Section 1

Principles of Best Practice

1 Evidence and Clinical Decision-making

Carolina Weller
School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia

Overview

- Evidence-based practice integrates the best available research evidence with information about patient preferences, clinician skills and available resources to make decisions about patient care.
- Barriers to the use of research-based evidence can occur when time, access to the literature, search skills, critical appraisal skills and implementation skills are lacking.
- Evidence-based clinical decision-making requires comparison of all relevant sources. In the absence of randomised controlled trials involving a direct comparison of treatments of interest, indirect treatment comparisons and systematic reviews provide useful evidence.
- Clinical guidelines appear to be one of the most effective methods of applying evidence to improve quality of care but little is known about the best way to implement them into everyday practice.
- Selective reading of high-quality evidence is one of the most effective strategies to improve research dissemination and changes in practice. There are now good sources of evidence-based information available on the Internet that help identify, appraise and apply research findings to clinical practice.

Introduction: what is effective clinical decision-making?

Clinical decision-making is an essential part of effective wound management and is based on clinical judgement which consists of professional performance and human judgement. Health care providers increasingly recognise the importance of making decisions based on the best possible evidence. Making decisions that will impact on the healing outcome of individuals in the clinical workplace take place every day but reliability of clinical judgement is often variable as many different factors will influence decisions; these include the type of clinical setting, interpersonal relationships, available diagnostic data, scope of practice and individual skill (DiCenso et al., 2010). The process of clinical decision-making should ideally include use of

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research findings, clinical guidelines, and evidence-based treatment algorithms (Rose, 2011). Improving the implementation of evidence-based practice (EBP) and public health depends on behaviour change. Health care outcomes such as choice of type of compression to encourage patient adherence to compression therapy are often based on decisions made within an organisation, which adds another layer of complexity to clinical decision-making. Clinical decisions that impact directly on patient safety and quality of care are made by health professionals based on previous knowledge and experience. The care received by patients in relation to wound care is often dependent on factors that are related to characteristics of individual health professionals, such as education and training in wound care as well as behaviour of people in the workplace (Grol, 2002). For patients to benefit from treatment, clinicians must have a mastery of skills, including history-taking and physical examination, although effective clinical decision-making does not begin or end there, continuous, self-directed lifelong learning is paramount to advance wound management and improve quality of care.

What is evidence-based health care?

Best practice research evidence refers to methodologically sound, clinically relevant research about the effectiveness and safety of interventions, the accuracy and precision of assessment measures, the power of prognostic indicators, the strength of causal relationships, the cost-effectiveness of interventions and the meaning of illness or patient experiences (Sackett et al., 1996).

Over 10 years ago, the Cochrane systematic reviews (Cullum et al., 2000; O'Meara et al., 2009) reported the importance of multi-component compression bandages to heal people with venous leg ulcers (VLUs) and the importance of Ankle Brachial Pressure Index (ABPI) assessment to exclude arterial disease prior to compression application. This type of evidence should guide clinical practice, but what if the clinician does not have access to a handheld Doppler and is unable to refer to a vascular laboratory or specialist wound clinic due to geographical or cost factors? Even if a Doppler is available the clinician may not have the confidence to assess the patients and measure the ABPI as found in a recent cross-sectional survey of practice nurses (PNs) working in Australian general practice clinics. This study identified that knowledge of VLU management was sub-optimal and current practice did not comply with evidence-based VLU management guidelines (Weller and Evans, 2012). Despite recognition by PNs that specialist wound clinics provide a valuable resource, more than 40% did not refer patients for treatment and a third retained patients for over 3 months before referring them for specialist assessment. In the United Kingdom, PNs typically have sole responsibility for determining the patient's treatment plan (Ertl, 1992; McGuckin and Kerstein, 1998). Despite 70% of PNs having some responsibility for determining VLU management, less than 20% stated that they used best practice guidelines to direct treatment (Weller and Evans, 2012).

Despite availability of evidence to support leg ulcer management, studies have identified deficiencies in general practice management of leg ulceration, specifically the under-use of ABPI measurements, over-reliance on dressings and lack of understanding of compression therapy (McGuckin and Kerstein, 1998; Graham et al., 2003; Sadler et al., 2006).

