary outcomes were ulcer healing, ulcer size and depth, time to healing, rate of healing, use of systemic antibacterials, health-related quality of life, adverse events, ease of use, patient acceptability and comfort, and any other relevant outcomes identified from the literature.

#### **4.6 The Scottish context**

The use of AWDs has increased rapidly in recent years and accounts for a quarter of wound dressings spend. The unit cost of the different AWDs varies. The community spend on honey and silver dressings in NHSScotland in 2012 was approximately £3.2 million (*Personal Communication; Paul Hornby; National Services Scotland*).

At present, due to the lack of robust evidence to support the use of AWDs, there is a reliance on best practice statements and consensus documents to guide practice. These are widely available electronically<sup>3, 4, 12, 20</sup>. Many documents are based on work supported by commercial company education grants. (*Personal Communication; Margaret Ryan, Lead Clinician Prescribing Services & Lynne Watret, Non Medical Prescribing Services; November 2013*).

At a national level, the use of AWDs is one of 10 National Therapeutic Indicators (the remaining being in relation to prescribing of medicines). These indicators have been developed as part of the Scottish Government prescribing Efficiency and Productivity workstream (2011-2014). The aim is to continue to improve the quality of prescribing in primary care whilst optimising efficiencies<sup>21</sup>.

#### **4.7 Aims of the HTA**

The overarching research questions addressed in this HTA are:

- What is the clinical and cost effectiveness of different AWDs, and their safety, compared with other dressings and techniques, for treating localised wound infection in chronic wounds in adults?
- What are the patient and organisational issues associated with the use of different AWDs in adult patients with chronic wounds?

More specific research questions will be presented at the start of each section.

## 5 Clinical effectiveness

### 5.1 Introduction

The main research question for this clinical effectiveness section was:

**What is the clinical effectiveness of different AWDs, compared with other dressings and techniques, for treating localised wound infection in chronic wounds?**

The following subsidiary question was also evaluated:

**What is the clinical effectiveness of different AWDs, compared with other dressings and techniques, for the healing of chronic wounds?**

The published literature was systematically reviewed using the methods described below.

### 5.2 Methods

#### 5.2.1 Evidence sources

The following bibliographic databases were searched to identify systematic reviews and primary studies:

- MEDLINE (Ovid)
- MEDLINE in Process (Ovid)
- EMBASE (Ovid)
- CINAHL (EBSCOHost)
- Web of Science (ISI)
- Cochrane Central Register of Controlled Trials – CENTRAL (Cochrane Library)

Various websites were also searched for relevant systematic reviews. These included the Cochrane Database of Systematic Reviews, HTA organisation websites and the websites of clinical guideline developers.

Manufacturers of AWDs were also invited to submit systematic reviews and RCTs.

#### 5.2.2 Literature search

Website and database searches, to identify systematic reviews relating to AWDs, were undertaken in January 2014. All searches combined the concepts of ‘chronic wounds’ and ‘antimicrobial wound dressings’, and aimed to be as comprehensive as possible using all relevant subject terms and keywords. Searches for systematic reviews were limited to 1990–2014 (publications before 1990 were deemed too old to be of relevance), and used the SIGN (Scottish Intercollegiate Guidelines Network) systematic review filter.

Searches for RCTs were run in July and August 2014. This involved database searches for selected wound and AWD combinations (see supplementary material for more details). Searches were limited to after the cut-off dates of the included systematic reviews. The Cochrane RCT filter, or an adaptation of it, was used in all primary literature searches. All searches were restricted to English language.

Relevant literature was also identified using ZETOC (the British Library table of contents service). Alerts were set up using keywords appearing in the title of articles and scanned for relevance.

An update search was conducted in January 2015 to identify any recently published systematic reviews or RCTs.

A list of sources searched and a copy of all the search strategies used in MEDLINE are available in the supplementary material. The MEDLINE strategies were adapted to search all other databases. A complete listing of all search strategies can be obtained by contacting Healthcare Improvement Scotland at [shtg.hcis@nhs.net](mailto:shtg.hcis@nhs.net).

### 5.2.3 Study selection

Literature was selected using the PICOS (Population, Intervention, Comparison, Outcome, Study design) framework.

For the systematic review search results, two researchers independently screened all titles and abstracts against the inclusion criteria detailed below. The full text of papers thought to be potentially relevant was obtained where possible. These full reports were again independently assessed against the inclusion criteria by two researchers. Any disagreement in selections was resolved by consensus, or by involving a third researcher. All exclusions were recorded, with reasons, in a table (see supplementary material).

For the RCTs not already identified by the systematic reviews, two researchers screened the articles against the inclusion criteria.

The PICOS criteria are detailed below.

#### *Population*

Adults (aged  $\geq 18$ ) with chronic wounds, treated in any care setting. The chronic wounds eligible for inclusion are:

- foot ulcers in people with diabetes
- pressure ulcers
- venous and/or arterial leg ulcers (including ulcers of lymphovenous origin), and
- dehisced surgical wounds/healing by secondary intention.

Any definition of these four wound types that were used in the included literature was accepted.

In studies which included mixed wound types – the data relating to the wounds of interest were extracted if possible. If the data were not presented separately for the different wound types, the study was not eligible for inclusion.

Although the primary outcome of this HTA related to wound infection, the population eligible for inclusion was not limited to those defined as having a chronic wound with localised infection. Studies reporting on the secondary outcomes of this HTA (for example time to healing) might have been missed if the population was limited to those defined as having infected chronic wounds.

We excluded studies on patients with acute wounds or abscesses (including burns). For clarification, an acute wound is an injury to the skin that occurs suddenly rather than over time. It heals at a predictable and expected rate according to the normal wound healing process. Studies in children and those aged under 18 were also excluded.

#### *Intervention*

Wound dressings, produced by any manufacturer, containing any of the following antimicrobial agents:

- iodine (cadexomer-iodine or povidone-iodine)
- honey
- silver (either impregnated or topical in the form of silver sulfadiazine)
- 'other': this category consists of all other antimicrobials listed in Appendix A5.3 of BNF68 that clinical experts told us were of interest, namely polihexanide (PHMB), alginate gels containing enzymes (for example glucose oxidase and lactoperoxidase), octenidine, chlorhexidine and dialkylcarbamoyl chloride (DACC).

Studies were also eligible for inclusion if the intervention involved an antimicrobial being in contact with a wound for a period of time. This would include dressings that are impregnated with the antimicrobials of interest, and also topical application of antimicrobials underneath a non-impregnated dressing (for example povidone-iodine ointment or honey being applied to a wound, and then held in place using a dry dressing).

There are some topical agents not listed in Appendix A5.3 of BNF68 that were still eligible for inclusion (provided they contain one of the antimicrobials listed above) for example silver sulfadiazine creams and povidone-iodine powder.

#### *Comparison*

- Dressings that do not contain any antimicrobial agent.
- Any study identified in the literature that compared one type of AWD with another was eligible for inclusion.
- Any other comparisons reported in the literature, including other wound management products/techniques that propose to reduce bioburden (for example Debrisoft® and debridement).

### *Outcomes*

The primary outcomes of interest were: resolution of localised wound infection, improvement in signs and symptoms of wound infection, and reduction of bioburden.

All studies that reported on wound infection were eligible for inclusion. There is no one clearly defined way to diagnose wound infection, or to measure the extent of microbial contamination, which makes them challenging to use as outcome measures. Therefore, the way in which infection is measured (for example by clinical signs and symptoms, or by bacteriological swabs) differs in the literature. All methods for measuring infection, or definitions used by the authors, were eligible for inclusion.

Secondary outcomes were all wound healing outcomes (for example wound size and depth, time to healing, rate of healing, proportion of wounds healed), use of systemic antibacterials, health-related quality of life (using any measure), adverse events, ease of use, and patient acceptability and comfort.

Studies that reported on any of the primary or secondary outcomes listed were eligible for inclusion.

Outcomes relating to the prevention of wound infection, in apparently uninfected wounds, were not extracted from the studies.

### *Study types*

We included published systematic reviews, with or without meta-analyses. Systematic reviews of all study types were included. Guidelines based on a systematic review were also eligible for inclusion, provided that sufficient details of the review were provided.

To be eligible for inclusion, the reviews had to evaluate the use of AWDs in the treatment of the wounds of relevance. Where reviews had a broader, or different, scope to this HTA, only the data of relevance was extracted.

RCTs were included if they were not already identified by the systematic reviews (either they were published after the systematic review, or did not meet the eligibility criteria for the systematic reviews, but met our eligibility criteria). However, meta-analyses were not updated if new RCTs were identified. The full texts of RCTs already included in the systematic reviews were only obtained if it was possible that they included some outcomes of relevance to the HTA (notably, treatment of wound infection) that were not extracted by the systematic reviews, or if there was some doubt about the accuracy of the data provided by the reviews.

Systematic reviews and RCTs published in languages other than English were not included. Abstracts were not eligible for inclusion. We decided not to search for primary studies beyond RCTs, as we did not feel that the inclusion of such studies would change the findings from the existing evidence and considered that the time and resource could be more usefully invested in other parts of the HTA.

We excluded animal studies, in-vitro studies, discussion articles, non-systematic reviews, editorials, letters to the editor, opinion papers, or other studies that did not report on patient-related outcomes.

#### 5.2.4 Quality assessment

The quality of the systematic reviews was assessed independently by two researchers. The SIGN methodological checklist for systematic reviews and meta-analyses was used. Disagreement was resolved through consensus, and when necessary a third reviewer was consulted. Reviews that were rated as being of high quality (++) or acceptable quality (+) were included. Reviews that were rated as being of unacceptable quality (-) were excluded at this point in the process. This was recorded in the table of exclusions (available in supplementary material).

The quality of the additional RCTs was assessed by two researchers. The SIGN methodology checklist for RCTs was used.

More details on the SIGN methodology checklists are available at:

<http://www.sign.ac.uk/methodology/checklists.html>

#### 5.2.5 Data extraction

Initially, the literature search was limited to secondary evidence. Therefore, most of the data extracted did not come straight from the primary studies. Where the reviews were deemed to be of sufficient quality, the assumption was made that the data presented was accurate and complete. Where more than one review reported on the same study, the data was cross-checked to ensure consistency. The full text of primary papers reported in reviews was only obtained if there was reason to suspect that the data presented in the reviews were incorrect or incomplete.

The following information was extracted from the systematic reviews.

- Study details:
  - year of publication
  - study objectives
  - selection criteria (main inclusions and exclusions).
- Quality (assessed using the SIGN checklist for systematic reviews/meta-analyses).
- Results:
  - number of included studies, and total number of participants
  - main characteristics of included studies (including those to allow an assessment of quality)
  - main results (pooled results; narrative summary).

For the RCTs, the main details of the study were extracted (using the PICOS framework).

Data extraction was recorded in evidence tables in Microsoft Word. A different evidence table was produced for each type of wound and category of antimicrobial. Data extraction was performed by one researcher, and then quality assured by a second.

#### 5.2.6 Data synthesis

For each of the different wound types, a narrative review of the evidence was written for each category of antimicrobial.

Rather than reappraising the same primary studies included in existing synthesised reports on AWDs, the narrative review focused initially on good quality systematic reviews. Any additional RCTs not incorporated into these reviews were also included.

The narrative review was written by one researcher and quality assured by a second.

### 5.3 Results

***A summary of the results has been presented. For a full narrative, with detailed descriptions of the individual studies and evidence tables, please refer to the supplementary material.***

The evidence is described separately for each wound type, and for each category of AWD. In each section, the evidence relating to the use of AWDs for treating localised wound infection and for healing chronic wounds is considered.

#### 5.3.1 Venous leg ulcers: iodine

##### 5.3.1.1 Cadexomer-iodine

A good quality systematic review included 11 RCTs (12 comparisons), encompassing 962 participants, that evaluated the use of cadexomer-iodine in the treatment of venous leg ulcers<sup>22</sup>. All 11 RCTs had a high or unclear risk of bias. Comparisons were: standard care (seven RCTs); hydrocolloid dressing (one RCT); paraffin gauze dressing (one RCT); dextranomer (two RCTs); and silver-impregnated dressing (one RCT). What the trial authors defined as 'standard care' varied between the studies, but normally consisted of ulcers being cleansed and then a non-adherent dressing being applied.

##### *Outcome – wound infection*

The evidence on the use of cadexomer-iodine in the treatment of localised wound infection in venous leg ulcers was insufficient (in terms of quality and quantity) to draw any conclusions.

##### *Outcome – wound healing*

The primary outcomes of the review related to wound healing (in particular, 'time to complete wound healing', 'proportion of ulcers healed during follow-up' and 'change in ulcer size'). Healing outcomes were better for cadexomer-iodine when compared with standard care. However, the incidence of adverse effects

was greater for those receiving cadexomer-iodine. The adverse events reported included itching, pain, eczema, pruritus, rashes and difficulty removing cadexomer-iodine from the ulcer. There was no difference in healing outcomes for the other comparisons<sup>22</sup>.

#### *Further information*

Two guidelines reported on an earlier version of this systematic review (which included largely the same evidence base). A SIGN guideline on chronic venous leg ulcers stated that there is inconsistent evidence on which to base a recommendation for cadexomer-iodine<sup>23</sup>. Another guideline from Australia and New Zealand makes the following B-grade recommendation\* for venous leg ulcers (VLUs): 'Cadexomer iodine could be used to promote healing in VLUs when there is known increased microbial burden'<sup>9</sup>.

#### *5.3.1.2 Povidone-iodine*

A good quality systematic review included six RCTs (seven comparisons), encompassing 639 participants, that evaluated the use of povidone-iodine preparations in the treatment of venous leg ulcers<sup>22</sup>. All six RCTs had a high or unclear risk of bias. Comparisons were: dextranomer (one RCT); growth factor (one RCT); hydrocolloid dressing (three RCTs); paraffin gauze dressing (one RCT); and moist or foam dressings given according to ulcer status (one RCT).

#### *Outcome – wound infection*

Overall, the evidence reported relating to the use of povidone-iodine in the treatment of localised wound infection in venous leg ulcers was insufficient (in terms of quality and quantity) to draw any conclusions. The review included an RCT, with a high risk of bias, which reported that the average eradication time for *Staphylococcus aureus* was shorter in a group treated with dextranomer, compared with a group treated with povidone-iodine.

#### *Outcome – wound healing*

There was no evidence from healing data to suggest a difference between treatment groups (estimates either indicated no difference, or were not reliable)<sup>22</sup>.

#### *Further information*

Based on an earlier version of this systematic review (which included largely the same evidence base), a SIGN guideline on chronic venous leg ulcers stated that there is inconsistent evidence on which to base a recommendation for povidone-iodine<sup>23</sup>.

#### *5.3.2 Venous leg ulcers: honey*

A good quality systematic review included two RCTs, encompassing 476 participants, that evaluated the use of honey in the treatment of venous leg ulcers<sup>22</sup>. Comparisons were: manuka honey topical application versus hydrogel

---

\* Australian and New Zealand guidelines describe B-grade recommendations as: 'good evidence – body of evidence can be trusted to guide practice in most situations.'<sup>9</sup>

(one RCT; high risk of bias); and honey-impregnated calcium alginate versus usual care (one RCT; low risk of bias). In the latter study, usual care was non-honey dressings applied according to the clinician's choice.

#### *Outcome – wound infection*

Overall, the evidence reported relating to the use of honey preparations in the treatment of localised wound infection in venous leg ulcers was insufficient (in terms of quality and quantity) to draw any conclusions. The RCT evaluating manuka honey topical application excluded participants with clinically infected wounds at baseline, but reported that some wounds were colonised with meticillin-resistant staphylococcus aureus (MRSA). No difference was detected between groups for eradication of MRSA at 4 weeks<sup>22</sup>.

#### *Outcome – wound healing*

Pooled data suggested no evidence of a difference between groups for the outcome of complete healing at 12 weeks. Furthermore, the RCT evaluating honey-impregnated calcium alginate reported no evidence of a difference between groups for time to healing and mean percentage change in ulcer area<sup>22</sup>.

#### *Further information*

Based on the same evidence, a SIGN guideline on chronic venous leg ulcers gives a B-grade recommendation<sup>†</sup>: 'Honey dressings are not recommended in the routine treatment of patients with venous leg ulcers'<sup>23</sup>. A guideline from Australia and New Zealand gives an A-grade recommendation<sup>‡</sup>: 'Honey offers no benefits over standard care in promoting healing in VLU's'<sup>9</sup>.

### 5.3.3 Venous leg ulcers: silver

A good quality systematic review included 12 RCTs (13 comparisons), encompassing 1,514 participants, that evaluated the use of silver in the treatment of venous leg ulcers<sup>22</sup>. Two of these had a low risk of bias, nine had an unclear risk of bias, and one had a high risk of bias. Silver sulfadiazine cream was compared with: usual care (one RCT); placebo (one RCT); growth factor (one RCT); and non-adherent dressing (one RCT). Silver-impregnated dressings were compared with alternative silver dressings (one RCT) and non-antimicrobial dressings (eight RCTs).

#### *Outcome – wound infection*

Overall, the evidence reported relating to the use of silver preparations in the treatment of localised wound infection in venous leg ulcers was insufficient (in terms of quality and quantity) to draw any conclusions.

#### *Outcome – wound healing*

The review reported that 'there was no difference between treatment groups for

---

<sup>†</sup> SIGN defines a B-grade recommendation as being based on high quality case-control or cohort studies, or systematic reviews of case-control or cohort studies; or extrapolated from high quality or well conducted RCTs, or systematic reviews of RCTs.<sup>23</sup>

<sup>‡</sup> Australian and New Zealand guidelines describe A-grade recommendations as: 'excellent evidence – body of evidence can be trusted to guide practice.'<sup>9</sup>

most healing outcomes; some short-term surrogate measures of healing suggested benefit of silver dressings compared with non-antimicrobial dressings, whilst others suggested no between-group difference. Data on secondary outcomes suggested no difference between silver-impregnated dressings and non-antimicrobial dressings for adverse effects and changes in health-related quality of life scores<sup>22</sup>.

#### *Further information*

Four additional RCTs were identified from other systematic reviews, and from a search of the primary literature (for further details, see the full clinical effectiveness write-up, available as supplementary material). Comparisons were: silver-impregnated dressing versus alternative silver-impregnated dressing (one RCT); silver-impregnated foam dressing versus foam dressing (one RCT); silver oxide ointment versus standard care (one RCT); and a membranous dressing with silver ions versus hydrocolloid dressing Unna's boot (one RCT). These do not alter the evidence base.

A SIGN guideline on chronic venous ulcers gave the following A-grade recommendation<sup>§</sup>: 'Silver dressings are not recommended in the routine treatment of patients with venous leg ulcers'<sup>23</sup>. Guidelines from Australia and New Zealand give a C-grade recommendation<sup>\*\*</sup>: 'Silver products offer no benefit over standard care in reducing the healing time of VLU's'<sup>9</sup>.

#### 5.3.4 Venous leg ulcers: other AWDs

##### *Outcome – wound infection*

No evidence on the use of other AWDs for treating localised infection in chronic wounds was identified.

##### *Outcome – wound healing*

A good quality systematic review included nine RCTs on 'other AWDs', but only one was of relevance to this HTA<sup>22</sup>. This RCT included 17 people with two leg ulcers, and had an unclear risk of bias. It reported no statistically significant difference between 5% chlorhexidine digluconate solution with usual care and usual care alone for the outcome of 'mean time to healing'.

#### *Further information*

The SIGN guideline on chronic venous leg ulcers gave the following good practice point: 'Routine long term use of topical antiseptics and antimicrobials is not recommended'<sup>23</sup>. Similarly, guidelines from Australia and New Zealand recommend that topical antimicrobial agents should not be used in the standard care of venous ulcers with no clinical signs of infection<sup>9</sup>. However, they also make the following consensus-based recommendation: 'There may be a role for

---

<sup>§</sup> SIGN defines an A-grade recommendation as being based on: at least one high quality RCT, or systematic review of RCTs; or more than one well-conducted RCTs, or systematic reviews of RCTs.<sup>23</sup>

<sup>\*\*</sup> Australian and New Zealand guidelines describe C-grade recommendations as: 'Some evidence – body of evidence provides some support for recommendation(s) but care should be taken in its application'.<sup>9</sup>

judicious use of topical antimicrobials when there is known or suspected increased microbial burden'<sup>9</sup>.

### 5.3.5 Arterial leg ulcers: all AWDs

One systematic review searched for RCTs that evaluated the effects of silver products on arterial leg ulcers<sup>24</sup>. None were identified that focused solely on arterial leg ulcers. Three RCTs were identified that included ulcers of mixed venous/arterial aetiologies, but these have already been addressed in the venous leg ulcers section.

### 5.3.6 Foot ulcers in people with diabetes: iodine

Seven systematic reviews<sup>25-31</sup> and one NICE guideline based on a systematic review<sup>32</sup> were identified that included evidence on the use of iodine products in foot ulcers in people who have diabetes. Together, these highlighted three RCTs. One was rated as having a low risk of bias, and two as being of 'poor quality' (that is a high risk of bias). Comparisons were: a fibrous-hydrocolloid dressing versus an iodine impregnated dressing (povidone-iodine) or a non-adherent dressing (one RCT; low risk of bias; n=317); honey daily versus povidone-iodine soaked gauze (one RCT; poor quality; n=30); and cadexomer-iodine dressings versus a standard topical treatment (one RCT; poor quality; n=41).

#### *Outcome – wound infection*

No evidence was reported relating to the use of iodine preparations in the treatment of localised wound infection in foot ulcers in people who have diabetes.

#### *Outcome – wound healing*

The primary outcomes related to wound healing. There was no statistically significant difference between the treatment groups for most healing outcomes.

### 5.3.7 Foot ulcers in people with diabetes: honey

#### *Outcome – wound infection*

A primary literature search identified an RCT with a high risk of bias (n=63)<sup>33</sup>. Patients were allocated into groups in an alternating fashion, which is not truly random. It compared manuka-honey impregnated dressings with conventional dressings; and reported that in the honey group, 78.13% of ulcers became 'sterile' during the first week compared with 35.5% in the conventional dressing group (p-value not reported)<sup>33</sup>. The authors state that manuka-impregnated honey dressings represent an effective treatment for foot ulcers in people with diabetes, but this conclusion should be treated with caution.

The evidence on the use of honey in the treatment of localised wound infection in foot ulcers in people with diabetes was insufficient (in terms of quality and quantity) to draw any conclusions.

#### *Outcome – wound healing*

Two systematic reviews<sup>26, 28</sup> report on the same small RCT (n=30) with an unclear risk of bias. This detected no statistically significant difference in the mean time to surgical closure in groups treated with either honey and gauze dressings or povidone-iodine and gauze dressings.

A primary literature search identified another RCT (n=63), which has a high risk of bias<sup>33</sup>. This compared manuka-honey impregnated dressings with conventional dressings. No statistically significant difference was reported between groups for the outcome of 'ulcers healed at 16 weeks'. A statistically significant between-group difference, in favour of honey, was reported for the mean duration of healing.

#### 5.3.8 Foot ulcers in people with diabetes: silver

Eight systematic reviews<sup>24-26, 34-38</sup> highlighted four RCTs on the use of silver products in foot ulcers in people who have diabetes. A search of the primary literature highlighted one additional RCT of relevance<sup>39</sup>. All of the RCTs had methodological short-comings. Comparisons were: standard care versus silver oxide ointment (one RCT; n=66); silver sulfadiazine cream versus oak bark extract (one RCT; n=40); calcium-alginate dressing versus a fibrous-hydrocolloid dressing with 1.2% ionic silver (one RCT; n=134); silver sulfadiazine cream versus polyherbal treatment (one RCT; n=40); and collagen/oxidized regenerated cellulose (ORC)/silver therapy versus standard care (one RCT; n=39).

#### *Outcome – wound infection*

In one RCT, eight out of nine infections resolved in a group treated with a fibrous-hydrocolloid dressing with 1.2% ionic silver, and 10 out of 13 resolved in the calcium-alginate group (p=0.48).

For the treatment of localised infection, the evidence is insufficient (in terms of quality or quantity) to draw conclusions on the use of silver-based preparations in foot ulcers in people with diabetes.

#### *Outcome – wound healing*

The primary outcomes in all the RCTs related to wound healing. In most, there was no statistically significant difference between the treatment groups for various healing outcomes. In one, the percentage of diabetic ulcers healed at 4 weeks was higher in the group treated with silver ointment than the group receiving standard care, and the difference was statistically significant. Another RCT reported some wound-healing benefits in a group treated with collagen/ORC/silver therapy compared with standard care. At each week throughout the 14-week study, the proportion of healed wounds in the collagen/ORC/silver group was higher than that in the control group, but the difference was not statistically significant (p>0.05). While some benefits were noted in the intervention group, the small study size means that the results need to be treated with caution.

For healing outcomes, the evidence is insufficient (in terms of quality or quantity) to draw conclusions in the use of silver-based preparations in foot ulcers in people with diabetes.

### 5.3.9 Foot ulcers in people with diabetes: other AWDs

#### *All outcomes*

Two reviews included a small unpublished RCT (n=29) that compared a hydrogel dressing with dry gauze dressings irrigated with chlorhexidine<sup>30, 40</sup>. The trial authors reported statistically significant improvements, in favour of the hydrogel group, for healing outcomes and infection incidence. However, methodological concerns with this study means that the results need to be treated with caution.

### 5.3.10 Pressure ulcers: iodine

A NICE guideline on the prevention and management of pressure ulcers<sup>41</sup>, from 2014, included three RCTs which evaluated the treatment of pressure ulcers with iodine preparations. All studies were of low methodological quality. Comparisons were: hydrogel versus povidone-iodine (n=49); hydrocolloid versus povidone-iodine (n=44); and cadexomer-iodine versus standard treatment (n=34).

#### *All outcomes*

Two of the RCTs reported no statistically significant differences between the groups for wound healing outcomes. The remaining RCT reported that cadexomer-iodine is a more effective treatment, compared with standard care, for the outcome of 'proportion of pressure ulcers reduced by 50%'; but also reported no statistically significant difference for 'mean cm<sup>2</sup> decrease in ulcer area after 3 weeks' and 'mean percentage reduction in ulcer area after 3 weeks'.

Some additional RCTs were identified by other systematic reviews, but overall the clinical evidence base is weak. For healing outcomes, and the treatment of localised infection, the evidence is insufficient (in terms of quality and quantity) to draw conclusions on the use of iodine.

#### *Further information*

Two guidelines made recommendations relating to the use of cadexomer-iodine in pressure ulcers. A guideline from the National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel (NPUAP and EPUAP) makes the following C-grade recommendations<sup>††</sup>.

- 'Consider the use of cadexomer iodine dressings in moderately to highly exudating pressure ulcers.'
- Avoid use of cadexomer iodine in individuals with iodine sensitivity and in those with thyroid disease.'

---

<sup>††</sup> NPUAP and EPUAP define a C-grade recommendation as one based on indirect evidence and/or expert opinion.

- ‘Avoid the use of cadexomer iodine in large-cavity ulcers that require frequent (daily) dressing changes’<sup>42</sup>.

Furthermore, a Pan Pacific guideline makes the following C-grade recommendation<sup>‡‡</sup>: ‘Cadexomer iodine could be used to promote healing in pressure injuries when there is a known increased microbial burden’<sup>11</sup>.

### 5.3.11 Pressure ulcers: honey

Seven systematic reviews<sup>11, 28, 41-45</sup> highlighted two low quality RCTs on the use of topical honey, or honey-impregnated dressings, in people with pressure ulcers. The comparisons were: honey dressing versus a saline soaked dressing (one RCT; n=40); and honey versus a treatment (ethoxydiaminoacridine and nitrofurazone) not used in clinical practice in the UK (one RCT; n=27).

#### *All outcomes*

Neither RCT reported outcomes related to the treatment of localised wound infection. Both RCTs reported improvements in wound healing outcomes in the honey group (although in one, the clinical significance of this improvement was questionable).

#### *Further information*

Guidelines from the NPUAP and EPUAP make the following C-grade recommendation<sup>§§</sup>: ‘Consider the use of dressings impregnated with medical-grade honey for the treatment of Category/Stage II and III pressure ulcers’<sup>42</sup>. Pan-Pacific guidelines give a D-grade recommendation<sup>\*\*\*</sup>: ‘Consider using topical medical grade honey to promote healing in pressure injuries’<sup>11</sup>.

### 5.3.12 Pressure ulcers: silver

Eight systematic reviews, four of which were part of clinical guidelines, were identified<sup>11, 34, 36, 41-44, 46</sup>. Collectively, these highlighted five low quality RCTs that evaluated silver containing products in the treatment of pressure ulcers. Comparisons were: silver alginate dressing versus silver free alginate dressing (two RCTs; n=24 and n=28); silver-releasing foam versus best practice (one RCT; n=43); silver mesh versus silver sulfadiazine cream (one RCT; n=40); and silver sulfazidine cream versus povidone-iodine versus physiologic saline (one RCT; n=45).

#### *Outcome – wound infection*

In one trial, the outcome was the ‘percentage decrease in infection score’. It did not detect evidence of a difference between groups treated with a silver alginate

---

<sup>‡‡</sup> Pan Pacific guidelines define a C-grade recommendation as: ‘Some evidence - body of evidence provides some support for recommendation(s) but care should be taken in its application’<sup>11</sup>.

<sup>§§</sup> NPUAP and EPUAP define a C-grade recommendation as one based on indirect evidence and/or expert opinion.

<sup>\*\*\*</sup> Pan Pacific guidelines define a D-grade recommendation as: ‘Weak evidence - body of evidence is weak and recommendation must be applied with caution’<sup>11</sup>.

dressing or a silver-free alginate dressing (52% versus 50%, respectively. No p-value given).

#### *Outcome – wound healing*

In the remaining RCTs, the outcomes related to wound healing. These suggested some advantage of using silver dressings over non-silver dressings. However, the methodological short-comings of the RCTs means that the results need to be treated with caution.

#### *Further information*

Guidelines from the NPUAP and EPUAP<sup>42</sup> make the following recommendations<sup>†††</sup>.

- ‘Consider use of silver dressings for pressure ulcers that are infected or heavily colonized. (Strength of Evidence = B).’
- ‘Consider use of silver dressings for ulcers at high risk of infection. (Strength of Evidence = B).’
- ‘Avoid prolonged use of silver dressings; discontinue when the infection is controlled. (Strength of Evidence = C).’
- ‘Consider use of silver sulfadiazine (Silvadene<sup>®</sup>) in heavily contaminated or infected pressure ulcers until definitive debridement is accomplished. (Strength of Evidence = C).’

Furthermore, Pan Pacific guidelines make the following consensus-based recommendation: ‘Consider using topical silver to promote healing in pressure injuries’<sup>11</sup>.

#### 5.3.13 Pressure ulcers: other AWDs

No evidence that could inform decision-making was identified on the use of other AWDs in the treatment of pressure ulcers.

Some guidelines make recommendations on the use of antimicrobials and antiseptics more generally. For example, NICE 2014 recommends against the routine use of topical antiseptics or antimicrobials to treat pressure ulcers in adults<sup>41</sup>. In addition, guidelines from Belgium (2013) state: ‘Consider improving wound healing environment by using modern dressings and topical agents (e.g. hydrocolloids, hydrogels, hydrofibres, foams, alginates, silver dressings) instead of basic dressing types (e.g. gauze, paraffin gauze and simple dressing pads)’<sup>43</sup>.

#### 5.3.14 Dehisced surgical wounds and wounds healing by secondary intention: all AWDs

##### *Outcome – wound infection*

No evidence relating to the use of AWDs in the treatment of localised wound infection in dehisced surgical wounds was identified.

---

<sup>†††</sup> NPUAP and EPUAP define a B-grade recommendation as being supported by direct evidence from properly designed series; and a C-grade recommendation as being based on indirect evidence and/or expert opinion<sup>42</sup>.

### *Outcome – wound healing*

For outcomes relating to wound healing, a good quality Cochrane review<sup>47</sup> included three RCTs on ‘other’ AWDs of relevance to this HTA. In all, the participants had an excised pilonidal sinus, and the comparisons were: silastic foam cavity dressing versus gauze soaked in 0.5% aqueous solution of chlorhexidine (n=80); calcium alginate rope versus povidone-iodine packing soaked gauze (n=70); and hydrocolloid dressing versus povidone-iodine soaked gauze (n=38). Overall, the evidence was insufficient to support or refute the use of any one AWD in people with dehisced surgical wounds/wounds healing by secondary intention.

An additional RCT was identified (Jurczak 2007) from three other systematic reviews<sup>31, 34, 38</sup>. This compared a silver impregnated hydrofiber dressing with a povidone-iodine soaked gauze dressing in 67 people with open surgical wounds or traumatic wounds left to heal by secondary intention. No evidence of a difference was reported for any of the healing parameters.

## **5.4 Conclusions and discussion**

### 5.4.1 Conclusions

- For treating localised wound infection in chronic wounds, the evidence is insufficient in terms of quality and quantity to draw conclusions on the use of AWDs.
- For the healing of chronic wounds, the evidence either:
  - does not support the use of AWDs, or
  - is insufficient in terms of quality and/or quantity to draw conclusions on the use of AWDs.

### 5.4.2 Discussion

On the whole, the included guidelines recommend against the use of AWDs in the routine treatment of clinically uninfected chronic wounds. When the guidelines did recommend AWDs as an option, it was almost always for wounds with known or suspected increased microbial burden. This is in accordance with BNF68, which states that: ‘Medical grade honey has antimicrobial and anti-inflammatory properties. Dressings impregnated with iodine can be used to treat clinically infected wounds. Dressings containing silver should be used only when clinical signs or symptoms of infection are present’<sup>48</sup>.

However, according to O’Meara *et al* evidence suggests that in clinical practice AWDs are used widely in chronic wounds, regardless of whether they are clinically infected at the outset of treatment<sup>22</sup>. Some of the included guidelines also cautioned against the long-term use of AWDs, stating that they should only be used for a limited period of time, or until the infection has cleared. It has been argued that long-term use of some AWDs is not only unnecessary, it may actually impede wound healing<sup>19</sup>. Again, it is not clear if AWDs are used for an appropriate duration of time in clinical practice.

