Methods for chronic wound research — A scoping systematic review of the recommendations, guidelines and standards

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ABSTRACT

Background This scoping systematic review aimed to investigate the existing literature for recommendations, guidelines and standards for research on chronic wound diagnosis, assessment, management and prevention; to identify gaps in this literature; and produce recommendations to support future wound management research.

Methods A scoping systematic literature review was undertaken in 2017–2018, which aligned with PRISMA guidelines and searched academic databases and grey literature published between 2007 and 2017.

Results Eighty-nine documents included recommendations or outcomes on research methods for studies on chronic wound diagnosis, assessment, management and/or prevention; covering the areas of research design, sampling, randomisation and blinding, independent and outcome measures and interventions for research in chronic wounds. Common themes regarding research gaps and flaws were identified.

Conclusion This review identified existing evidence, guidelines, recommendations and standards regarding the conduct of chronic wound research internationally. Recommendations include the need for standardised vocabulary, standardised checklists for wound research, development of core outcome datasets and an agreed and standardised set of economic parameters and methodology for cost-effectiveness. Establishment of a centralised national methodology service for wound research to assist with methodology design would be beneficial.

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INTRODUCTION

Chronic wounds do not proceed through an orderly or timely reparative process, instead having a delayed, arrested or repetitive cycle of the phases of wound healing, with progress ceasing or slow[1-3]. These wounds are costly, with up to 4% of the total health care expenditure consumed on chronic wound care in Western countries[4,5]. In Australia, this equates to up to A$5 billion annually[6]. These wounds can be debilitating and often result in a decreased quality of life[7,8].

The health care challenges associated with chronic wounds has seen increasing numbers of health professionals completing studies in this area. However, rigorous, high-

quality evidence outcomes from research can be difficult to achieve. While some organisations have published guidelines, consensus documents and protocols addressing research methods in the areas of wound assessment, management and prevention, studies or recommendations on research methods are rarely reported in the literature, usually occurring as an add-on to other research projects. Previous articles concluded that guidelines were needed for research methodologies for chronic wounds[9,10], as inconsistencies in study protocols, designs and themes, along with inadequate reporting often limit recommendations in relation to research outcomes.

This study aimed to review the literature on current evaluations, recommendations, guidelines and standards for research on chronic wound diagnosis, assessment, management and prevention; and identify gaps in this literature to guide recommendations on development of standards for wound management research to assist clinicians, researchers, academics, industry and policy makers.

MATERIALS AND METHODS

Search strategy

This descriptive scoping systematic review is reported in accordance with preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines[11]. For further information, see Table 1. Academic databases searched included: CINAHL, Medline, Embase, Joanna Briggs Institute Library (JBI), and the Cochrane Library. Grey literature sources searched included websites and publications of the Association for the Advancement of Wound Care (AAWC); Wounds Australia (formerly Australian Wound Management Association (AWMA)); European Pressure Ulcer Advisory Panel (EPUAP); European Wound Management Association (EWMA); International Compression Club (ICC); International Diabetes Federation (IDF); National Guideline Clearinghouse; ethics-related publications and guidelines; National Health and Medical Research Council (NHMRC) guidelines; National Institute for Health and Care Excellence (NICE); Registered Nurses Association of Ontario (RNAO); Scottish Intercollegiate Guidelines Network (SIGN); Wounds Canada; Wounds International; World Union of Wound Healing Societies (WUWHS), Wounds UK and the Welsh Wound Innovation Centre (WWIC).

Selection criteria

Search terms were refined to: *(guide* OR method* OR consensus* OR position OR best practice OR protocol* OR recommend*) AND (research OR stud* OR investigat*) AND (wound* OR ulcer* OR tear OR pressure) AND [(chronic) NOT (pulmonary) NOT (respiratory) NOT (renal) NOT (kidney) NOT (gastrointestinal)].*

Inclusion criteria for documents included:

- published documents from 2007 to July 2017;
- published in English;
- document types included guides, guidelines, method studies or papers, consensus statements, recommendations, position statements, systematic reviews or grey literature;
- documents pertaining to or including recommendations on, or evaluations of, research methods for diagnosis, assessment, management or prevention of chronic wounds.