Research evidence alone is never sufficient to make a clinical decision. Clinicians often weigh up the benefits and risks, inconvenience and costs associated with alternative management strategies, and in doing so consider the patient's values. Patient values and preferences refer to the underlying assumptions and beliefs that are involved when clinicians, together with patients, weigh what they will gain making a clinical management decision such as choosing a compression system that is easy for the nurse to apply, is less expensive and is more comfortable for the patient. Healing time can be improved simply by addressing the issue of nurse application, patient adherence and cost-effectiveness (Weller et al., 2010b, 2010c). EBP involves the incorporation of research evidence, clinical expertise and client values in clinical decision-making (Sackett et al., 1996). Application of high-quality evidence to clinical decision-making requires knowledge of how to access evidence in the first place; includes an understanding of literature searching and application of critical appraisal skills to differentiate lower- from higher-quality clinical studies (Weller, 2009).

Common misperceptions about evidence-based practice

- Clinicians believe they already 'do' EBP;
- EBP is a passing trend;
- EBP leads to 'cook book' medicine;
- EBP is expensive and time-consuming;
- EBP is a restriction of clinical freedom;
- 'I have always done it this way, so I know it works'.

How does evidence fit into clinical decision-making in clinical practice?

The skills necessary to provide an evidence-based solution to a clinical problem includes several aspects such as defining the problem, conducting an efficient search to locate the best evidence, critically appraising the evidence and considering that evidence and its implications in the context of patients' circumstances and values (Box 1.1).

Clinicians report that the major barrier to using current research evidence is time, effort and skills needed to access the right information (Cabana et al., 1999). A high proportion of new research articles are peer reviewed and published, although the addition of systematically combining results in context of other similar studies is still lacking. Ideally, clinicians could access updated well-conducted systematic reviews for all clinical questions, however only about 10% of randomised controlled trials (RCTs) are incorporated in Cochrane reviews (Mallett and Clarke, 2003) and at least 90% of reviews recommended further research (El Dib et al., 2007). Despite these limitations, systematic reviews can improve decision-making (Box 1.2).

EBP integrates the best available research evidence with information about patient preferences, clinician skill level and available resources to make decisions about patient care (Sackett et al., 1996). Attaining these skills requires knowledge, motivation and application (Guyatt et al., 2000). Clinicians often have questions about the care of their patients, but many go unanswered (Dawes and Sampson, 2003). Barriers to the use of research-based evidence can occur when time, access to journal articles, search skills, critical appraisal skills and understanding of the language used in research are lacking.

The aim of evidence-based health care is to provide the appropriate means for making effective clinical decisions, not only for avoiding habitual practice but also for enhancing clinical performance. An EBP culture connects research evidence, patient preferences, the available resources and clinical expertise, to include these factors in the decision-making process. Clinical judgement provides health professionals with a methodology for comparing decisions between practitioners with different training and experience, and improving decision-making. Keeping up to date with wound care research is a mammoth task and is a challenge for busy clinicians. Evidence-based health care requires clinicians to engage with research evidence in decision-making at the workplace. But is it unrealistic to assume that research results will be implemented in clinical practice as translational research can be hindered by two main aspects: how the evidence is generated, and how the evidence is implemented? When generating evidence, one major barrier to uptake of research into clinical practice is that the 'practice' described in clinical trials or research environments may not be generalisable from the setting (hospital community), circumstances (number of clinicians with wound management knowledge), patient groups (chronic, acute wounds) and resources (Doppler ultrasound, wound dressings, compression bandages) available in daily practice of many clinicians.

For evidence to be translated to clinical practice the clinician needs to be aware of the evidence, and accept and adhere to findings. Although it is broadly accepted that effective health care decisions require the integration of research evidence and individual preferences, it is not unusual to find that evidence generated by researchers does not always get implemented in a timely and dependable way and may not take into account patient input (Cabana et al., 1999). One could question whether practitioners and patients benefit from current best practice and whether EBP affects treatment outcomes in a positive way when research that should change practice is often ignored for years, for example pressure ulcer risk assessment and prevention, moist wound healing principles (Winter, 1995, 1962, 2006; Cullum et al., 2000) and compression for treatment of venous ulcers (Fletcher et al., 1997; Cullum et al., 2001; O'Meara et al., 2009).