#### 5.4.2.1 *Quality of the research*

This literature review highlighted several up-to-date and high quality systematic reviews of relevance. The conclusions of the included reviews are likely to be reliable. However, the studies included within the reviews were generally methodologically weak. Many were small with short follow-up, and clinical heterogeneity often prevented meta-analyses. There is no reason specific to chronic wounds or AWDs that should prevent good quality RCTs being conducted. Many of the RCTs included in the reviews were published before the CONSORT statement, which may explain why they did not meet expected standards.

Of all the studies included in the reviews, only four were judged by the review authors as having a low risk of bias (Michaels 2009; Kerihuel 2010; Jeffcoate 2009; Jull 2008).

#### 5.4.2.2 *Wound healing as an outcome*

Despite being at a low risk of bias, some discussion surrounding the RCT by Michaels 2009 (otherwise known as the VULCAN study) have been reported in the literature<sup>49</sup>. In this RCT, 213 people with venous leg ulcers were randomised to treatment with either a silver dressing (any one of the following: Aquacel<sup>®</sup> Ag, Acticoat<sup>™</sup>, Acticoat<sup>™</sup> 7, Acticoat<sup>™</sup> Absorbent, Contreet<sup>®</sup> Foam and Urgotul<sup>®</sup> SSD) or any non-antimicrobial wound dressing. The study found no difference between the groups for the number of ulcers healed at 12 weeks, overall median time to healing, or various secondary endpoints. The authors concluded that there was no evidence to support the routine use of silver-donating dressings beneath compression for venous ulceration<sup>50</sup>. This RCT was well conducted, and the conclusion is likely to be reliable.

Leaper and Drake 2011 argue that the VULCAN study did not use silver dressings as recommended<sup>49</sup>. They state that the main purpose of silver dressings (and other AWDs) is not to promote wound healing, but is to 'prevent the progression of critical colonisation, infection or recurrence of infection in those patients who have chronic wounds and are at increased risk...or to treat established localised or spreading infection in chronic wounds'<sup>49</sup>. They also state that AWDs should be discontinued when signs and symptoms of infection resolve, and prolonged use is possibly counterproductive to healing. The VULCAN study used silver dressings for a prolonged period (up to 12 weeks). It excluded people who were receiving oral or parenteral antibiotic treatment, but otherwise does not mention wound infection status.

In response to these challenges, the authors of the VULCAN study stated that the design of the trial was based on a survey of current practice of AWDs and a review of advice given in manufacturers' literature<sup>51</sup>. They argue that the advice that AWDs be used on groups 'at high risk of infection' could be applied to any patient with an open wound.

The conclusion of the VULCAN study is justified and reasonable; there is no evidence to support the routine use of silver-donating dressings beneath

compression for venous ulceration. However, the VULCAN study did not evaluate the short-term use of silver dressings in venous leg ulcers with signs and symptoms of localised infection. It is possible that there are some sub-groups in whom the use of AWDs may be clinically effective, but there is a need for well conducted-trials in this area.

The three other studies rated by the review authors as having a low risk of bias also had primary outcomes relating to wound healing (Jull 2008; Kerihuel 2010; Jeffcoate 2009). None of these trials reported on outcomes relating to the treatment of localised wound infection, or the reduction of bioburden.

#### 5.4.2.3 *Wound infection as a primary outcome*

Most of the studies evaluating the use of AWDs in chronic wounds have endpoints relating to wound healing (for example complete ulcer healing, time to healing or change in ulcer size). However, there is some disagreement in the literature about how appropriate this is, given that all chronic wounds are difficult to heal<sup>19</sup>. The argument given is that the primary purpose of AWDs is not to promote healing, but is to reduce wound bioburden and to treat local infection before it escalates into a systemic infection. With this in mind, the clinical experts for the HTA advised that the most appropriate primary outcomes for the literature review should relate to wound infection (Section 5.2.3). This is supported by a document published by the European Wound Management Association whose view is that: 'Wound infection is a valid primary, but most often secondary, endpoint'<sup>52</sup>.

The use of wound infection-related outcomes in this review was associated with significant challenges. Most importantly, they were not reported on in many studies. In the studies that did include wound infection-related outcomes, they were almost always reported as secondary outcomes, with the studies normally being designed around the primary outcome of healing. There is no one exact definition of wound infection in the literature, and so we accepted all definitions used by the authors. The wound infection outcomes used in the studies varied, and included: bacterial growth (using swabs), eradication of certain bacterial organisms, average eradication time, signs of bacterial colonisation, and resolved infection. The baseline wound infection status of the participants included in the studies varied. Some studies included people with infected wounds, some excluded them, and in many studies eligibility for inclusion based on wound infection status was not mentioned. Furthermore, some studies included people on oral/systemic antibacterials, others excluded them, and some did not mention antibacterial drug use.

#### 5.4.2.4 *Ulcer infection and wound healing*

According to O'Meara *et al*, the relationship between ulcer infection and wound healing is unclear<sup>22</sup>. They discuss two RCTs that assess the impact of wound infection or bacterial colonisation on healing: 'For bacterial colonisation, one study showed a statistically significant association between positive post-treatment wound cultures and lower healing rates (Alinovi 1986), whilst the other suggested that bacterial contamination of ulcers with *Staphylococcus*

*aureus* did not appear to delay healing (Huovinen 1994)<sup>22</sup>. Three of the RCTs (evaluating cadexomer-iodine) included in the O'Meara analysis also assessed the association between ulcer infection and healing (Skog 1983, Moss 1987, Miller 2010). These all suggested that improved healing rates were associated with reduced bioburden with certain bacterial species; but all were small studies and so the results may not be reliable.

#### 5.4.2.5 Limitations of this review

This review had a very broad scope, with many interventions meeting the eligibility criteria for inclusion. In addition to the different antimicrobials, there is a variety of ways in which the antimicrobials can be delivered (for example gauze, foams, creams, hydrocolloids). This makes it difficult to separate the effect of the antimicrobial from various other dressing characteristics. We also included several types of chronic wounds, numerous eligible comparators, and a number of outcome measures. This has made combining the results into a succinct narrative challenging.

During the protocol stage, the scope of the HTA was discussed with topic experts, and was considered during an open consultation period. Those consulted stressed that it would be helpful to produce a report that considered all the interventions and wounds types together, in the hope that it could inform on which AWD should be used in which circumstance and for how long. Unfortunately, the clinical evidence reviewed does not give clear direction.

Given the scope of the review, a decision was made to focus on good quality systematic reviews and meta-analyses. A search for RCTs was done in order to update the included reviews, but other study types were not searched for (for example observational studies). This approach freed up time and resource to work on examining the patient and organisational issues in more detail. It seemed more appropriate to invest time in these other areas of the HTA, rather than searching through lower quality evidence.

Other reviews in wound care have been criticised for not including lower levels of evidence. Conclusions of 'more research is required' are seen as frustrating and unhelpful to clinical practice<sup>53</sup>. However, inclusion of other study designs would not have helped in removing uncertainty and as this HTA considers more than the clinical evidence, we believe that the decision to limit this section to review and RCT evidence was justified.

The decision to not include *in-vitro* studies was challenged when the protocol was consulted on. As stated above, it was felt that the extra effort and resource taken to look at this type of evidence would mean that less time could be spent on other parts of the HTA. While *in-vitro* studies are undoubtedly helpful in developing our understanding around chronic wounds, infection and antimicrobials, they cannot be used to support clinical recommendations.

Most of the published evidence relates to venous leg ulcers, therefore some of the other ulcer types are not as well represented in this clinical effectiveness section.

Articles were not eligible for inclusion if they were not available in English.

## **5.5 More information**

A full version of the clinical effectiveness section is available on the Healthcare Improvement Scotland website as supplementary material. This includes:

- a flow diagram, summarising the number of studies screened, excluded and included
- a list of included and excluded studies
- a table summarising the quality of the included reviews
- evidence tables, and
- a more thorough narrative of the literature.

## 6 Cost effectiveness

### 6.1 Introduction

The main research question for this cost effectiveness section was:

**What is the cost effectiveness of different AWDs, compared with other dressings and techniques, for treating localised wound infection in chronic wounds?**

A small number of published studies that are deemed relevant to the topic were reviewed.

During the initial phases of the HTA it was decided that any development of a *de novo* economic model would be dependent on the availability of good quality clinical data. Upon carrying out our clinical effectiveness review, it became apparent that there would not be sufficiently robust clinical data to inform the parameters within an economic model – for the model output would only be as good as the quality of the model inputs. With this in mind, a *de novo* economic model was not developed.

### 6.2 Methods

#### 6.2.1 Evidence sources and literature search

Specialist economic search engines and the websites of international health economics research centres were searched in January 2014 to identify relevant economic evaluations. Results were limited to publications from 1990–2014 in English.

Searches of the primary literature were undertaken in January 2014 using the concepts of ‘chronic wounds’ and ‘antimicrobial wound dressings’. The following bibliographic databases were searched:

- MEDLINE (Ovid)
- MEDLINE in Process (Ovid)
- CINAHL (EBSCOHost)
- Health Economic Evaluations Database - HEED (Wiley Online)
- NHS Economic Evaluation Database - NHSEED (Cochrane Library)

The SIGN economics filter was used in all database searches except those conducted in the Health Economic Evaluations Database (HEED) and the NHS Economic Evaluation Database (NHSEED). All primary literature searches were limited to 1990–2014 and English language.

The search strategies are available in the supplementary material.

## 6.2.2 Study selection and data extraction

The relevance of each identified study was assessed according not only to the inclusion and exclusion criteria described in Section 5.2.3, but also whether the studies reported both the costs and outcomes of the interventions. In some instances, such as for a cost-minimisation analysis, it is worth noting that the outcomes may be assumed to be equal rather than incremental (that is one intervention shown to be better than another).

Two health economists independently screened all titles and abstracts against the inclusion criteria. Any disagreement in selections was resolved by consensus.

A narrative review of the cost effectiveness evidence has been provided separately for each study and, where possible, grouped by wound type. However, the overall paucity of relevant cost effectiveness literature meant that, for many of the wound types, there were no economic evaluations.

## 6.3 Results

### 6.3.1 Venous leg ulcers

Three cost effectiveness analyses were identified that included an economic assessment on the use of AWDs in venous leg ulcers<sup>50, 54-56</sup>. Two of the studies – one from the UK and one from the United States (US) – compared silver dressings with ‘standard’ dressings with no antimicrobial agent, while the third study – also from the UK – compared various silver dressings alongside an iodine dressing.

The first of the economic evaluations, a UK HTA carried out by Michaels *et al*<sup>50, 55</sup>, was conducted to examine the effectiveness and cost effectiveness of antimicrobial silver-donating dressings for venous leg ulcers compared with simple non-adherent dressings with no antimicrobial agent. An open-label, multicentre RCT was undertaken (the VULCAN study), the results of which were fed into a cost effectiveness analysis, carried out from a UK perspective. The economic analysis comprised a cost-utility analysis which directly used the RCT data, and a longer term model with a lifetime time horizon that extrapolated outcomes beyond the RCT. The silver dressings included in the analysis were as follows; Urgotul<sup>®</sup> SSD, Acticoat<sup>®</sup> 7, Aquacel<sup>®</sup> Ag, Contreet<sup>®</sup> Foam, while the non-adherent dressings were Urgotul<sup>®</sup> (non silver-containing version), Biatain<sup>™</sup>, Atrauman<sup>™</sup> and Allevyn<sup>™</sup>.

In the RCT carried out to establish the relative clinical effectiveness of the dressings, patients included in the study presented with a venous ulceration (for at least 6 weeks) with a diameter greater than 1 cm. People with insulin-controlled diabetes and patients on oral or parenteral antibiotic treatment were excluded from randomisation. Patients within the RCT received silver dressings for a prolonged period (up to 12 weeks), but it was not clear whether the wounds were infected. As already discussed in Section 5.4.2.2, the design of the VULCAN study was based on a survey of current practice of AWDs and a

review of advice given in manufacturers' literature<sup>51</sup>. However, some argue that the use of silver dressings in clinical practice should be limited to wounds that are infected, and that the use of silver dressings should be discontinued if the infection is resolved<sup>19</sup>.

The primary outcome was complete ulcer healing at 12 weeks in the index limb. Secondary measures were costs and resource use, quality adjusted life-years (QALYs), cost effectiveness, time to healing, and recurrence rates at 6 months and 1 year. Dressings were changed on a weekly basis. Compression bandaging was applied at each dressing change until the wounds were fully healed.

The results of the RCT can be summarised as follows (full description provided in the clinical effectiveness supplementary material). Difference in complete healing at 12 months indicated that 90/213 (42%) of participants healed on silver and 76/211 (36%) experienced healing on non-antimicrobial dressings (RR 1.17; 95% CI 0.95 to 1.45). This difference is not statistically significant. No evidence of a difference was detected between the treatment groups for the following secondary outcome measures: complete healing at 6 months, complete healing at 12 months, median time to healing and ulcer recurrence within the first year.

Michaels *et al* conducted a cost-effective analysis based on the patients in the RCT who had provided EQ-5D quality of life (QoL) responses. Outcomes and QoL data included in the economic analysis were based directly on the results of the RCT.

In terms of costs, the analysis included the average number of ulcer clinic visits, community nurse home visits, GP contacts and chiropody contacts. The number of clinic/home visits was used as a surrogate for the number of dressings and bandages used, as these were both changed at each visit. Table 1 contains the average number of visits/contacts.

**Table 1: Average number of visits/contacts per patient**

Resource	Average number of visits/contacts per patient (95% CI)	
	Control group	Silver group
Ulcer clinic visits*	5.61 (4.55 to 6.67)	8.00 (6.92 to 9.08)
Community nurse home visits	9.58 (5.45 to 12.71)	10.57 (7.42 to 13.72)
GP contacts	2.00 (1.06 to 2.94)	2.09 (1.53 to 2.65)
Chiropody contacts	1.82 (1.39 to 2.24)	1.60 (1.25 to 1.95)

\* statistically significant difference

The biggest contributor to total costs for both groups was the total cost of attending the ulcer clinics, which accounted for between 61% and 66% of total costs. Ulcer clinic costs were significantly higher in the silver group, as were dressing costs.

The results of the economic evaluation demonstrated that silver dressings were associated with an incremental QALY gain of 0.0002 (that is equivalent to a 1.7 hour gain in life) compared with the control dressings and an incremental cost of £97.85. This resulted in a cost per QALY of £489,250 which showing that silver dressings are not cost-effective according to currently accepted thresholds.

It is worth noting that the analysis was also carried out based on the results of the patients who had completed an alternative QoL assessment, the SF-6D. The results of this analysis demonstrated an increase in the cost difference between the two treatment arms, and that silver dressings generated less QALYs – and as such were dominated (ie silver dressings were more expensive and less effective) by the control dressings.

Michaels *et al* also undertook further economic modelling in order to allow the results from the clinical trial to be generalised beyond the trial population and also to test the uncertainty that comes from focusing on a finite trial population. A lifetime time horizon was used for this part of the economic analysis.

The structure of the model was designed so that a hypothetical group of patients were assessed in terms of their costs and outcomes depending on whether they received a silver dressing or a standard control dressing. For each patient in each cohort, long-term incremental efficacy of the time to ulcer healing outcome was determined through parametric distributions derived from the clinical data.

In the first step of the model, patients present with an ulcer and time to healing is estimated based on patient characteristics and a survival model is employed. In the next stage the patient remains with the ulcer, accruing costs and disutility.

Finally, the patient then exits the model when the ulcer heals, the timing of which will vary according to the type of dressing applied.

The disutility associated with having an ulcer was estimated to be 0.00251, based on the difference in EQ-5D values between healed and unhealed ulcers found in the RCT. The costs per week of the silver and standard control dressing were estimated to be £32.15 and £24.62 respectively, with the modelling incorporating the finding that those receiving silver dressings would visit ulcer clinics more frequently. The distributions around these estimates were sampled in the model.

Table 2 contains the scenarios modeled by the authors.

**Table 2: The scenarios modelled**

Scenario	Survival analysis	Assumed ulcer utility decrement
Base case	Only statistically significantly different variables from trial included in the economic model	Not applicable – dressing type found not to be a significant predictor
Scenario 1	Statistically significant variables included, plus dressing type even though not statistically significant	0.00251 (based on respective healing within the trial)
Scenario 2	Statistically significant variables included, plus dressing type even though not statistically significant	0.10576 (based on naïve analysis of those with and without an ulcer)

In the base case scenario, dressing type was not assumed to affect healing time, that is no difference in healing time between the two groups. Since the cost per week was greater for the silver dressings, the silver dressings were said to be dominated by the standard control dressing.

For scenario 1, the mean cost per QALY was estimated to be more than £600,000, with probabilistic sensitivity analysis indicating that there would be a 27% and 32% chance of silver dressings being cost-effective at thresholds of £20,000 and £30,000 respectively.

For scenario 2, the mean cost per QALY was estimated to be consistently less than £20,000, with probabilistic sensitivity analysis indicating that there would be a 53% and 62% chance of silver dressings being cost-effective at thresholds of £20,000 and £30,000 respectively. As such, it is shown that only based on maximum estimates of utility benefit from ulcer healing would silver dressings be considered cost-effective, and it should be noted that this maximum estimate takes no account of the confounding effects of co-morbidities.

In terms of weaknesses and uncertainties associated with the analysis, there are a number of simplified assumptions upon which the modelling is based. For example, patients are assumed not to die within the model, and ulcers are

assumed not to reoccur. However, these assumptions are not deemed to impact upon the paper's conclusions.

The main driver surrounding the conclusion of the economic evaluation appears to be the cost of each treatment arm since the dressings appear to be similar in terms of QALYs gained. Here, it has been shown that patients with silver dressings have more healthcare professional contacts than those receiving a standard dressing which, on top of the fact that silver dressings are more expensive than standard dressings, leads to the silver arm being shown to be of higher cost.

In summary, the results of the economic evaluation indicate that silver dressings are highly unlikely to be cost-effective compared with control dressings given that these dressings were shown to be more expensive and did not generate a statistically significant improvement in the health outcomes.

However, when considering these results, it is important to reiterate that for the patient population within the VULCAN study – used to populate the economic model – it was not clear whether the wounds were infected. Leaper and Drake state the main purpose of silver dressings is to control infection and that once the infection is resolved, the use of silver dressings should be halted<sup>49</sup>. If silver dressings were to be used in clinical practice as described by Leaper and Drake, then the results of the economic evaluation may be undermined.

The second study in which silver dressings were compared with standard dressings, was a US costing analysis by Lantis and Price that was conducted to compare the cost of wound treatment with ALLEVYN<sup>TM</sup> Ag (silver) versus standard care for the management of hard to heal venous leg ulcers<sup>54</sup>. The perspective used was that of a US reimbursement payer.

The clinical data to support the analysis were drawn from a non-randomised, prospective, 8-week single arm study by Lantis and Gendics (2011) that analysed silver dressing related outcomes. Patients in this study had a mean ulcer duration of 70.6 weeks at baseline, a mean ulcer area of 20.1 cm<sup>2</sup>, and all wounds were critically colonised (bioburden equal to or above 10<sup>5</sup> CFU/g). The mean age of patients was 59.8 years. Compression was applied to all wounds and wounds were assessed on a weekly basis or until wound closure. Dressing changes and debridement were performed on a weekly basis.

Due to the study by Lantis and Gendics being a single arm study, the clinical data for the standard care arm were drawn from a separate 6-week, randomised study by Skog *et al* (1983) that compared standard care with cadexomer-iodine for the treatment of patients with chronic ulcers (only the standard care arm was used to inform the cost analysis). In the Skog *et al* study, dressing changes were made daily. Patients in the study had failed on other treatments (for example dextranomer, fucidic acid, trypure powder, polymyxin and silver nitrate), had a mean ulcer duration of 22 months, a mean wound area of 34 cm<sup>2</sup> and the mean age of patients was 72.1 years.

Based on these studies, in their economic evaluation, Lantis and Price assumed that, regardless of treatment arm, the duration of treatment was 84 days (12 weeks), the mean time to wound closure was 57.3 days (8 weeks) and the duration of each community nurse visit was 30 minutes. However, the differences in the treatment arms were as follows: a wear time of 7.2 days for the silver dressing arm, compared with a wear time of 3.5 days for the standard care arm. The wound closure rates were 45.8% in the silver dressing arm as reported in Lantis and Gendics, and only 5% (assumption) in the standard dressing arm. In terms of costs, the cost of community nurse visit was detailed, although dressing costs were not provided.

The results of the analysis demonstrated that once-weekly dressing changes – as a result of using silver dressings - may save US\$158 (£105) per patient in material costs and a further US\$314 (£208) per patient in reduced nursing time – a total saving of US\$472 (£313) per patient over 12 weeks.

There are a number of weaknesses and uncertainties surrounding the analysis, with the key weakness relating to the naive indirect comparison upon which the analysis was based – with markedly different studies used to inform the parameters for the silver and standard care arms. There was potential heterogeneity in the wound care procedures within these studies, and debridement was only performed in the patients treated with the silver dressing, which may lead to bias. A further difference relates to the baseline characteristics of patients as patients in the standard care arm had failed other treatments, however it is unknown whether this applied to patients treated with the silver dressing. The mean age for patients in the intervention arm was also lower than that of the control arm and it is expected that younger patients' wounds heal faster.

Essentially, comparative efficacy was assumed throughout the evaluation, but not clinically demonstrated, with no systematic review undertaken to identify more suitable studies for comparison.

In conclusion, although the results of the study suggest that silver dressings are cost saving compared with standard dressings, the results are undermined by the significant limitations with the study design.

The third of the cost effectiveness studies relating to the treatment of venous leg ulcers was an economic evaluation by Scanlon *et al*<sup>66</sup>, conducted to evaluate the relative cost effectiveness of Contreet<sup>®</sup> Foam (hereafter 'Protocol A') – a sustained silver-releasing dressing – versus different antimicrobial dressings. Protocol A was compared with the following antibacterial dressings: Aquacel<sup>®</sup> Ag (Protocol B), Actisorb<sup>®</sup> Silver (Protocol C) and Iodoflex<sup>®</sup> (Protocol D) for the treatment of venous leg ulcers. The perspective used was the UK NHS. A 4-week model was constructed to analyse the cost of relative wound area reduction, with the results feeding into a subsequent 26-week Markov model to assess comparative complete healing rates.

The clinical evidence was derived from a literature search that included six published studies. It is unclear how the data from each of the studies were

combined in order to determine the estimated wound reduction associated with each protocol within the economic study. Long-term outcomes were extrapolated within a Markov model that linked the cost effectiveness of reduction in wound area to complete wound healing. In the long term model, patients could progress from the unhealed to the healed health state in weekly cycles. The primary outcomes of the models were cost per percentage reduction in wound area and cost per healed wound respectively.

Costs were divided into costs of an initial assessment by a district nurse (nursing time), costs of dressing change (dressing change frequency, nursing time, transportation of nurse, wound cleansing and autolytical debridement, dressing materials, and ancillary supplies), and costs of treatment of a clinical wound infection (treatment with systemic antibiotics). The direct cost of each dressing was also incorporated. Cost data were drawn from the NHS Drug Tariff (March 2004) and from 'Unit costs of health and social care' (Personal Social Services Research Unit, 2003). Hospitalisation costs due to wound infection were not included. The unit cost of each dressing is shown in Table 3.

**Table 3: Unit costs used in the analysis**

Protocol	Unit cost (£)
A (Contreet <sup>®</sup> Foam – a sustained silver-releasing dressing)	6.95
B (Aquacel <sup>®</sup> Ag)	3.93
C (Actisorb <sup>®</sup> Silver)	1.94
D (Iodoflex <sup>®</sup> )	7.80

In the health economic analysis, all patients were assumed to receive an initial wound assessment by a district nurse, with all subsequent dressing changes carried out by a nurse in the patient's home. Nurse time required was based on advice from an expert panel. The frequency of dressing changes used in the model were based on manufacturers' instructions for use and an expert panel's advice – the number of changes per dressing are displayed in Table 4.

The results of the model showed that the wound size reduced in Protocols A, B, C and D by 50.2%, 23.9%, 44.6% and 36% respectively after 4 weeks of treatment. The cost per week of treatment found for each protocol was £111 for Protocol A, compared with £96 to £176 for the other dressings. Importantly however, when healing progression rate data were factored into the analysis, protocol A (Contreet<sup>®</sup> Foam) was reported to be the most cost-effective with a cost per percentage reduction in wound area of £9.51 compared with £16.48–£17.58 for the other dressings (see Table 4).

**Table 4: Cost effectiveness results data**

Protocol	4-week model			
	Cost per dressing change (£)	Number of dressing changes per week	Cost per week of treatment (£)	Cost per % reduction in wound area (£)
A	50.75	2.19	111.13	9.51
B	49.67	1.90	96.86	17.58
C	49.01	3.60	176.42	16.54
D	51.91	2.70	140.15	16.48

Sensitivity analyses (variations of  $\pm 20\%$ ) to key parameters such as the reduction in wound size after 4 weeks, dressing change frequency, Protocol C dressing cost, weekly healing rate or the district nurse visit cost were undertaken. The results showed that the nurse time is the major cost driver, yet Protocol A remained the most cost-effective treatment.

A number of uncertainties/weaknesses were found.

- The individual studies used to estimate the clinical effectiveness figures for the economic analysis were not fully described; therefore, no information on the heterogeneity and robustness of the analysis was reported. Heterogeneity may be an issue for outcomes such as the size of ulcers at baseline, the microbial colonisation level at the baseline, or the criteria used for changing the dressings. The inclusion and exclusion criteria for study selection were also not adequately described.
- For Protocol B, long-term outcomes were not calculated at all as clinical data were said not to be available.
- Patients were treated with oral antibiotics, which may bias antimicrobial outcomes.
- Non-antimicrobial dressings were not included as a comparator. This precluded a comparison between an antimicrobial dressing and a non-antimicrobial dressing.
- Following on from the above, the study includes only a select group of comparators, which limits the generalisability of the findings.
- It is also worth noting that the costs are drawn from data that are 11 years old, which therefore represents a limitation in interpretation.

In conclusion, the study reports that Protocol A is more cost-effective than Aquacel<sup>®</sup> Ag, Actisorb<sup>®</sup> Silver and Iodoflex<sup>®</sup>. However, there are a number of uncertainties associated with the study and the cost effectiveness of Protocol A compared with other antimicrobial dressings and, importantly, non-antimicrobial dressings has not been assessed within this study.

### 6.3.1.1 Venous leg ulcers summary

There is insufficient evidence to show that AWDs improve outcomes relative to non-AWDs. As such, the cost effectiveness of AWDs is likely to be dependent on the relative costs of the dressings. Owing to the fact that the unit costs of AWDs presented in these studies have tended to be higher than non-AWDs, any additional AWD unit costs would need to be offset by lower resource use associated with the use of the AWDs – and there is no economic evidence to support this assumption. In contrast, the study by Michaels *et al* found that dressing changes were more frequent in the AWD group.

### 6.3.2 Foot ulcers in people with diabetes

An HTA carried out by Jeffcoate *et al*<sup>57</sup> assessed the cost effectiveness of three types of dressings: simple non-adherent gauze (N-A), iodine-impregnated dressing (Inadine<sup>®</sup>) and a hydrocolloid preparation (Aquacel<sup>®</sup>), for the management of chronic ulceration of the foot in diabetes patients. The perspective used for the analysis was that of the UK NHS.

The clinical evidence was drawn from a UK multicentre, observer-blinded, RCT in which 317 patients were randomised 1:1:1 to receive one of the aforementioned dressings. Inclusion criteria required patients with either type 1 or type 2 diabetes, with a chronic wound (presented for at least 6 weeks), and that had a cross-sectional area between 25 and 2,500 mm<sup>2</sup>. Soft tissue wound infection and bone infection patients were excluded.

The results of the trial found that there was no difference between the dressings in terms of percentage healed by 24 weeks, or in the mean time to healing, regardless of whether the analysis was carried out on the basis of intention to treat (N-A 38.7%, Inadine<sup>®</sup> 44.4%, Aquacel<sup>®</sup> 44.7%; not significant) or per protocol (N-A 59.4%, Inadine<sup>®</sup> 55.2%, Aquacel<sup>®</sup> 63.0%; not significant). There was also found to be no difference in the quality of wound healing or in the incidence of adverse events.

QoL was measured using the SF-36 questionnaire at baseline, 12 weeks, and 24 weeks. No differences were observed between the groups across any of the health domains at any of the three time points. However, it should be noted that in terms of the pain associated with dressing changes, there was a significant difference where those who received N-A dressings experienced least pain.

Owing to the fact that there were no statistically significant differences in effects of the dressings between the three groups, the economic evaluation was carried out in the form of a cost-minimisation analysis.

A bottom-up approach was conducted to analyse the costs of the interventions. Dressings and healthcare-professional costs were included and taken from UK NHS related sources such as the BNF or the Personal Social Services Research Unit or Department of Health data. The unit costs of N-A, Inadine<sup>®</sup> and Aquacel<sup>®</sup> were £0.32, £0.29, and £0.97 respectively.

The results of the cost-minimisation analysis showed that mean cost per patient for the provision of each dressing was £14.85 for N-A, £17.48 for Inadine<sup>®</sup>, and £43.60 for Aquacel<sup>®</sup>. The higher cost per unit of Aquacel<sup>®</sup> was not offset by any reduction in number of dressings required, with total costs per person by dressing type of £141.18 for N-A, £183.60 for Inadine<sup>®</sup>, and £191.33 for Aquacel<sup>®</sup>.

Despite these results, the authors note that the clinical trial – upon which the economic evaluation was based - was not set up to demonstrate equivalence between the dressings, so rather unusually they go on to present analysis to illustrate the value for money of the respective dressings. The results of this analysis found that the cost of generating a healed ulcer using N-A amounted to £362, while each healed ulcer using Inadine<sup>®</sup> and Aquacel<sup>®</sup> would cost £848 and £836 respectively.

In terms of weaknesses associated with the analysis, the cross-sectional areas of the ulcers in the Aquacel<sup>®</sup> arm seemed smaller than those for other comparators and there appears to be fewer smokers in the Aquacel<sup>®</sup> arm. This may bias the results in favour of Aquacel<sup>®</sup>. However, these factors are unlikely to affect the overall conclusions.

In summary, there was found to be no differences in outcomes between the following dressings; N-A, Inadine<sup>®</sup> and Aquacel<sup>®</sup>. As such the cost effectiveness of the dressings was determined by respective costs, where the higher unit costs of Inadine<sup>®</sup> and Aquacel<sup>®</sup> relative to N-A were not offset by any reduction in number of dressings required and healthcare professional contacts.

### 6.3.3 Pressure ulcers

Chuangsuwanich *et al*<sup>68</sup> compared the cost effectiveness of alginate silver dressing (AISD) with silver zinc sulfadiazine cream (AgZnSD) in the treatment of pressure ulcers. The time horizon was 8 weeks, and the analysis was carried out from a Thai healthcare provider perspective.

The clinical effectiveness evidence was drawn from a prospective RCT conducted in Thailand in patients suffering from a pressure ulcer(s). The primary objective of the study was wound size reduction, and the Pressure Ulcer Scale for Healing (PUSH) score was used as the indicator of the healing. The demographic and wound characteristics of the patients were comparable. Patients were randomised to receive treatment with either the AISD dressing or AgZnSD cream (and dry gauze) by drawing from a sealed envelope. In the patients treated with AISD, the dressing was changed every 3 days. In the patients treated with the AgZnSD cream, the dressing was changed daily and dry gauze was applied each time. All patients were scheduled for a weekly hospital visit until completion of the 8-week study period. The cost of treatment for each arm was recorded in the study. At the end of 8 weeks' treatment, the results showed that there was no significant difference in wound size reduction between the treatment arms (AISD 44.27% versus AgZnSD 51.07% (p=0.504)).

Owing to the finding of non-significant difference in outcomes, the cost effectiveness assessment focused on the respective costs of the dressings. The costs of treatment included the dressing unit cost, debridement cost, the AISD dressing cost, and the AgZnSD cream cost. Over the treatment period of 8 weeks, the average overall cost of treatment was US\$377.17 (£239) for the AISD dressing arm and US\$467.74 (£297) for the AgZnSD cream arm. The alginate silver dressing was therefore reported to be a cost-minimising treatment with a \$91 (£58) lower cost – and thus the more cost-effective of the two options. The key driver of the result was the dressing unit cost, where AISD was less expensive than AgZnSD cream (and dry gauze).

There are a number of weaknesses surrounding this analysis, particularly relating to a lack of transparency. For example, the methodology used to calculate the total costs is not presented. More generally, the perspective (Thailand) of the analysis may limit the generalisability of the results to NHSScotland both from a standard wound care point of view and also in terms of patient characteristics. Finally, the analysis focuses only on two types of silver dressings, so the usefulness of the results to decision-making across the wide range of antimicrobial dressings is limited.

In summary, the AISD dressing is reported to be cost-effective compared with AgZnSD cream, largely owing to the lower unit cost of the AISD dressing. However, the results must be treated with caution for the reasons noted above.

#### *6.3.3.1 Foot ulcers in people with diabetes and pressure ulcers summary*

Very few economic studies were identified in this section and therefore, similarly to the venous leg ulcer summary, there is insufficient evidence to determine the cost effectiveness of AWDs relative to non-AWDs for the treatment of foot ulcers associated with diabetes or pressure ulcers.

The most robust of the economic evaluations included foot ulcers in people with diabetes, and the results demonstrated no differences in outcomes between a non-antimicrobial dressing, an iodine dressing, and the Aquacel dressing. The higher unit costs of the AWDs relative to the non-AWDs were not offset by any reduction in the number of AWDs required. As such, AWDs were found unlikely to be cost-effective.

Of the studies comparing an AWD with other AWDs, silver dressing was found to be more cost-effective than a silver cream for the treatment of pressure ulcers. However, these product-specific assessments must be treated with caution owing to the considerable limitations with the studies and also the limited focus of the studies.

## **6.4 Conclusions**

A systematic review of the economic evidence highlighted a small number of relevant studies. However, taken together there is insufficient evidence in terms of quality and quantity to determine the cost effectiveness of AWDs relative to

on-AWDs for the treatment of localised wound infection and healing of chronic wounds.