Exclusion criteria were individual studies not meeting the inclusion criteria, and those not providing data and/or evaluation on methods for chronic wound management research.

Data extraction

Results from searches of the databases were imported into Endnote libraries and stored on a secure access drive. Two reviewers independently extracted and assessed all documents for eligibility. A third reviewer arbitrated documents where there was disagreement. This process was followed for the screening phase, abstract eligibility assessment phase, and final full-text assessment for inclusion in the literature review.

Data analysis

Due to the lack of quantitative research studies evaluating research methods in chronic wound research, a narrative synthesis was undertaken of the reported outcomes and recommendations in the articles found from the search strategy.

Results

The initial database and grey literature searches resulted in 6415 articles. After excluding duplicates and articles not fitting the inclusion criteria, 89 eligible articles remained (Figure 1).

The majority of these articles were systematic/scoping reviews (n=58) and literature/narrative reviews (n=8) on various chronic wound topics, which included recommendations for research methodology. The remaining articles included recommendations based on expert opinion (n=12); clinical practice/evidence-based guidelines (n=8), and descriptive, prospective or survey studies (n=3). These studies are summarised in supplementary Table 2, which can be found in the electronic version of this article at https://doi.org/10.33235/wpr.27.2.62-73.

Only a few of the included articles specifically evaluated any methods for wound research. Two articles reviewed clinical data collection and analysis methods of wound trials[12,13], and another aimed to provide specific recommendations to product developers and clinical researchers on the design of comparative effectiveness studies for the treatment of chronic wounds[14]. Liu *et al.* analysed the nature and specification of outcomes in Cochrane systematic reviews related to wound care[15], while Jeffcoate *et al.* summarised the core details required in the planning and reporting of intervention studies for diabetic foot ulcers[16]. Consequently,

Table 1: PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	62
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	62
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	62-63
Objectives	4	Provide an explicit statement of questions being addressed, with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	63
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	63
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	63
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	63
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	63 & 66
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	63 & 66
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	N/A
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