Box 1.1 Steps for appraising the literature

1. Ask an answerable question from a clinical issue

PICOT is one technique that can used to develop clinical research questions. PICOT is an acronym for the five different areas the technique considers: patient/population, intervention or issue, comparison with another intervention or issue, outcome and timeframe; e.g. *Which interventions help people adhere to compression therapies for venous leg ulceration?*

2. Search for valid external evidence

Quick access to pre-appraised information is available at

- The Cochrane Library
- PubMed Clinical Queries
- ACP Journal Club
- Evidence-based Medicine

3. Critically appraise the evidence for relevance and validity

Methods

Consider

- Study design, e.g. randomised controlled trial, cohort study, survey;
- Clinical setting, e.g. hospital, community;
- Patient population, e.g. sample size, inclusion/exclusion criteria;
- Describe intervention group and control group;
- Blinding (if applicable), e.g. double blind, single blind;
- Statistical analysis, e.g. suitability of tests;
- Relevance of outcome measures, e.g. time to complete healing;
- Follow-up, e.g. duration, all patients accounted for.

Results

Consider

- Relevance of outcomes, e.g. number needed to treat, sensitivity, specificity;
- Time points of reporting;
- Compliance with intervention/therapy/medications;
- Adverse effects.

4. Apply the results back to the patient

There is low-quality evidence that leg ulcer clinical care may not improve adherence to compression therapy or healing rates or prevent recurrence when compared to home care. Because of the lack of reliable evidence, it is not possible to recommend nurse clinical care interventions. There is a need to improve and increase interaction with patients emphasising the adherence in future compression trials (Field, 1994).

5. Record the information for the future

Audit your clinical practice by checking your everyday practice against published EBP on a regular basis.

Although EBP has an increasingly broad-based support in health care, it remains difficult to get health care professionals to engage and practice it (Thompson et al., 2005). Across most domains in wound care, practice has lagged behind research and knowledge by at least several years and often longer (Bates et al., 2003). There are many impediments to introducing evidence and clinical

Box 1.2 Summary of systematic review: compression for venous leg ulcers (O'Meara et al., 2009)

Objectives: To undertake a systematic review of all RCTs of the clinical effectiveness of compression bandage or stocking systems in the treatment of venous leg ulceration.

Specific questions addressed by the review are

- Does the application of compression bandages or stockings aid venous ulcer healing?
- Which compression bandage or stocking system is the most effective?

Search strategy: For this update the Cochrane Wounds Group Specialised Register (14/10/08) was searched; the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 4 2008); Ovid MEDLINE (1950 to October Week 1 2008); Ovid EMBASE (1980 to 2008 Week 41); and Ovid CINAHL (1982 to October Week 1 2008). No date or language restrictions were applied.

Selection criteria: RCTs recruiting people with venous leg ulceration that evaluated any type of compression bandage system or compression hosiery were eligible for inclusion. Comparators included no compression (e.g. primary dressing alone, non-compressive bandage) or an alternative type of compression. Trials had to report an objective measure of ulcer healing in order to be included (primary outcome for the review). Secondary outcomes of the review included ulcer recurrence, costs, quality of life, pain, adverse events and withdrawals. There was no restriction on date, language or publication status of trials.

Data collection and analysis: Details of eligible studies were extracted and summarised using a data extraction table. Data extraction was performed by one review author and verified independently by a second review author.

Main results: Overall, 39 RCTs reporting 47 comparisons were included. Review question 1: there was reasonable evidence from seven RCTs that venous ulcers heal more rapidly with compression than without. Review question 2: findings from six trials of single-component compression suggested that this strategy was less effective than multi-component compression.

Authors' conclusions: Compression increases ulcer healing rates compared with no compression. Multi-component systems are more effective than single-component systems. Multi-component systems containing an elastic bandage appear more effective than those composed mainly of inelastic constituents.

guidelines into routine daily practice (Grol and Grimshaw, 2003).

One aspect that researchers need to consider when designing a clinical trial is that the population, measurement tools and interventions will be relevant to the clinical patient group. Some have argued that RCTs are too limited (Gottrup, 2010; Gottrup and Apelqvist, 2010) but others disagree and argue that wound care research needs high-level evidence reported in a transparent way so clinicians and health policymakers can improve wound care with the best available evidence to guide practice (Barton, 2000; Weller et al., 2010d; Weller and McNeil, 2010). For implementing evidence, clinical guidelines appear to be one of the most promising and effective tool for improving the quality of care but little is known about the optimal implementation strategy. There are many good examples of internationally agreed clinical guidelines in wound management that define best practice and are easy to implement to guide local practice (SIGN, 2010; Australian Wound Management Association Inc. and New Zealand Wound Care Society Inc., 2011).