## **7 Patient issues**

### **7.1 Introduction**

The overall aim of this patient issues section was to explore and describe patients' experiences of chronic wounds and wound dressings (including AWDs), and to inform the use of AWDs in NHSScotland.

The research was guided by the following sub-questions:

1. What is the burden of a wound on the daily lives of patients?
2. What are patients' current experiences of wound dressings?
3. What would patients like to see in the future with regards to the use of AWDs?
4. What information on dressings is being communicated and shared by healthcare professionals with patients and their family/carers?
5. What are the views of patients and their carers on these dressings?
6. What factors affect access to AWDs?

### **7.2 Methods**

This chapter describes two separate pieces of research: a synthesis of existing qualitative research on patient experiences of chronic wounds and wound dressings; and primary qualitative research with a sample of people with chronic wounds.

These two pieces of work have been written up in full (including a full description of the methods and results), and are available in the supplementary material.

This work was conducted by three researchers from Healthcare Improvement Scotland. All have masters-level qualifications in Health Services Research or Public Health, which included training in qualitative research methods. The protocol for the research, and a draft of the analysis and write-up, was quality assured by an expert in qualitative research at the University of Aberdeen.

#### **7.2.1 Synthesis of qualitative research**

A literature search to identify studies exploring patients' perspectives on AWDs and to provide information on the patient issues sub-questions of this HTA revealed a lack of research focused on AWDs specifically, therefore a broader qualitative synthesis of patient perspectives on chronic wounds and wound dressings was undertaken.

The synthesis includes primary qualitative research studies which, using methods such as interviews and focus groups, explicitly asked adults about their experiences of having a chronic wound and its treatment.

A systematic search to identify relevant literature was conducted and studies were selected using predefined inclusion and exclusion criteria. Included studies were critically appraised using the Critical Appraisal Skills Programme (CASP)<sup>59</sup> quality assessment tool for qualitative studies. The analysis and write-up was performed by one researcher, and quality-assured by a second.

There is currently a wide range of approaches available for synthesising qualitative research<sup>60</sup>. Framework synthesis, based on the framework approach for the analysis of primary data<sup>61</sup>, was used in this analysis. This method was selected because it provides a detailed and rigorous method of charting and summarising data, and provides an audit trail leading directly back to the data supporting any findings. It also offers flexibility in the use of *a priori* and emergent themes for the development of a thematic framework<sup>62</sup> and it is recommended where data available may be 'thin' (lacking in rich detail) and theory development may be limited. Data analysis was carried out in QSR NVivo10<sup>63</sup>.

A thorough description of the methods is available in the supplementary material.

### 7.2.2 Primary qualitative research

The literature synthesis failed to identify any qualitative research focused on AWDs, and only a limited number of studies focused on wound dressings. Therefore, a decision was made to conduct primary research specifically on AWDs.

A focus group (n=8) and six telephone interviews were conducted.

An application to conduct the research was made to the NHS Health Research Authority and a favourable opinion was granted by NRES Committee West Midlands – Black Country. Access to Glasgow Royal Infirmary to conduct the focus group was granted by NHS Greater Glasgow and Clyde R&D management office.

Participants were identified by a practising tissue viability nurse in one NHS board. Patients who had been treated with an AWD in the tissue viability department within a 3-month period prior to the start of the study were identified. The sampling was purposive, aiming to include people who had experience of different wound types and AWDs.

Participants who expressed an interest in taking part had the study explained to them by the recruiting tissue viability nurse. Informed consent was obtained from participants, and participants were assured that consent could be withdrawn at any time.

Basic demographic information on people who refused to take part was not collected.

The focus group and telephone interviews were guided by a schedule that consisted of nine questions, each with several prompts/sub-questions (available from supplementary material). These questions were informed by the research questions listed in section 7.1. The prompts/sub-questions were only used if needed, to encourage discussion. The researchers were flexible and responsive, allowing conversations to flow spontaneously, changing the order of the questions if it made sense to do so, and keeping researcher input to a minimum.

Data analysis was carried out in QSR NVivo10. The data were analysed using the framework analysis technique described by Ritchie and Spencer<sup>61</sup>.

A thorough description of the methods is available in the supplementary material.

## 7.3 Results

### 7.3.1 Synthesis of qualitative research

#### 7.3.1.1 Description of studies

Twenty studies were included in the synthesis<sup>64-83</sup>. One study was published in two parts<sup>65, 84</sup>: part 1 contains the methodology and part 2 contains the findings of the analysis. For the purposes of the synthesis, only part 2<sup>65</sup> was included in the framework analysis, while part 1<sup>84</sup> was used for data extraction. Only two of these papers focused on wound dressings specifically: one was focused on the patient experience during dressing changes<sup>68</sup> and the other on the adherence to compression bandaging<sup>77</sup>. Two papers focused on the chronic wound patient's experience of pain<sup>75, 78</sup>. One paper was part of a broader research project into the quality of life of patients with pressure ulcers<sup>70</sup>. All the other studies had a broad focus on the patient experience of chronic wounds<sup>64-67, 69, 71-74, 76, 79-83</sup>.

The studies were published between 1995 and 2013. A number of countries were represented: 11 were based in the UK<sup>64, 65, 67, 69, 70, 72, 77, 78, 81-83</sup>, four in the USA<sup>66, 75, 76, 79</sup>, two in Norway<sup>71, 80</sup>, one in Sweden<sup>68</sup>, one in Australia<sup>74</sup>, and one study had multiple sites based in the UK and Belgium<sup>73</sup>.

By far the most represented wound types were leg ulcers for which 12 studies were included in the synthesis<sup>65-68, 71, 72, 74, 75, 77, 78, 82, 83</sup>. Five studies on people with pressure ulcers were included<sup>69, 70, 73, 76, 81</sup>, and two studies on people with foot ulcers associated with diabetes<sup>64, 80</sup>. One study's sample included individuals with a mix of the three different types of chronic wound included in the other studies<sup>79</sup>. No qualitative studies of any other wound types were identified.

Six of the included studies were rated as high quality<sup>67, 72-74, 76, 79</sup>, nine as moderate quality<sup>64, 66, 68, 70-72, 75, 81, 82</sup> and five as low quality<sup>65, 69, 77, 78, 80</sup>. Please

see the supplementary material for more details on the quality of the studies included in the synthesis.

### 7.3.1.2 Results of the framework synthesis

Analysis of the 20 included studies identified seven themes, each with a set of subthemes (Table 5). Where differences were identified in the experience of patients of different wound types this is highlighted in the text. A table containing the extracted data supporting the framework synthesis is available on request.

**Table 5: Synthesis of qualitative research: themes and subthemes**

Theme	Subtheme
<b>Theme 1: Physical impact</b>	1.1 Pain
	1.2 Odour and exudate
	1.3 Infection
	1.4 Other physical features
<b>Theme 2: Psychological impact</b>	2.1 Emotional impact – helplessness and hopelessness
	2.2 Loss of independence and identity change
	2.3 Being on guard
<b>Theme 3: Restrictions to lifestyle</b>	3.1 Impaired mobility and restrictions on social life
	3.2 Work and financial restrictions
<b>Theme 4: Dressings</b>	4.1 Dressing changes
	4.2 Purpose of dressings
	4.3 AWDs
<b>Theme 5: The chronic wound journey</b>	5.1 Onset and cause of the wound
	5.2 Co-morbidity
	5.3 Length of time to healing and recurrence
	5.4 Knowledge of wound care
<b>Theme 6: The patient and the healthcare system</b>	6.1 Healing versus wellbeing
	6.2 Positive aspects of interacting with healthcare professionals
	6.3 Negative aspects of interacting with healthcare professionals
<b>Theme 7: Coping</b>	7.1 Acceptance and hope of healing
	7.2 Staying positive and minimisation of illness
	7.3 Care from family and friends

### 7.3.1.3 Synthesised themes

#### Theme 1: Physical impact

##### Subtheme 1.1 Pain

*“[Its] the worst thing that I have ever gone through in my life. And believe me, I’ve had surgery, multiple surgeries, I’ve never had nothing hurt like this. Never. It feels like someone’s sticking a hot poker in you. They’re sticking pins in you...And it never stops hurting. The damn thing never stops hurting. I had one day that my leg didn’t hurt.” [Krasner, p.162<sup>75</sup>]*

Pain was a major theme in many studies and its detrimental impact on patients’ quality of life and functioning was discussed by all the included studies<sup>64-83</sup>.

The pain experienced by many of those with a chronic wound can be severe and unbearable at times, having a major impact on the patient’s wellbeing<sup>64, 67, 72-76, 78, 79, 81-83</sup>. A feature of the pain from a chronic wound is patients’ descriptions of it as ‘ever present’<sup>73</sup>. Some experience the pain constantly and others intermittently. However, even those who gain relief from the pain temporarily or through the healing of the wound are anxious about its return<sup>64, 67, 69, 73-76, 78, 82, 83</sup>.

The studies indicated that pain was a major feature of chronic wounds; however, this experience seemed more variable for those with a pressure ulcer<sup>69, 76, 81</sup>. Two studies suggested that, for some people with a pressure ulcer, the underlying condition is so severe that the pressure ulcer was only a minor additional problem and the ability to experience pain in the affected area may also be reduced<sup>76, 81</sup>. However, the studies indicated that people with a pressure ulcer frequently experience pain from the wound, even if it extends into the subcutaneous tissue and deep fascia, and regardless of the position of the ulcer<sup>69, 73, 81</sup>.

The studies indicated that ineffective pain management for chronic wounds is common and analgesia is often inadequate or ineffective<sup>64, 67, 70, 73, 75, 81-83</sup>. Multiple studies suggested that it is common for patients to feel that healthcare professionals do not understand or acknowledge their levels of pain<sup>64, 67-70, 73, 81, 82</sup>.

Studies of people with leg or diabetic ulcers suggested that if patient reports of pain or discomfort caused by treatment are ignored by healthcare professionals then non-adherence to treatment is likely, even if the patients know that this may affect healing<sup>65-67, 71, 80</sup>. However, reluctance in patients to take analgesia, due to being on multiple medications for co-morbidities, and concerns regarding addiction, reduced efficacy, and stigma, were also identified in multiple studies<sup>64, 66, 74, 76, 78, 80, 83</sup>.

A strong finding across many studies was the link between the uncontrolled pain from the chronic wound and sleeplessness<sup>64, 67, 69, 74, 75, 78-80, 82, 83</sup>. Sleep

deprivation can lead to fatigue and contribute to impairment in the patient's functioning<sup>64, 67, 78-80, 83</sup>.

### Subtheme 1.2 Odour and exudate

*"Oh, and when you first have them, I wondered what the smell was—it's terrible the smell, it all comes out, a lot of rubbish. When you went anywhere, you didn't get too close to people, because I can smell it, terrible."* Ellen [Green et al, p.62<sup>83</sup>]

Although odour was named as a theme in a relatively small number of papers<sup>67, 74, 79, 82, 83</sup>, many studies identified it as a common and highly distressing feature of these wounds, which can cause 'horror' and 'dismay' for patients<sup>66, 67, 72-74, 79, 81-83</sup>. Fear of others detecting the odour from the wound, and the associated shame and embarrassment, prevents many people from engaging in social activities<sup>67, 72-74, 79, 82, 83</sup>.

Studies identified exudate as another common feature of chronic wounds, which can be very distressing for the patient and difficult to manage adequately with dressings<sup>67, 69, 74, 79, 81-83</sup>. Exudate presented problems for patients both inside and outside the home, but was particularly concerning for patients in social settings due to fears of embarrassment if they were unable to contain it<sup>67, 74, 79, 82, 83</sup>.

Odour and exudate were not identified as themes in the two studies of people with a diabetic foot ulcer<sup>64, 80</sup>. However, this may be a feature of the limited number of studies identified for people with diabetic foot ulcers rather than a difference in the experience of these patients.

### Subtheme 1.3 Infection

*'Overwhelmingly, however, the greatest issue was the unpredictability of recurrent infections. The participants all expressed a fear of infection and this was particularly prominent during the dressing change process as it was perceived to be the most infectious.'* [Mudge et al, p.24<sup>78</sup>]

Infection was not one of the most prominent themes. However, several studies mentioned that patients frequently experience repeated and unpredictable infections<sup>74, 75, 78-81</sup>, and one study indicated that patients' fears of infection were a major issue, particularly during dressing changes<sup>78</sup>.

These infections can delay healing, lead to additional health difficulties and increased pain/discomfort<sup>74, 75, 78-81</sup>. All but one of the studies of people with a pressure ulcer highlighted their experiences of infection leading to life-threatening complications, hospitalisation, and multiple additional treatments<sup>69, 73, 76, 81</sup>. The worry that infection could lead to hospitalisation was also mentioned by a small number of studies of other wound types<sup>74, 79, 80</sup>. Studies suggested that patients who had experienced a serious infection feared subsequent infection and its treatment burden<sup>69, 73, 74, 76, 79-81</sup>.

## Subtheme 1.4 Other physical features

*“My wound would also itch a lot. It was hard to keep my hands off it. And when I would scratch it, it would feel so good so I would scratch it until it got bloody. Isn’t that awful?”* [Neil et al, p.32<sup>79</sup>]

Wound itchiness was highlighted by just two studies<sup>66, 79</sup>. However, these studies describe itchiness as a frequent complaint that can be difficult to tolerate. Itchiness can be interpreted both as a sign of healing, but can also be the first sign of recurrence of an ulcer<sup>66, 79</sup>. Swelling and its link with pain was mentioned by three leg ulcer studies<sup>66, 68, 75</sup>. Krasner<sup>75</sup> in particular discusses swelling and its interaction with other symptoms leading to restricted activity levels.

## Theme 2: Psychological impact

### Subtheme 2.1 Emotional impact – helplessness and hopelessness

*‘Some were striving to maintain their “normal” functioning, whereas others suffered from anxiety and depression, with one respondent disclosing that he had had suicidal thoughts. “It’s just depressing really, if you think about it. I am on antidepressants. I just have to put up with it— it’s either that or kill myself.”* Steve [Green et al, p.62<sup>83</sup>]

The psychological, and social, impact of the chronic wound was a common theme among studies. Studies highlighted that depression, anxiety, poor self-image, and fear of others’ reactions to the wound are common psychological consequences<sup>64, 65, 69, 73, 75, 76, 81, 83</sup>. The extent of the psychological impact of the wound varied, with some patients reporting severe depression and even suicidal thoughts<sup>75, 83</sup>.

The studies identified a variety of factors that may contribute to adverse psychological impacts. For some patients, the onset of the wound can lead to an extreme role reversal from an independent person to one dependent on care from others<sup>64, 66, 67, 73, 79, 83</sup>. The unpredictable and severe pain that some people experience can lead to a sense of powerlessness and frustration<sup>64, 65, 67, 69, 76, 80</sup>. This can combine with the persistence and recurrence of the wounds to precipitate feelings of helplessness/loss of control, hopelessness/depression and low self-esteem<sup>64, 65, 67, 69, 72, 76, 80</sup>. Factors explored under other themes, including the physical symptoms of the chronic wound, decreased mobility, fear of further bodily trauma and pain, social isolation, and dependence on others are also likely to contribute to feelings of helplessness and hopelessness in patients with a chronic wound.

### Subtheme 2.2 Loss of independence and identity change

*‘Venous ulcers represent both the literal breakdown of the skin and the figurative breakdown of the embodied self. Venous ulcers cause chronic illness that profoundly changes the meaning of life when compared with its meaning as perceived by a healthy person.’* [Krasner, p.165<sup>75</sup>]

The onset and persistence of a chronic wound can lead to alterations in body image and personal identity, which many studies linked to lowered self-worth<sup>66-68, 72, 73, 76-80, 82</sup>. The loss of the ability to perform previous roles in life, such as caring for others, which can precipitate depression, can also have a major impact on personal identity<sup>66-68, 72, 73, 76-80, 82</sup>.

People with chronic wounds are often dependent on others for treatment; they frequently experience greatly reduced mobility, and particularly people with a pressure ulcer may require assistance to reposition themselves<sup>64-83</sup>. This dependence on others can be very distressing, prompting an attempt to retain as much control and independence over daily living and self-care as possible<sup>64, 66, 67, 69, 71, 73, 76, 78-80</sup>.

In people with a pressure ulcer, the nature of the underlying condition led to a substantial variation in reported levels of dependence on others<sup>81</sup>. Many of those with chronic pre-existent conditions, such as spinal cord injury, had learnt to cope and adapt to living with their pre-existent conditions and the onset of a pressure ulcer caused them to lose this independence<sup>70</sup>. While it may not be possible to separate the impact of the chronic wound from the underlying health conditions, or impact of ageing, for all these patient groups, all studies described additional restrictions resulting from the onset of the wound<sup>64-83</sup>.

Body image can be greatly impaired by the chronic wound. Studies reported some patients seeing themselves as 'dirty' or 'disgusting', leading to feelings of shame and embarrassment and avoidance of others<sup>66, 67, 69, 72, 74, 76, 77, 79, 82, 83</sup>. The patient's loss of the ability to dress as they used to, because of the bulkiness of dressings or the location of wound(s), can also threaten self-image<sup>69, 77, 82, 83</sup>. Several studies suggested that female patients may find this and symptoms, such as wound odour, particularly detrimental to self-image because of the threat to traditional notions of femininity and attractiveness<sup>69, 74, 77</sup>.

Studies described some patients' failure to acknowledge the wound as part of the self<sup>64, 66, 70, 75, 76, 79, 81</sup>.

*"My butt ain't my butt anymore. It ain't the butt I was born with. I have muscle from all other parts of my body holding it together down there'. It ain't a 'pretty sight'."* [Langemo *et al*, p.230<sup>76</sup>]

One study suggests that this is explained by the experience of the wound as a violation of the body, leading the patient to objectify bodily experiences by hiding the wound from others and seeing the wound as separate to the self<sup>66</sup>. Indeed, two studies discussed patients who did not want to see the wound, or any images of it, even when it was present for a long period<sup>79, 81</sup>. This refusal to acknowledge the wound as part of the self may in some way protect the patient from its negative impact on body image and self-esteem. However, patients reacted to the bodily presence of the wound in different ways and two studies described patients for whom the wound had become a fundamental part of their self-image. They were no longer able to envision their life, or their body without it<sup>72, 79</sup>.

The theme of body image was less prominent in the studies of people with diabetic foot ulcers<sup>64, 80</sup> however the small number of these papers identified makes it difficult to draw any conclusions from this.

### Subtheme 2.3 Being on guard

*‘Others stayed at home in order to limit their contact with others or to avoid further injury. For whatever reason, normal daily life was interrupted for many as a result of ulceration. “I’m frightened in the supermarket. I am frightened when I’m out, when I have been at the supermarket cause some people, they do push their trolleys everywhere. So it means that you’re on your guard all the time.” Margaret’ [Green et al, p.64<sup>83</sup>]*

Studies described patients’ experiences of being ‘on your guard’, living in a state of hypervigilance to pain and bodily trauma. The studies indicated that leg ulcer patients believed that new ulcers may develop because of any trauma to the body, like a knock to a vulnerable area<sup>67, 72, 77, 82</sup>. This belief, combined with fear of pain from any, even minor trauma to the wound or body, can lead people with leg and foot ulcers to avoid places or activities associated with any such risk, limiting their social life<sup>64, 65, 67, 74, 77, 78, 82, 83</sup>. Such fears may be partially due to ageing and co-morbidities, but are clearly amplified by the presence of the wound.

Studies also described patients’ awareness of the risk of their condition worsening, leading to a fear of amputation or other complications<sup>66, 74, 76, 79, 80, 83</sup>. Two leg ulcer studies indicated that many patients did not understand the difference between arterial and venous leg ulcers and were, therefore, unnecessarily fearful of amputation from their lower risk venous disease<sup>66, 72</sup>. One study describes a leg ulcer patient’s attempts to protect their limbs from the threat of amputation<sup>74</sup>:

*“It was getting no better so they put me into hospital and he [the surgeon] says, ‘Well I’ll have an exploratory’. I said, ‘Alright’, so when the anaesthetist came he said... ‘I see you’re having your leg off’. I said, ‘No I’m just having an exploratory’...he said, ‘Well I’ll ring the doctor up’ . . . he said, ‘Yes you’re going to have an exploratory, but on the bottom it says, if necessary amputation’.” [Hyde et al, p.194<sup>74</sup>]*

This person awoke to find that their leg had been amputated and then describes having to argue with her surgeon to prevent her other leg being amputated. This person attempted ‘to maintain the integrity of her body regardless of the consequences’<sup>74</sup> and had to be vigilant in order to do so. For this person, amputation was a catastrophic outcome, however some studies describe patients’ willingness to have a limb amputated to eliminate symptoms and reduce treatment burden<sup>64, 66, 79</sup>.

### Theme 3: Restrictions to lifestyle

#### Subtheme 3.1 Impaired mobility and restrictions on social life

*'Leg ulcer patients describe limitations to their mobility and activity that are at times profound. When asked what area of her life had been affected by ulcer disease, one woman responded, "What area of my life? My whole life. I cannot do anything I want to do. I cannot go any place. [after a pause, and with sadness] I kind of got used to it".'* [Chase et al, p.75<sup>66</sup>]

The impact of the chronic wound on mobility and social life was one of the most widely discussed themes in the studies. Many of the studies highlighted severe restrictions on mobility which has a profound effect on lifestyle, reducing the ability to get out of the home and socialise with others<sup>64, 66, 67, 72-74, 76, 77, 79-81, 83</sup>. The impairment in mobility (resulting from the wound) is mostly a result of pain<sup>64, 69, 72, 73, 75, 78-82</sup>, but is also impacted on by poorly-controlled exudate and odour<sup>66, 67, 72-74, 77, 79, 81, 83</sup>, bulky dressings<sup>65, 66, 69, 77-79, 83</sup>, and difficulties with footwear<sup>64, 80</sup>. The psychological impact of the wound, and fear of further physical trauma, can also greatly restrict the patient's social life<sup>64, 65, 69, 72-74, 76, 77, 79-81, 83</sup>. Some studies suggest that social withdrawal may form a cycle with feelings of powerlessness, low self-worth, fatigue and depression adversely effecting social life and wellbeing<sup>64, 72, 76, 80</sup>.

Healthcare professionals' prescribed limits on movement frequently led to isolation, boredom and limitations in daily activities. Patients often believed that it was better for them to be more active and did not always adhere strictly to such limits<sup>67, 70, 73, 76, 79-81</sup>. The negative impact of prescribed immobility and restrictive pressure relieving equipment<sup>76, 79</sup> was a notable finding for the people with a pressure ulcer<sup>28, 31</sup>.

Many studies highlighted patients' shame and embarrassment when others noticed symptoms, in particular odour/exudate, or visible dressings. This led them to limit social activity unless they were confident of being able to hide these signs of illness<sup>66, 67, 72-74, 77, 79, 81, 83</sup>. Dressings are frequently ineffective at containing symptoms, leading patients to withdraw from social contact<sup>65, 69, 70, 79</sup>.

Studies described variation in the level of social isolation experienced by people with a leg ulcer, suggesting that some patients do manage to maintain a relatively active social life<sup>65, 66, 68, 78</sup>. Several studies suggested that they do not necessarily suffer higher levels of loneliness than their 'healthy' peers without leg ulcers<sup>65, 78</sup>. It is not possible to completely separate the impact of ageing and co-morbidities on the patient's limited mobility and restricted social life, and these factors are likely to underlie some of the variation in levels of social isolation described in the studies.

### Subtheme 3.2 Work and financial restrictions

*'Although most participants were retired, they all vividly recalled their experiences of coping with exudate at work: "Used to try all sorts but in the end wore wellington boots at work... anything to hide the leakage."' [Douglas, p.358<sup>67</sup>]*

A number of studies highlighted patients' inabilities to work because of the symptoms of the wound or their struggle to find ways to cope with symptoms at work<sup>66, 70, 75, 79, 80</sup>. However, difficulties at work are not mentioned by the majority of studies. This is likely to reflect the older age and co-morbidities of the samples which may have already had a major impact on the patient's ability to work. Studies suggest that patients who do continue to work may find it difficult to manage exudate and odour. They described adapting clothing and taking other measures to hide these symptoms<sup>67, 74, 79</sup>. Patients were especially worried about the shame or embarrassment that would result from others noticing the wound's symptoms in a working environment.

There was very limited discussion of financial restrictions in the studies. Only one UK study of people with pressure ulcers<sup>70</sup> and one US based study of people with leg ulcers<sup>66</sup> mentioned the financial implications of receiving treatment for a chronic wound. The US study highlighted the difficulties experienced by disadvantaged groups, such as people experiencing homelessness, in accessing healthcare and buying dressings. Gorecki *et al*<sup>70</sup> noted the costs incurred by people with a pressure ulcer (for example buying topical lotions, dressings, pressure-relieving cushions and replacing stained bedding), and the difficulties involved in managing financial obligations during a hospital admission.

## Theme 4: Dressings

### Subtheme 4.1 Dressing changes

*'The participants complained that they did not receive enough pain medication or other assistance during the painful process of changing the bandages. As one said: "That is exactly what I thought, but they don't listen to me. I thought about that, when it ached and also about that gauze bandage. Can't they hear what I say? Why don't they listen?"' [Ebbeskog *et al*, p.1228<sup>68</sup>]*

Dressing changes can take place frequently and take up a considerable amount of the patient's time, impacting on their social life<sup>65, 70-73, 77, 81, 83</sup>. By far the most frequent issue about dressing changes raised in the studies was the pain experienced during the procedure, which can persist for some time after it<sup>64, 66-68, 72-75, 77, 78, 81</sup>. However the levels of pain experienced by patients during dressing changes is variable<sup>64, 66</sup>. Factors that influenced the experience of pain during dressing changes included: tenderness of the wound and the application of pressure to it, the technique of the healthcare professional, adverse reactions to the dressing, the adhesiveness of the dressing material and problems with the application of the dressing<sup>64, 66-68, 72-75, 77, 78, 81</sup>. Two studies explicitly highlight patients' difficulties in dealing with the anticipation of pain from

cleansing and dressing changes<sup>68, 78</sup>. One study discusses this in some depth stating that:

*'The regularity of dressing changes ensures that the anticipation of pain is never far from the patient's mind and as such largely dictates how they lead their day-to-day life.'* [Mudge et al, p.26<sup>78</sup>]

This study also acknowledges patients' positive experiences at dressing changes, namely the opportunity to monitor the wound's progress, relieve compression (if it is in place) and have the area washed, but notes that they are always balanced by anxiety regarding pain<sup>78</sup>. Just one study of people with pressure ulcers describes a patient who experienced dressing changes as comforting and actually looked forward to them<sup>81</sup>.

Mudge et al<sup>78</sup> also highlight some methods used by patients to cope with dressing changes and the pain associated with them. This included distraction during the procedure (for example thinking about a treat for after the change), having some element of involvement in the dressing change procedure, and having some control over the environment (such as having changes done at home). Some patients also took pain relieving medication before the dressing change and found this essential to bearing the process.

#### Subtheme 4.2 Purpose of dressings

*'One woman, a retired teacher, described the way she used to cope at work when the ulcer suppuration leaked through the bandages. "Oh, terrible [the seepage]. All the time and that's why I used to have to rush home of an afternoon and change the bandages . . . because they'd be soaking wet.'"* [Hyde et al, p.193<sup>74</sup>]

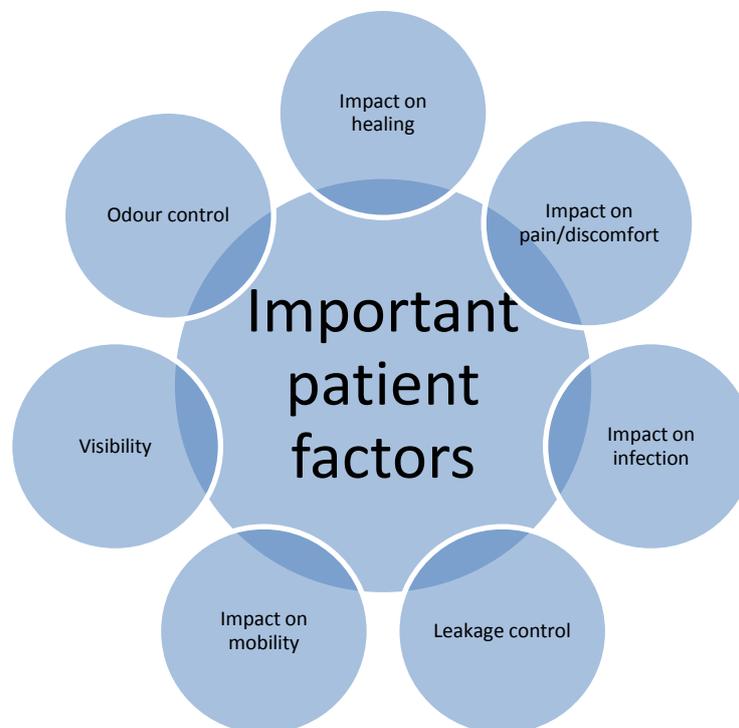
Studies indicated that patients want dressings that will aid healing<sup>65, 68, 70, 81</sup>. However, patients also want dressings that are comfortable and effectively contain symptoms<sup>67, 69, 71, 72, 74, 79, 81, 82</sup>. Leg ulcer studies indicated that certain types of dressings, such as compression bandaging, can cause considerable discomfort and even pain<sup>65, 67, 68, 77, 78, 82</sup>.

Restrictions from bulky and uncomfortable dressings<sup>65, 66, 69, 77-79, 83</sup>, such as compression bandaging, can be so severe that patients may be willing to trade off potential healing for freedom from bandaging<sup>65</sup>. One study describes a patient's decision to ask healthcare professionals to 'take my leg off' because of a dressing's inability to contain exudate and the restrictions on her social life that this caused. This patient:

*'..voiced tremendous relief at not having to sleep in the recliner, not having to go to whirlpool therapy and endure debridement three times a week, and foremost, being able to go out and resume her social life. She said she had lost a year with her friends and church because she had not been able to go out with her thick, wet bandage.'* [Neil et al, p.36<sup>79</sup>]

Figure 1 has been developed during the synthesis process to illustrate the factors highlighted as important in dressing acceptability by the authors of the studies. The qualities of wound dressings are represented non-hierarchically because the synthesis suggests that the various qualities of wound dressings will be more or less important to different patients and at different times. Healing seems to be of paramount importance to patients who expect a full recovery, while for others who have had a long history of chronicity and/or recurrence, other factors may gain in importance. Therefore the value attached to each will differ for each individual. For example, a patient who already has severely impaired mobility at the onset of the chronic wound (more common in those with pressure ulcers), may not experience a further reduction in mobility because of a bulky dressing and therefore this aspect of dressings will be of little importance.

**Figure 1: Factors to consider in selecting a dressing for a chronic wound**



Another restriction mentioned by several leg ulcer studies is a dressing's impact on patients' abilities to bathe and adequately maintain their personal hygiene<sup>66, 82, 83</sup>. In order to keep the dressing dry and fulfill other treatment restrictions, patients went for longer periods of time without bathing or washing the affected area than they felt comfortable with<sup>66, 82, 83</sup>.

A small number of studies identified concerns from patients that 'nothing gets a chance to work'<sup>67</sup> because of the many types of dressing available and the frequent changes of dressing type by healthcare professionals<sup>68, 70, 83</sup>. When a dressing has appeared to be effective in wound healing, patients may develop great faith in it<sup>77, 83</sup> and this can make them reluctant to try a new dressing<sup>77</sup>. Conversely, a small number of studies directly raised patients' concerns about

healthcare professionals persistence with dressings they viewed as ineffective, both in terms of healing and symptom containment<sup>68, 70, 81</sup>. Although it is only raised in one study, patients may view the persistence with non-preferred dressings as motivated by attempts to minimise costs to the healthcare provider<sup>68</sup>.

#### Subtheme 4.3 AWDs

*“You name it, all the different patches with stuff in and creams and the patches come out with the silver in and we went through every one of them. Errr... I’ve gone through loads of different stuff—they’ve put, I’ve had trials of different stuffs put on and some worked and some hasn’t.” Steve [Green et al, p.64<sup>83</sup>]*

No studies focusing on AWDs were identified in the literature review, and no study contained a named theme focused on AWDs. However, several studies indicated that patients perceived the healing properties of topical antibiotic creams and AWDs positively<sup>65, 66, 70, 75</sup>. In two studies, patients mentioned having tried many different products, including different types of AWDs<sup>71, 83</sup>, and indicated that some appeared to have been effective while others had not<sup>83</sup>. In this study, the patient seemed to believe that trial and error was used in the selection of these products until one ‘worked’ and the wound improved<sup>83</sup>.

An adverse reaction to the use of an AWD is mentioned in just one study, and was linked by the patient to care from primary care instead of specialist healthcare professionals:

*“This ulcer on this leg was caused by bandages from the doctor (GP) really. Well, not from the doctor, from the nurse, because it wasn't done tidy...you go to your local surgery and they bandage and say, oh yeah, put iodine on it or Inadine sometimes, and that's it. And when I went to ••• (specialist wound clinic) a couple of months ago my leg was disgusting. It was all from the Inadine pads apparently because it had burnt me.” [Mudge et al, p.1168<sup>77</sup>]*

While AWDs were mentioned more often in studies of leg ulcers than in any other type of wound, no conclusions can be reached from this since none of the studies had intended to examine patients’ perceptions of their use, and this might be a reflection of the larger number of studies on leg ulcers identified in the literature search.

### Theme 5: The chronic wound journey

#### Subtheme 5.1 Onset and cause of the wound

*‘This group of patients was not able to describe what causes leg ulcers. Patients frequently look for a reason for the ulcer. “Could that break and that fracture have something to do with this?” Another man wondered if a knee problem caused the leg ulcer.’ [Chase et al, p.76<sup>66</sup>]*

Studies of all wound types mentioned patients’ attempts to self-manage the wound for some time before seeking input from professionals. This tended to be

based on a failure to realise the severity of the wound and help seeking was only prompted by deterioration<sup>66, 70, 79-81, 83</sup>.