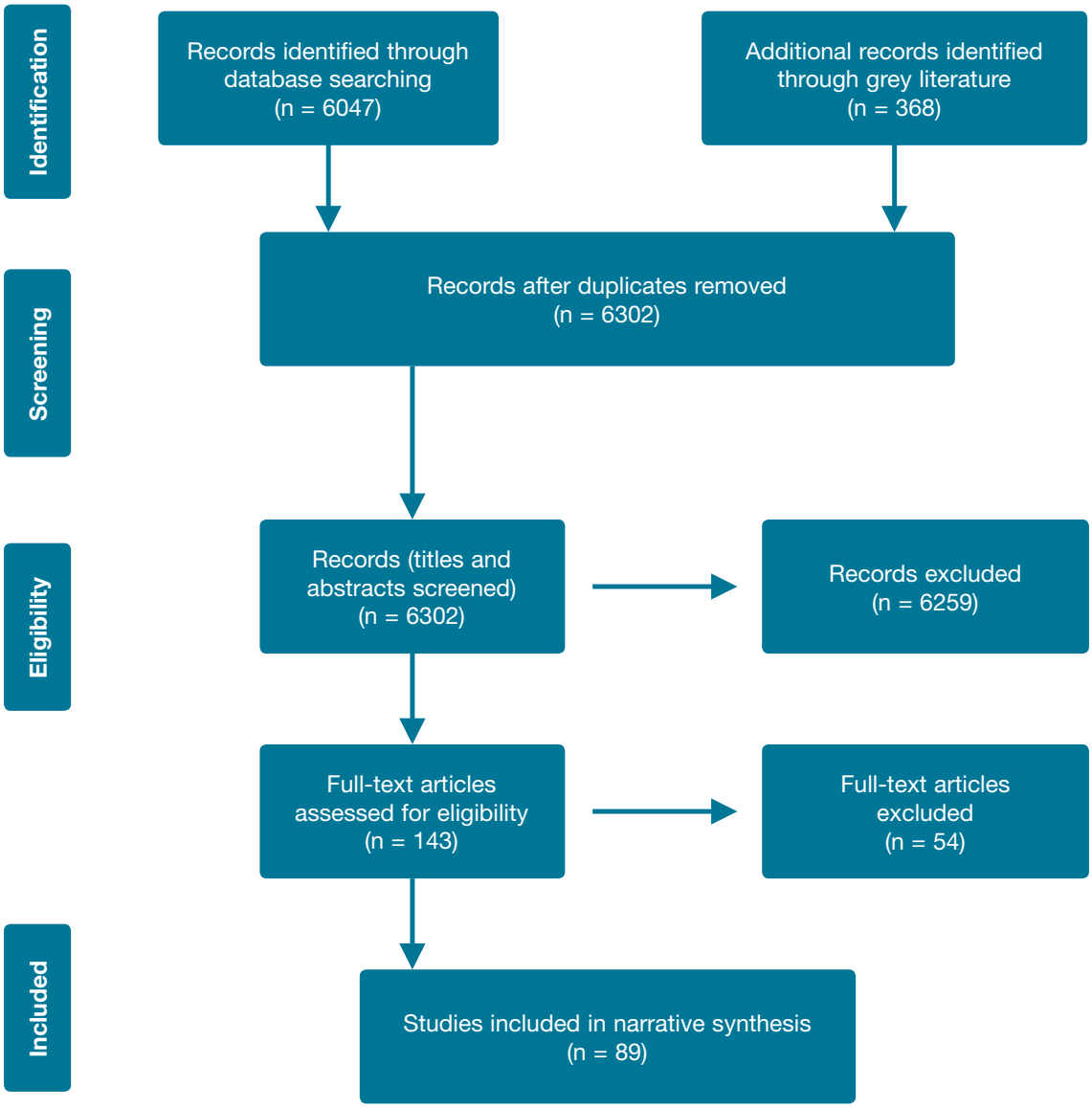
Table 1 continued: PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	63
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	66-69
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group; and (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarise the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers).	69-70
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	70
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	70
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	70

From: Moher D, Liberati A, Tetzlaff J, Altman DG. The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 2009;6(7):e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Figure 1: Flowchart of literature review



the findings of this review comprise a summary of expert opinion based on systematic reviews and expert consensus, which were often secondary discussions from studies.

The results have been grouped and reported under the methodology sections of research design; sampling; randomisation and blinding; independent and outcome measures; interventions and analysis for research in chronic wounds.

RESULTS

Findings on research design

Forty-three articles included recommendations on research design, covering study development and overall design. These articles included 35 systematic/literature/narrative reviews, seven expert opinion/consensus documents and one prospective study. The literature identified a gap in high-quality evidence from well-designed and rigorous, prospective studies[17,18] or randomised controlled trials (RCTs)[14,19-28], with poorly designed studies leading to the inability to pool study results and conduct meta-analysis[29]. The use of a CONSORT statement has been recommended in multiple articles to improve reporting of controlled trials[22,24,26,30-42], to show valid and reliable results[30,43,44] and to allow trials to be accurately assessed by readers and reviewers[21,36].

A study design should commence with a clearly defined research question/s and hypotheses based on a thorough literature search using patient problem, intervention, comparison and outcome (PICO) and basing studies on a conceptual framework that is clearly defined[45]. Two systematic reviews concluded that it was essential that research questions be developed that are of a high priority to patients and other decision makers, and collaboration of stakeholders is needed to be able to answer the questions most relevant to patient care[46,47].

Any RCTs should include a suite of uniform methodologies[18,48], treatment comparisons and outcomes[49] and process evaluations[50,51] in order to establish the efficacy of commonly used therapies/interventions on chronic wounds[49]. It is essential that research be conducted by independent researchers and reporting be free from suggestion that the analysis or conclusions were substantially influenced by people with commercial or other personal interests in the findings[16,26].