Challenges to changing practice

Even when most clinicians are aware of evidence, there may be little impact on quality of care due to the many complexities involved in changing practice. Change within organisation structures may be hindered by many factors, and barriers to transforming clinical competence into clinical performance can arise due to varied reasons (Thompson et al., 2005). For example, the patient or health care system may not be able to afford effective best practice treatments. Practitioners may experience excessive workloads, inadequate practice organisation, financial pressures and lack of time they are able to spend with each patient which may result in less than optimal care. To introduce evidence into clinical practice it is appropriate to identify the groups affected by the proposed change/s in practice. It is paramount to assess the preparedness of the group to change and identify likely enabling factors, including resources, skills and knowledge.

In addition, the practice of 'traditional habits', e.g. failing to apply compression bandage routinely

in people with venous ulcers (omission) or inappropriate use of 'new' dressing (commission) can impact negatively on healing outcomes and quality of life for people with chronic wounds. Although individual clinical practice environments will vary for each health professional, aspects such as professional discipline, availability of information and current resources in the workplace need to be considered when considering change to health service environment. The amount, structure and type of clinical information available are often out of date, not evidence based, variable across clinical domains and not centrally organised on information which leads to uncertainty associated with clinical decision-making. However, the first hurdle to overcome is the awareness and ability to identify high-quality evidence.

Health professionals work in different settings/institutions with differing levels of expertise and may handle similar decisions very differently. Clinical organisations limit or shape choices associated with clinical decisions. Some solutions developed in one place may not be directly transferable or applicable to another health care environment or patient group. Although there are many RCTs and published systematic reviews in wound care providing information on decisions about compression therapy as the best practice treatment for people with VLUs, there are still examples of lack of compression application by some communities and PNs (Annells et al., 2008; Newall et al., 2009). Evidence-based health care decision-making requires comparison of all relevant competing interventions. In the absence of RCTs involving a direct comparison of all treatments of interest, indirect treatment comparisons and network meta-analysis provide useful evidence for judiciously selecting the best treatment(s) (Hoaglin et al., 2011). To implement an intervention requires both access and knowledge. For compression, this is challenging enough; becoming familiar with the many different types of bandages, contraindications of application, adverse effects and monitoring require improved education and better specific training in wound care to lead to better wound care outcomes for patients (Gottrup, 2004). Patients must also contend with competing claims and advice from clinicians, adverse effects; or the fear of, and sometimes the lack of funding to pay for compression treatments.

EBP implementation remains limited in clinical practice. There are practical problems of implementation, which include training, access to research, and development of and access to tools to display evidence and support for decision-making. There may also be practical difficulties of implementation due to the disease burden of the patient group, funding models and workforce shortages which have been reported to have hindered successful adoption of evidence-based strategy that was known to improve health outcomes in a wound care group. A supportive professional environment can greatly influence the use of research-based evidence to inform clinical decisions of an individual (Spring, 2008).

Factors influencing clinical judgement

Clinical decision-making is the ability to sift and synthesise information, make decisions and appropriately implement them. Clinical decision-making is a complex process whereby practitioners determine the type of information they collect, recognise problems according to the cues identified during information collection, e.g. wound assessment, and then decide upon appropriate interventions to address those problems (Sox et al., 2010).

Although many factors influence the decision-making process, there are a myriad of other factors that serve as barriers to this process. Even when clinicians know and accept what to do, it is possible that with workloads they forget or neglect to do it (Glasziou and Haynes, 2005). To achieve effective clinical decision-making, health professionals need to be encouraged to make decisions and assume responsibility for their decisions. Evidence from successful health service change projects suggests that an environment that is genuinely collaborative, cooperative, democratic and involves all stakeholder groups including the patient is imperative for success (Atallah, 1999; Adderley and Thompson, 2007; Grol et al., 2007; Avorn and Fischer, 2010). Factors affecting decision-making must be identified and aspects such as adequate time, technical support and sufficient resources to implement the proposed change must be evaluated to encourage shared decision-making. These factors must be understood, the barriers be identified and strategies to minimise these barriers be developed and implemented (Griffin et al., 2011). Habits do not change easily, despite best intentions. Omissions are particularly easy for preventive measures such as

compression hosiery when the venous ulcer has healed, as these aspects are not the pressing focus of the management visit.

