

PRIMARY RESEARCH

Balancing the evidence: incorporating the synthesis of qualitative data into systematic reviews

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Abstract

Techniques for the systematic review of evidence of effectiveness are now well established. Health-care professionals argue, however, for a need to recognise evidence of appropriateness and feasibility and for the development of methodologies to appraise and synthesise the results of qualitative research. This paper describes a participatory project designed to develop systems to systematically review qualitative evidence. The Qualitative Assessment and Review Instrument is described in detail, and a suite of programs designed to conduct comprehensive reviews of evidence for health-care practice is outlined. As evidence-based practice increases in sophistication, and its influence in health service delivery expands, the need for broadening the view of what constitutes legitimate evidence is advanced by clinicians and the approach described attempts to achieve a balance in evidence review that recognises the value of quantitative and qualitative evidence.

Key words: evidence, meta-synthesis, qualitative research, systematic review.

Introduction

Most health professions are increasingly embracing the concept of evidence-based practice and many use evidence-based guidelines to inform (rather than direct) practice. In North America, considerable resources have been invested in high quality, high cost research and development programs to develop evidence-based clinical guidelines. In the UK, policy initiatives have directed health-care provider agencies to develop research and development strategies, to establish research and development units and to promote practices based on the best knowledge available. At the same time, the UK Government has established a number of Centres for Evidence-Based Practice and health research centres.

At an international level, the Cochrane Collaboration has linked research and development sites across the world to review and analyse randomised clinical trials from an international perspective, to generate reports to inform practitioners, to influence practice and to be a resource in the development of consensus guidelines.

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Practical application of rigorously reviewed evidence is now promoted via the development and dissemination of practice guidelines in most developed health-care systems. Clinical practice guidelines consist of statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances that are systematically developed on the basis of consensus within expert groups. An increasing number of well-constructed, practical and evidence-based guidelines are being developed.

Evidence-based practice is now almost institutionalised in most industrialised countries, especially in Europe, the UK, North America and Australasia. Many of these countries have established centres for evidence-based health care, evidence-based medicine and evidence-based nursing. For example, there are Cochrane Centres in all of these countries and centres for evidence-based nursing in the UK and North America. The Joanna Briggs Institute (JBI), based in Australia, has collaborating nursing centres in China, Thailand, Spain, England and South Africa, in addition to its Australian centres in Queensland, New South Wales, Victoria, South Australia, Western Australia and the Northern Territory. The JBI also has multidisciplinary centres for rural health and aged care, physiotherapy, occupational therapy, podiatry, medical radiation and nutrition and dietetics.

Essentially, evidence-based practice is the combination of evidence derived from individual clinical or professional expertise with the best available external evidence to produce practice that is most likely to lead to a positive outcome for a client or patient. The evidence-based approach to practice is of relevance to all professionals who work in health care. Sackett *et al.* contend that evidence-based health care is 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'.¹

Evidence-based approaches have provoked some controversy, however. The most controversial issue relates to the current focus on evidence of effectiveness. The prevailing orthodoxy in systematically reviewing evidence elevates the results of experimental research to a position of superiority in terms of quality and applicability to practice, disregarding the results of non-quantifiable research as legitimate evidence for practice because of its interest in subjectivity and interpretation. Critics of the prevailing privileging of the randomised controlled trial (RCT) and quantitative research cite the arguments inherent in critiques of traditional science and the emergence of new paradigms for knowledge. For example, FitzGerald argues that, although traditional scientific method, with its emphasis on objectivity, plays an important role in the development of knowledge

and technology, '...the dominance of traditional science needs to be challenged [in health if practitioners] wish to make a place for different ways of knowing in their practice'.²

Although the RCT is probably the 'best' approach to generating evidence of effectiveness, nurses, medical practitioners and allied health professionals are concerned with more than cause and effect questions, and this is reflected in the wide range of research approaches utilised in the health field to generate knowledge for practice. Although its proponents would argue that evidence-based practice is not limited to the utilisation of the results of traditional research, it is difficult to defend such an argument given the considerable emphasis placed on RCTs and meta-analyses to date. This has drawn criticism from those professions who regard qualitative research methods as equally valid forms of research that generate legitimate evidence for practice.

Knowledge acquired from qualitative approaches to research is largely absent in current approaches to systematic reviews. This is partly because the rapid development of accepted approaches to the appraisal and synthesis of evidence by quantitative researchers has not been accompanied by similar efforts by those with expertise in qualitative approaches to inquiry. Questions such as 'what is evidence?' and 'what are acceptable research results in terms of generating knowledge that amounts to evidence for the purpose of informing practice?', inspire conflicting views. These differences generally align with the various positions that characterise the long-standing debate between qualitative and quantitative researchers. This is clearly not an easily resolved argument, but it is vitally important in terms of ascertaining the value of research-generated 'evidence' to health-care practice.

This paper describes an initial attempt to recognise the results of non-quantitative research as appropriate evidence for health-care practitioners.

What counts as evidence?

Evidence in health-care practice

In general terms, evidence refers to data or information used to decide whether or not a claim or view should be trusted. In health care, practitioners and patients make numerous decisions and, in doing so, weigh up numerous types of information before taking action. Although the results of well-designed research are an obvious source of evidence, the results of formal research are by no means the only data used in everyday practice. Other determinants include the patient and his/her relevant others, the practitioner's own

experiences and the nature and norms of the setting and culture in which the health care is being delivered; these are all rich sources of evidence to draw upon in making clinical decisions.