Management in the control group should be what is expected in routine clinical practice[16], with the standard-of-care arm receiving widely accepted care that follows high-quality, evidence-based clinical guidelines[14,39]. Data should be collected in a uniform manner to capture the scale of the problem[52] using specific tools, if appropriate[53]. Basic care, conventional care or standard care must be defined and standardised[12,45,54] and specific details reported as this is likely to vary — particularly in dressing type, debridement type, frequency and intensity, and follow-up[54,55]; and all interventions should use the same models/versions of devices for all patients[14,45] to ensure replicability[16].

Six systematic reviews and one expert opinion document[13,14,32,38,39,42,56] recommend a need for multicentre studies across a range of settings, as single-centre studies may be challenged to recruit sufficient participants for studies researching specific areas[35].

Findings on sample considerations

Thirty-eight studies included some recommendations on sample considerations such as sample sizes and inclusion/exclusion criteria. These included 33 systematic/scoping/literature reviews, four expert opinion/consensus documents and one clinical practice guideline. The recommendations include the need for research studies to include analysis of power size and calculation of sample size[22,25,41,45,57]. Trials should estimate and have adequate, appropriate and large enough sample sizes[32,43,44,58-61]. They should be appropriately and adequately powered for clinically important primary outcome measures in order to detect significant treatment effects that are able to detect differences in wound healing rates, where sample size estimates[10,19-21,31,33,34,36,39,40,62-68] should be based on a priori sample size calculation[16,35,38,62]. An RCT sample size should be large enough to be able to detect both a statistically significant effect and to allow for subgroup analyses[23]. Trials need clear inclusion and exclusion criteria for participants[43,44,62], particularly with reference to baseline infection and the definitions of criteria and procedures for subject withdrawal or discontinuation[45,68].

There must be consideration of the extent to which a recruited population is likely to represent patients seen in clinical practice, for example with respect to mobility, ulcer size and presence of ulcer infection[14,24,31,40,55]. It is recommended to clearly report baseline participant characteristics including defining the setting and location of data collection, patient characteristics, number of patients, time lines, allocation ratio of patients to the groups being compared, the procedures for diagnosing different wound types and the stage of the wound(s)[16,30,33,34,45]. There should be comparable groups at baseline (that is, stratification for ulcer size and duration)[21,63], where the comparators used in the clinical study are clearly characterised[36,41,68,69].

Findings on randomisation and blinding

Thirty-two studies included recommendations for randomisation and blinding, which comprised 25 systematic/literature reviews, four expert opinion/consensus documents and three clinical practice guidelines. The majority of these documents recommend that RCTs should employ robust valid methods of randomisation and include random sequence generation, treatment allocation and concealment of allocation of procedures (treatment) to minimise the risk of bias[10,16,21,24,31,35,40,43,44,57,58,63,68,70,71]. Studies should match ulcer characteristics, participant characteristics and the various interventions for appropriate randomisation, adjustment and stratification[23]. This could include computer-generated randomisation programmes with allocation concealment, for example, by using a remote, telephone randomisation service[38,62]. Clear reporting of the methods of randomisation is also essential to help ensure comparability of treatment groups at baseline[45,62].

Trials should apply concealed allocation strategies, with effective blinding of participants (to study groups and outcome measures), personnel (where assessors should be blinded to treatment allocation), the data analyser and outcome assessment or measures; and these methods of blinding should be clearly reported[10,14,16,21,22,24,25,30,32,35-37,40,43,45,46,57,60,62,63,72,73]. While blinding in some studies is difficult and would clearly be unethical, one of the main weaknesses reported for many RCTs was a lack of blinding[74]. With adequate resources, blinding is often possible and is recommended[39].

Findings on independent and dependent variable measures

Fifty-three studies included recommendations regarding independent and dependent variable measures. These included 44 systematic, narrative/literature or scoping reviews, six expert opinion/consensus documents and three clinical practice guidelines.