Patient safety and quality of care will benefit from clarification of decision-making strategies, in the development of guidelines and care pathways. Clinical decision support may include a variety of tools (printed and electronic) that make knowledge and information available to the clinician to access important information (Kawamoto et al., 2005). Much has been written about effecting organisational change within health care (Oxman et al., 1995; Walter et al., 2003; Davies et al., 2008; Wilkinson et al., 2011) and more recently in wound health care (Gottrup et al., 2010), though the need to further promote knowledge and evidence to already busy health professionals can be improved. Groups such as the Cochrane Collaboration, national health and research organisations such as the National Health Scheme, National Health and Medical Research Council, National Institute of Clinical Studies Joanna Briggs Centre and high-quality wound journals that provide high-quality appraisal of research findings and existing evidence can help the clinician to take up the information offered. Some resources available include, but are not limited to, the NHS Evidence Base, American College of Physicians (ACP) database/journal updates journal clubs, online services, BMJ clinical, EBM/Practice Databases, EBM clinical decision support, DYNAMED clinical, Database of Abstracts of Reviews of Effectiveness Centre, Centre for Evidence-Based Medicine, McMaster University Evidence Based Medicine.

Even when high-quality syntheses of evidence is presented to clinicians, the information presented will be shaped by the clinician's previous knowledge (Davies et al., 2008). Clinician's experience is then connected to the context and culture where individuals work, as well as to their role and position in the organisation to shape effective use and implementation of evidence in practice. One aspect that has been successful in part is the initiation of wound care champions (McNees and Kueven, 2011) who take on the responsibility of promoting effective change using research evidence to improve quality of care for people with compromised skin integrity.

Personal contact with respected wound care and dermatology colleagues can bring about change, although it is imperative that these key leaders are competent in identifying and critically appraising the best available evidence and take responsibility for designing and implementing research that is robust. This mechanism may not work if the professional practice of these distinguished and respected wound care experts includes traditional unproven ways of doing things and may in turn be highly resistant to effective implementation of evidence-based care. To achieve EBP in wound care, clinical decision-making should be scientifically based. Future research should focus on which interventions are most effective in optimising wound healing, as well as investigating cost-effectiveness of treatment (Cowan and Stechmiller, 2009).

Evidence-based practice: hierarchy of evidence

Hierarchies of evidence refer to a method of grading the 'best' sources of evidence to support clinical decision-making. These hierarchies of evidence are often depicted as a pyramid with three, four or five levels and although consensus does not exist, one of the most widely accepted is illustrated in Figure 1.1. Research that can be generalised (applied to whole populations), such as Systematic Reviews and RCTs, is positioned at the apex of the

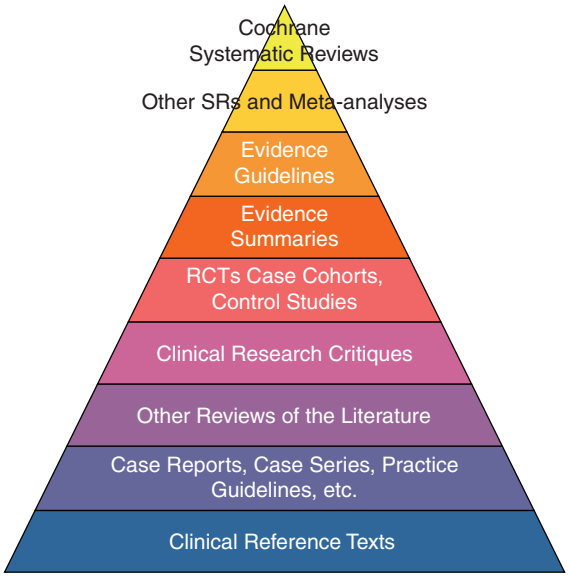

Figure 1.1 The Hierarchy of Evidence. Pyramid modified from *Navigating the Maze*, University of Virginia, Health Sciences Library (2009).

pyramid and evidence where it is not appropriate to generalise, such as data obtained from qualitative research and expert opinion, is usually found at the bottom of these hierarchies. The hierarchy indicates the relative importance that can be given to a particular study design. The higher a methodology is ranked, the stronger it is assumed to be. At the top is the systematic review/meta-analysis which integrates results of a number of similar trials to produce findings of higher statistical power. At the bottom is the opinions of respected authorities, e.g. consensus clinical guidelines thought to provide the weakest level of evidence.

Systematic reviews

A systematic review is a way of summarising the results of multiple research studies in a format that gives a critical assessment of the efficacy and safety of the specific intervention under review. The main objective of a systematic review is to provide summary information to help clinicians make decisions about health care interventions based on best evidence available (Box 1.2).