Many studies highlighted patients' lack of understanding of the underlying cause of their chronic wound, leaving them to seek out an understandable rationale<sup>65-67, 70-72, 76, 77, 79, 80, 82, 83</sup>. People with leg ulcers seemed to frequently attribute the cause to a knock of some kind without an understanding of the underlying condition or why healing was so slow<sup>67, 72, 77, 82</sup>. Several leg ulcer studies also mentioned patients' explanations of their condition as rooted in a family history of leg ulcers apparently leading to a sense of resignation or acceptance of the condition and the likelihood of recurrence<sup>67, 72, 82, 83</sup>.

Studies of people with a pressure ulcer discussed patients' attribution of blame for its onset, with some patients placing the blame on healthcare professionals (such as injury from a hoist)<sup>70, 76, 81</sup>, or factors to do with their pre-existent medical conditions (such as reduced sensation and immobility)<sup>70, 81</sup>. Others blamed failures in their own self-care (such as failure to check skin, lack of knowledge about wound care, and poor hygiene)<sup>70, 76, 81</sup>.

#### Subtheme 5.2 Co-morbidity

*'The participants in our study all had comorbidities, the most common being significant arthritis, which already served to restrict their lives. For this reason, age, their life experiences and health to date possibly further mediated the impact of restriction.'* [Hopkins et al, p.351<sup>73</sup>]

The impact of co-morbidities on the lifestyles of people with leg or foot ulcers was highlighted in several studies<sup>64, 65, 79, 80, 83</sup>. Some patients had suffered considerable difficulties with mobility and other impairments before the onset of the chronic wound<sup>64, 65, 79</sup>. In the cases of people with diabetic foot ulcers, the overall impact of diabetes on the patient's physical wellbeing was acknowledged<sup>80</sup>. However, several studies indicated that regardless of the patient's level of functioning before the onset of the ulcer, its onset prevented them from functioning at their maximum capacity<sup>64, 82, 83</sup>.

Pressure ulcers are commonly a consequence of a condition that limits mobility and the studies of people with pressure ulcers reveal the major impact of co-morbidities on the patients' experience<sup>73, 81</sup>. For some people with a pressure ulcer with chronic underlying conditions (for example multiple sclerosis), studies reported that the wound represented a serious threat to their independence since they had learned to function and live within the restrictions of their existing condition<sup>70, 81</sup>. For some people with a pressure ulcer with an acute condition (such as a major accident), the wound was described as 'just another irritation' given the burden of their overall condition<sup>70, 81</sup>. However one study is clear that the pressure ulcer has a 'marked impact' on the patient regardless of the nature of the underlying condition<sup>73</sup> and others highlight delays to recovery/rehabilitation<sup>70, 73, 81</sup>.

For all the chronic wound types, but particularly pressure ulcers, the impact of co-morbidities and underlying conditions are difficult to separate from the

experience of the chronic wound itself<sup>64, 65, 73, 76, 80, 81</sup>. This is further compounded by the impact of ageing, since many of these patients are older adults. Ageing may be a factor in mobility restrictions and other impairments discussed in this synthesis, and is likely to effect the patient's ability to accept these impairments<sup>65, 73, 82</sup>.

#### Subtheme 5.3 Length of time to healing and recurrence

*'Another man living with the condition for years said, "It's like a forever healing process, not getting better, not getting worse."' [Chase et al, p.74<sup>66</sup>]*

Recurrence, and living with the possibility of recurrence, is described as a major feature of the leg ulcer experience<sup>65-67, 72, 74, 83</sup>. While it is not as prominent in the studies of people with diabetic or pressure ulcers, it is also a feature of the experience of the patients in these studies<sup>64, 70, 80, 81</sup>. For people with a chronic wound, the unpredictable nature of healing and recurrence, and the emotions associated with this, is part of living with the condition. Studies describe patients experiencing guilt, frustration, disappointment, worry and sadness because of the persistence of the chronic wound<sup>64, 66-69, 72, 73, 76, 79, 81, 83</sup>, and the fear of never regaining previous levels of functioning and independence.

#### Subtheme 5.4 Knowledge of wound care

*'Many respondents who had experienced a PU [pressure ulcer] demonstrated knowledge and understanding related to prevention and care of a PU, while others revealed a significant lack of knowledge in these areas.'* [Langemo et al, p.231<sup>76</sup>]

Studies described patients' lack of understanding about the rationale behind treatments, such as compression bandaging, and a lack of clarity around expectations of healing<sup>65-67, 70, 71, 76, 77, 80-82</sup>. Patients can be frustrated by healthcare professionals failure to keep them well informed, which may exacerbate the feelings of helplessness and hopelessness experienced by many<sup>64, 67, 68, 70, 72, 76, 77, 80, 81</sup>. Studies suggested that patients whose healthcare professionals keep them informed about the wound and treatment rationale, and feel involved in the decision-making process, are more likely to adhere to treatments<sup>67, 70, 75, 82</sup>.

Some studies described patients becoming an expert in wound care, treatment and prevention, enabling the prediction of the progression and onset of a wound<sup>65, 68, 71, 72, 74-76, 83</sup>. Patients who have become such experts can work in partnership with healthcare professionals, even alerting them to the need for prophylactic treatment of infection and managing their own pain treatments<sup>68, 74, 83</sup>.

*'The women cited in the present study, at this stage, had doctors who responded to their requests for prophylactic or prompt treatment with antibiotics. It is important for visiting nurses to be aware of this potential for self-expertise among clients with long-term conditions, because it is likely that earlier in the*

*clients' lives their medical practitioners were not necessarily so responsive.'*  
[Hyde et al, p.196<sup>74</sup>]

Studies also describe variation in patients' desires to be actively involved in wound care and management. Some patients are described as motivated and seeking involvement in decisions about wound care and prevention<sup>70, 71</sup>, while others minimise their involvement with the wound and its treatment<sup>66, 68, 71, 82</sup>.

## Theme 6: The patient and the healthcare system

### Subtheme 6.1 Healing versus wellbeing

*'...nurses may have viewed complete wound healing as the only desirable treatment outcome, whereas for many participants, alleviation of the distressing symptoms experienced was more important than complete wound closure. While aware of the benefits of compression therapy, they were willing to trade off potential healing against relief of unpleasant side effects of treatment.'*  
[Brown, p.988<sup>65</sup>]

Multiple studies suggest that healthcare professionals tend to be focused on achieving complete wound closure as the sole outcome of treatment<sup>64-66, 69, 73, 82, 83</sup>. This can lead to a lack of acknowledgement of the chronic nature of the wound, the likelihood of recurrence and a failure to focus sufficiently on symptom alleviation, comfort and other quality of life issues<sup>64-66, 69, 73, 82, 83</sup>. To redress this balance, these studies suggest a focus on the holistic treatment of the patient, identifying the priorities for each individual<sup>64, 65, 69, 75, 76</sup>, and giving: 'as much importance to comfort and symptom control as to speed of healing'<sup>82</sup>.

Patients wished to live as 'normal' a lifestyle as possible and therefore treatments that can interfere with this, such as compression bandaging and pressure relieving equipment, were challenging<sup>65, 73, 82</sup>. They may experience a tension between following treatment plans in order to achieve healing and the restrictions that treatment can place on their lives, influencing adherence<sup>65, 73, 82</sup>. This may be compounded by the apparent ineffectiveness of treatments if the wound continues to persist or recur. As Brown<sup>65</sup> noted, even if the patient is aware of the rationale behind a treatment, the need for maximising wellbeing within the restrictions of their health may lead to a willingness to forego the healing potential of a treatment if it causes significant discomfort. Many factors will affect the extent to which the patient is focused on wellbeing or healing and this is discussed more under Subtheme 7.1.

### Subtheme 6.2 Positive aspects of interacting with healthcare professionals

*'The therapeutic relationship with the district nurse was linked to the importance of feeling known, feeling heard and appreciated as people. The visits are marked by enjoyment, a "laugh and a joke". They move beyond the task in hand to friendship...It appears that by showing interest in the participant as an individual this promoted confidence and hope for the future....where these interactions are absent, the patients' needs will be left unfulfilled or frustrated.'*  
[Hopkins et al, p.562<sup>72</sup>]

The relationship between patients and healthcare professionals was a prominent theme across studies. It was plain from multiple studies that patients value a strong therapeutic and personal relationship with a consistent healthcare professional<sup>64-66, 68, 70-72, 78, 80, 82, 83</sup>. Studies described a good relationship with a healthcare professional to be one of trust and confidence, in which the patient feels listened to and respected, informed about treatment, and able to ask questions<sup>64, 65, 68, 70-72, 80, 82, 83</sup>.

Studies, mainly of people with leg ulcers, suggested that by forming a trusting and collaborative relationship with the patient, in which the patient feels that they have some control over treatment, the healthcare professional is able to instil hope for the future in the patient, and also a feeling of increased control over their own lives<sup>67, 68, 72, 76, 82, 83</sup>. One study highlights that the patients spoke highly of their nurses and maintained faith in their abilities in spite of the 'the failure to heal their ulcers'<sup>65</sup>, suggesting that the positive impact of the relationship may be achieved even in the absence of healing.

### Subtheme 6.3 Negative aspects of interacting with healthcare professionals

*'The word "they" was used to refer to staff who changed the dressings in a perfunctory manner: "There are many who have come and gone during all these the years of treatment. You could say they didn't show the same consideration... You get the feeling that they do not know what they are doing...It's just a matter of routine for them. They change the bandage, and then you can go home.'*[Ebbeskog et al, p.1226<sup>68</sup>]

A common criticism of healthcare professionals was their failure to empathise with the patient's condition, and to truly attempt to understand it from their perspective<sup>64, 67, 68, 70, 71, 73, 74, 76, 79-82</sup>. This lack of empathy was perceived by patients in many different ways, including the failure of some healthcare professionals to communicate with them about the wound, or to acknowledge their pain level and the discomfort and lifestyle implications caused by some treatments<sup>64, 67, 68, 72, 76, 77, 80, 81</sup>. Two studies of people with pressure ulcers even described some patients' perception that they were not respected by healthcare professionals<sup>70, 76</sup>.

Studies also mentioned patients concerns about healthcare professionals level of competence and knowledge of wound care<sup>64, 67, 68, 70, 71, 73, 77</sup>. Conflicting advice and treatment from healthcare professionals and the perception that they did not spend sufficient time or attention on the care of their wound contributed to these concerns<sup>64, 67, 68, 70, 71, 73, 77, 81</sup>. The perception of healthcare professional competence was also linked to being identified as 'rough handed'<sup>64</sup>, patients reporting some healthcare professionals taking insufficient care during treatment, resulting in increased pain and even injury<sup>64, 68, 70, 71, 74, 77</sup>. Two leg ulcer studies discussed patients' preference for care from specialist services (for example wound clinics or district nurses) because they did not believe that the healthcare professionals in primary care had the required skills to effectively dress and treat their wound<sup>68, 77</sup>.

A lack of staff continuity or the use of agency staff was identified as a difficulty for patients by some studies<sup>65, 70, 72, 83</sup>. The preference for continuity of care was due to feeling uncomfortable raising concerns with unknown healthcare professionals, inconsistencies in care, and a lack of information and insight into wound progression<sup>65, 70, 72, 83</sup>.

Some studies reported patients feeling disempowered in their relationship with healthcare professionals<sup>68, 70, 71, 74, 76</sup>. This was related to a lack of involvement in decision-making about treatment and loss of independence<sup>74, 76</sup>. A small number of studies reported patients' fears of the consequences of questioning healthcare professionals, or non-compliance with treatment<sup>65, 83</sup>, leading them to 'put up' with things that they did not agree with or which caused pain<sup>70, 71</sup>. The studies of people with diabetic foot ulcers did not discuss patients' experiences of disempowerment.

## Theme 7: Coping

### Subtheme 7.1 Acceptance and hope of healing

*'All of the participants revealed various ways of coping with leg ulceration. The main feature was that of pure acceptance of their situation, using such phrases as "the way it is" and "you get used to it".'* [Hopkins et al, p.558<sup>72</sup>]

A coping strategy mentioned by multiple studies is that of acceptance of the long-term nature of their difficulties<sup>64, 66, 67, 70, 72, 73, 82</sup>. Some studies link patients' acceptance of their situation with a fatalistic stance on healing, while others discuss the difficulty of separating acceptance as a coping strategy from the patient having 'given up' on healing<sup>66, 73, 79, 80, 82</sup>. The patients who had accepted the chronic nature of their wound or/and underlying health conditions appeared to be more satisfied with their life and were able to focus on improving their lifestyle within these limitations<sup>66, 72-74, 76, 77, 82</sup>.

One study of people with leg ulcers suggests that healthcare professionals should help patients to acknowledge the uncertainty inherent in living with a condition in which recurrence is a possibility, even if healing is achieved, or they risk delaying the patients' acceptance of lifestyle accommodations that may allow them to lead a more fulfilling life<sup>66</sup>. However, many studies also acknowledge that hope of healing is important, and is generally retained, even in patients who have experienced multiple recurrences and believe that full healing is unlikely<sup>67, 71, 72, 74, 79, 80, 83</sup>. Two studies emphasised that acceptance of their situation, and even a 'cheerful' appearance, does not indicate that the patient does not desire complete healing, just that they are finding ways to accept and cope with the persistence of the chronic wound<sup>65, 82</sup>.

*'Despite these serious limitations, others fought to maintain their functioning; attempting to engage as they had before their current episode of ulceration and a theme of hope, especially for healing, was evident for all.'* [Green et al, p.65<sup>83</sup>]

Some studies suggested that patients only adhered to treatments that they believed would heal the wound. This means that adherence may well tail off if

treatments prove ineffective for long periods of time<sup>70, 71, 79</sup>. A positive relationship with healthcare professionals, in which the patient feels cared for and is kept well informed about the progression of the wound, can inspire the required hope of healing and therefore may help to maintain adherence<sup>67, 68, 72, 82</sup>.

### Subtheme 7.2 Staying positive and minimisation of illness

*'Most informants tried to be positive about the experience, often negating the symptoms as "not bad at all", or describing themselves as lucky "Oh, sort of on and on, it's one of those horrible pains, that keeps on, especially at night sometimes I am very lucky at the moment because I am not so bad".'* [Walshe, p.1098<sup>82</sup>]

Studies highlighted patients' need to stay positive in their outlook. Giving into negative thinking was considered counter-productive and would prevent them from 'carrying on'<sup>72</sup> or gaining maximum control and functioning in their lives<sup>67</sup> in spite of their health difficulties<sup>64, 67, 70, 72, 75, 76, 83</sup>. It appears that pain may present the biggest obstacle to maintaining a positive attitude<sup>64, 82</sup>. Maintaining any activities that are still possible from before the onset of the chronic wound and taking up new activities that are possible within its restrictions enables the patient to stay active and feel more in control of life, having a positive effect on mood and functioning<sup>64, 66, 67, 70, 72, 75, 76, 79, 83</sup>.

Studies of people with leg or pressure ulcers mentioned patients' uses of comparison with other people whom they considered worse off than themselves, or times when they had been more ill, which helped them to stay positive about their own condition<sup>65, 70, 72, 73, 76, 82</sup>. However, some studies acknowledged that while staying positive was adaptive, some patients were minimising the impact of the chronic wound in order to make their genuine concerns 'more tolerable'<sup>72</sup> or to 'put on a brave face'<sup>65</sup> for others<sup>73, 76, 78, 83</sup>. The studies of people with pressure ulcers in particular mentioned both patients' tendency to downplay the enormity of the impact or seriousness of the wound<sup>73, 76, 81</sup> and even to deny 'that the pressure ulcer was a part of them'<sup>70</sup> at all.

### Subtheme 7.3 Care from family and friends

*"Sam' was also distressed by his limited mobility. He had severe pain in his right foot when he walked and was supposed to be on bedrest with his foot elevated. His wife Judy said: "He went from being a tractor trailer driver and (having) a grass-cutting business to not being able to do anything. He's always been very active, and it's frustrating now. He hasn't been able to do anything but lay around. He has to stay completely off his feet. We haven't been able to do anything not even go to dinner."* [Neil et al, p.34<sup>79</sup>]

This synthesis did not seek out studies on carers of people with a chronic wound and below reflects only the views of the patients themselves, and a small number of carers whose views were collected unplanned in the primary studies.

For the patients, carers can be instrumental in coping with the wound by providing practical and emotional support<sup>64, 70, 73, 80, 81</sup>. The restrictions on the patient caused by symptoms such as pain and impaired mobility also restrict the activities and psychological functioning of the patient's family/carers, potentially having a profound effect on their lives<sup>66, 67, 69, 70, 73, 76, 79</sup>. This can leave the patient feeling guilty and they may view themselves as a burden on their family and friends<sup>64, 66, 73, 80, 81</sup>.

It was not unusual for carers to have a role in changing the dressings of a family member<sup>64, 69, 70</sup>, which some found stressful<sup>69, 70</sup>. Their role in applying dressings leads to the family being less dependent on healthcare professional input, freeing up a considerable amount of time spent waiting for input from healthcare professionals<sup>70</sup>. Carers can become experts in changing dressings and this can lead them to become critical of healthcare professional's methods<sup>70</sup>. In one leg ulcer study, all carers mentioned finding the conflicting advice given by different healthcare professionals frustrating<sup>67</sup>. It also suggested that carers did not feel listened to or understood by healthcare professionals. They longed for support and recognition from healthcare professionals, and felt these needs were not being met<sup>67</sup>.

### 7.3.2 Primary qualitative research

#### 7.3.2.1 *Participants*

The focus group consisted of eight participants, seven of whom had experiences of chronic wounds, and one who was a relative of someone with a chronic wound. There were seven women and one man. A wide range of age groups were represented (mid-thirties up to mid-seventies). The wound types that the focus group participants had or could relate to were: foot ulcers associated with diabetes, venous leg ulcers, pressure ulcers, dehisced surgical wounds, and unspecified chronic wounds. The AWDs that the participants talked about were honey, iodine, silver and Flaminal<sup>®</sup> (described by manufacturer as an 'enzyme alginogel') dressings.

Six people took part in telephone interviews. There were three males and three females, aged from mid-fifties to mid-seventies. The wound types that the telephone participants had were: foot ulcers associated with diabetes, pressure ulcers, leg ulcers and unspecified chronic wounds. Collectively, the telephone participants had experiences of honey, iodine and silver dressings.

To protect the identities of the participants, they are each represented in the text using a number (P1-P14). The letters 'FG' mean that they were focus group participants, and 'TI' means that they were telephone interview participants. A table of participant characteristics has not been included because of concerns around some people being identifiable.

#### 7.3.2.2 *The thematic framework*

A new thematic framework was generated from the primary qualitative research. Some of the themes and subthemes overlapped with the qualitative synthesis.

**Table 6: Primary qualitative research: themes and subthemes**

<b>Theme</b>	<b>Subtheme</b>
<b>Theme A: Living with a chronic wound</b>	A.1 Extensive and ongoing
	A.2 Pain, odour, exudate and other physical features
	A.3 Emotional impact
	A.4 Impaired mobility and restrictions on lifestyle
	A.5 Support from family and friends
<b>Theme B: The patient and the healthcare system</b>	B.1 Positive aspects of interacting with healthcare professionals
	B.2 Negative aspects of interacting with healthcare professionals
	B.3 A false economy
<b>Theme C: Knowledge and understanding of AWDs</b>	C.1 Understanding the purpose of AWDs
	C.2 Awareness and knowledge of AWDs, dressings and wounds
	C.3 Becoming experts in AWDs and wound care
<b>Theme D: Perception of AWDs</b>	D.1 Wounds healing, or healing more quickly
	D.2 Improvement in wound's physical features or symptoms
	D.3 Length of time for AWDs to work
	D.4 Side-effects
	D.5 Impact of AWDs on people's lives
<b>Theme E: What people who have chronic wounds want</b>	E.1 Healing, control of symptoms and prevention of wound deterioration
	E.2 Wound to be dressed
	E.3 To try anything
<b>Theme F: How AWDs are used</b>	F.1 Length of use
	F.2 Frequency of dressing changes
	F.3 One size does not fit all

### 7.3.2.3 Themes

#### Theme A: Living with a chronic wound

While all the questions we asked related specifically to people's experiences and perceptions of AWDs, the challenges associated with living with a chronic wound emerged in the discussions. The impact on the participants' lives was considerable. As well as dealing with the inconvenience and physical aspects (like pain and limited mobility), several people talked about struggling emotionally. The subthemes below largely mirror those that were identified in the qualitative literature synthesis.

## Subtheme A.1 Extensive and ongoing

*“...both feet at one time were really, really bad, away at the very beginning, talking about ten years ago now, eleven maybe...” (FG, P7)*

Most of the people talked about having underlying health conditions, which put them at greater risk of ulceration. Their conditions also meant that their ulcers/wounds were harder to heal, prone to deteriorating, and were more likely to recur. Some people had multiple and extensive ulcerations.

The study was limited to people with chronic wounds, so all participants had lived with wounds for a long time. For some people, their ulcers/wounds would heal relatively quickly (a couple of months). However, for most participants, healing took several months, sometimes years, or healing had not yet been achieved.

Participants commonly talked about their wounds reaching a ‘standstill’ or a ‘plateau’. They said that their ulcers/wounds would reach a point where they would not get better, or get worse; they would just stay the same. This was a source of frustration, especially if they had previously appeared to be progressing well. The need for ‘perseverance’ was mentioned.

Some participants said that their wounds would start as relatively minor bumps or scrapes, which would rapidly deteriorate and get out of hand. Some also expressed their disappointment when there were set-backs in their wound’s progress; people described ulcers/wounds that appeared to be getting better and reaching the point of healing, which suddenly got worse again, or got infected. This might happen several times, repeatedly dashing people’s hopes for healing.

## Subtheme A.2 Pain, odour, exudate and other physical features

*“You think ‘everybody can smell me.... I used to dread my visitors, and any visitors that was coming up, at first your ‘can he smell anything?’ But all he can smell is perfume at the door, because I was like that [mimics squirting a perfume bottle], you know, everywhere!” (FG, P1)*

Some people talked about their wounds quite generally, describing them as ‘disgusting’ or ‘yucky’. However, more commonly, people discussed specific symptoms that they had to deal with. The wound symptoms that participants discussed the most were pain, odour and exudate.

The pain that participants had to deal with was often considerable, impacting on their general quality of life and wellbeing. The consequences of the pain included limited mobility, feelings of isolation and loss of appetite.

While malodour was not reported by everyone, participants often talked about the odour that came from their ulcers/wounds. They were repulsed by the smell, and described it as overpowering and embarrassing. This embarrassment can be isolating for people, who talked about avoiding or dreading social contact.

Some people described their wounds as being very 'wet', or said that they leaked badly. People talked about changing their bedding daily, getting rubber sheets for their bed, and ruining carpets in their house.

#### Subtheme A.3 Emotional impact

*"Well, when I went to the podiatrist and I had been told, 'well, it's kinda worse', I used to go out on a right downer. Because it had been doing so well, and then, 'poof!' and you think, you know, 'what else, what else?' Because it doesn't take much to put you over the edge, emotionally."* (FG, P2)

People who had extensive ulcerations, or had lived with ulcers/wounds for a number of years, spoke about the impact on their mental wellbeing. People talked about feeling down, or 'down in the dumps', when their wounds were particularly bad, or when they had taken a turn for the worse. Some people described feeling emotionally vulnerable, on a 'cliff edge', with any small setback sending them 'over the edge'.

Some people had faced the prospect of having an amputation. Most did not actually go on to have an amputation, but even the prospect was difficult to deal with, was sometimes unexpected, and came as a 'terrible shock'.

Less commonly experienced was a feeling of having 'had enough' of trying different treatments to no avail, and an acceptance of amputation as a last resort.

#### Subtheme A.4 Impaired mobility and restrictions on lifestyle

- *"It's terrible, you can't even get up and walk.*
- *I walked in the door today to come down here, that's the most I've walked in about a year.*
- *That's the most I've walked in a long time, too."* (FG, P2, P5 & P7)

Some people described being unable to go out, mostly because of physical limitations, but also because of feeling emotionally unable.

For the people who spoke of having limited mobility, this could be attributed to the pain in their ulcers/wounds, or to their co-morbidities. Limited mobility for some was also caused by having to wear bulky, foam podiatry boots, not being able to wear shoes, or having to keep weight off pressure ulcers.

Participants described feeling annoyed by their limited mobility, their diminished ability to care for themselves, and their reliance on others for support with daily living. For some people of pre-retirement age, their restricted mobility prevented them from working. People also said that not being able to exercise had caused them to gain weight, or to lose muscle and body strength.

#### Subtheme A.5 Support from family and friends

*"But then I've always thought, 'what happens if I'm single?' You know, 'what if I'm..."* (FG, P3)

Several of the participants relied on support from family members (children, partners or siblings). This included emotional support, help with dressing changes, assistance with day to day living, and assistance during hospitalisations. Some people implied that without this additional support, they might not have been able to cope.

## Theme B: The patient and the healthcare system

The participants talked about positive and negative elements of their care. While several had some negative experiences, most people referred to healthcare professionals who they had clearly developed a good relationship with, who they trusted and who they felt went the extra mile for them. There was a general feeling at the focus group that clinicians who were not providing AWDs were purely motivated by costs, that this was short-sighted, and that there was a need to 'speak up for yourself'.

### Subtheme B.1 Positive aspects of interacting with healthcare professionals

*"But I cannae fault the nurses. The nurses have been brilliant. They have been great." (T1, P13)*

People discussed positive elements of their care, with several referring to named healthcare professionals. People valued healthcare professionals whom they trusted, who used their initiative, who challenged budgets, or who they felt did not 'give up' on them.

Some people had clearly developed good relationships with their treating healthcare professionals, saying they had 'known them for years', and talked about having 'banter' and 'a good bit of fun'. This helped to foster good working relationships, and appeared to make people feel supported and like they were getting 'personal' treatment.

The importance of good chiropody was mentioned by one participant, who said that something as small as cutting a toenail properly could give people a 'new lease of life'. This implies that the value of seemingly quite simple treatments should not be underestimated.

### Subtheme B.2 Negative aspects of interacting with healthcare professionals

*"And they were saying 'We shouldn't be giving you that'. It should be just initial and you'll get the dressings from your GP but you know the girls are there to help us out so they would just give us what we need to go away ...you know, they shouldn't...they said they shouldn't be giving out dressings on a long-term basis like that." (FG, P3)*

The main problem that participants reported related to inconsistent care in relation to the provision of AWDs. Some of the people who we spoke with had experienced inconsistent access to AWDs. Examples were given of how people had been treated with AWDs in one care setting (for example, in hospital), but were then unable to get the same AWDs in another care setting (for example,

from GPs). As a consequence, they 'stocked up' on AWDs, given to them by clinicians who used them. This inconsistency was frustrating and inconvenient, and appeared to be an additional burden to people. Participants clearly valued the healthcare professionals who provided them with stocks that would enable them to continue using their preferred AWD.

Other negative aspects of healthcare related to treatment becoming less personal, with some participants saying they felt like a 'number', or they saw different healthcare professionals on every visit. Communication with healthcare professionals was not always satisfactory. For example, a participant described having a wound assessed by plastic surgeons, but not being made aware of who they were. This person had been left theorising unnecessarily about what was happening, and worrying that they were facing an amputation.

Someone also described how their access to a tissue viability nurse had been delayed due to a 'breakdown in communication' amongst healthcare professionals.

While not discussed at length, everyone at the focus group agreed that there was a need not to just accept any treatment, but to challenge restricted access to preferred treatments.

#### Subtheme B.3 A false economy

*"If someone said to me 'this is the cheapest product [name] and you'll be healed in six months, or this is a dear product [name] and you'll be healed in six weeks'. I know what one I'll take. And I think that's for a, for a healthier Scotland, I think that's the direction they should be looking at. Spending money looking, you know, upfront to save money in the long term."* (FG, P6)

The focus group participants felt that restricted access to AWDs was purely due to the cost. This was viewed as a 'false economy'. They felt that AWDs helped to heal wounds faster, were better than non-AWDs, and that this was not being considered in decisions around provision. They argued that, by not using AWDs, the costs would be greater in the long run due to increased staff time and amputations.

#### Theme C: Knowledge and understanding of AWDs

Most participants were aware when an AWD was used on their wounds, and knew that the purpose was to treat localised infection. Knowledge of AWDs was surprisingly high, suggesting good communication from healthcare professionals. People were aware of brand names, understood how the dressings should be used, and several had developed expertise in dressing their own, or their relative's, wounds.

### Subtheme C.1 Understanding the purpose of AWDs

Understanding about the role of AWDs in treating infection in a wound was high. Some patients appeared to have detailed knowledge about dressings in general, talking about them reducing 'slough' and promoting 'granulation'. Despite this, there were varying levels of knowledge, and some patients may have no understanding of the purpose of AWDs.

### Subtheme C.2 Awareness and knowledge of AWDs, dressings and wounds

People's knowledge around dressings, and wound care more generally, was good. Some people indicated that they did not know very much, but would then go on to talk in detail about the treatment they had received.

Most participants were aware that they had been treated with an AWD. They were able to tell us what different types of AWD they had been treated with, for how long, and the ones they preferred. Most people even referred to specific brand names. People also seemed to have a good understanding of how the AWDs were used, and could describe in detail what happened at their dressing changes.

Some participants also seemed to have a good understanding of how factors other than dressings impact on wound healing. For example, people talked about keeping weight off pressure ulcers, compression bandaging for venous leg ulcers, and how important it was to remain in 'good diabetic control'.

Despite all this, it is apparent from our discussions with the participants that sometimes people are treated with an AWD and are not aware that it is an AWD being used.

### Subtheme C.3 Becoming experts in AWDs and wound care

*"and I had to actually go up and dressed it. And then the nurse says, 'could you show how you are doing that dressing?'"(FG, P8)*

The participants who had extensive wounds, or had lived with wounds/ulcerations for a long time, had become experts themselves in wound care. Several participants also spoke about how they relied on family members (partners, children or siblings), who had developed expertise in how to look after the wounds, and use the dressings. This expertise was sometimes shared with healthcare professionals who had not cared for the participants previously.

There was variation in how much information participants sought on dressings. Some talked about going home to 'Google' them, to read more about the research behind the dressings. Others were satisfied with the level of detail that they got from their healthcare professionals.

## Theme D: Perception of AWDs

People were generally positive about AWDs. Most felt that they had helped to heal their wounds, or to heal their wounds faster, although this was not universal. Several also talked about AWDs improving wound symptoms, with some saying that the effects were notable very quickly. Some people said that AWDs had allowed them to get their life back, or had meant that they had avoided a far worse prospect (for example, amputation).

### Subtheme D.1 Wounds healing, or healing more quickly

*“And I think it helps a good bit. It has healed me.” (FG, P1)*

*“Well, I’ve not really had enough experience of them so far so I don’t really know whether it’s going to make a difference” (FG, P4)*

*“I hoped it, it hoped the ulcer would get smaller, you know. And heal. But nothing happened. No matter what they did, nothing happened.” (TI, P13)*

The majority of participants felt AWDs had helped (or were helping) to heal their wounds. For some, the effects of the AWD appeared considerable. The improvement in wounds was described as ‘unbelievable’. However, this was not universal, and for some there was uncertainty of the helpfulness of AWDs in wound healing, or a perception that they had made no difference.

There was no one AWD that stood out as being a favourite. Some people attributed their wounds healing to honey, others to silver, or to iodine or ‘flagogel’ (likely to mean ‘Flaminal<sup>®</sup>’). Several participants had been treated with more than one AWD. It was apparent that a trial and error approach had been used in these people, with several dressings (including AWDs) failing to make a difference. Eventually, an AWD was tried that helped their wound/ulcer. As a result, these participants tended to credit one particular AWD for marking the turning point in their wounds progress.

For some people, their wound/ulcer healed relatively quickly (in a few months), others took longer. For people who had recurring ulcers, there was a perception that AWDs healed their wounds faster than non-AWDs that had been tried previously.

### Subtheme D.2 Improvement in wound’s physical features or symptoms

*“And it’s the first year I haven’t been in hospital with an infection which is a big thing for me because sometimes it can be two and three times a year.” (FG, P7)*

Other improvements in ulcers/wounds, besides healing, were attributed to AWDs. The improvements most frequently mentioned related to pain, odour and control of infection. These were important outcomes to the participants.

Several participants told us that the AWDs had helped with the pain they felt in their wounds, or with the odour. Even in participants whose wounds/ulcers had not yet healed, and where the likelihood of healing was uncertain, there was a

feeling that AWDs helped to control odour, or more extensive infections (that might have required hospitalisation or antibiotic treatment).

Most people talked generally about their wounds improving with AWDs. They talked about wounds appearing healthier, an improvement in slough, and seeing the edges of the skin trying to come in.

#### Subtheme D.3 Length of time for AWDs to work

*“...at first I was thinking ‘mmm is there going to be much improvement here’ but in four weeks eh I started to see improvement. I wouldn’t say it worked straight away but I did see an improvement in the last month. I would say I was on it two months, uh huh. I must admit I do see an improvement.” (T1, P11)*

*“Really and it was horrible. And then started with honey and then it was, maybe a few weeks, that’s when we’ve started seeing it and now it’s, like, totally levelled.” (FG, P8)*

A number of the participants perceived an improvement in their (or their relative’s) ulcer/wound quite quickly after starting treatment with an AWD. As already stated, they implied that wounds ‘turned a corner’ with a particular AWD. Some people said they noticed improvement in symptoms (like odour) ‘the minute’ an AWD was applied. For others, it took a few weeks, or months, before improvements were seen.

In some people, AWDs had been used for a long time, and there were reports of wounds deteriorating when AWDs were stopped.

#### Subtheme D.4 Side-effects

- *“I do. It’s got a drawing effect I must say. But I find that good cause I know it’s doing something.*
- *Yeah, it’s a throbbing so you know it’s working.*
- *It’s taking something away.*
- *Yeah, mmm, it’s like a drawing effect.” (FG, P1, P3 & P6)*

Participants initially reported that they had not experienced any side-effects with AWDs. With prompting from the researcher, there were reports of honey causing a ‘throbbing’, ‘drawing’, ‘nipping’ or ‘stinging’. The pain was enough for some people to take over-the-counter painkillers. Honey dressings also leak for some people. However, the leakage and pain did not put participants off using honey. In fact, some perceived the pain as a sign that the honey was doing something beneficial.