Importantly, there should be agreement and definition of which outcome measures should be used in studies at the outset of a study[75], including a rationale for why the outcome measures were selected[72]. A 2017 systematic review of outcomes in wound care studies recommended development of core outcome data sets (as in other health care fields), as this would enable examination and comparison of the effectiveness of different clinical interventions based on a core set of outcomes[15]. Outcome measures should be objective, consistent, clinically relevant and standardised in terms of what is included and how these are measured[12,16,32,46,68,73,76-78], using pre-defined, widely accepted criteria or definitions for

measurement[12,79] that matter to patients, carers and health professionals[47,67]. Development should involve a consensus process to define outcome measures, be data-driven, iterative, and prepared by expert working groups, including patients, wound specialists, health professionals, trialists, methodologists, scientists from industry, health economists and regulators[15]. This will facilitate comparison of results[57,72].

It is important to define both primary and secondary outcome measure(s)[45]. Such variables are likely to include: incidence, time to complete wound healing, ulcer-free survival following treatment, healing rates and ulcer area, time to ulcer closure, percentage and absolute change in wound size (surface area or volume), quality of life measures, mortality, health resource utilisation and cost of treatment, pain, acceptability, cosmetic outcomes, patient comfort, accessibility of interventions, satisfaction, ulcer recurrence rates and adverse events, such as infection[26,30,35,36,39,46,58,59,64,77,80,81].

Different core outcome sets will be needed for different wound types[15]. For example, identification of the time of surgical wound healing is difficult, hence it may be more relevant to count surgical wound healing problems (such as infection or dehiscence)[15]. Different wounds should be considered different entities as the aetiology and cause of the injury are different[37, 74] and for each patient, a single reference ulcer should be selected for a study[38]. Trials that combine different types of conditions (acute, sub-acute and chronic) should present results of each condition group separately[27].

Outcomes should be tested for effectiveness and impact[82] — including parameters such as individual self-management strategies[83]. Clinically relevant endpoints (such as ulcer healing or amputations) may mean more in practice but may be only partially dependent on any effect of the chosen intervention[84]. Conversely, surrogate endpoints (such as change in wound bed appearance or ulcer area) may more closely relate to the effect of the product being tested but have little relevance to clinical outcomes[84]. It is important that studies are designed to include meaningful endpoints, even in participants where wound healing is never achieved[73], and that alternative endpoints to healing are evaluated as being equally suitable for the evaluation of various wound interventions[12,85].

Trial protocols need to address outcome measure heterogeneity — an issue in the absence of agreement about key outcomes[65]. Reporting outcomes is often very heterogeneous, with some trials reporting mean or median time for complete wound closure; however, few used relative risk or odds ratio, survival analysis, or reported hazard ratios[31,73].

There is a need for clinical outcomes and health-related quality of life (HRQoL) that should be considered in clinical trials as routine alongside clinical and economic criteria[86] to be reported using validated assessment tools[59,70]. Instruments that measure the generic factors of HRQoL, as well as the disease-specific domains should be used[62,86]. HRQoL assessment should be undertaken using a standardised, valid and reliable assessment instrument with findings reported in full[24,31,37,40,46] — and should include patient satisfaction of any intervention[28].

Outcome measures to investigate the subset of disease severity/classification most likely to benefit from the therapy/intervention and the expected duration of benefits should be included and reported[25]. Trials should analyse particular participant subgroups to ascertain potential differing responses and, if efficacy is demonstrated, to establish the point in a treatment regimen at which it should be applied[36]. Assessment of subgroup effects is important because it is likely that treatment effects will vary across the spectrum of patients[13].

Trials must include well-defined, long-term adequate follow-up for all participants[10,42,44,56,64,66,81], be of sufficient duration to capture a meaningful proportion or effect of events and/or interventions[21,38], be able to ascertain the completeness and durability of ulcer healing[58] and should include detailed clinical assessment to detect the true rate of outcomes such as recurrence[42]. While there is little agreement in the literature regarding follow-up periods and they are likely to be different for different wounds, a recent review found that most studies used only a short follow-up period (that is, 14 days), and therefore concluded that longer follow-up periods were needed[59]. Long-term follow-up is needed to provide evidence on ulcer recurrence and the occurrence of lower limb amputations[73] and this includes long-term follow-up examinations after completion of the studies and reporting of this data[60]. A range of trial durations have been suggested including: 20 weeks to allow for comparisons to be made across trials, and provide a more robust evaluation of the benefits and harms of interventions[35], at least six months 'was essential' for any wound healing effect to be detectable in chronic wounds[46], and at least 30 days postoperatively was required to ensure all complications of surgical wounds were reported[57].