Systematic reviews are a very efficient way to access the body of research as they save time for busy clinicians who can read a critical synopsis of current research evidence in one document. Searches are undertaken on multiple electronic databases such as CENTRAL and include MEDLINE, EMBASE and other specialist databases (e.g. TRoPHI, CINAHL, LILACS), which ensure a comprehensive search. The search strategy often includes grey literature, trials registers citations, references and may include contacting experts in the field and are not limited by language, year, location and publication status. A systematic review of the literature differs from a literature review, being based on a scientific design, which aims to reduce *bias* and increase reliability and provide a comprehensive picture of all of the available evidence. The information available in a systematic review includes critical appraisal, interpretation of results and reliable basis for decision-making for health care, policy and future research.

Cochrane systematic reviews (Cochrane Wound Group) aim to bring together the body of evidence to inform decision-making. Cochrane reviews are peer reviewed, updated regularly and are free of conflicted funding. Protocols are published prior to review and outline the question definition, eligibility criteria and outcome measures to reduce impact of bias and are published in The Cochrane Library. Cochrane reviews can be accessed via the Cochrane Library: www.thecochranelibrary.com

A systematic review is comprised of

- clearly stated objectives;
- pre-defined eligibility criteria;
- explicit, reproducible methodology;
- a systematic search;
- assessment of validity of included studies;
- systematic synthesis and presentation of findings.

Other sources of systematic reviews include

- Agency for Healthcare Research and Quality: www.ahrq.gov;
- Joanna Briggs Institute: www.joannabriggs.edu.au;
- BMJ Clinical Evidence: www.clinicalevidence.com;
- Bandolier: www.medicine.ox.ac.uk/bandolier.

Randomised controlled trials

The RCT is considered the best research design to determine the effectiveness of health care interventions. Study participants are randomly assigned to receive a new intervention (experimental group) or standard intervention or no intervention (control group). Randomisation should ensure that chance determines the allocation of participants to one group or other so that the only difference between the two groups should be the intervention. Participants progress is monitored over a specified time period (follow up) and then specific outcomes are evaluated. The random allocation of participants is used to ensure that the intervention and control groups are similar in all respects (which is difficult in chronic conditions) with the exception of the therapeutic or preventative measure being tested (Weller et al., 2010a, 2010c).

Practice point

Is the RCT the best way to provide the evidence base to support wound management decisions?

Originally in medicine RCTs were perceived as the 'gold standard' in terms of levels of evidence and research. In contrast, social science approaches used to explore

aspects of patient experience have traditionally been undervalued and seen as unscientific. However, in 1995, Gyatt et al. recognised the greater value of systematic reviews and meta-analyses as they form a comparative analysis of research. Since then, concerns have been raised about the ranking of evidence in relation to which is the most relevant to clinical practice.

The hierarchy is not fixed and there is debate about the relative positions of different research methodologies. Although the RCT is traditionally considered as being an objective method of removing bias, its design is expensive, slow and produces results that may not reflect everyday practice. Methodologies that are lower in ranking are not always inferior, for example a well-conducted observational study may provide more convincing evidence about a treatment than a poorly conducted RCT. Although randomised studies are considered more robust, it would be unethical to perform an RCT which exposed patients to a risk of skin integrity breakdown, for example a study evaluating the effect of no intervention in patients at high risk of pressure ulceration.

Finally, the evidence hierarchy focuses on quantitative research methodologies; however, it is important to choose the most appropriate study design to answer the research question. For example, it is usually not possible to identify individual's feelings and personal experience of living with a chronic wound such as a leg ulcer without using qualitative techniques.

It is therefore important for health care professionals to develop skills to critically evaluate a range of sources of evidence and to raise awareness of the value of evaluating a balanced portfolio of credible evidence when suggesting changes to practice.

Evidence-informed decisions

As stated by Sackett, almost 15 years ago, external clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament and preferences, and thus whether it should be applied (Sackett et al., 1996).

A busy clinician will look for the result overview. Aspects such as the type of study, the type of participants and the outcome measures are important as these should be evaluated in their own context of clinical practice. Some questions that will help when weighing up the relevance of evidence are

(1) Are the participants described similar to my patient group?
(2) Is the intervention something that is used in my practice?
(3) Is the setting similar to my clinical practice environment?
(4) Are the resources used in the study available in my clinical practice for my patient group?

If the answers to these questions are yes, clinicians can make a judgement about the overall quality of evidence based on the criteria as follows:

- risk of bias;
- heterogeneity;
- precision;
- reporting bias;
- generalisability;
- quality (level) of evidence.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group has developed a commonsense and transparent approach to grading quality of evidence and strength of recommendations. Many international organizations endorse this approach including the World Health Organisation and the Cochrane Collaboration.