For some, dressing changes can be painful, particularly if a dressing has dried onto a wound. For others, dressing changes do not cause considerable discomfort. Unsurprisingly, people with less extensive wounds reported less pain at changes.

## Subtheme D.5 Impact of AWDs on people's lives

*"...and to me I think if I never got the treatment, this kind of treatment, I don't know what kind of wound I would..." (FG, P1)*

Most participants were positive about AWDs. Even in people whose wounds had not healed, they felt that AWDs had helped with their wound symptoms.

Some people implied that the impact of AWDs on their lives had been considerable. They said that AWDs allowed them to get 'back on their feet again' or back to their 'day to day' business. Some people also felt that AWDs had meant that they had to attend fewer clinical appointments, or had avoided hospitalisation. Finally, some said that thanks to AWDs, they had avoided a far worse situation, including amputation.

## Theme E: What people who have chronic wounds want

Participants were asked specifically what they wanted from treatment. For people with chronic wounds, the thing they want the most is for the wound to heal. Control of symptoms, and not allowing wounds to deteriorate, were also important. This mirrors what was highlighted as important to patients under Theme D, and so Subtheme E.1 has not been discussed at length. Some people said they were prepared to try anything to achieve these outcomes.

### Subtheme E.1 Healing, control of symptoms, and prevention of wound deterioration

Wound healing was important to the participants, regardless of whether they had their wounds for a few months or several years. People also said, more specifically, that they valued anything that would heal their wound faster.

Control of symptoms (like pain and odour), and wounds not being allowed to deteriorate, were also highlighted as important to patients.

### Subtheme E.2 Wound to be dressed

Leaving wounds undressed, even for relatively short periods of time, may cause distress for people with extensive ulcers/wounds. This can lead to feelings of anxiety, and a perception of being more vulnerable to infection.

### Subtheme E.3 To try anything

*"And to be perfectly frank, having endured this thing since May last year, if the guy said, 'you know, we are going to bring in a parrot, it will bite off the scabs', I would endure that as well. If it had to be." (TI, P12)*

Some of the participants reported wanting to 'try anything' or feel that 'anything is worth a shot'. Even if AWDs had not worked, some people were glad they had tried them, and felt that to try different things was people's 'right'. Innovative products, which have just come from 'the factory floor', were viewed favourably by some.

Amputation was viewed as a last resort, with people wanting to be sure that they had tried everything else before taking that path.

#### Theme F: How AWDs are used

Most of the participants said that AWDs had been used for a long time on their wounds, but it was not always clear if this use was only limited to times when the wound was infected. Wound dressings needed to be changed several times a week. There was no one favourite AWD, and what worked for one person may not work for another.

##### Subtheme F.1 Length of use

Some people implied that they had been treated with AWDs for quite a long time (several months in most cases, years in a few cases). However, it was not always clear if this use was consistent, or if the healthcare providers were switching between AWDs and non-AWDs. Some people specifically said that they had been treated with AWDs on and off for several months or years, with AWDs only being used if their wound was showing signs and symptoms of infection.

In other people, AWDs had only been used for a short time (weeks). These people had less extensive ulcerations.

##### Subtheme F.2 Frequency of dressing changes

All participants had required (or still required) fairly frequent dressing changes. This varied from once a week, to every second day. As people's wounds progressed towards healing, the dressing changes became less frequent.

##### Subtheme F.3 One size does not fit all

- *"But everybody's different.*
- *Aye. oh aye, we're all different*
- *It's not like one size fits all. It doesn't."* (FG, P2 and P6)

As mentioned previously, it was apparent from speaking with all the participants that the AWD that worked for one person, did not work for another. Participants themselves were aware that it is not a 'one size fits all' situation.

## 7.4 Discussion

We identified seven major themes associated with the patient experience of chronic wounds and wound dressings from the synthesis of qualitative studies: physical impact; psychological impact; restrictions to lifestyle; dressings; the chronic wound journey; the patient and the healthcare system; and coping.

The synthesis included different wound types. In order of the prevalence of identified studies, they were: leg ulcers, pressure ulcers and diabetic foot ulcers. It was notable that the patient experience was often similar across the three wound types. However, patients with a pressure ulcer did differ to those with the

other two wound types and differences have been highlighted where identified. Due to the small number of studies identified on people with diabetic foot ulcers, it is uncertain to what extent their experiences differ from the other two groups.

The results of this synthesis are consistent with the results of previous reviews of QOL and qualitative research in leg ulcer patients<sup>85-87</sup>, which strengthens its validity. It has also added to previous work by including studies on other chronic wound types, and specifically extracting findings on wound dressings.

The primary research highlighted six major themes associated with the patient experience of chronic wounds, and AWDs more specifically: living with a chronic wound; the patient and the healthcare system; knowledge and understanding on AWDs; perception of AWDs; what people who have chronic wounds want; and how AWDs are used.

With regards to people's experiences of chronic wounds, this research mirrors the results of the qualitative synthesis. Accounts of the physical and emotional impact, and the reliance on family members, were corroborated. This research also adds to existing knowledge by describing people's experiences and perceptions of AWDs specifically.

#### 7.4.1 Limitations

##### 7.4.1.1 *Synthesis of qualitative research*

The literature search failed to identify any qualitative research focused on AWDs, and only a limited number of studies focused on wound dressings. The synthesis is also reliant on what researchers chose to report from within their primary data and it is therefore possible that information that was available on dressings and AWDs was not reported in the primary studies included. These limitations necessitated conducting our own primary research.

The scope of the synthesis was wide, in terms of including studies of multiple chronic wound types and exploring the patient burden of having a chronic wound, and was therefore focused on the commonality between the different wound types. The primary studies identified were overwhelmingly skewed towards leg ulcer patients, while all studies of other eligible wound types were included, the findings may therefore reflect leg ulcer patients' experiences more extensively than diabetic foot ulcer or pressure ulcer patients.

The extent to which findings from qualitative research can be transferred to different contexts and cultures is debatable<sup>62, 88</sup>, therefore it should not be assumed that all findings from this synthesis will apply across different socio-cultural settings. However, the authors of the framework method of synthesis suggest that findings from qualitative research and synthesis can have a degree of transferability given that due attention is paid to the validity and reliability of the research or synthesis process<sup>62</sup>. The growing use of qualitative synthesis in HTA and health services research suggests that acceptance of the transferability of rigorously conducted qualitative research may be increasing<sup>89, 90</sup>.

It is difficult to set clear boundaries around themes because of the strong inter-relationship between them. To avoid repetition, subthemes have been placed within the theme that they appeared to be most strongly associated, but aspects of these themes could appear in others.

#### *7.4.1.2 Primary qualitative research*

The aim of the primary research was to gain insight into people's experiences and perceptions of AWDs. Given that the sample was small, from one NHS board and non-randomised, it is not appropriate to make any quantitative or comparative statements. While a variety of people (in terms of gender, age, wound types and AWDs) were successfully included in the research, such a small study is not expected or able to represent the entire spectrum of the potential patient population. In addition, the people who volunteered to take part in the research might differ from people who did not.

A practising tissue viability nurse recruited participants to the study. It is possible that if she had strong feelings in favour of AWDs, this could have influenced her selection of people to the study. However, it was apparent that care was taken to recruit an unbiased sample; while most participants had positive experiences of AWDs, a spectrum of views were represented. Some people talked about particular AWDs that had not worked for them, but spoke passionately about another AWD that had. Some people had extensive experience of several AWDs, others had limited experience of one. Participants also freely discussed positive and negative elements of their care more generally.

Participants appeared to be engaged in the focus group discussion. Everyone contributed, and prompts and questions from the researchers were kept to a minimum. Contributions were often responses to other participants' comments, rather than responses to research questions. On the other hand, sometimes the conversations in the telephone interviews did not flow as well. It was difficult to establish a rapport with someone without the face-to-face element. Telephone interviewees tended to give shorter answers, and required more prompting. Despite this, all participants provided meaningful and useful input, and all expressed an interest in the work.

Both the researchers who facilitated the focus group agreed that the participants appeared to have suspicions about AWDs being made unavailable through NHS services. When asked specifically at the end of the discussion if they had heard rumours to that effect, they said they had not. Given some participants' experiences of inconsistent access to AWDs, and their perception that it was due to costs, it was possible that they have become concerned about their ongoing provision.

## 7.5 Conclusions

### *Living with a chronic wound*

- The impact of chronic wounds on people's lives is considerable. The persistence, recurrence and symptoms of a chronic wound can have severe physical, psychological and social consequences.
- Patients report that the extent and impact of pain from chronic wounds can be considerable. Reports of pain are not always acknowledged by healthcare professionals, and it seemed that pain frequently remains uncontrolled.
- Support from family and friends can be very helpful in coping with lifestyle restrictions, and in wound care generally. However, patients may feel that they are a burden on their family members.

### *Dressings*

- People's knowledge around dressings, and wound care more generally, was good.
- There is often a 'trial and error' approach to dressing selection, and this process can continue until the wound begins to heal. People may then credit a particular dressing type with healing their wound.
- The synthesis suggested that patients want dressings that minimise the impact of pain, odour and exudate on their lives, while also helping with wound healing. Similarly, the primary research suggested that wound healing was usually the most important outcome to patients, but control of symptoms, and prevention of infection and wound deterioration were also important. People in the primary research reported wanting to 'try anything' to achieve these outcomes.
- Patients want wound healing. However, the restrictions of treatment can cause a tension between healing the wound and maximising wellbeing within its restrictions.
- Dressing changes can be time consuming and painful. Patients can be fearful of infection during dressing changes, or if wounds are left undressed.
- People who took part in the primary research were generally positive about AWDs. People felt that they helped (or were helping) to heal their wound, and/or they helped with wound symptoms. There was no one favourite AWD, and what worked for one person may not work for another.
- Some people said honey dressings caused throbbing and pain, and they felt that this showed the honey was working. There may be a need to challenge the perception among some patients that pain means that something works.

### *The patient and the healthcare system*

- Holistic and empathetic, patient-focused care is very important for these patients' wellbeing and satisfaction. People value care that they feel is personal, and from healthcare professionals who they trust and who are persistent with their wounds, even when wound healing is slow.

- The primary research indicated inconsistent access to AWDs across healthcare settings. This led to frustration and inconvenience for people with a chronic wound as they had to source access to their preferred AWD, often from a particular healthcare professional. This inconsistency can make people feel that the best treatments are being withheld from them because of costs.

## **8 Organisational issues**

### **8.1 Introduction**

This section is concerned with exploring how services relating to AWDs are organised and delivered, the role of staff within services, infrastructure issues, costs and budget implications.

The research was guided by the following sub-questions:

1. In what clinical settings are AWDs being used for chronic wounds? Who decides which patients should be treated with an AWD?
2. How are decisions currently being made by healthcare professionals about which dressings to use? What decision aids are there, and are they being used?
3. What volume and types of AWDs are used in NHSScotland at national and NHS board level?
4. Are AWDs being purchased nationally or locally, and is there any overlap?
5. What kind of staff training is currently given, and by whom?
6. How confident do healthcare professionals feel about their decision-making around prescribing AWDs?

### **8.2 Methods**

A variety of methods were used to answer these questions, including a review of the literature, a survey of NHSScotland staff, a NHS board level survey, and a review of costing data from ISD Scotland and NHS National Procurement.

#### **8.2.1 Review of the literature**

In July 2014, a search was undertaken to identify studies that would help answer the questions listed above. The following databases were searched:

- MEDLINE (Ovid)
- MEDLINE in process (Ovid)
- EMBASE (Ovid)
- CINAHL (EBSCOHost)
- PsycInfo (EBSCOHost)

The search used the concepts of 'chronic wounds' and 'dressings'. Search terms were not limited to antimicrobial dressings to enable the identification of the maximum number of relevant papers. Given the nature of the research questions, the search was not limited to a particular study type. The searches

were limited to 1990–2014 and English language papers only were included. Search strategies are available in the supplementary material.

From the search results, papers were selected based on title and abstract if: the study sample included staff who treated adult patients with a chronic wound; they included staff views or a staff perspective on treatment; they provided information on care pathways; they covered service delivery issues; or other issues relating to the management of chronic wounds. Studies were excluded if the full paper was a commentary, editorial, letter, conference abstract, non-systematic literature review, primarily discussed methodology, a dissertation or annotated bibliography.

### 8.2.2 A staff survey

A questionnaire was distributed throughout NHSScotland, targeting staff who use or may use AWDs. The survey was piloted within the research team, and with some clinical experts identified by the topic group. The questionnaire was designed in Survey Monkey (<https://www.surveymonkey.com/>), and was open for responses from 2 December 2014 until 5 January 2015. For a complete description of how the survey was distributed, please refer to the supplementary material.

### 8.2.3 An NHS board level survey

A questionnaire was developed for distribution to NHS boards, with input from members of the Healthcare Improvement Scotland research team and the HTA topic group. The questionnaires were distributed in mid-December 2014 to NHS board formulary pharmacists in mainland boards (a contact was not identified for island boards). Reminders were sent before the deadline for response in January 2015, and again after the deadline passed. Only seven NHS boards provided a response. The respondents were given the opportunity to check a draft write-up of the results.

### 8.2.4 Spend on AWDs in community and acute settings

There are numerous ways in which AWDs are purchased within NHSScotland. Some are purchased through national contracts awarded by NHS National Procurement. Data on community spend on silver dressings and acute spend on all AWDs were obtained from NHS National Procurement. Data on all other non-silver community spend were obtained from ISD Scotland.

### 8.2.5 Case studies

Two case studies were identified. The first relates to the reduced use of silver dressings in NHS Lothian. The second describes a project that is under way at Comrie Medical Centre; the aim of which is to ensure use of AWDs is compliant with NHS Tayside's Wound Management Guidelines.

## 8.3 Results

### 8.3.1 Review of the literature

This is a summary of the literature review. For the full review, please refer to the supplementary material.

The literature was examined and grouped into three themes: staff training in the use of AWDs; decision-making and wound management; and decision-making support.

#### 8.3.1.1 *Staff training in the use of AWDs*

The review did not identify any studies which considered training or knowledge gaps specifically in staff in NHSScotland. However, three papers which examined staff training and knowledge in other locations were identified. One was a systematic review with a focus on venous leg ulcers<sup>91</sup>. The remaining two were survey-based studies, which focused on training for all types of chronic wound<sup>92, 93</sup>.

The systematic review included 16 studies describing nurses' knowledge in venous leg ulcer nursing<sup>91</sup>. Five of the included studies were from the UK, four from Ireland, three from Norway and one each from Hong Kong, Canada, Belgium and Australia. The reviewed studies showed knowledge gaps in assessment, physiology and the healing process, related nursing care, as well as dressings and compression treatment. The authors concluded that nurses may not be using the available evidence base sufficiently to support ulcer healing and patient wellbeing.

The surveys were conducted in Canada and Sweden, and so are not necessarily relevant to the Scottish context. They are discussed in the full literature review, available in the supplementary material.

#### 8.3.1.2 *Decision-making and wound management*

Seven papers were identified which focused on decision-making and wound management. One was a quantitative study conducted alongside an RCT<sup>94</sup> and four presented the results of staff surveys<sup>95-98</sup>. There were two independent qualitative studies: one used a qualitative interview methodology<sup>99</sup>; and the other reported on a focus group<sup>100</sup>. The age and setting of these studies means that their relevance to NHSScotland today may be limited. However, a brief review of the key points from these studies is presented below. More details of these studies are available in the supplementary material.

Only one study focused on the prescribing of an AWD, it examined the rationale for prescribing a silver releasing dressing in 242 French doctors<sup>98</sup>. The presence of infection and healing delay prompted use in 82% of the cases.

An Australian study indicated that there is little relationship between nurses' assessment of the clinical signs of wound infection and the bacterial burden detected by semi-quantitative bacteriology<sup>94</sup>. The authors recommend use of

both methods of detecting infection given that it is difficult to conclude anything about which method is the most reliable given the inadequacy of swab samples in the detection of infection, and the lack of international consensus on the signs of infection.

A limited amount of research focused on dressing selection in the UK was identified. A postal survey of 1,000 nurses (375 respondents) in the UK with an interest in wound management indicated that practitioners' main consideration was preventing trauma to the wound (47%) and the avoidance of causing pain (34%)<sup>97</sup>. These considerations are likely to be influenced by the belief held by 81% of respondents that most pain is experienced by patients at dressing removal. Strategies for the prevention of pain/trauma at dressing change included: use of low adherence and non-traumatising dressings, soaking the dressing before removal (although the authors state that this practice is rarely effective and may increase risk of skin maceration), and analgesia. The study highlighted concerns about nurses' unfamiliarity with the evidence base surrounding wound care, including the use of inappropriate dressings, ineffective dressing removal techniques, and a lack of awareness of products aimed at reducing pain and trauma. These concerns about familiarity with the evidence base echo the systematic review<sup>91</sup> described in Section 8.3.1.1. Despite these concerns, a study comparing the management of chronic leg ulcers in community, primary and nursing home care, suggested that UK nurses use the evidence base in treating these patients more than a comparison group of Swedish nurses<sup>96</sup>.

A postal survey of 187 GP practices in Scotland examined the management of leg ulcers in primary care. It highlighted that just 15% of practices used a protocol in the management of leg ulcer patients<sup>95</sup>. District nurses and practice nurses were the principal providers of care for these patients. While across all staff groups, journals and hospital departments were the primary source of information on leg ulcer management, 65% of district nurses found private company representatives a valuable source of information. However, it should be noted that this study was carried out in 1998, therefore is unlikely to reflect current practice.

A more recent study suggested that for the UK nurses engaged in wound care, the pharmaceutical industry was a more frequently consulted source of information than in a Swedish comparison group<sup>96</sup>.

### *8.3.1.3 Decision-making support*

Five papers were identified which focused on decision-making support. One was an assessment of care pathway use<sup>101</sup>, one a sequential pre/post intervention audit<sup>102</sup>, and one an action research project to develop and introduce a standardised approach to wound care<sup>103</sup>. The remaining two were surveys of staff, one included testing of an algorithm by non-expert staff<sup>104</sup>, the other determining levels of nursing autonomy<sup>105</sup>. More details of these studies are available in the supplementary material.

A UK-based study trialled two care pathways, a standard pathway for new wounds and a complex pathway for recurrent wounds<sup>101</sup>. These were developed by local stakeholders and piloted in conjunction with an education programme for staff. The introduction of care pathways appeared to improve healing rates. However, methodological limitations mean strong conclusions cannot be drawn about the effectiveness of these care pathways.

One study adopted an action research approach in the development and audit of a standardised approach to wound care in Wales<sup>103</sup>. In a four-stage process, a tool was developed, audited, improved and put into use. The authors suggest that an evidence-based wound dressing formulary can be used to deliver high quality and effective care and a dressing selection tool can enhance the process of formulary implementation. The authors also highlight that the tool could be adapted for use alongside other formularies.

A small US-based sequential pre/post intervention audit examined the development and trial of a standardised protocol-based approach to wound care in a hospital setting<sup>102</sup>. The approach was introduced with concurrent education for nurses within the institution and emphasised hand hygiene and sterile forceps technique in dressing changes. The results suggested that a standardised wound dressing protocol was associated with improvements in consistency of care, lower wound contamination and infection as well as higher levels of hand hygiene, in the short term. There was no change in the duration or cost of wound dressings.

A cross-sectional, mixed methods, quantitative survey study aimed to validate the use of the Solutions<sup>®</sup> Algorithms (developed by ConvaTec and consisting of one pressure ulcer prevention and eight wound care algorithms) by non-expert registered nurses<sup>104</sup>. This study provides some evidence that wound care algorithms promote safe, effective wound care, but also suggests that multiple factors may affect their optimal use. Most critically, users identified their lack of wound assessment education (for example, assessment of necrotic versus healthy tissue) as a barrier to best use. Consequently, optimal use cannot be expected unless instruction has been provided in basic algorithm function and focus as well as the fundamentals of wound assessment and wound care.

#### *8.3.1.4 The rationale for conducting a staff survey*

The international literature review highlighted gaps in knowledge, challenges in management and suggests that there may be benefits in adopting standardised approaches to care or more systematic, evidence-based interventions. However, provision of training, its uptake and its usefulness in increasing confidence and competence in the use of AWDs is not addressed in the literature. It is also not apparent which particular decision aids are used in Scotland. There is little literature focused specifically on infected wounds and the appropriate use of AWDs. Therefore, a survey of NHS staff and NHS board level representatives for each territorial NHS board was undertaken to gather more information about current practice in NHSScotland.

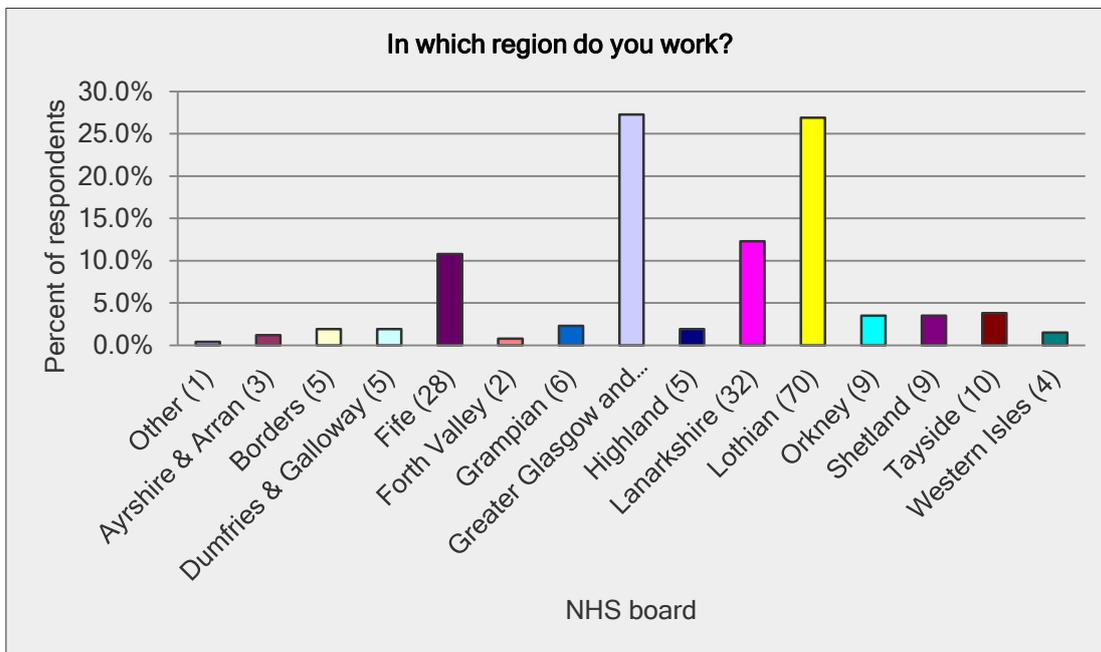
### 8.3.2 Staff survey

A total of 263 people responded to the questionnaire, including staff from all of the territorial NHS boards. This is a summary of the findings, for the full write-up, please refer to the supplementary material. While it was made clear in the questionnaire that the focus was on the use of AWDs in chronic wounds, four people responded regarding their use of AWDs in other wound types (necrotic fungating tumours, and burns). Due to the nature of the analysis, it was problematic to remove these responses from the write-up. However, their inclusion does not alter the overall results.

#### 8.3.2.1 Demographics

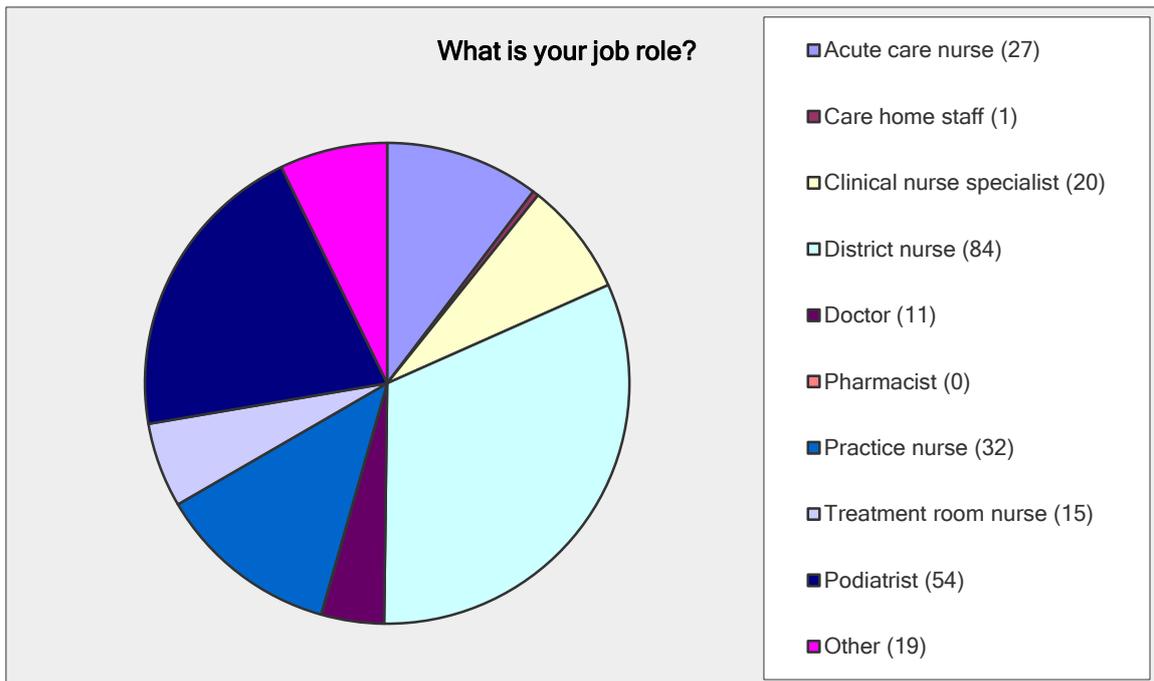
Responses were received from all territorial NHS boards in Scotland. Most responses came from NHS Greater Glasgow and Clyde (27% of all responses received) and NHS Lothian (27%) (Figure 2).

**Figure 2: In which region do you work?**



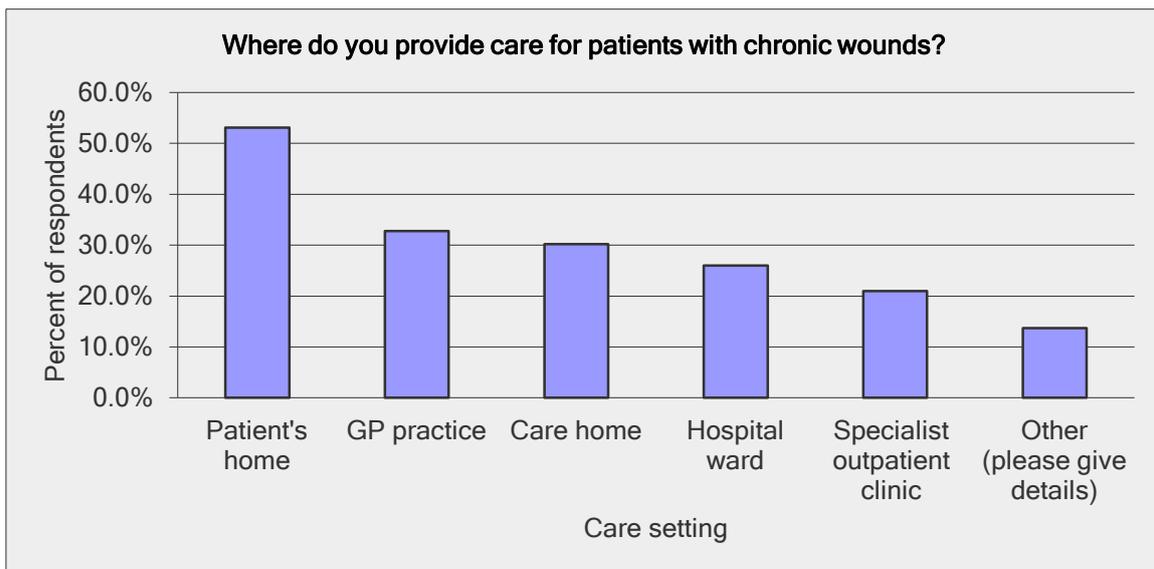
Most of the respondents were district nurses (31.9%) or podiatrists (20.5%) (see Figure 3). Approximately half (47%) of the respondents said that they were independent/non-medical prescribers.

**Figure 3: What is your job role?**



Respondents were asked where they provided care for patients with chronic wounds (ticking all that applied). The most commonly selected answer was 'patient's home' (53.1%). However, a wide range of care settings was represented (Figure 4). In the comments box, respondents also mentioned a number of other settings, most commonly podiatry clinics, plastics and burns outreach, diabetes multidisciplinary team clinics (including diabetic foot clinics), care of the elderly wards and community clinics and hospices.

**Figure 4: Where do you provide care for patients with chronic wounds?**

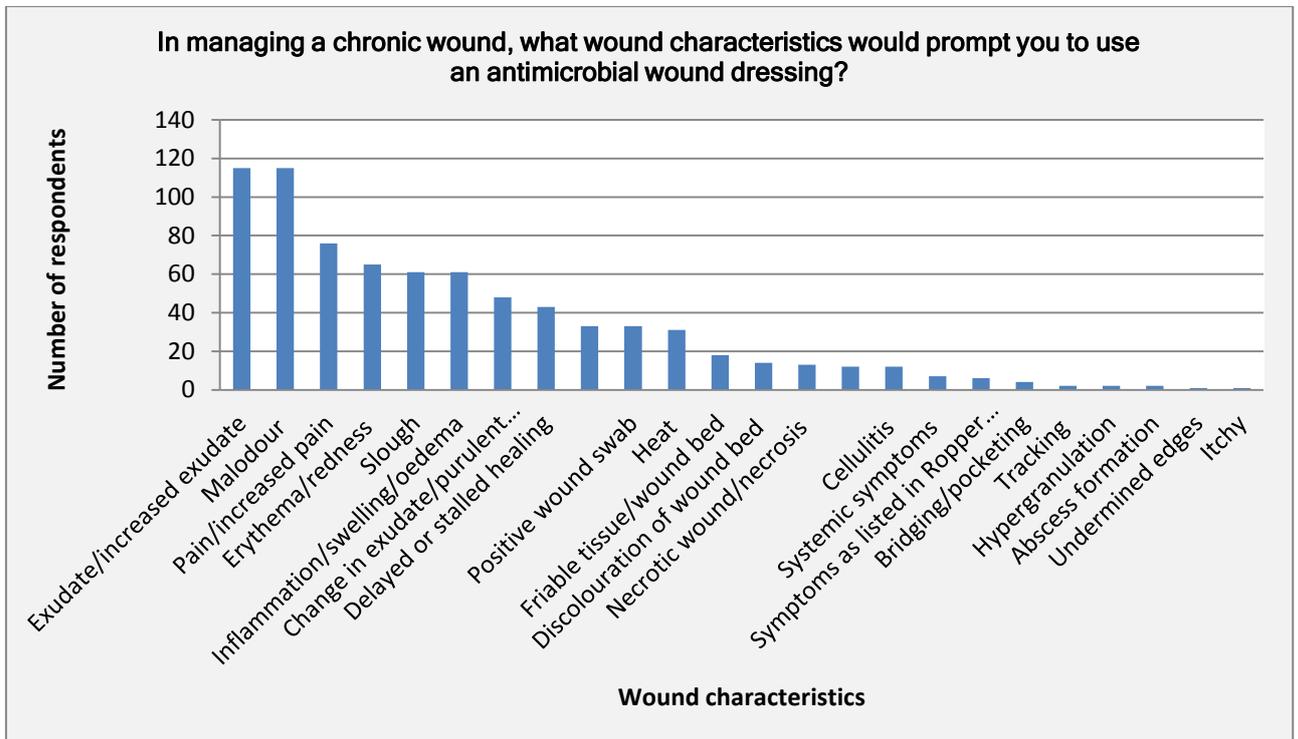


### 8.3.2.2 Current practice

#### Wound characteristics that prompt AWD use

Respondents were asked what wound characteristics would prompt them to use an AWD. The vast majority (96%) said that they would use an AWD if a wound was showing signs and symptoms of infection. Some (18%) simply stated that signs and symptoms of infection would prompt them to use an AWD, without giving further details. However, most respondents (78%) listed symptoms of infection. The most frequently listed symptoms were increased exudate, malodour, increased pain, erythema/redness, slough and inflammation/swelling (Figure 5).

**Figure 5: Wound characteristics that prompt use of AWD**



Other reasons, besides signs and symptoms of infection, which prompted the use of AWDs were also given:

- 13 respondents (5%) said that they would consider the prophylactic use of AWDs.
- 4 respondents (1.6%) said that they would consider the use of AWDs in people with peripheral vascular disease/poor peripheral circulation/arterial and venous insufficiency.
- 4 respondents (1.6%) said that they would use AWDs on the advice of specialist colleagues/other professionals/tissue viability nurses/from existing care plans.
- 4 respondents (1.6%) listed certain wound types that they might use AWDs for (for example pressure sores, leg ulcers, diabetic patients with active foot disease, large/deep wounds).

- 3 respondents (1.2%) said that they might use AWDs in patients intolerant to oral antibiotics/unable to swallow antibiotics.
- 2 respondents (0.8%) said that they might consider AWDs in patients recently treated with systemic antibacterial drugs, as AWDs may avoid further treatment with antibacterial drugs.

#### *Wound characteristics that would stop AWD use*

Most respondents (72%) stated that the wound characteristics that would prompt them to stop using an AWD would be:

- an improvement in the wound (for example granulating tissue, wound healing, reduction in size), and/or
- an improvement or resolution in the symptoms of infection.