Findings on interventions

Eight studies included some recommendations on intervention considerations in wound research. These included six systematic reviews and two expert opinion/consensus documents.

The intervention must be described and accurately and appropriately reported in sufficient detail to allow replication of studies, and include: the rationale behind the intervention, details of the intervention (for example, compression), prognostic factors, administration, treatment regimen, other components of treatment, rationale for control or comparator, description of control or comparator, setting and context of the intervention, and the background/qualifications and training of the responsible clinicians[46,69]. Practical clinical information, such as the location of wounds, frequency

of treatment application, combination or sequencing and duration of treatment modalities, must be documented; and compliance must be reported[36,39,55,58,87].

Findings on analysis

Databases and analysis

Twenty-four studies included some recommendations on analysis considerations in relation to databases. These included 22 systematic or literature reviews, one expert opinion/consensus document and one clinical practice guideline. Appropriate statistical analysis[16,57,58] and reporting all patients' flow through studies, analysis of losses to follow-up and missing data[58] is recommended. Where participants have been lost to follow-up, appropriate and valid methods of imputation should be used and reported with the patient the unit of randomisation and analysis, rather than individual wounds[31,37]. For consistency of multicentre trials, standards are required to standardise analysis of results between sites[58].

Standards are required for statistical methods to account for confounding, effect modification and clustering of patients[58,88]. Control for confounding may occur by restricting the study population, using pre-stratification (for example, aetiology), and statistical adjustment[13]. Multiple ulcers on a patient should not be randomised individually and considered independent unless the trial has been specifically designed to accommodate this, and appropriate statistical analysis, that accounts for clustering, should be specified[38].

Intention-to-treat and time-to-event principle analysis should be adopted in order to minimise bias[10,16,21,24,31,35-38,40,43,58,62,63,65,66] and have a pre-determined method for dealing with missing data to minimise the potential for attrition bias[65]. Where trials are measuring a time-to-event outcome such as time to healing, they should employ survival analysis[37,38,40-42] or approaches which account for censoring[37], with adjustment for prognostic covariates such as ulcer area and duration[24,31,41].

A National Wounds Registry may aid research by identifying the scope of the wound burden, benchmarking healing, and aiding cost-effectiveness analyses[10,49,89]. There is a need to register all trials with a register that meets World Health Organization (WHO) criteria and principal investigators should keep their contact details up to date on the register[31,37]. Outcomes of a trial should be prospectively declared in a clinical trial database, including the nature and timing of the primary outcome[65].

Analysis of costs

Thirty studies included some recommendations on analysis considerations in relation to costs. These included 18 systematic or literature reviews, four clinical practice guidelines, five expert opinion/consensus documents and three prospective/survey/descriptive studies. It is agreed across a breadth of literature that health economic studies are essential for future research[56,75,82], including a need for objective evidence on the costs and benefits of evidence-based wound management[86,89] and for an economic case to be developed for wound care and wound care services[90] taking a holistic approach[61,91]. Wound care as a clinical area suffers from a paucity of robust economic data and, therefore, a true understanding of the costs[52]. Trials should include and report full clear and meaningful economic evaluations and cost–effectiveness analysis so that health care providers can make informed decisions about which technique is more efficient and cost-effective[24,25,27,31,40-44,57,68,80,85,92-95]. Studies should strive to calculate a disease-specific cost or net cost using a matched non-disease cohort[96] including measurement of the costs of alternative treatments and assessment and reporting of the cost-effectiveness[37] of interventions[25,70,71]. Standardising methods for cost-of-illness studies in general will allow researchers and policy makers to establish and understand the importance of chronic ulcers in comparison with other diseases and may encourage research and policy initiatives for the prevention and treatment of chronic wounds[96].