Critical appraisal frameworks

Critical appraisal of research includes both qualitative and quantitative methods, though concentrates on the analysis of the approaches taken to data analysis. Applying a framework of questions to critique a paper allows the reader to critically appraise published work, identify its strengths and limitations and give opportunities to make informed judgements about the study (Box 1.3). The critical appraisal of published research can inform the development of research questions, hypothesis and methodological approaches, or confirm that the body of knowledge that exists is sufficiently robust. Appraising any publication requires three main elements:

(1) What are the results?
(2) Are the results of the study valid?
(3) Are the results applicable to my patients?

Box 1.3 Assessing validity: checklist for various study designs

RCT

- Was the randomisation method outlined adequately?
- Was the randomisation method concealed?
- Were treatment and control groups similar in characteristics (age, gender, etc.) at baseline?
- Were patients and clinicians blinded to treatment?
- Were outcomes assessed objectively?
- Were all patients starting trial accounted for at conclusion?
- Were patients analysed in the groups to which they were randomised, e.g. analysed by intention to treat?

Cohort

- Is the study prospective or retrospective?
- Were the control and study group similar in characteristics at baseline (except for exposure)?
- Were all patients starting the trial accounted for at conclusion?
- Were researchers conducting assessment of outcome blind to exposure status?
- Were the main potential confounders identified and taken into account in the analysis?

Case–control

- Were the cases clearly defined?
- Were cases and controls taken from comparable populations?
- What percentage of cases and controls participated in the study?
- Were study measures identical for cases and controls?
- Were study measures objective or subjective and is recall bias likely if they were subjective?
- Were the main potential confounders identified and taken into account in the analysis?

Cross-sectional study

- Was the study sample clearly defined?
- Was a representative sample achieved?
- Were all relevant exposures, potential confounding factors and outcomes measured accurately?
- Were patients with a wide range of severity of disease assessed?

Case study

- Were cases identified prospectively or retrospectively?
- Are the cases a representative sample?
- Were all relevant exposures, potential confounding factors and outcomes measured accurately?

Other considerations

- Discuss strengths and weaknesses of study (internal and external validity, see above).
- Discuss the study in context of other available literature and/or current standard of care.
- What is the best study design for investigating the research question?
- Can the study outcomes be generalised to your patients?
- What are the clinical implications of this study?

Specific frameworks such as the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher et al., 2010) provides guidance on how to conduct a rigorous RCT for researchers but it can also be used by clinicians as a framework when appraising the results. The CONSORT statement has the potential to play a crucial role in influencing the quality of research and clinical practice and to improve wound care. Implementation of the CONSORT statement can clarify to the reader what exactly was done in the RCT, to whom and when, so that practitioners and health care providers can determine study validity and relevance to their patient group. RCTs are one methodological approach to add to the body of evidence which can inform clinical practice. There are many other quantitative and qualitative approaches that can also inform clinical practice.

Clinical guidelines

Clinical guidelines are 'systematically developed statements to assist clinician and patient decisions about appropriate healthcare for specific circumstances' (Field, 1994). The main purpose of clinical guidelines is to help clinicians provide quality care and to aid in the evaluation of that care with best practice. The development and implementation of (evidence-based) clinical practice guidelines is one of the promising and effective tools for improving the quality of care (Barker and Weller, 2010). However, many guidelines are not used after dissemination. Implementation activities frequently produce only moderate improvement in patient management (Grol and Buchan, 2006; Grol, 2010). Clinical wound care practice guidelines, including specific guidelines for VLUs, skin tears, diabetic foot, pressure ulcers, are now available in many countries (SIGN, 2010) and most take time and resources to collate and distribute.

Practice point

There are many clinical guidelines available for wound and skin care; almost every country has its own version of clinical practice guidelines. Clinicians are faced with the dilemma of choosing from an abundance of guidelines of variable quality or developing new guidelines of their own.

Clinical guidelines should be critically evaluated to ensure that they

- focus on aspects of care delivery that are concerned with difficult decisions or choices to make clinical management easier;
- are based on current scientific evidence drawn from well-designed clinical trials or meta-analyses and clear arguments based on clinical skills and experience;
- contain clear practice recommendations that provide a clear description of desired performance and specific advice about what to do in which situation and which factors should be taken into account;
- are compatible with existing norms and values of clinicians and are not too controversial.