In addition:

- 65 (25%) said that they would stop using an AWD if the wound had not changed.
- 54 (21%) said that they would stop using AWDs if the patients had an allergic reaction/sensitivity/skin irritation/or discomfort.
- 34 (13%) said that if a wound deteriorated, they would stop using an AWD.
- 12 (5%) said that a negative wound swab would prompt them to stop using an AWD.
- other prompts to stop using an AWD were: spreading infection/antibiotics commenced (n=5; 2%); overgranulation (n=3; 1.2%); advice from colleagues (n=2; 0.8%); presence of a biofilm (n=1; 0.4%); and changes in appearance (n=1; 0.4%).

Fifty-one (20%) of the respondents included a time component in their answer:

- 30 out of 51 respondents said that they would review a wound after 2 weeks. Some said they would stop using the AWD at 2 weeks; some said they would stop using the AWD if there was improvement in the wound at 2 weeks; and some said they would stop using the AWD if there was no improvement/deterioration of the wound at 2 weeks.
- 14 said they would follow guidelines for length of usage/manufacturer's instructions, or said they would just use AWDs for a 'short time'.
- the remaining seven respondents referred to different time periods, ranging from 1–6 weeks.

#### *Other dressings or techniques used to reduce bacterial burden*

Respondents were asked what dressings or techniques they would use to reduce bacterial burden, as an alternative to AWDs. The most frequently selected options were non-medicated absorbent dressings (67%), mechanical debridement (52%) and Debrisoft<sup>®</sup> (48%). Other answers given included larvae (39%), negative pressure wound therapy (29%) and super absorbers (24%).

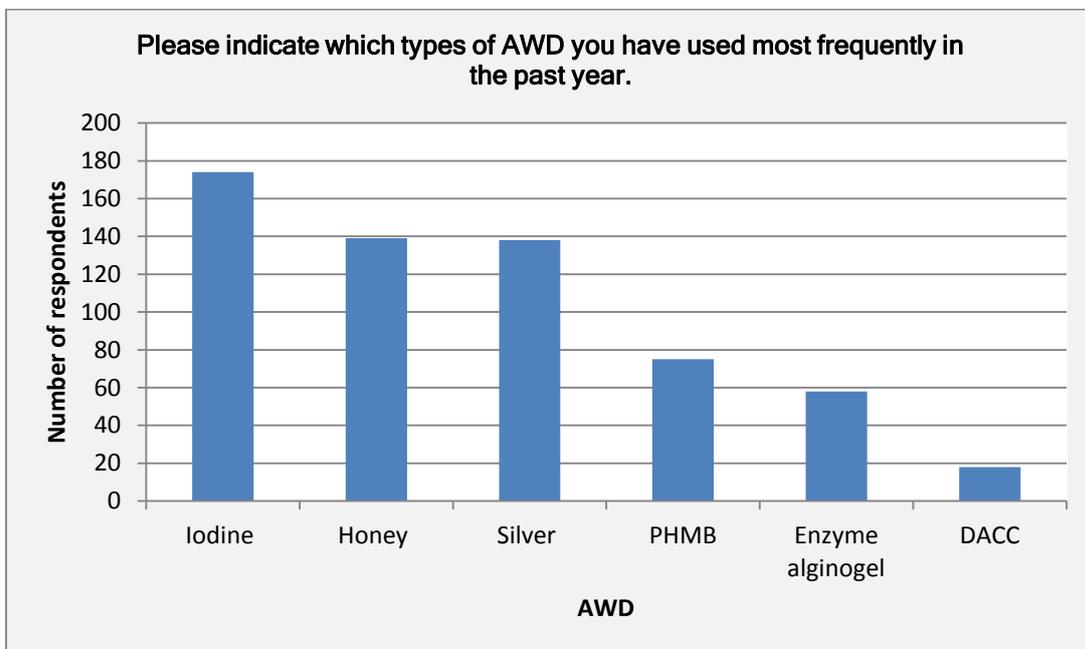
### 8.3.2.3 Preferred dressing choice

#### *AWDs most frequently used in the past year*

The majority of respondents had used AWDs in the past year. Of the 255 who answered the question, only six said that they had not used an AWD in the past year: 82% had used honey dressings; 86% iodine dressings; 80% silver dressings; and 72% other AWDs (including PHMB- and DACC-containing dressings and alginate gels containing enzymes described by the manufacturer as an 'enzyme alginogels').

Respondents were asked to list which AWDs they had used most frequently in the past year. The most common answer was iodine dressings (given by 69% of respondents), followed by honey and silver dressings (55% each) (Figure 6). Please note that use might be influenced by what is available on clinicians' local formularies.

**Figure 6: AWDs you have used most frequently in the past year**



#### *Preferred AWD for different wound types*

Respondents were asked if they had a preference for certain AWDs for different wound types. The results are summarised in Figure 7. For pressure ulcers, the most frequently selected dressing type was honey; for venous leg ulcers it was iodine; for arterial leg ulcers it was silver; for foot ulcers in people with diabetes it was silver and iodine; and for dehisced surgical wounds it was silver. It should be noted that preferences might be influenced by what is available on clinicians' local formularies.

Flaminal<sup>®</sup> was the AWD most frequently mentioned in the 'other' category.

#### 8.3.2.4 What influences clinician's decision-making?

##### *Decision aids/prescribing algorithms/guidelines*

Most respondents mentioned more than one decision aid that guides their decision-making. The most common answer was that local guidelines and/or formularies were used (mentioned by 132 of the 199 respondents who answered this question; 66%). The Ropper Lothian Ladder (Figure 9) was also mentioned by 48 respondents (24%).

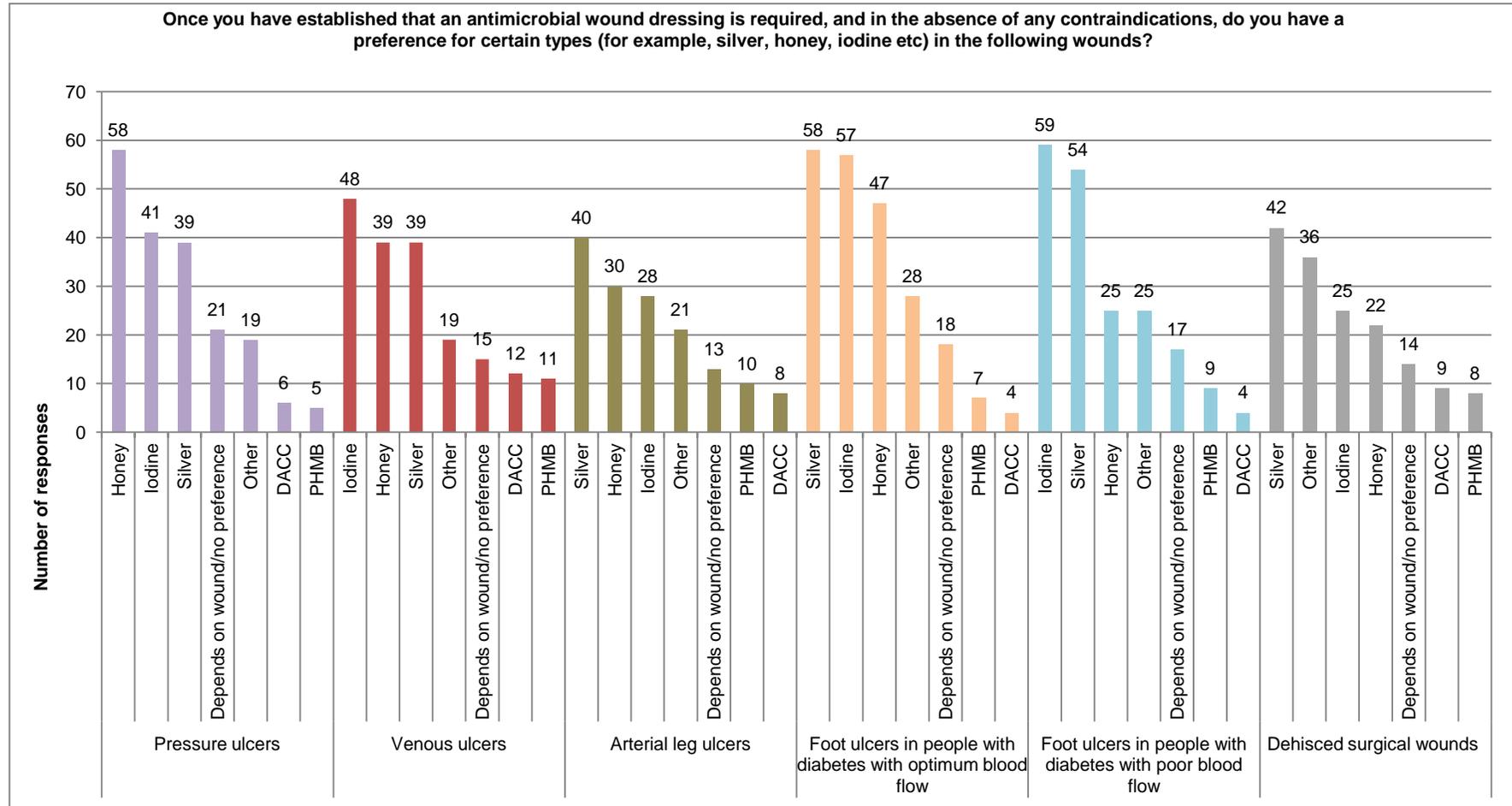
##### *Advice from designated clinical specialists*

Most respondents (83%) said that they asked advice from designated clinical specialists on wound care. Many respondents (n=177) gave further qualitative details in the comments box, with 110 saying that they would ask advice from tissue viability nurses. The next most common answer was podiatry/specialist podiatrists (mentioned by 24 respondents). Other answers included colleagues generally, a vascular team/nurse, a dermatology team/nurse, a diabetes foot care team and manufacturer representatives.

A minority of respondents (n=5) gave a negative comment about the specialist advice (or lack of specialist advice) that was available to them:

- 'Usually not helpful at all as they seem to follow a tickbox.'
- 'Yes but issues with Tissue Viability 'assessing' wounds by telephone therefore no confidence in service some of the time.'
- 'No longer have tissue viability nurse in this area.'
- 'Used to when we had a specialist nurse...'
- 'Occasionally have a Tissue Viability input...now poorly resourced and over stretched with little experience...had much better service in past.'

**Figure 7: Once you have established that an AWD is required, do you have a preference for certain types?**



### 8.3.2.5 Clinician knowledge

#### *Clinicians' competence and confidence in using AWDs*

The vast majority of respondents (92%) said that they felt competent/very competent about assessing a wound for its suitability to start the use of an AWD. Similarly, most (89%) said that they felt confident/very confident about their decision-making on the appropriate use of AWDs.

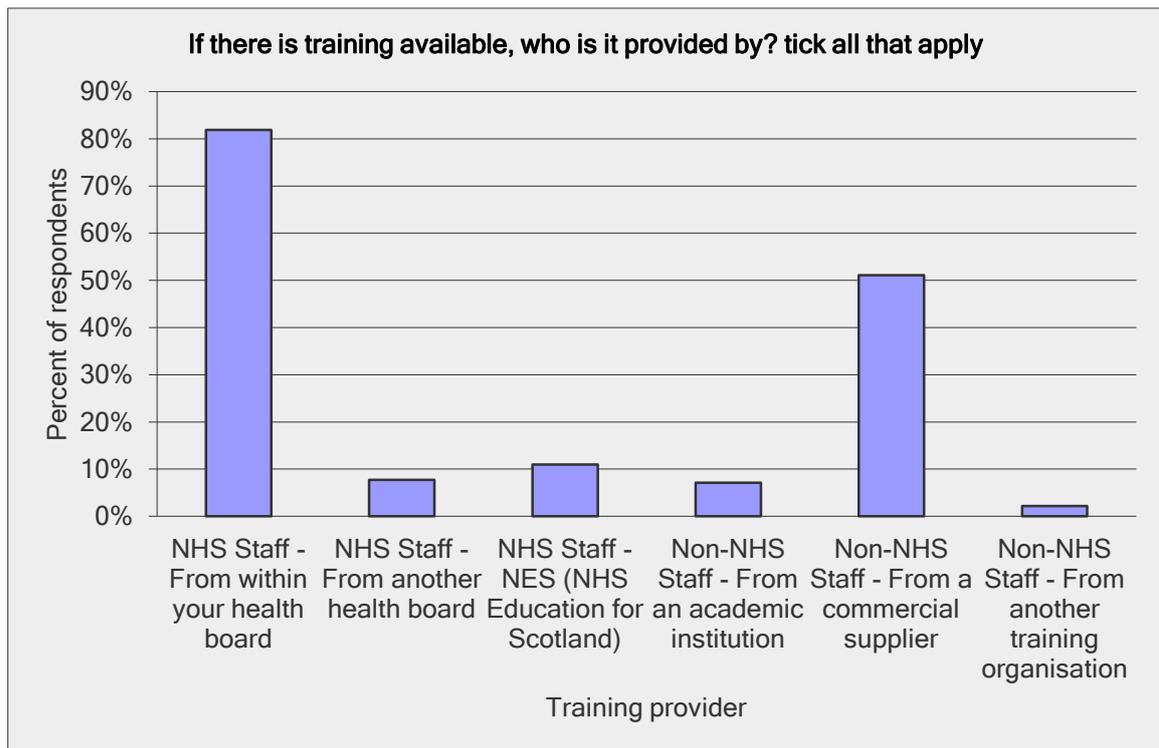
#### *Training*

Most respondents (69%) said that training on the use of AWDs was provided in their NHS board area. Just over half (54%) of the respondents said that they had attended training in the past year.

Most training seems to come from NHS staff from within the respondents own NHS board (selected by 82% of respondents); followed by commercial suppliers (selected by 51% of respondents) (Figure 8).

Respondents were asked if there was anything preventing them from attending training, and 41% answered 'yes'. The main reasons given were lack of time, clinical pressures and staffing issues.

**Figure 8: If there is training available, who is it provided by?**



### 8.3.2.6 Safety issues/adverse events

Most respondents said that they had not experienced any adverse events/safety issues (84%).

The adverse events reported for different AWDs were:

- **honey dressings:** 11 respondents listed pain/discomfort for honey dressings. Other adverse events reported were: contact allergy (n=2 respondents); increased wound maceration (n=2); difficult to wash off (n=1); and increased blood sugars in people with diabetes (n=1).
- **silver dressings:** Eight respondents listed localised reactions/inflammation associated with the use of silver. Other adverse events reported by single respondents were:
  - ‘...chronic pressure ulcers on one patient improved with discontinuation of silver...’
  - silver toxicity after long-term use
  - ‘a patient having flamazine applied when diagnosed with kidney failure’
  - discolouration
  - ‘generally arterial wound patients report intolerance to silver’
  - ‘neutropaenia in a burns patient referred to us who had prolonged use of topical silver sulfadiazine’
  - Pain, and
  - ‘inappropriate use of silver dressings in palliative patients who were about to receive radiotherapy...’
- **iodine dressings:** five respondents mentioned monitoring thyroid function with use of iodine. Other adverse events reported were: contact sensitivity (n=3); allergy (n=2); pain (n=1); and ‘too drying’ (IODOSORB<sup>®</sup>; n=1).
- **other dressings:** Flaminal<sup>®</sup> was mentioned by two respondents:
  - ‘significant (but allergic) reaction to Flaminal Hydro<sup>®</sup>, and
  - ‘one patient could not tolerate Flaminal Forte<sup>®</sup> but could tolerate Flaminal Hydro<sup>®</sup> due to reduced levels of alginate present’.
- **general adverse events:** Some respondents listed adverse events, but did not apply them to a dressing type:
  - allergy/intolerance (n=5)
  - pain (n=3)
  - damage to surrounding skin (n=2)
  - increased inflammatory process (n=1)
  - adherence to wound bed (n=1).

#### 8.3.2.7 Any other comments

Respondents were asked to give their comments generally on AWDs. A full thematic analysis was not done. A rapid analysis was conducted, which involved grouping the quotes into common themes. This yielded eight themes. These are listed below, with supporting quotes for illustrative purposes. For all the quotes, please refer to the full description of the staff survey (available as supplementary material).

##### *Theme 1: It is not a one-size fits all situation*

*‘I do think that each wound is different and the question of what type of antimicrobial for a specific wound type -ie arterial, venous etc is very hard to*

*say one antimicrobial only to this type. i have yet to see one type of wound that does not have other factors for consideration!* [clinical nurse specialist, dermatology]

*'My decision is based upon an individual holistic assessment of the patient concerned not wound type.'* [tissue viability nurse]

*Theme 2: AWDs are useful, if they are used correctly*

There was considerable support for AWDs, but an acknowledgement that they are only of value when they are used appropriately.

*'When used appropriately, anti-microbial wound dressings form an essential element of holistic wound management.'* [lead staff nurse]

*'I feel that silver dressings when used appropriately can be very useful in diabetic foot ulcers. It is very unfortunate that there is very little evidence for their use therefore their use is restricted.'* [podiatrist]

*Theme 3: AWDs might negate the need for antibiotics*

Several respondents felt that by using AWDs, they were avoiding the use of oral/systemic antibiotics.

*'I feel that the use of antimicrobial wound dressings are needed to aid in healing and prevent the use of oral antibiotics'* [practice nurse]

*'They play an important part in healing wounds and can prevent deterioration reducing the need for antibiotic therapy. They also can enhance antibiotic therapy.'* [district nurse]

*Theme 4: What is available on the formulary is not adequate/dressings not available*

*'I would like to have the ability to choose a silver dressing if I think it appropriate without having to justify it in paper work and send it off. We should be making decisions in the best interests of our patients.'* [practice nurse]

*'We are VERY limited due to formula and find it frustrating when speak to tissue viability nurses and experts ie dermatology and they go off formula. Always had good results with iodine but can't use routinely filling out forms all the time to go off formula not helpful.'* [practice nurse]

*Theme 5: AWDs are of minimal benefit/AWDs are overused*

A small number of respondents were opposed to the use of AWDs. Several respondents commented that AWDs were overused.

*'They are overused and expensive and bring very little to the party in chronic wound management but there is the odd occasion that I would use them.'* [district nurse]

*'There is a fantastic amount of money wasted on wound dressings, particularly in the community, with no scientific evidence to back the use of most dressings.'* [doctor, surgery]

*'Very aware of overuse and inappropriate use in patients returning, or referred to our service. Antimicrobials are reserved for instances listed above where normal sequence of wound repair/remodelling is interrupted.'* [acute care nurse]

#### *Theme 6: Industry influences use of AWDs*

Views were expressed by a few relating to the influence of industry on AWD use.

*'...Also as far as I am aware there is no studies or evidence to say that using silver dressings has any benefit in wound care, most of the push for silver dressings seems to come from the suppliers and their reps. Many of these dressings are not evidence based but seemed to be produced as dressing companies compete with one another then promoted as gospel with anecdotal evidence from some other clinic which you are supposed to be impressed by.'* [podiatrist]

#### *Theme 7: AWDs are sometimes used prophylactically*

Some respondents mentioned that AWDs were sometimes used prophylactically.

*'When dealing with high risk diabetic wounds which can easily become infected with the risk of amputation, (especially if that person has had a previous amputation), there is always the thought at the back of your mind that it's safer to use antimicrobials to prevent infection as the possible consequences will be disastrous...'* [podiatrist]

#### *Theme 8: Personal preferences*

Some respondents stated what their preferred AWDs were. There was no one dressing that stood out as being the favourite.

#### *8.3.2.8 Consensus questions for guiding decision-making in areas where the evidence base is insufficient*

The respondents were asked what question would be most useful to address, using consensus methods, to support their decision-making. An answer was given by 107 respondents (41%).

The areas that most of the respondents seem to want guidance on are:

- the clinical indications to justify the use of AWDs, and guidance on when an AWD should not be used.
- when to stop use of AWDs/more guidance on the '2 week challenge' (often recommended as a timeframe to trial an AWD).
- which AWD to use on different wound types.

There was strong support for simple decision aids/algorithms, and suggestions of adding to existing tools rather than 're-inventing the wheel'.

Some respondents expressed concerns about making recommendations in the absence of scientific evidence.

### 8.3.3 NHS board level survey results

Responses were received from:

- NHS Ayrshire & Arran
- NHS Dumfries & Galloway
- NHS Fife
- NHS Forth Valley
- NHS Greater Glasgow and Clyde
- NHS Lothian
- NHS Tayside

#### *8.3.3.1 Does your board have a wound formulary covering hospital and/or community care?*

All responding NHS boards had joint formularies covering both primary and secondary care with the exception of NHS Ayrshire & Arran which had separate formularies.

#### *8.3.3.2 Is compliance with this formulary monitored?*

All but one responding NHS board monitored compliance with their formulary in both primary and secondary care; NHS Ayrshire & Arran monitored compliance in primary care, but had no means of monitoring compliance within hospitals.

#### *8.3.3.3 How is formulary compliance monitored in relation to AWDs?*

There were various levels of detail from each respondent within the answers to this question.

In primary care settings:

- NHS Dumfries & Galloway, NHS Greater Glasgow and Clyde, NHS Fife, NHS Forth Valley and NHS Lothian all use the Prescribing Information System for Scotland (PRISMS), hosted by ISD Scotland, to monitor formulary compliance.
- NHS Ayrshire & Arran has undertaken work in recent years to monitor usage in primary care and they expect a newly appointed Prescribing Support Nurse to further enhance this.

In secondary care settings, there are varied ways within NHS boards of monitoring compliance:

- NHS Dumfries & Galloway and NHS Lothian use JAC computing medicines management software.

- NHS Fife has an Information and Compliance Officer, a prescribing team and tissue viability co-ordinators who monitor and deal with compliance issues.
- NHS Greater Glasgow and Clyde uses audit and procurement reporting in acute care services.

NHS Lothian undertakes prescribing trend analysis for both primary and secondary care using both PRISMS and JAC computing medicines management software. NHS Tayside's Tissue Viability Network monitors prescribing of silver dressings and produces a quarterly report and plan on extending this monitoring to other dressing types.

*8.3.3.4 What decision aids, care pathways, prescribing algorithms and checklists are available to staff on the use of AWDs dressings (eg Ropper Lothian Ladder)? Please list these.*

NHS Fife, NHS Forth Valley and NHS Lothian use or incorporate the Ropper Lothian Ladder in their available support material.

The other four NHS boards did not mention the Ropper Lothian Ladder in their responses. In addition:

- NHS Fife wound formulary and wound management guidelines discuss: bacterial burden and management of infection, monographs for dressings, availability of wound swabs for microbiology and an additional Standard Operating Procedure for silver dressings in primary care.
- NHS Lothian and NHS Tayside include additional support material in their formulary.
- NHS Ayrshire & Arran uses the Adapted Scottish Wound Assessment and Action Guide.
- NHS Greater Glasgow and Clyde provides a wound clarification and product selection guide as well as formulary prescribing guidance notes in its wound formulary.

NHS Dumfries & Galloway did not provide an answer to this question.

*8.3.3.5 What training do you provide to staff on the use of AWDs?*

There are data from the staff questionnaire on training and its availability and uptake. NHS board respondents were formulary pharmacists and could only supply limited information on available training.

NHS Dumfries & Galloway, NHS Forth Valley and NHS Tayside stated they had no training available specifically on the use of AWDs. The other NHS boards do have locally available in-house training, with only NHS Greater Glasgow and Clyde offering staff additional formal education sessions.

*8.3.3.6 Are the numbers of wound infections linked to chronic wounds collated on a regular basis?*

The respondents indicated they were either not aware or had no way of monitoring the number of wound infections linked to chronic wounds. NHS Greater Glasgow and Clyde mentioned enhanced *Staphylococcus aureus* surveillance in their response to this question. However, this would not capture all wound infections linked to chronic wounds.

*8.3.3.7 Have organisations within your NHS board introduced steps to change practice in the use of AWDs?*

All NHS boards who responded indicated some combination of formulary changes, compliance monitoring and education to reduce some or all AWD prescribing. Six of the seven NHS board respondents indicated they had reduced the number of different dressings available on their formularies, with NHS Fife and NHS Lothian specifically mentioning silver dressings being removed or restricted, and NHS Ayrshire & Arran taking measures to encourage staff to reduce their use of silver dressings (however, they stressed there was no information or education on the wider range of antimicrobial products). NHS Dumfries & Galloway has mandated in their formulary that AWDs are for short-term use only. NHS Fife stated that the restricted formulary list is also included on prescribing systems within GP practices.

*8.3.3.8 If there have been changes in practice in the use of AWDs, have wound infections increased, decreased or remain unchanged?*

NHS Fife said they did not perceive an increase in infections following reduced use of silver AWD. Such data is not currently routinely collected, but NHS Fife intends to collect this routinely in future. None of the other NHS boards had data on infection rates. NHS Dumfries & Galloway reported static AWD use in the past 4 years. NHS Tayside reported that prescription monitoring and reporting has had no impact on overall use of AWDs.

**8.3.4 Spend on AWDs in community and acute settings**

This section provides an overview of community and acute spend on AWDs within NHSScotland, and presents data both at NHS board and NHSScotland level. Please note that it is not possible to get spend data purely on AWD use in chronic wounds. The data here relate to AWD use in all wound types.

The data on acute spend comes from NHS National Procurement only. As there are other purchasing routes, it is likely that the data for acute spend are incomplete. It is noted that the figure for some NHS boards (in particular NHS Lothian), is unexpectedly low. The reason for this variation is unclear.

The data provided (Table 7) show that most spend on AWDs was in the community. This includes spend from community pharmacies and dispensing doctors. The lowest per capita spend on AWDs is in NHS Fife and NHS Western Isles, and the highest is in NHS Orkney. The higher proportion of

spend in both community and acute settings within NHSScotland is on silver dressings (Tables 8 and 10). It is unclear from the data whether this is attributable to higher volumes being purchased or higher unit costs.

The annual national community spend on AWDs was approximately £2.9 million (based on data from April to September 2014) and spend on dressings dispensed in acute settings was approximately £641,000 (Table 7).

**Table 7: Annual spend on AWDs in community and acute (based on data from April to September 2014)**

NHS board	Community spend	Acute spend	Total spend on AWDs	Per capita spend
NHS Ayrshire & Arran	£198,666	£47,601	£246,267	£0.66
NHS Borders	£56,213	£4,561	£60,774	£0.53
NHS Dumfries & Galloway	£73,213	£11,302	£84,515	£0.56
NHS Fife	£130,888	£20,885	£151,773	£0.41
NHS Forth Valley	£123,608	£40,788	£164,396	£0.55
NHS Grampian	£398,703	£53,888	£452,591	£0.78
NHS Greater Glasgow and Clyde	£686,384	£248,821	£935,205	£0.82
NHS Highland	£197,260	£36,705	£233,965	£0.73
NHS Lanarkshire	£402,572	£94,978	£497,550	£0.76
NHS Lothian	£439,765	£27,004	£466,769	£0.55
NHS Orkney	£22,675	£546	£23,221	£1.08
NHS Shetland	£9,921	£3,213	£13,134	£0.57
NHS Tayside	£180,314	£50,327	£230,641	£0.56
NHS Western Isles	£11,033	£134	£11,167	£0.41
<b>Grand total</b>	<b>£2,931,215</b>	<b>£640,753</b>	<b>£3,571,968</b>	

With regards to spend on AWDs in the community within NHSScotland, the highest proportion in all NHS boards is silver dressings, equating to an annual total spend of approximately £1.9 million and representing 67% of all spend (Table 8). The data indicate that most money is spent on silver dressings

within all NHS boards, ranging from 34% in NHS Fife to 86% in NHS Grampian. The lowest spend within NHSScotland was on octenidine dressings.

**Table 8: Total annual community spend on AWDs by NHS board**

NHS board (% of overall board spend on AWDs)	Silver	Povidone iodine	Dialkylcarba moyl	Glucose Oxidase	Polihexanide	Honey	Cadoxomer iodine	Octenidine	Grand total community spend	% of total NHSScotland spend on AWDs
NHS Ayrshire & Arran	£110,562 (56%)	£41,891 (21%)	£3,555 (2%)	£18,524 (9%)	£6,013 (3%)	£5,654 (3%)	£12,443 (6%)	£24 (0%)	<b>£198,666</b>	7%
NHS Borders	£45,627 (81%)	£5,655 (10%)	£241 (0%)	£2,712 (5%)	£537 (1%)	£137 (0%)	£1,304 (2%)	£0 (0%)	<b>£56,213</b>	2%
NHS Dumfries & Galloway	£49,415 (67%)	£10,696 (15%)	£313 (0%)	£2,386 (3%)	£6,807 (9%)	£830 (1%)	£2,766 (4%)	£0 (0%)	<b>£73,213</b>	2%
NHS Fife	£44,181 (34%)	£21,639 (17%)	£26,186 (20%)	£14,883 (11%)	£13,786 (11%)	£2,819 (2%)	£7,394 (6%)	£0 (0%)	<b>£130,888</b>	4%
NHS Forth Valley	£74,464 (60%)	£11,882 (10%)	£3,754 (3%)	£11,954 (10%)	£14,241 (12%)	£4,998 (4%)	£2,315 (2%)	£0 (0%)	<b>£123,608</b>	4%
NHS Grampian	£341,040 (86%)	£33,853 (8%)	£260 (0%)	£705 (0%)	£10,166 (3%)	£5,206 (1%)	£7,473 (2%)	£0 (0%)	<b>£398,703</b>	14%

NHS board (% of overall board spend on AWDs)	Silver	Povidone iodine	Dialkylcarba moyl	Glucose Oxidase	Polihexanide	Honey	Cadexomer iodine	Octenidine	Grand total community spend	% of total NHSScotland spend on AWDs
NHS Greater Glasgow and Clyde	£481,336 (70%)	£70,416 (10%)	£59,592 (9%)	£33,194 (5%)	£14,929 (2%)	£5,276 (1%)	£18,472 (3%)	£3,169 (0%)	<b>£686,384</b>	23%
NHS Highland	£162,122 (82%)	£10,755 (5%)	£7,376 (4%)	£3,648 (2%)	£9,997 (5%)	£690 (0%)	£2,672 (1%)	£0 (0%)	<b>£197,260</b>	7%
NHS Lanarkshire	£203,045 (50%)	£21,200 (5%)	£89,688 (22%)	£67,675 (17%)	£5,024 (1%)	£13,152 (3%)	£2,783 (1%)	£5 (0%)	<b>£402,572</b>	14%
NHS Lothian	£300,297 (68%)	£6,051 (1%)	£43,402 (10%)	£11,419 (3%)	£26,896 (6%)	£31,284 (7%)	£20,402 (5%)	£14 (0%)	<b>£439,765</b>	15%
NHS Orkney	£19,262 (85%)	£1,337 (6%)	£130 (1%)	£76 (0%)	£1,229 (5%)	£222 (1%)	£419 (2%)	£0 (0%)	<b>£22,675</b>	1%
NHS Shetland	£6,827 (69%)	£579 (6%)	£0 (0%)	£0 (0%)	£2,243 (23%)	£112 (1%)	£160 (2%)	£0 (0%)	<b>£9,921</b>	0%

NHS board (% of overall board spend on AWDs)	Silver	Povidone iodine	Dialkylcarba moyl	Glucose Oxidase	Polihexanide	Honey	Cadexomer iodine	Octenidine	Grand total community spend	% of total NHSScotland spend on AWDs
NHS Tayside	£133,924 (74%)	£19,801 (11%)	£0 (0%)	£15,608 (9%)	£615 (0%)	£9,403 (5%)	£963 (1%)	£0 (0%)	<b>£180,314</b>	6%
NHS Western Isles	£8,259 (75%)	£1,796 (16%)	£40 (0%)	£91 (1%)	£656 (6%)	£33 (0%)	£158 (1%)	£0 (0%)	<b>£11,033</b>	0%
<b>Grand total</b>	<b>£1,917,362</b> <b>(67%)</b>	<b>£257,551</b> <b>(9%)</b>	<b>£234,497</b> <b>(8%)</b>	<b>£182,874</b> <b>(6%)</b>	<b>£113,140</b> <b>(4%)</b>	<b>£79,816</b> <b>(3%)</b>	<b>£79,724</b> <b>(3%)</b>	<b>£3,212</b> <b>(0%)</b>	<b>£2,931,215</b>	100%

For silver, honey and iodine dressings dispensed in the community setting, the total per capita spend has been calculated over the period for April 2012 to March 2015 (Table 9). This has been taken from the PRISMS database, and is not officially published information on the ISD Scotland website. It highlights that the lowest per capita spend on silver is in NHS Fife (£0.45), and the highest in NHS Orkney (£2.14). The lower spend in NHS Fife most likely reflects the efforts that have been made in this NHS board to reduce spend on silver dressings. The per capita spend on honey and iodine dressings in NHS Fife is close to the national average, suggesting that the reduced spend on silver has not necessarily resulted in a transfer of spending towards honey and iodine.

**Table 9: Silver, honey and iodine dressings dispensed in community setting, per capita spend for April 2012–March 2015**

<b>NHS Board</b>	<b>Silver</b>	<b>Honey</b>	<b>Iodine</b>
NHS Ayrshire & Arran	£0.98	£0.99	£0.49
NHS Borders	£1.12	£0.02	£0.20
NHS Dumfries & Galloway	£1.10	£0.07	£0.29
NHS Fife	£0.45	£0.07	£0.26
NHS Forth Valley	£0.68	£0.09	£0.14
NHS Grampian	£1.79	£0.12	£0.25
NHS Greater Glasgow and Clyde	£1.04	£0.05	£0.25
NHS Highland	£1.78	£0.06	£0.19
NHS Lanarkshire	£1.16	£0.20	£0.12
NHS Lothian	£1.40	£0.22	£0.15
NHS Orkney	£2.14	£0.06	£0.29
NHS Shetland	£0.97	£0.04	£0.29
NHS Tayside	£1.07	£0.14	£0.16
NHS Western Isles	£0.98	£0.03	£0.24
<b>Average</b>	<b>£1.19</b>	<b>£0.09</b>	<b>£0.24</b>
<b>Sum</b>	<b>£16.67</b>	<b>£1.22</b>	<b>£3.35</b>

With regards to AWDs dispensed in acute settings within NHSScotland, the majority of spend in all NHS boards is also on silver dressings, equating to an annual total spend of approximately £340,000 and representing 53% of all spend on AWDs dispensed in acute settings (Table 10). The data indicate that spend on silver dressings represents the highest proportion within the majority of NHS boards, other than NHS Borders, NHS Fife and NHS Orkney, with the proportion ranging from 44% in NHS Lothian to 90% in NHS Highland. Within NHS Borders, NHS Fife and NHS Orkney, the AWDs representing the biggest proportion of spend is povidone-iodine. The type of AWDs that the least is spent on within the acute setting in NHSScotland is antimicrobial alginate gel.