DISCUSSION

Common themes regarding research gaps and flaws have been identified in the areas of research design, sampling, randomisation and blinding, independent and outcome measures and interventions. In general, there is a need to improve the quality of evidence from wound care research, formulate guidelines within differing areas and investigate different types of evidence that might be required by different authorities[12]. Due to variation of definitions in terms related to wound care and wound healing across the literature there is also a need for the language to be standardised in a way that allows for comparison of studies. Chronic, delayed healing, non-healing, standard care, basic care and conventional care are all examples of varying terminology used interchangeably across the range of studies; however, these are not always with identical meanings.

There is a need for greater inclusion of translation and implementation methods to ensure the issues related to chronic wound research are addressed. Outside dedicated trial settings, there is also a need to ascertain and clearly document how to translate best wound care practices into all clinical (that is, 'typical') settings where therapies are delivered by 'typical' clinicians[10]. Examining system factors will promote or support delivery of best practice recommendations and could include the use of facility-wide protocols that guide the delivery of chronic wound care interventions[41].

A national approach to the issue of wound care research is essential for improving the quality of evidence in relation to assessment, management and prevention of wounds. An evidence-based wound assessment minimum data set may reduce unwarranted variation in chronic wound care[90] and assist in the highest priorities for research, which

have been noted to in the literature to include areas such as debridement, risk assessment, diabetic foot problems, nutrition and pressure redistribution[97-99].

Inconsistencies in study protocols, language/definitions, designs and themes, along with inadequate reporting, often limit recommendations in relation to wound care research. This systematic literature review has informed a number of high-priority areas that are likely to improve the quality, usefulness and value of future wound care research.

Limitations

While 89 articles from the literature review met the broad inclusion criteria, there were only a few that were specifically related to methods of research in assessment, management and prevention of chronic wounds. The majority of information was scattered across the literature and often difficult to find. Examples include a single sentence on a recommendation for future research methods at the end of an RCT. Hence, there was no one document that contained a comprehensive list of all the requirements for quality research in this area.

The various websites with relevant grey literature proved difficult to reliably navigate and contained numerous cross-references to other relevant bodies and associations. Some documents were readily and freely available; others required registration but were free, while some sites would not permit access to documents that appeared relevant. Some of these documents were available via formal academic libraries and publications.

CONCLUSION AND RECOMMENDATIONS

Recommendations to address the issue of chronic wound research include the establishment of working groups and a consensus process for production and publication of consensus documents pertinent to research on chronic wound diagnosis, assessment, management and prevention. These should include:

1. Standardised vocabulary and definitions for chronic wound research criteria.
2. A standardised checklist for chronic wound research and the standardised reporting of trials.
3. Development of core outcome data sets for all chronic wound research.
4. Development of an agreed and standardised set of economic parameters and appropriate and applicable economic evaluations/tools/methods that can be incorporated into all chronic wound research studies.
5. Establishment and development of a centralised methodology service for chronic wound research to provide guidance and assistance with methodology design and review, appropriate power analysis and a remote randomisaton, blinding, and blinded outcome assessment service.

The robustness, usefulness and value of wound care research will be greatly enhanced if results of study/trials are published according to standardised, tailored wound research methodology checklists using standardised definitions, outcome measures and economic analysis measures. The outcomes of future wound research will then have more complete, consistent and uniform elements/components. This will allow for more robust and meaningful pooling of data/studies and therefore higher quality evidence from systematic reviews and/or meta-analyses, which ultimately will deliver better clinical care and improved patient outcomes.

Ultimately, it is impossible to be confident that 100% of potentially relevant grey literature information has been found, despite extensive efforts to do so. Ultimately, a lot of useful information is already available relating to wound care research; however, it is difficult to reliably find and access and there is no single simple, central, well-organised repository for the information that already exists.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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SUPPLEMENTARY TABLE

Supplementary Table 2 can be accessed in the electronic version of this article at https://doi.org/10.33235/wpr.27.2.62-73.

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