(Burgers et al., 2003)

As users of clinical practice guidelines, health care professionals need to know how much confidence they can place in the practice recommendations made. Systematic methods of making judgements can reduce errors and improve communication, although some guidelines contradict other publications. A system for grading the quality of evidence and the strength of recommendations that can be applied across a wide range of interventions and contexts has been developed (Brouwers et al., 2010). Clinical judgements about the strength of a recommendation require consideration of the balance between benefits and harms, the quality of the evidence and translation of the evidence into specific circumstances. Understanding of EBP is a useful resource when making such judgements. Resource utilisation or how cost-effective the intervention is often lacking in published study results. Good evidence for the cost-effectiveness of many treatments aimed at improving skin integrity are lacking (Grimshaw et al., 2004).

Summary

There is an international effort to improve evidence-based, cost-effective and accountable clinical practice. In Australia, the National Health and Hospitals Reform Commission has a strong focus on continuous learning and evidence-based improvements to health care delivery (Bennett, 2009). In the United States, the Institute of Medicine is building the concept of a value and science-driven learning health care system that is effective and efficient; and in the

United Kingdom, guidance from the National Institute for Health and Clinical Excellence, combined with quality and outcome frameworks that include financial incentives, seeks to align clinical practice with best available evidence (Scott, 2009; Scott and Glasziou, 2012).

Evidence-based guideline development reflects one approach to improving patient care: it assumes health professionals are rational decision-makers who will act on convincing information. A belief that developing and disseminating systematic reviews and guidelines will improve patient outcomes ignores the complexity of change in health care. Guidelines do not implement themselves, they need to be developed, well executed and sustained in implementation programs and even then such programmes usually have only a moderate effect on performance in terms of improvements in patient care (Solberg et al., 2000). Many factors play crucial roles in hindering changes in health care. These factors are related not only to professional decision-making but also to patient behaviour, interaction with colleagues, team functioning and organisational conditions for change, resources and economic or legal conditions (Grol and Buchan, 2006). Challenges can arise when clinical guidelines are introduced into routine daily practice as clinicians find it difficult to be aware of all the relevant valid evidence due to the volume of published research. Plans for change in practice should be based on characteristics of the evidence or guideline itself and barriers and facilitators to change (Grol and Grimshaw, 2003). Some barriers to adoption of evidence may be information overload as it is not uncommon that clinicians find it difficult to be aware of all published evidence as there are so many journals to consider. Even if evidence is accepted, clinicians and guidelines may not target correct groups. To carry out a clinical intervention requires both access and knowledge.

Evidence-based research provides information on which to base clinical decisions and a support for decision-making by providing best outcome data. Comparative effectiveness research using systematic review analysis to compare similar treatments or procedures in maximising the choice of the most effective cost/benefit option within the context of best evidence is a valuable adjunct to protect patients from ineffective or harmful treatments (Lean et al., 2008).

Translational research is the process evolving from EBP that translates the results of clinical trials into sustainable changes in practice (Lean et al., 2008). It has become a useful tool in improving decision-making in the clinical setting and was developed to be a foundation between researchers, clinicians and patients. Translational research using evidence-based and comparative effectiveness research will continue to evolve, and may prove to be a useful tool to improve decision-making in the clinical setting (Bauer and Chiappelli, 2010). EBP that integrates best available research evidence with information about patient preferences, clinician skills and available resources can improve clinical decisions in wound care.

Useful resources

Canadian resources

http://ktclearinghouse.ca – The KT Clearinghouse website is funded by the Canadian Institute of Health Research (CIHR) and is a comprehensive resource incorporating the Centre for Evidence Based Medicine in Toronto.

McMaster University.

European resources

www.thecochranelibrary.com – *Cochrane Systematic Reviews* covers all areas of clinical practice including the Cochrane Skin Group and the Cochrane Wound Group.

www.cks.nhs.uk – It provides summary of evidence-based clinical guidelines (UK).

www.evidence.nhs.uk – National Health Service (UK) approved evidence website.

International resource

The GRADE system to evaluate the quality (level) of evidence and strength of recommendations. Available at: www.gradeworkinggroup.org.

Useful critical appraisal frameworks

CONSORT (Consolidated Standards of Reporting Trials) Transparent Reporting of Trails. Available at: http://www.consort-statement.org/home/

Registered Nurses Association of Ontario. Available at: www.rnao.org/bestpractices
NHS National Institute for Health and Clinical Studies. Available at: www.guidance.nice.org.au
Critical Appraisal Skill Program (CASP). Available at: www.phru.nhs.uk/casp/critical_appraisal_tools.htm

Further reading

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