**Table 10: Total annual acute spend by NHS board**

<b>NHS board</b>	<b>Silver</b>	<b>Povidone iodine</b>	<b>Honey</b>	<b>Dialkylcarba moyl</b>	<b>Antimicrobial alginate gel</b>	<b>Grand total acute spend</b>
NHS Ayrshire & Arran	£26,705 (56%)	£16,648 (35%)	£4,248 (9%)	£0 (0%)	£0 (0%)	<b>£47,601</b>
NHS Borders	£26 (1%)	£4,535 (99%)	£0 (0%)	£0 (0%)	£0 (0%)	<b>£4,561</b>
NHS Dumfries & Galloway	£6,318 (56%)	£3,848 (34%)	£1,136 (10%)	£0 (0%)	£0 (0%)	<b>£11,302</b>
NHS Fife	£5,660 (27%)	£9,244 (44%)	£4,518 (22%)	£1,164 (6%)	£299 (1%)	<b>£20,885</b>
NHS Forth Valley	£29,984 (74%)	£7,787 (19%)	£3,017 (7%)	£0 (0%)	£0 (0%)	<b>£40,788</b>
NHS Grampian	£32,893 (61%)	£15,351 (28%)	£5,644 (10%)	£0 (0%)	£0 (0%)	<b>£53,888</b>

<b>NHS board</b>	<b>Silver</b>	<b>Povidone iodine</b>	<b>Honey</b>	<b>Dialkylcarba moyl</b>	<b>Antimicrobial alginate gel</b>	<b>Grand total acute spend</b>
NHS Greater Glasgow and Clyde	£114, 47 (46%)	£71,444 (29%)	£25,483 (10%)	£35,573 (14%)	£1,843 (1%)	<b>£248,821</b>
NHS Highland	£32,948 (90%)	£3,109 (8%)	£648 (2%)	£0 (0%)	£0 (0%)	<b>£36,705</b>
NHS Lanarkshire	£42,357 (45%)	£15,351 (16%)	£24,823 (26%)	£11,799 (12%)	£648 (1%)	<b>£94,978</b>
NHS Lothian	£11,869 (44%)	£6 (0%)	£14,595 (54%)	£534 (2%)	£0 (0%)	<b>£27,004</b>
NHS Orkney	£233 (43%)	£313 (57%)	£0 (0%)	£0 (0%)	£0 (0%)	<b>£546</b>
NHS Shetland	£2,433 (76%)	£780 (24%)	£0 (0%)	£0 (0%)	£0 (0%)	<b>£3,213</b>
NHS Tayside	£33,731 (67%)	£6,827 (14%)	£9,769 (19%)	£0 (0%)	£0 (0%)	<b>£50,327</b>

<b>NHS board</b>	<b>Silver</b>	<b>Povidone iodine</b>	<b>Honey</b>	<b>Dialkylcarba moyl</b>	<b>Antimicrobial alginate gel</b>	<b>Grand total acute spend</b>
NHS Western Isles	£106 (79%)	£28 (21%)	£0 (0%)	£0 (0%)	£0 (0%)	<b>£134</b>
<b>Grand total</b>	<b>£339,741 (53%)</b>	<b>£155,270 (24%)</b>	<b>£93,882 (15%)</b>	<b>£51,796 (8%)</b>	<b>£2,790 (0%)</b>	<b>£640,753</b>

Data from both ISD Scotland and NHS National Procurement which show the variation in annual spend on the different types of AWDs in both community and acute settings does not indicate any consistent pattern in use year on year.

### 8.3.5 Case studies

#### 8.3.5.1 Case study 1: NHS Lothian

Based on advice from the SHTG, from 2013, NHS Lothian removed silver dressings from their formulary and aimed to ensure any non-formulary use of silver dressings was justified.

The aim of the work in NHS Lothian was to promote adherence with the wound dressings specified in the Lothian Joint Formulary and to reduce the use of silver dressing with the use of the Ropper LothianLadder. Actions were taken in primary and secondary care, and efforts revolved around education and training. Silver dressings were withdrawn from all clinical areas. Clinicians who wanted to use silver dressings were required to complete non-formulary dressing request forms.

The work achieved a reduction in silver dressing expenditure of £278,000 in primary care and £38,000 in secondary care (comparing 2012/13 to 2013/14). However, the reduction in overall expenditure on dressings was small (1%) as expenditure on alternative dressings increased. In previous years, an increase of around 4.7% on dressing expenditure was observed, and so as well as a small cash releasing saving in 2013/14 (1%), there was a cost avoidance of around 4.7%.

For more information, refer to: Boot, M (2014) Promoting Quality and Cost-Effectiveness in the use of Wound Dressings. Available from: <http://www.qihub.scot.nhs.uk/media/673607/promoting%20quality%20and%20cost%20effectiveness%20in%20the%20use%20of%20wound%20dressings.pdf>

#### 8.3.5.2 Case study 2: Comrie Medical Centre

In response to the National Therapeutic Indicator on AWDs, staff nurses from Comrie Medical Centre audited their use of AWDs. They included prescriptions from the last quarter of 2014 (from PRISMS data). They examined whether the way that AWDs were used complied with NHS Tayside's Wound Management Guidelines.

The audit identified 19 patients who had been treated with AWDs. In one patient, the use of AWDs had complied with NHS Tayside's Wound Management Guidelines. In the remaining 18, the use of AWDs had not complied with the guidelines. Issues highlighted included:

- AWDs had been used for longer than 2 weeks without review.
- AWDs had been prescribed and then not used.
- alternative AWDs had been used with no reason recorded for change.
- AWDs had been used on wounds of less than 4 week's duration.
- AWDs had been prescribed for the 'prevention' of localised infection.
- wound swabs were taken when only localised infection was likely instead of when evidence of systemic infection/cellulitis was present.

This audit has encouraged staff to improve their wound assessment and recording practice. Various measures have been taken, for example:

- nursing staff meeting to discuss wounds and to jointly review wounds.
- increasing knowledge by reading, sharing learning and self-directed study.
- routinely performing formal wound assessments to ensure a more consistent approach.
- making staff aware of the cost of each of the AWDs.

There are plans to repeat the audit, but early indications are that all the nursing staff are engaged in the project, and the use of AWDs is reducing.

*(Personal communication; Paula Moor, Community Staff Nurse, Comrie Medical Centre; August 2015).*

#### **8.4 Discussion**

The staff survey indicated that there was strong support for AWDs, but also awareness that they were often overused, or used inappropriately. Most respondents said that in treating chronic wounds, they limited their use of AWDs to wounds showing signs and symptoms of infection. However, there did not appear to be agreement on what would prompt them to stop using an AWD.

Over 20 symptoms were listed as possibly indicating local infection. The most frequently listed symptoms were increased exudate, malodour, increased pain, erythema/redness, slough and inflammation/swelling. However, it was not clear which of these needs to be present, alone or in combination, to indicate infection. This reflects the general lack of consensus on the signs and symptoms of local infection, as discussed in the study by Miller 2010. It may also reflect the fact that all wounds are different.

The NHS boards do not routinely collect data on whether AWD use in chronic wounds is limited to those showing signs of local infection. This would be helpful data to have, but there are likely to be practical issues with collecting it routinely. If local audits capturing this information are undertaken, it would be beneficial to share learning from these with the other NHS boards.

The literature review illustrated the value of standardised approaches to wound care. Both the staff survey and NHS board level questionnaire showed that, along with formularies, local guidelines and support materials are in place, and that they help to guide decision-making. The Ropper LothianLadder was mentioned frequently, and has been incorporated into some formularies.

Despite this, the staff survey and analysis of the spend data highlight inconsistency across NHSScotland with regards to AWD use. These inconsistencies exist between NHS boards, and between staff. In the staff

survey, no one AWD stood out as being the preferred choice for each wound type.

The analysis of spend data shows that considerably more is spent on silver dressings, as compared with the other AWDs, in both the acute and community settings in NHSScotland. It is not clear why this is, and also if the higher spend is the result of more silver dressings being purchased or because the ones that are being purchased are more expensive. In the staff survey, respondents indicated that they most frequently used iodine dressings.

Just over half of the survey respondents said that they had attended training in the past year. Most training came from NHS staff (82%), followed by commercial suppliers (51%). Lack of time, clinical pressures and staffing issues were reported as reasons for not attending training.

The staff survey helped to highlight the areas where consensus of clinical experts might be helpful. These were:

- starting and stopping rules for AWDs.
- which AWDs to use in different situations.

#### 8.4.1 Limitations

Given the nature of the questions in this section of the HTA, it was not appropriate to undertake a systematic literature review systematic. While the search was exhaustive, the selection of studies and write-up of results was only performed by one researcher. The quality of the included studies was not formally assessed.

For the staff survey, it was not possible to calculate a response rate. Given the broad distribution method, a denominator was not available. It is possible that the time of year limited response (over Christmas). Despite this, all the NHS boards were represented, as was the range of clinical specialties that would be expected to be involved in wound care.

There was a poor response to the NHS board level survey. This was due to difficulties in identifying named individuals to target the survey at.

On reflection, it would have been interesting to get more information, from the staff and NHS board level survey, about the influence of the manufacturers on clinicians' decision-making.

## 8.5 Conclusions

### 8.5.1 Literature review

- The literature review highlights the challenges in wound management, and suggests that there may be benefits in adopting standardised approaches to wound care.

- While the literature highlighted broad organisational issues associated with wound management, it was not specific to the current NHSScotland context. Therefore, a staff survey and NHS board level survey was conducted.

### 8.5.2 Staff survey

- Most respondents to the staff survey had used AWDs in the previous year (98%). The ones that they reported using most frequently were iodine dressings (listed by 69% of respondents), followed by honey and silver dressings (55% each).
- Most respondents (96%) reported that they used AWDs when a chronic wound was showing signs and symptoms of infection. The most frequently listed symptoms of infection were increased exudate, malodour, increased pain, erythema/rednes, slough and inflammation/swelling.
- Most respondents (72%) said that they would stop using an AWD if there was an improvement in the wound, or an improvement or resolution in the symptoms of infection.
- Other reasons for stopping an AWD were if a wound had not changed (25%) or if a wound deteriorated (13%).
- A fifth of the respondents said that they would review a wound after a period of time (most commonly 2 weeks). However, there did not appear to be agreement on what wound characteristics would prompt them to stop using an AWD, or to continue using an AWD.
- Respondents were asked if they had a preference for certain AWDs for different wound types. However, no one AWD stood out as being the preferred choice.
- The vast majority of respondents felt competent about assessing wounds for suitability to start using an AWD (92%), and felt confident in their decision-making on the appropriate use of AWDs (89%).
- Most respondents used local guidelines/formularies to guide their decision-making. The Ropper Lothian Ladder was also frequently mentioned by respondents.
- Over half of the respondents (54%) had attended training on AWDs in the past year. This training is most commonly provided by NHS staff, followed by commercial suppliers. The main reason for not attending training was lack of time and resource.
- Most respondents (84%) said that they had not experienced any adverse events or safety issues with AWDs. The ones mentioned most frequently were pain, localised reactions and thyroid issues (iodine only).
- Overall, there was strong support for AWDs, but an acknowledgement that they are often overused or used inappropriately. Some people were opposed to their use completely.
- The questions that people would most like guidance on (using consensus methodology) are:
  - the clinical indications to justify the use of AWDs, and guidance on when an AWD should not be used.

- when to stop use of AWDs/more guidance generally on the ‘2 week challenge’.
- which AWD to use on different wound types.
- Challenges to answering these questions using a consensus approach were also highlighted by respondents:
  - many respondents stressed that every wound is different, so a ‘one size fits all’ approach is not possible.
  - in the absence of clinical evidence, it is not appropriate to make recommendations.

#### 8.5.3 NHS board level questionnaire

- A limited response was received to the NHS board level questionnaire (seven NHS boards).
- Six of the seven NHS board respondents indicated that they had reduced the number of different dressings available on the formularies.

#### 8.5.4 Spend on AWDs in community and acute settings

- The majority of AWDs used within NHSScotland are dispensed within the community.
- The per capita spend on AWDs varies between NHS boards. The types of AWDs used in the different NHS boards also vary.
- The highest proportion of spend on AWDs in NHSScotland is on silver dressings. However, some NHS boards have successfully reduced spending on silver dressings.

#### 8.5.5 Case studies

- NHS Lothian has reduced use of silver dressings. This has resulted in reduced spending on dressings overall. However, the decrease was small as spending on alternative dressings increased.
- An audit undertaken by staff at Comrie medical centre highlighted that the majority of AWD use did not comply with NHS Tayside’s wound management guidelines.

### 8.6 More information

A full write-up of the staff survey and the organisational issues literature review is included in the supplementary material published alongside this report.

## 9 Principal findings and recommendations

### 9.1 Principal findings

#### 9.1.1 Clinical effectiveness

Based on a systematic review of the clinical evidence:

- for treating localised wound infection in chronic wounds, the evidence is insufficient in terms of quality and quantity to draw conclusions on the use of AWDs.
- for the healing of chronic wounds, the evidence either:
  - does not support the use of AWDs, or
  - is insufficient in terms of quality and/or quantity to draw conclusions on the use of AWDs.

#### 9.1.2 Cost effectiveness

A systematic review of the economic evidence highlighted a small number of relevant studies. However, taken together there is insufficient evidence in terms of quality and quantity to determine the cost effectiveness of AWDs relative to non-AWDs for the treatment of localised wound infection and healing of chronic wounds.

#### 9.1.3 Patient issues

A review of qualitative literature, and primary qualitative research highlighted the following.

- The impact of chronic wounds on people's lives is considerable. The persistence, recurrence and symptoms of a chronic wound can have severe physical, psychological and social consequences.
- People's knowledge around dressings, and wound care more generally, is good.
- There is often a 'trial and error' approach to dressing selection, and this process can continue until the wound begins to heal. People may then credit a particular dressing type with healing their wound.
- Wound healing usually was the most important outcome to patients, but control of symptoms, and prevention of infection and wound deterioration were also important. People often report wanting to 'try anything' to achieve these outcomes.
- Patients report that the extent and impact of pain from chronic wounds can be considerable. Reports of pain are not always acknowledged by healthcare professionals, and it seemed that pain frequently remains uncontrolled.
- The people who took part in the primary research (n=14) were generally positive about AWDs. People felt that they helped (or were helping) to heal their wound, and/or they helped with wound symptoms.

There was no one favourite AWD, and what worked for one person may not work for another.

- People value care that they feel is personal, and from healthcare professionals who they trust and are persistent with treating their wounds, even when wound healing is slow.
- The primary research indicated inconsistent access to AWDs across healthcare settings. This led to frustration and inconvenience for some people with chronic wounds who had to source their preferred AWD, often from a particular healthcare professional. This inconsistency can make people feel that the best treatments are being withheld from them because of costs.

#### 9.1.4 Organisational issues

This section was informed by a review of the literature, a survey of NHSScotland staff, a NHS board level survey, and a review of costing data from ISD Scotland and NHS National Procurement. The principal findings are as follows.

- Most respondents to the staff survey had used AWDs in the previous year (98%). The ones that they reported using most frequently were iodine dressings (listed by 69% of respondents), followed by honey and silver dressings (55% each).
- There may be benefits in adopting standardised approaches to wound care. Clinicians in NHSScotland reported that they use local guidelines/formularies to guide their decision-making.
- Most respondents (96%) to the staff survey reported that they used AWDs when a chronic wound was showing signs and symptoms of infection. The most frequently listed symptoms of infection were increased exudate, malodour, increased pain, erythema/redness, slough and inflammation/swelling.
- Most respondents (72%) said that they would stop using an AWD if there was an improvement in the wound, or an improvement or resolution in the symptoms of infection. Other reasons for stopping an AWD are if a wound had not changed (25%) or if a wound deteriorated (13%).
- A fifth of the respondents said that they would review a wound after a period of time (most commonly 2 weeks). However, there did not appear to be agreement on what wound characteristics would prompt them to stop using an AWD, or to continue using an AWD.
- The vast majority of respondents felt competent about assessing wounds for suitability to start using an AWD (92%) and felt confident in their decision-making on the appropriate use of AWDs (89%).
- Overall, there was strong support for AWDs, but an acknowledgement that they are often overused or used inappropriately. Some people were opposed to their use completely.
- The questions that people would most like guidance on (using consensus methodology) are:

- the clinical indications to justify the use of AWDs, and guidance on when an AWD should not be used.
- when to stop use of AWDs/more guidance generally on the ‘two week challenge’.
- which AWD to use on different wound types.
- Six of the seven NHS board respondents indicated that they had reduced the number of different dressings available on their formularies.
- The majority of AWDs used within NHSScotland are dispensed within the community. The highest proportion of spend on AWDs in NHSScotland is on silver dressings. The per capita spend on AWDs, and the types of AWDs being used, varies between NHS boards.

## 9.2 Recommendations based on HTA

*For healing of chronic wounds, the clinical and cost effectiveness evidence was either insufficient to draw conclusions on the use of AWDs, or showed no difference in healing outcomes compared with non-AWDs.*

*Good quality clinical guidelines generally recommend against the use of AWDs in the routine treatment of clinically uninfected chronic wounds.*

### **Recommendation 1:**

***The routine use of AWDs to heal chronic wounds is not recommended.***

*There is insufficient clinical evidence to support the use of AWDs to treat local infection in chronic wounds. Despite this, they are currently used for this indication in NHSScotland. This HTA has highlighted that the approach used varies between and within NHS boards. There are no clear starting and stopping rules for AWDs, and the range of AWDs available for clinicians to use varies. This inconsistency is frustrating for staff, and can be an additional burden to patients. There is a need for a more consistent approach until the clinical evidence becomes more informative.*

### **Recommendation 2:**

***In the absence of sufficient clinical evidence to guide decision-making, NHSScotland should adopt a consistent approach to guide usage of AWDs in treating localised wound infection in chronic wounds. A national management algorithm should be agreed.***

***Refer to consensus statements.***

Wound healing was usually the most important outcome to patients, but control of signs and symptoms (like odour, exudate and pain), and prevention of infection and wound deterioration were also important. Some patients may also want dressings that are not visible through clothing, or dressings that do not impair their mobility.

**Recommendation 3:**

**When selecting a dressing for people with chronic wounds, alongside holistic clinical assessment, consider the factors of importance to the patient such as odour, pain/discomfort, leakage and mobility as well as healing.**

The use of AWDs varies across NHS boards. There is marked variation in NHS board expenditure, with no clear rationale. In the absence of clinical and cost effectiveness evidence to support use of one AWD over another, the costs of AWDs should guide their use. Reference should be made to local formularies.

**Recommendation 4:**

**Having first taken into account patient and wound-specific factors, the costs of dressings relative to their benefits should guide their use.**

**Refer to consensus statements.**

There is a lack of good quality RCTs in this area, which follow the principles of the CONSORT statement. The clinical experts on this topic group highlighted the need for studies reporting on outcomes relating to the treatment of wound infection, rather than wound healing. However, this may not be feasible unless a valid way to measure localised wound infection is established. The relationship between ulcer infection and wound healing is also unclear. There is currently consensus work being done to establish a list of the minimum outcomes that should be reported in RCTs for the treatment of venous leg ulcers (<http://www.comet-initiative.org/studies/details/680>).

Following from the above, there is a need for good quality economic evaluations. These should conform to the Consolidated Health Economics Evaluation Reporting Standards (CHEERS <http://www.bmj.com/content/346/bmj.f1049>).

**Recommendation 5:**

**There is a need for good quality RCTs on the use of AWDs to treat localised infection in chronic wounds. The subsequent impact of reduced infection on patient outcomes (for example healing, improvement in signs and symptoms) also needs to be explored.**

**There is also a need for good quality economic evaluations.**

The patient issues section highlighted the importance of consistent and clear

*messages from healthcare professionals. A patient version of this HTA has been prepared, which can be used to help patients understand the purpose of AWDs, and the issues around lack of evidence. However, there is a need for a national patient leaflet which explains to patients about chronic wounds, how they should manage them, and what their treatment options are. This leaflet should be developed in conjunction with relevant patient organisations.*

**Recommendation 6:**

***A national patient leaflet should be developed, which can be used as an aid to support shared decision-making between patients with chronic wounds and healthcare professionals.***

*Despite most respondents to the staff survey saying that they felt competent and confident in their decision-making around AWDs, there was also an acknowledgement that they can be used inappropriately and/or are overused. Healthcare professionals need training in order to support evidence-informed discussions about courses of treatment with patients. Respondents said that time/resource issues, as well as travel, might make attending training difficult for them. This HTA should be used to inform training material.*

**Recommendation 7:**

***There is a need for accessible and evidence-based education and training on the appropriate use of AWDs in chronic wounds.***

*There is a need for a national group to take this work forward; otherwise it is unlikely that the goal of a consistent approach will be achieved.*

**Recommendation 8:**

***The Therapeutics Branch in the Pharmacy and Medicines Division at Scottish Government would be well placed to take forward the implementation of the recommendations in this HTA.***

#### 9.2.1 Previous technologies scoping report on silver dressings

In January 2013, Healthcare Improvement Scotland published a technologies scoping report examining the clinical and cost effectiveness of silver dressings for the healing of infected wounds and the prevention of wound infection relative to other types of dressings (Technologies scoping report 12<sup>106</sup>).

This report concluded: 'Based on studies with short follow-up periods, we found insufficient evidence to determine whether or not silver dressings are any more effective than other types of dressing for the healing of infected wounds or the prevention of wound infection.'

In conjunction with the report, the Scottish Health Technologies Group (SHTG) issued an advice statement.

This HTA supersedes technologies scoping report 12 and the associated SHTG advice statement. However, the conclusion that the clinical and cost effectiveness evidence is insufficient has not changed.

#### 9.2.2 Upcoming publications of interest from Healthcare Improvement Scotland

Pressure ulcer standards are due to be published in November 2016. For more details refer to the Healthcare Improvement Scotland website (<http://www.healthcareimprovementscotland.org/>).

## **10 Consensus guidelines**

### **10.1 Introduction**

#### 10.1.1 Justification for developing consensus guidelines

For the treatment of local infection in chronic wounds, the published literature is insufficient to draw conclusions. For the healing of chronic wounds, the evidence either does not support the use of AWDs, or is insufficient to draw conclusions. The guidelines included in the clinical effectiveness section generally recommend against the use of AWDs in the routine treatment of clinically uninfected wounds. When AWDs were recommended as an option, it was in wounds with known or suspected increased microbial burden.

The majority of the respondents to the staff survey indicated that they supported the use of AWDs in wounds with signs and symptoms of local infection. Some felt that they reduced the need for systemic antibacterial drugs. However, respondents to the survey also reported that AWDs were overused, and often used unnecessarily.

The lack of clarity on when AWDs should be used has resulted in an inconsistent approach across NHSScotland. This uncertainty appeared to be a source of frustration for clinicians. Section 7 also highlighted that this inconsistent approach meant that patients were getting conflicting messages from different healthcare professionals, with AWDs that they had been treated with in one setting not being available to them in another. This is an additional burden to people, who feel that their preferred treatments are being withheld from them.

In the absence of sufficient clinical and cost effectiveness evidence, it could be argued that AWDs should not be used in chronic wounds with local infection. However, this HTA has gone beyond the clinical and cost effectiveness evidence, and sought input from patients and NHS staff. This highlighted strong support for AWDs in certain situations, and concerns around the impact on patient care of them being made unavailable for these specific situations. Therefore, until the evidence becomes more compelling either in support of, or against, the use of AWDs, guidance on AWD use based on the consensus of clinical experts was considered helpful. It was felt that a consistent approach, which clinicians support, would result in better care for patients, and discourage the inappropriate use of AWDs.

### **10.2 Methods**

Questions on the use of AWDs were developed, based on the findings of the staff survey (see the organisational issues chapter). Clinical experts also contacted Healthcare Improvement Scotland researchers separately detailing the clinical questions that they felt would be most usefully answered using consensus methodology. This resulted in five questions to be consulted on.

A call for participants was issued across NHSScotland. This involved placing an advert on the SIGN and Healthcare Improvement Scotland websites; sending targeted emails to certain appropriate topic groups/experts; asking the HTA expert group to forward the invitation to colleagues; and sending blanket emails using various Healthcare Improvement Scotland distribution lists. Clinicians who treat, or are involved in supporting the treatment of, chronic wounds were eligible for involvement. Undergraduate students were not considered eligible.

Consensus was reached using a modified Delphi approach. This involved three rounds of questioning, conducted by email. Participants were given 1 week to respond to each questionnaire. They were informed of the dates that they would receive the questionnaires at the start of the process to ensure their commitment.

After each round, the results were analysed and fed back anonymously to participants. Participants were asked to reconsider their answers in light of all responses. The questionnaires were refined for each round.

Participants were asked to indicate their agreement with each statement in the questionnaires using a five-point scale (strongly agree, agree, neither agree or disagree, disagree, strongly disagree). The threshold for consensus was 70% of people strongly agreeing or agreeing. If there were suggested changes to the wording of statements, participants were given the opportunity to comment in subsequent rounds.

The results of each round are available, along with the three questionnaires, from Healthcare Improvement Scotland on request. All participants were required to complete 'declaration of interests' forms.

### **10.3 Results**

Of the 59 people who volunteered to take part in the process, 30 people took part in round 1 (51% response rate). The 29 people who did not take part were excluded from the remaining rounds. The following specialties were represented: tissue viability nursing (n=8); district nursing (n=4); staff nursing (n=1); podiatry (n=6); practice nursing (n=1); pharmacy (n=1); community staff nursing (n=6); and dermatology (n=2). The following NHS boards were represented: NHS Greater Glasgow and Clyde (n=10); NHS Fife (n=5); NHS Lanarkshire (n=2); NHS Forth Valley (n=1); NHS Highland (n=2); NHS Lothian (n=5); NHS Tayside (n=3) and NHS Orkney (n=1). A lecturer in nursing was also included.

Twenty-three, out of 30 people, took part in round 2 (77% response rate). The seven people who did not take part were excluded from the remaining rounds.

Twenty-one, out of 23 people, took part in round 3 (91% response rate).

### 10.3.1 Consensus statements

1

- a. ***When treating a patient with a chronic wound, symptoms of localised infection must be present before use of an AWD is commenced.***

Consensus was achieved on this statement in round 2 of the process (21/23 people strongly agreed or agreed).

- b. ***However, in certain patients with underlying health conditions some of the signs and symptoms of localised infection might be masked.***

Consensus was achieved on this statement in round 3 of the process (18/21 people strongly agreed or agreed).

2.

- a. ***Clinical experts agreed that the most commonly observed signs and symptoms of localised infection, which might prompt use of AWDs, include:***

- ***pain/increased pain***
- ***erythema/redness***
- ***heat***
- ***wound deteriorating/getting bigger***
- ***exudate: thick, haemopurulent or purulent and/or high volumes***
- ***inflammation/swelling/oedema***
- ***delayed or stalled healing***
- ***malodour***
  
- ***Positive wound swab***

Consensus was achieved on this statement in round 2 of the process (21/23 people strongly agreed or agreed). While there was agreement on the list of signs and symptoms, the addition of 'positive wound swab' was questioned by members of the consensus group and peer reviewers. It is not a 'symptom', and is not practical in certain settings (for example community). It was also argued that inclusion of this sign could increase inappropriate swabbing of wounds. Following further discussion, the HTA topic group agreed that this sign should not be on the list.

- b. ***Some of the above signs and symptoms can be caused by patient factors other than localised wound infection. Therefore, a holistic assessment of the patient is required to rule out causes other than localised infection.***

Consensus was achieved on this statement in round 3 of the process (20/21 people strongly agreed or agreed).

- 3. After 2 weeks of using an AWD, if the symptoms of localised infection have ceased entirely, stop using the AWD and dress wound as per formulary recommendation**

Consensus was achieved on this statement in round 2 of the process (22/23 people strongly agreed or agreed).

- 4. After 2 weeks of using an AWD, if the symptoms of localised infection have improved but not ceased entirely, consider continued use of the AWD but review at weekly intervals.**

Consensus was achieved on this statement in round 2 of the process (22/23 people strongly agreed or agreed).

- 5. If, after 2 weeks of using an AWD, the symptoms of localised infection have not changed or have become worse, follow the guidance given in stage 3 of 'The Ropper Lothian Ladder' in tandem with your local policies and procedures.**

See Figure 9.

Consensus was achieved on this statement in round 3 of the process (19/21 people strongly agreed or agreed). However, there was debate around this statement as swabbing for localised infection would not be supported by some NHS boards. The HTA topic group advised that wound swabbing is not appropriate for localised infection.

- 6. Do not use an AWD for longer than 2 weeks without reassessing wound progress.**

Consensus was achieved on this statement in round 2 of the process (everyone strongly agreed or agreed).

- 7. AWDs should not normally be used for longer than recommended by the product information, or as documented within local policies or procedures.**

Consensus was achieved on this statement in round 3 of the process (18/21 strongly agreed or agreed). However, there was some disagreement around the value of this statement.

- 8. Having taken into account patient and wound specific factors, the costs of dressings relative to their benefits should guide their use.**

Consensus was achieved on this statement in round 2 of the process (22/23 either strongly agreed or agreed).

#### 10.3.2 Areas where consensus was not achieved.

- Consensus could not be reached on which type of AWD to use for different wound types. Therefore, when selecting AWDs clinicians should be guided by their local formularies and guidelines.
- It was not possible to reach consensus on how long to use AWDs in patients with chronic wounds in whom signs of infection were

improving, but not clearing entirely (other than to review wound progress at weekly intervals, as Statement 4 suggests). In such cases AWDs could theoretically be used for extended periods of time. This is an area for which more research or consensus work is needed, as AWDs should not be used for indefinite periods of time.

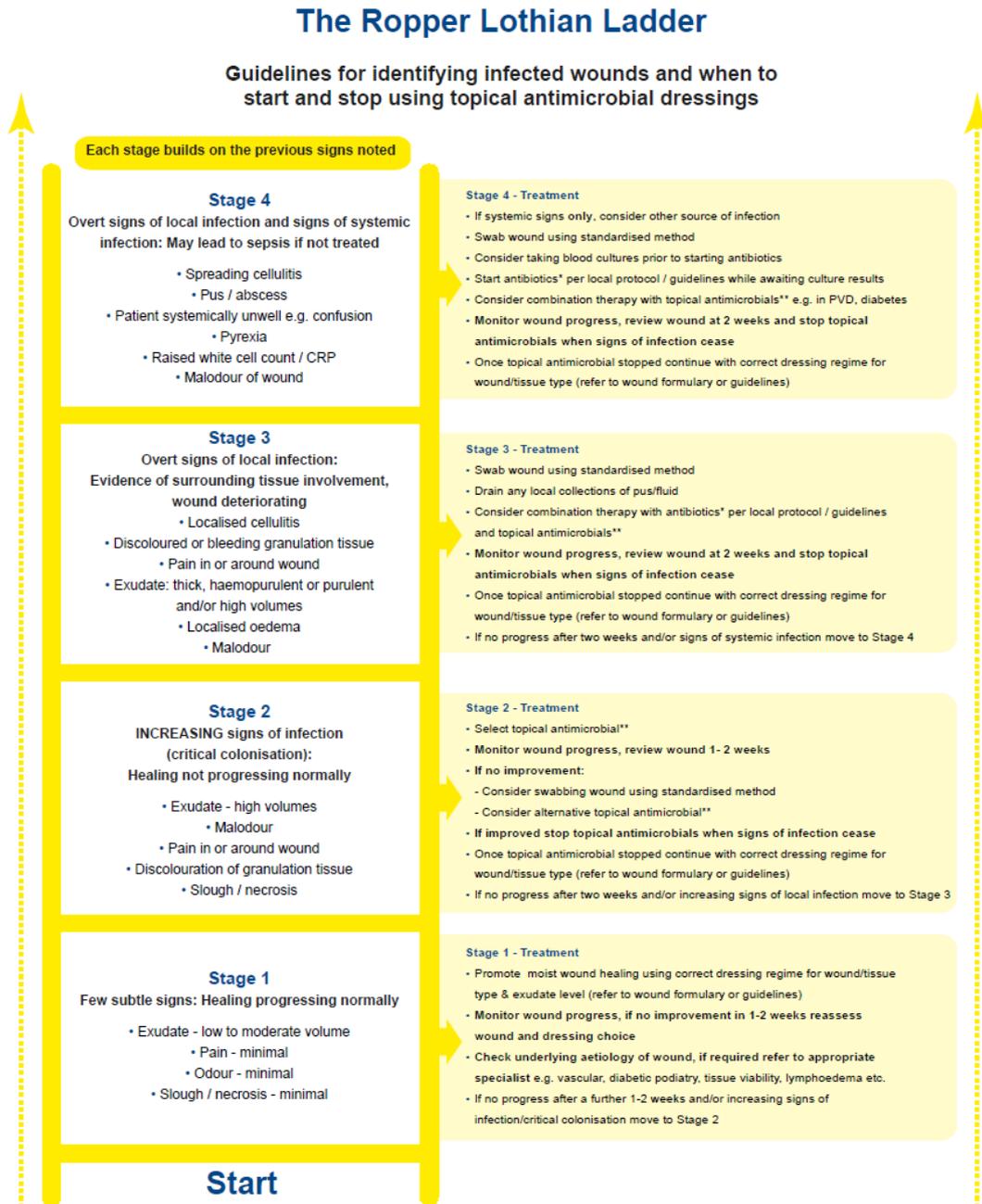
#### **10.4 Limitations**

Despite 59 people volunteering to take part at the outset, only 30 people responded to the first round of questioning. Twenty-one people took part in the final round. Despite this relatively low number, consensus on the included statements is high. It is also of value to have the opinion of people who use these dressings, and treat these wounds, on a daily basis.

While various nursing specialties and podiatry were well represented, other clinical specialties (for example pharmacists and doctors) were not. In addition, some NHS boards were not represented (NHS Ayrshire & Arran, NHS Borders, NHS Dumfries & Galloway, NHS Grampian, NHS Shetland and NHS Western Isles). However, this HTA was subject to an open consultation, where individuals from these specialties and NHS boards had the opportunity to comment.

As part of the consultation process, it was suggested that a consensus statement on contraindications to AWD use would have been helpful.

**Figure 9: The Ropper Lothian Ladder.**  
(Reproduced with permission from Ruth Ropper, NHS Lothian)



This guide should be used along with clinical judgement in complex patients; in particular patients with diabetic wounds (refer to diabetic podiatry team), vascular problems and immunocompromised patients may require antimicrobials for prophylaxis as well as treatment. \*Systemic Antibiotics - follow local Antibiotic Policy. \*\*Topical Antimicrobial - refer to Wound Formulary. Topical antimicrobials can include honey, iodine, silver, PHMB, DACC and enzymatic products. Not all of these are formulary products, see local protocol for guidance on their use. Contact TVN team for more info if required.

**References:**  
European Wound Management Association (2005) Position Document: *Identifying criteria for wound infection*. MEP, London  
European Wound Management Association (2009) Position Document: *Management of wound infection*. MEP, London  
*Best Practice Statement: Use of topical antiseptic/antimicrobial agents in wound management*, Wounds UK Aberdeen (2010)  
*Medical Photography Service, NHS Lothian University Hospital Division - 13.01.14*

Ruth Ropper  
Lead Nurse Tissue Viability, NHS Lothian  
email: ruth.opper@nhslothian.scot.nhs.uk

## 11 Acknowledgements

Healthcare Improvement Scotland is grateful to all members of the HTA topic group who have given generously of their time and expertise to contribute constructively to the writing of this report.

We would also like to thank the following:

- Juliet Brown, Evidence and Information Scientist, Scottish Intercollegiate Guidelines Network
- Paul Hornby, Strategic Sourcing Manager, NHS National Procurement
- Danny McQueen, Public Partner, Healthcare Improvement Scotland
- James Miller, Director of Strategic Sourcing, NHS National Procurement
- Paula Moor, Community Staff Nurse, Comrie Medical Centre
- Heather Morgan, Research Fellow, Health Services Research Unit, University of Aberdeen
- Hester Ward, Consultant in Public Health Medicine, Information Services Division and Health Protection Scotland
- Derek Yuille, Deputy Director of Finance, NHS Lanarkshire
- The Evidence Review Committee, Scottish Health Technologies Group

## **12 The team**

### **12.1 Healthcare Improvement Scotland project team**

- Joanna Kelly, Health Services Researcher (Lead Author)
- Edward Clifton, Senior Health Economist
- Naomi Fearn, Health Services Researcher
- Jenny Harbour, Health Information Scientist
- Stephen Heller-Murphy, Health Services Researcher
- Paul Herbert, Health Information Scientist
- Marina Logan, Team Support Administrator
- Karen Macpherson, Lead Health Services Researcher/Project Lead
- Susan Myles, Lead Health Economist/Project Lead
- Doreen Pedlar, Project Co-ordinator
- Valdemar Santo, Health Economist
- Lisa Wilson, Health Economist

### **12.2 Topic proposers**

- Margaret Ryan, Lead Clinician Prescribing Services, NHS Greater Glasgow and Clyde
- Lynne Watret, Non Medical Prescribing Advisor, NHS Greater Glasgow and Clyde

### **12.3 HTA topic group membership (as of May 2014)**

- Glynis Billimore, Vascular Nurse Specialist, Chair of Leg Ulcer Forum Scotland
- Julie Brittenden, Senior Lecturer in Vascular Surgery, University of Aberdeen
- Lorna Brown, Lead for Prescribing and Clinical Pharmacy, NHS Greater Glasgow and Clyde
- Jo Dumville, Senior Lecturer in Applied Health Research, University of Manchester
- Gavin Gorman, Non Medical Prescribing Lead, NHS Greater Glasgow and Clyde
- David Gray, Honorary Professor/Tissue Viability Nurse Specialist, NHS Grampian, Scottish Tissue Viability Nurses representative
- Teresa Inkster, Consultant Microbiologist, NHS Greater Glasgow and Clyde
- Alison Johnstone, Tissue Viability Nurse, NHS Greater Glasgow and Clyde, Scottish Tissue Viability Nurses representative
- Alistair Leanord, HAI Medical Adviser, Scottish Government

- May Loney, Dermatology Nurse Specialist, Leg Ulcer Forum Scotland
- Celia Macaskill, Dermatology Nurse Specialist, Leg Ulcer Forum Scotland
- Joanne McCardle, Diabetic Podiatrist, NHS Lothian
- Graeme McIntosh, Commodity Manager, NHS National Procurement
- Nils Michael, Economist, Scottish Government
- Abigail Mullings, Deputy Chief Nursing Officer – Safe Care, Scottish Government
- Jill Nowell, Lead Pharmacist for Medicines Utilisation, NHS Forth Valley, Directors of Pharmacy Group representative
- Linda Primmer, Community Tissue Viability Nurse, NHS Lothian, Scottish Tissue Viability Nurses representative
- Thomas Ross, Lead Pharmacist (South & Mid), NHS Highland, Directors of Pharmacy Group representative
- Margaret Ryan, Lead Clinician Prescribing Services, NHS Greater Glasgow and Clyde
- Ailsa Sharp, Lecturer in Adult Nursing/Tissue Viability, Napier University, Scottish Tissue Viability Nurses representative
- Jacqueline Sneddon, Project Lead for Scottish Antimicrobial Prescribing Group, Healthcare Improvement Scotland
- Lynne Watret, Non Medical Prescribing Advisor, NHS Greater Glasgow and Clyde
- Richard White, Professor of Tissue Viability, University of Worcester

## 13 Glossary

<b>acute wound</b>	An injury to the skin that occurs suddenly rather than over time. It heals in a predictable and expected rate according to the normal wound healing process.
<b>antibacterial</b>	Active against bacteria.
<b>antibiotics</b>	Agents that act selectively against bacteria and are normally administered systemically. They usually have one specific target of disruptive activity in bacterial cells and act against a narrower range of bacteria than antiseptics.
<b>antimicrobial</b>	Any agent that kills or prevents the multiplication of micro-organisms for example bacteria or fungi. Antimicrobials may be antibiotics, antiseptics or disinfectants.
<b>antimicrobial wound dressing</b>	A dressing that carries or delivers an antimicrobial agent. Dressings to be included in this HTA are fabric, viscose knitted fabric gauze or tulle, calcium alginate, hydrogel, paste, ointment, low adherent polyester, polyurethane foam, soft polymer, silicone, hydrocolloid, carboxymethylcellulose, low adherent acetate and starch based dressings. Antimicrobial agents to be included are honey, iodine, silver, polihexanide (PHMB), enzyme (for example glucose oxidase and lactoperoxidase) alginogels, octenidine, chlorhexidine and dialkylcarbamoyl chloride (DACC).
<b>antiseptics</b>	Chemical agents that can be applied topically to the skin or wounds. They are relatively non-selective agents that inhibit multiplication of, or kill, microorganisms.
<b>bioburden</b>	The extent of microbial contamination.
<b>biofilm</b>	Complex polymicrobial communities that attach to a surface.

<b>chronic wound</b>	A chronic wound develops when an acute wound fails to heal within the expected period for that type of wound, which might be anything from a couple of weeks to several weeks. For the purpose of this HTA, the wounds of interest are foot ulcers in people with diabetes, pressure ulcers, and venous/arterial ulcers. Other wounds may be included if time and resources allow (for example dehisced surgical wounds).
<b>clinical effectiveness</b>	The benefit of using a technology, programme or intervention to address a specific problem under general or routine conditions, rather than under controlled conditions, for example, by a physician in a hospital or by a patient at home.
<b>cost effectiveness</b>	A form of economic analysis which compares two interventions in terms of both their costs and their effect on patients, to ascertain whether the additional cost of the more expensive intervention gives rise to sufficient additional benefits to warrant the additional cost.
<b>critical colonisation or localised infection</b>	Microbes multiply and the wound moves from benign colonisation to an infected state with impaired healing, but without tissue invasion or host immunological response. There is currently no consensus on how to define or identify critical colonisation.
<b>DACC</b>	Dialkylcarbamoyl chloride
<b>debridement</b>	The process of cleaning an open wound by removal of foreign material and dead tissue, so that healing may occur without hindrance.
<b>dehisced surgical wound</b>	A dehisced surgical wound is a surgical wound where the suture line has failed to heal so that the wound re-opens when the sutures are removed.
<b>diabetic neuropathy</b>	Damage to the nerves seen in some people with long-standing diabetes. It most commonly affects the legs, causing pain or numbness working up from the feet.

<b>disinfectant</b>	Relatively non-selective agents often with multiple sites of action that kill a wide range of microorganisms including bacteria and fungi. Disinfectants are generally not suitable for use on body tissue because they are toxic to human cells.
<b>dominance</b>	A treatment option may be said to dominate another if its effectiveness is higher, and its costs lower.
<b>excoriation</b>	The destruction and removal of the surface of the skin or the covering of an organ by scraping, the application of a chemical, or other means.
<b>granulation</b>	The formation of tissue during healing.
<b>induration</b>	Abnormal hardening of a tissue or organ.
<b>maceration</b>	The softening of a solid by leaving it immersed in a liquid.
<b>necrosis</b>	Death of tissues.
<b>PHMB</b>	Polihexanide.
<b>pressure ulcer</b>	Localised injury to skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.
<b>protease</b>	Any enzyme that catalyses the splitting of a protein.
<b>slough</b>	A layer of dead tissue that has become separated from living tissue.
<b>venous ulcer</b>	Venous ulcers arise from venous valve incompetence and calf muscle pump insufficiency which leads to venous stasis and hypertension. This results in microcirculatory changes and localised tissue ischaemia.

## 14 References

1. Schultz G, Dowsett C. Technology update: wound bed preparation revisited. *Wounds International*. 2012;3(1):25-9.
2. Agency for Healthcare Research and Quality. Chronic venous ulcers: A comparative effectiveness review of treatment modalities. 2014 [cited 2014 Jan 13]; Available from: <http://effectivehealthcare.ahrq.gov/ehc/products/367/1737/venous-ulcers-treatment-report-erratum-140127.pdf>
3. European Wound Management Association (EWMA). Hard-to-heal wounds: a holistic approach. 2008 [cited 2014 Jan 13]; Available from: [http://ewma.org/fileadmin/user\\_upload/EWMA/pdf/Position\\_Documents/2008/English\\_EWMA\\_Hard2Heal\\_2008.pdf](http://ewma.org/fileadmin/user_upload/EWMA/pdf/Position_Documents/2008/English_EWMA_Hard2Heal_2008.pdf).
4. The Royal Children's Hospital Melbourne. Clinical Guidelines (Nursing): Wound Care. 2012 [cited 2014 Jan 13]; Available from: [http://www.rch.org.au/rchcpg/hospital\\_clinical\\_guideline\\_index/Wound\\_care/](http://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Wound_care/).
5. Phillips TJ, Machado F, Trout R, Porter J, Olin J, Falanga V. Prognostic indicators in venous ulcers. *J Am Acad Dermatol*. 2000;43(4):627-30.
6. Mustoe TA, O'Shaughnessy K, Kloeters O. Chronic wound pathogenesis and current treatment strategies: a unifying hypothesis. *Plast Reconstr Surg*. 2006;117 suppl 7:S35-41.
7. Werdin F, Tennenhaus M, Schaller H-E, Rennekampff H-O. Evidence-based Management Strategies for Treatment of Chronic Wounds. *Eplasty*. 2009; 9: e19.
8. Scottish Intercollegiate Guidelines Network (SIGN). Management of chronic venous leg ulcers. 2010 [cited 2014 Jan 15]; Available from: <http://www.sign.ac.uk/pdf/sign120.pdf>.
9. Australian Wound Management Association Inc, New Zealand Wound Care Society. Australian and New Zealand clinical practice guideline for prevention and management of venous leg ulcers. 2011 [cited 2014 Jan 7]; Available from: [http://www.nhmrc.gov.au/files\\_nhmrc/publications/attachments/ext003\\_venous\\_leg\\_ulcers\\_aust\\_nz\\_0.pdf](http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/ext003_venous_leg_ulcers_aust_nz_0.pdf).
10. Patient.co.uk. Diabetic Foot. 2014 [cited 2014 Jan 13]; Available from: <http://www.patient.co.uk/doctor/diabetic-foot>.
11. Australian Wound Management Association. Pan Pacific clinical practice guideline for the prevention and management of pressure injury. 2012 [cited 2014 Jan 13]; Available from: [http://www.awma.com.au/publications/2012\\_AWMA\\_Pan\\_Pacific\\_Guidelines.pdf](http://www.awma.com.au/publications/2012_AWMA_Pan_Pacific_Guidelines.pdf).
12. Wounds UK. Best Practice Statement: The use of topical antimicrobial agents in wound management. 2013 [cited 2014 Jan 13]; Available from: [http://www.wounds-uk.com/pdf/content\\_10964.pdf](http://www.wounds-uk.com/pdf/content_10964.pdf).

13. Lipsky BA, Hoey C. Topical antimicrobial therapy for treating chronic wounds. *Clin Infect Dis*. 2009;49(10):1541-9.
14. World Union of Wound Healing Societies (WUWHS). Principles of best practice: Wound infection in clinical practice. An international consensus. 2008 [cited 2014 Jan 13]; Available at: [http://www.woundsinternational.com/pdf/content\\_31.pdf](http://www.woundsinternational.com/pdf/content_31.pdf).
15. European Wound Management Association (EWMA). Identifying criteria for wound infection. 2005 [cited 2014 Apr 3]; Available from: [http://www.cslr.cz/download/English\\_pos\\_doc\\_final.pdf](http://www.cslr.cz/download/English_pos_doc_final.pdf).
16. Wounds International. International consensus: appropriate use of silver dressings in wounds. 2012 [cited 2014 Jan 13]; Available from: [http://www.woundsinternational.com/pdf/content\\_10381.pdf](http://www.woundsinternational.com/pdf/content_10381.pdf).
17. Moore Z. How to...Top tips on when to use silver dressings. *Wounds International*. 2013;4(1):15-8.
18. Parsons D, Bowler PG, Myles V, Jones S. Silver antimicrobial dressings in wound management: a comparison of antibacterial, physical, and chemical characteristics. *Wounds*. 2005;17(8):222-32.
19. White R. An open response to the technology scoping report examining the clinical and cost effectiveness of silver. *J Wound Care*. 2013;22(9):514-9.
20. Swedish Council on Technology Assessment in Healthcare. Silver-releasing dressings in treating chronic wounds. 2010 [cited 2014 Jan 15]; Available from: [http://www.sbu.se/upload/Publikationer/Content0/3/SilverReleasing\\_Dr essings\\_Chronic\\_Wounds\\_201002.pdf](http://www.sbu.se/upload/Publikationer/Content0/3/SilverReleasing_Dr essings_Chronic_Wounds_201002.pdf).
21. Hurding S, MacBride-Stewart S. National therapeutic indicators 2012: baseline data. 2012 [cited 2014 Jan 13]; Available from: [http://www.sehd.scot.nhs.uk/pca/PCA2012\(M\)08report.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2012(M)08report.pdf).
22. O'Meara S, Al-Kurdi D, Ologun Y, Ovington Liza G, Martyn-St James M, Richardson R. Antibiotics and antiseptics for venous leg ulcers. *The Cochrane Database of Systematic Reviews* 2014, Issue 1.
23. SIGN. Management of chronic venous leg ulcers. 2010 [cited 2013 Oct 15]; Available from: <http://www.sign.ac.uk/pdf/sign120.pdf>.
24. VA Health Care. Advanced wound care therapies for non-healing diabetic, venous, and arterial ulcers: a systematic review. 2012 [cited 2014 Jan 17]; Available from: <http://www.hsrd.research.va.gov/publications/esp/wound-care-EXEC.pdf>.
25. Dumville JC, Deshpande S, O'Meara S, Speak K. Hydrocolloid dressings for healing diabetic foot ulcers. *The Cochrane Database of Systematic Reviews* 2012, Issue 2.

26. Game FL, Hinchliffe RJ, Apelqvist J, Armstrong DG, Bakker K, Hartemann A, *et al.* A systematic review of interventions to enhance the healing of chronic ulcers of the foot in diabetes. *Diabetes Metab Res Rev.* 2012;28 Suppl 1:119-41.
27. Hinchliffe RJ, Valk GD, Apelqvist J, Armstrong DG, Bakker K, Game FL, *et al.* A systematic review of the effectiveness of interventions to enhance the healing of chronic ulcers of the foot in diabetes. *Diabetes Metab Res Rev.* 2008;24 Suppl 1:S119-44.
28. Jull AB, Walker N, Deshpande S. Honey as a topical treatment for wounds. *The Cochrane Database of Systematic Reviews* 2013, Issue 2.
29. Mason J, O'Keeffe C, Hutchinson A, McIntosh A, Young R, Booth A. A systematic review of foot ulcer in patients with type 2 diabetes mellitus. II: Treatment. *Diabet Med.* 1999;16(11):889-909.
30. Nelson EA, O'Meara S, Craid D, Iglesias C, Golder S, Dalton J, *et al.* A series of systematic reviews to inform a decision analysis for sampling and treating infected diabetic foot ulcers. 2006 [cited 2014 Jan 10]; Available from: [http://www.journalslibrary.nihr.ac.uk/\\_data/assets/pdf\\_file/0018/64602/FullReport-hta10120.pdf](http://www.journalslibrary.nihr.ac.uk/_data/assets/pdf_file/0018/64602/FullReport-hta10120.pdf).
31. Vermeulen H, Westerbos SJ, Ubbink DT. Benefit and harm of iodine in wound care: a systematic review. *J Hosp Infect.* 2010;76(3):191-9.
32. NICE. Clinical guidelines for type 2 diabetes: prevention and management of foot problems. 2004 [cited 2014 Jan 8]; Available from: <http://www.nice.org.uk/guidance/cg10>
33. Kamaratos AV, Tzirogiannis KN, Iraklianiou SA, Panoutsopoulos GI, Kanellos IE, Melidonis AI. Manuka honey-impregnated dressings in the treatment of neuropathic diabetic foot ulcers. *Int Wound J.* 2014;11(3):259-63.
34. Carter MJ, Tingley-Kelley K, Warriner RA. Silver treatments and silver-impregnated dressings for the healing of leg wounds and ulcers: a systematic review and meta-analysis. *J Am Acad Dermatol.* 2010;63(4):668-79.
35. Dumville JC, O'Meara S, Deshpande S, Speak K. Alginate dressings for healing diabetic foot ulcers. *The Cochrane Database of Systematic Reviews* 2012, Issue 2.
36. Lo SF, Chang CJ, Hu WY, Hayter M, Chang YT. The effectiveness of silver-releasing dressings in the management of non-healing chronic wounds: A meta-analysis. *J Clin Nurs.* 2009;18(5):716-28.
37. Storm-Versloot M, Vos CG, DT U, H V. Topical silver for preventing wound infection. *The Cochrane Database of Systematic Reviews* 2010, Issue 3.
38. Moore C, Young J. Systematic Review: Effectiveness of silver in wound care treatment. *Phys Ther Rev.* 2011;16(3):201-9.

39. Gottrup F, Cullen BM, Karlsmark T, Bischoff-Mikkelsen M, Nisbet L, Gibson MC. Randomized controlled trial on collagen/oxidized regenerated cellulose/silver treatment. *Wound Repair Regen.* 2013;21(2):216-25.
40. O'Meara S, Cullum N, Majid M, Sheldon T. Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration. *Health Technol Assess.* 2000;4(21):1-228.
41. NICE. Pressure ulcer management: the prevention and management of pressure ulcers in primary and secondary care. 2014 [cited 2014 Apr 3]; Available from: <http://publications.nice.org.uk/pressure-ulcers-prevention-and-management-of-pressure-ulcers-cg179>.
42. Cuddigan J. NPUAP-EPUAP pressure ulcer prevention and treatment guidelines. 2009 [cited 2014 Jan 7]; Available from: <http://www.npuap.org/wp-content/uploads/2012/03/Final-2009-Treatment-Technical-Report1.pdf>  
[http://www.epuap.org/guidelines/Final\\_Quick\\_Treatment.pdf](http://www.epuap.org/guidelines/Final_Quick_Treatment.pdf).
43. Beeckman D, Matheï C, Van Lancker A, Vanwalleghem G, Van Houdt S, Gryson L, *et al.* A national guideline for the treatment of pressure ulcers. 2013 [cited 2014 Jan 7]; Available from: [https://kce.fgov.be/sites/default/files/page\\_documents/KCE\\_203\\_pressure\\_ulcers.pdf](https://kce.fgov.be/sites/default/files/page_documents/KCE_203_pressure_ulcers.pdf).
44. Health Quality Ontario. Management of chronic pressure ulcers: an evidence-based analysis. *Ont Health Technol Assess Ser.* 2009;9(3):1-203.
45. Reddy M, Gill SS, Kalkar SR, Wu W, Anderson PJ, Rochon PA. Treatment of pressure ulcers: A systematic review. *JAMA.* 2008;300(22):2647-62.
46. Chaby G, Senet P, Vaneau M, Martel P, Guillaume JC, Meaume S, *et al.* Dressings for acute and chronic wounds: a systematic review. *Arch Dermatol.* 2007;143(10):1297-304..
47. Vermeulen H, Ubbink DT, Goossens A, De Vos R, Legemate DA. Dressings and topical agents for surgical wounds healing by secondary intention. *The Cochrane Database of Systematic Reviews* 2009, Issue 4.
48. Joint Formulary Committee. *British National Formulary (BNF) 68.* 68<sup>th</sup> ed. London: Pharmaceutical Press; 2014.
49. Leaper DJ, Drake R. Should one size fit all? An overview and critique of the VULCAN study on silver dressings. *Int Wound J.* 2011;8(1):1-4.
50. Michaels JA, Campbell B, King B, Palfreyman SJ, Shackley P, Stevenson M. Randomized controlled trial and cost effectiveness analysis of silver-donating antimicrobial dressings for venous leg ulcers (VULCAN trial). *Br J Surg.* 2009;96(10):1147-56.

51. Authors' reply: Randomized controlled trial and cost effectiveness analysis of silver-donating antimicrobial dressings for venous leg ulcers (VULCAN trial) (Br J Surg 2009; 96: 1147–1156).
52. European Wound Management Association. Antimicrobials and non-healing wounds: evidence, controversies and suggestions. 2013 [cited 2014 Jan 13]; Available from: [http://ewma.org/fileadmin/user\\_upload/EWMA/pdf/EWMA\\_Projects/Antimicrobial/JWC\\_EWMA\\_supplement\\_NO\\_CROPS.pdf](http://ewma.org/fileadmin/user_upload/EWMA/pdf/EWMA_Projects/Antimicrobial/JWC_EWMA_supplement_NO_CROPS.pdf).
53. Leaper DJ. Evidence-based wound care in the UK. Int Wound J. 2009;6(2):89-91.
54. Lantis J, Price P. The role of Allevyn(R) Ag in the management of hard-to-heal wounds. Wounds International. 2011;2(4):29-35.
55. Michaels JA, Campbell WB, King BM, MacIntyre J, Palfreyman SJ, Shackley P, *et al*. A prospective randomised controlled trial and economic modelling of antimicrobial silver dressings versus non-adherent control dressings for venous leg ulcers: the VULCAN trial. Health Technol Assess. 2009;13(56):1-114.
56. Scanlon E, Karlsmark T, Leaper DJ, Carter K, Poulsen PB, Hart-Hansen K, *et al*. Cost-effective faster wound healing with a sustained silver-releasing foam dressing in delayed healing leg ulcers: a health-economic analysis. Int Wound J. 2005;2(2):150-60.
57. Jeffcoate WJ, Price PE, Phillips CJ, Game FL, Mudge E, Davies S, *et al*. Randomised controlled trial of the use of three dressing preparations in the management of chronic ulceration of the foot in diabetes. Health Technol Assess. 2009;13(54):1-86.
58. Chuangsuwanich A, Charnsanti O, Lohsiriwat V, Kangwanpoom C, Thong-In N. The efficacy of silver mesh dressing compared with silver sulfadiazine cream for the treatment of pressure ulcers. J Med Assoc Thai. 2011;94(5):559-65.
59. Critical Appraisal Skills Programme (CASP). 10 questions to help you make sense of qualitative research. 2013 [cited 2014 Jan 13]; Available from: <http://www.biomedcentral.com/content/supplementary/2046-4053-3-139-S8.pdf>
60. Ring N, Ritchie K, Mandava L, Jepson RA. A guide to synthesising qualitative research for researchers undertaking health technology assessments and systematic reviews. 2011 [cited 2014 Jan 13]; Available from: [http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/programme\\_resources/synth\\_qualitative\\_research.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/programme_resources/synth_qualitative_research.aspx)
61. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess R, editors. Analyzing qualitative data. Abingdon: Routledge; 1994.

62. Ritchie J, Lewis J. *Qualitative Research Practice*. London: Sage Publications; 2009.
63. Noyes J, Lewin S. *Supplemental Guidance on Selecting a Method of Qualitative Evidence Synthesis, and Integrating Qualitative Evidence with Cochrane Intervention Reviews*. 2011 [cited 2014 Jan 13]; Available from: <http://cgim.cochrane.org/supplemental-handbook-guidance>.
64. Bradbury SE, E Price P. Diabetic foot ulcer pain: The hidden burden (Part two). *EWMA Journal*. 2011;11(2):25-37.
65. Brown A. Chronic leg ulcers, part 2: Do they affect a patient's social life? *Br J Nurs*. 2005;14(18):986-9.
66. Chase SK, Melloni M, Savage A. A forever healing: the lived experience of venous ulcer disease. *J Vasc Nurs* 1997;15(2):73-8.
67. Douglas V. Living with a chronic leg ulcer: an insight into patients' experiences and feelings. *J Wound Care*. 2001;10(9):355-60.
68. Ebbeskog B, Emami A. Older patients' experience of dressing changes on venous leg ulcers: more than just a docile patient. *J Clin Nurs*. 2005;14(10):1223-31.
69. Fox C. Living with a pressure ulcer: a descriptive study of patients' experiences. *Br J Community Nurs*. 2002;(7 Suppl 6):10, 12, 14, 16, 20, 22.
70. Gorecki C, Nixon J, Madill A, Firth J, Brown JM. What influences the impact of pressure ulcers on health-related quality of life? A qualitative patient-focused exploration of contributory factors. *J Tissue Viability*. 2012;21(1):3-12.
71. Haram RB, Dagfinn N. Errors and discrepancies: a patient perspective on leg ulcer treatment at home. *J Wound Care*. 2003;12(5):195-9.
72. Hopkins A. Disrupted lives: investigating coping strategies for non-healing leg ulcers. *Br J Nurs*. 2004;13(9):556-63.
73. Hopkins A, Dealey C, Bale S, Defloor T, Worboys F. Patient stories of living with a pressure ulcer. *J Adv Nurs*. 2006;56(4):345-53.
74. Hyde C, Ward B, Horsfall J, Winder G. Older women's experience of living with chronic leg ulceration. *Int J Nurs Pract*. 1999;5(4):189-98.
75. Krasner D. Painful venous ulcers: themes and stories about living with the pain and suffering. *J Wound Ostomy Continence Nurs*. 1998;25(3):158-68.
76. Langemo DK, Melland H, Hanson D, Olson B, Hunter S. The lived experience of having a pressure ulcer: a qualitative analysis. *Adv Skin Wound Care*. 2000;13(5):225-35.
77. Mudge E, Holloway S, Simmonds W, Price P. Living with venous leg ulceration: issues concerning adherence. *Br J Nurs*. 2006;15(21):1166-71.

78. Mudge E, Spanou C, Price P. A focus group study into patients' perception of chronic wound pain. *Wounds UK*. 2008;4(2):21-8.
79. Neil JA, Munjas BA. Living with a chronic wound: the voices of sufferers. *Ostomy Wound Manage*. 2000;46(5):28-34, 36-8.
80. Ribu L, Wahl A. Living with diabetic foot ulcers: a life of fear, restrictions, and pain. *Ostomy Wound Manage*. 2004;50(2):57-67.
81. Spilsbury K, Nelson A, Cullum N, Iglesias C, Nixon J, Mason S. Pressure ulcers and their treatment and effects on quality of life: hospital inpatient perspectives. *J Adv Nurs*. 2007;57(5):494-504.
82. Walshe C. Living with a venous leg ulcer: a descriptive study of patients' experiences. *J Adv Nurs*. 1995;22(6):1092-100.
83. Green J, Jester R, McKinley R, Pooler A. Patient perspectives of their leg ulcer journey. *J Wound Care*. 2013;22(2):58, 60-2, 64-6.
84. Brown A. Chronic leg ulcers, part 1: do they affect a patient's social life? *Br J Nurs*. 2005;14(18):894-8.
85. Persoon A, Heinen MM, Van Der Vleuten CJM, De Rooij MJ, Van De Kerkhof PCM, Van Achterberg T. Leg ulcers: a review of their impact on daily life. *J Clin Nurs*. 2004;13(3):341-54.
86. Herber O, Schnepf W, Rieger M. A systematic review on the impact of leg ulceration on patients' quality of life. *Health Qual Life Outcomes*. 2007;5(1):44.
87. Briggs M, Flemming K. Living with leg ulceration: a synthesis of qualitative research. *J Adv Nurs*. 2007;59(4):319-28.
88. Swedish Council on Health Technology Assessment. Evaluation and synthesis of studies using qualitative methods of analysis. 2013 [cited 2014 Sep 12]; Available from: [www.sbu.se/handbook](http://www.sbu.se/handbook).
89. Glenton C, Colvin Christopher J, Carlsen B, Swartz A, Lewin S, Noyes J, *et al*. Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: qualitative evidence synthesis. *The Cochrane Database of Systematic Reviews* 2013, Issue 10.
90. Brazier J, Connell J, Papaioannou D, Mukuria C, Mulhern B, Peasgood T, *et al*. A systematic review, psychometric analysis and qualitative assessment of generic preference-based measures of health in mental health populations and the estimation of mapping functions from widely used specific measures. *Health Technol Assess*. 2014;18(34):1-188.
91. Ylonen M, Stolt M, Leino-Kilpi H, Suhonen R. Nurses' knowledge about venous leg ulcer care: a literature review. *Int Nurs Rev*. 2014;61(2):194-202.
92. Graham ID, Harrison MB, Shafey M, Keast D. Knowledge and attitudes regarding care of leg ulcers. Survey of family physicians. *Can Fam Physician*. 2003;49:896-902.

93. Hjelm K, Nyberg P, Apelqvist J. Chronic leg ulcers in Sweden: a survey of wound management. *J Wound Care*. 2000;9(3):131-6.
94. Miller CN, Carville K, Newall N, Kapp S, Lewin G, Karimi L, *et al*. Assessing bacterial burden in wounds: comparing clinical observation and wound swabs. *Int Wound J*. 2011;8(1):45-55.
95. Hickie S, Ross S, Bond C. A survey of the management of leg ulcers in primary care settings in Scotland. *J Clin Nurs*. 1998;7(1):45-50.
96. Hjelm K, Rolfe M, Bryar RM, Andersson B, Fletcher M. Management of chronic leg ulcers by nurses working in the community in Sweden and the UK. *J Wound Care*. 2003;12(3):93-8.
97. Hollinworth H, Collier M. Nurses' views about pain and trauma at dressing changes: results of a national survey. *J Wound Care*. 2000;9(8):369-73.
98. Truchetet F, Guibon O, Meaume S. Clinicians' rationale for using a silver dressing: the French OMAg+E observational study. *J Wound Care*. 2012;21(12):620, 622-5.
99. Friman A, Klang B, Ebbeskog B. Wound care by district nurses at primary healthcare centres: a challenging task without authority or resources. *Scand J Caring Sci*. 2011;25(3):426-34.
100. Flanagan M. Variables influencing nurses' selection of wound dressings. *J Wound Care*. 1992;1(1):33-43.
101. Gardner S. Using treatment pathways to improve healing of venous leg ulceration. *Wounds UK*. 2013;9(1):67-75.
102. Wuerz T, Hanley M, Close R, Dow G. The impact of a standardized protocol on the quality of wound dressing procedures in hospitalized patients. *Can J Infect Control*. 2011;26(3):175-9.
103. Keen D, James J. A tool to aid nurses' decision making in relation to dressing selection. *Br J Nurs*. 2004;13(15):S6-14.
104. Beitz JM, van Rijswijk L. A cross-sectional study to validate wound care algorithms for use by registered nurses. *Ostomy Wound Manage*. 2010;56(4):46-59.
105. Boxer E, Maynard C. The management of chronic wounds: factors that affect nurses' decision-making. *J Wound Care*. 1999;8(8):409-12.
106. Healthcare Improvement Scotland. Are silver dressings clinically effective and cost-effective for the healing of infected wounds and the prevention of wound infection relative to other types of dressing? 2013 [cited 2014 Jan 13]; Available from: [http://www.healthcareimprovementscotland.org/our\\_work/technologies\\_and\\_medicines/shtg\\_scoping\\_reports/technologies\\_scoping\\_report\\_12.aspx](http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg_scoping_reports/technologies_scoping_report_12.aspx).

You can read and download this document from our website. We are happy to consider requests for other languages or formats. Please contact our Equality and Diversity Officer on **0141 225 6999** or email **[contactpublicinvolvement.his@nhs.net](mailto:contactpublicinvolvement.his@nhs.net)**

**[www.healthcareimprovementscotland.org](http://www.healthcareimprovementscotland.org)**



**Edinburgh Office:** Gyle Square | 1 South Gyle Crescent | Edinburgh | EH12 9EB

**Telephone:** 0131 623 4300

**Glasgow Office:** Delta House | 50 West Nile Street | Glasgow | G1 2NP

**Telephone:** 0141 225 6999

The Healthcare Environment Inspectorate, the Scottish Health Council, the Scottish Health Technologies Group, the Scottish Intercollegiate Guidelines Network (SIGN) and Scottish Medicines Consortium are part of our organisation.