The dominant orthodoxy of regarding the results of quantitative research as evidence and all other knowledge as something other than evidence does not reflect the understanding of practice held by many clinicians. This is not surprising, given the nature and meaning of evidence in everyday life.

Evidence in its most generic sense has been defined as being 'the available facts, circumstances, etc. supporting or otherwise a belief, proposition, etc. or indicating whether a thing is true or valid'.³ Evidence in a legal sense has been defined as being 'information given personally or drawn from a document, etc. and tending to prove a fact or proposition ... or ... statements or proofs admissible as testimony in a law court'.³

For philosophers, evidence is understood to be information bearing on the truth or falsity of a proposition. According to Audi,

A person's evidence is generally taken to be all the information a person has, positive or negative, relevant to a proposition. The notion of evidence used in philosophy thus differs from the ordinary notion according to which physical objects, such as a strand of hair or a drop of blood, counts as evidence. One's information about such objects could count as evidence in the philosophical sense.⁴

It is important, from a philosophical standpoint, to understand that the concept of evidence plays a key role in our understanding of knowledge and rationality. Traditionally, 'one has knowledge only when one has a true belief based on very strong evidence'.⁴ Moreover, for belief to be rational it must be based on adequate evidence, even when that evidence is insufficient to ground knowledge.

Evidence for health professionals

Some serious consideration has been given to the meaning of evidence in relation to the evidence-based health-care movement. Dixon-Woods *et al.*, for example, discuss the relevance of evidence elicited through qualitative research in systematic reviews and Noblit and Hare describe how ethnographic approaches to inquiry generate evidence appropriate to practice.^{5,6}

According to Humphris, the term 'evidence-based' in health care 'implies the use and application of research evidence as a basis on which to make health-care decisions, as opposed to decisions not based on evidence'.⁷ Within the mainstream health field led by medicine and medical sci-

ence, research has been narrowly confined to the empirico-analytical paradigm, focusing on objectivity, measurement and statistical significance. This process of knowledge generation involves testing a hypothesis or a set of hypotheses by deriving consequences from it and then testing whether those consequences hold true by experiment and observation. A theory of evidence assists here to the extent that it indicates what relationship should exist between the observation reports and the hypotheses if those reports are to constitute evidence for the hypotheses.

There is some legitimacy in regarding the RCT, and other approaches that focus on measurement and statistical analysis, as the most desirable approach to evidence generation when the question relates to cause-and-effect relationships. However, health professionals have broader evidence interests that relate to the experience of health, illness and health care. Indeed, it is not unusual within the broad field of health care to find that the 'best available' evidence on a given topic cannot be reduced to a quantifiable value. Expert opinion – whether it is expressed by an individual, a learned body or by a group of experts in the form of a consensus guideline – draws on the experience of practitioners. Well-designed qualitative research, while often not properly understood by researchers grounded in the physical sciences, constitutes 'good' human science.

Pearson argues for a pluralistic approach when considering 'what counts as evidence' for health-care practices and Evans and Pearson suggest reviews that include both (or either) qualitative evidence and quantitative evidence are of importance to most practitioners.^{8,9} However, they go on to suggest that, '... optimal methods for reviewing qualitative research are still evolving'.⁹

Evidence-based practice

Clinical effectiveness: an evidence base for practice?

The evidence-based practice movement currently focuses on the effectiveness of interventions and activities and the term 'systematic review' is now interpreted as a process that summarises and synthesises the results of experimental and other quantitative studies. The results of descriptive, observational and interpretative inquiry are afforded little, if any, status in most systematic reviews. Evans and Pearson aver:

It can be argued that the approach of the systematic review should be used for all summaries of the research, ensuring that the care and rigour that was utilised by the primary researcher is maintained by the reviewer. However, this concept has not received wide acceptance and so the focus of most systematic reviews has remained predominantly fixed on the randomised controlled trial.⁹

Evans and Pearson go on to argue that the systematic review process should be expanded to include findings generated from all forms of rigorous research, as well as those from RCTs. The systematic review process originated in the field of organisational psychology, from which medical research took it and refined it.

Writing in 1982, Salipente *et al.* clearly describe how the process was conceptualised to synthesise research grounded in any tradition.¹⁰ Thus, within this context, Evans and Pearson's plea to 'expand' the remit of systematic reviews could be better expressed as returning to the original nature of the systematic review.

The systematic review

The core of evidence-based practice is the systematic review of the literature on a particular condition, intervention or issue. The systematic review is essentially an analysis of all of the available literature (that is, evidence) and a judgement of the effectiveness or otherwise of a particular practice. Currently, the systematic review involves the following steps.

- 1 The development of a rigorous proposal or protocol is vital for a high quality systematic review. The review protocol provides a predetermined plan to ensure scientific thoroughness and the minimisation of potential bias. It also allows for periodic updating of the review if necessary.
- 2 The protocol should state in detail the questions or hypotheses to be discussed in the review. Questions regarding the patients, setting, interventions and outcomes to be investigated should be specific.
- 3 The protocol must describe the criteria that will be used to select the literature. The inclusion criteria should address the participants of the primary studies, the intervention and the outcomes. In addition to this, it should also specify what research methodologies will be considered for inclusion in the review (e.g. RCTs, clinical trials, case studies).
- 4 The protocol should provide a detailed strategy that will be used to identify all relevant literature within a specified time frame. This should include databases and bibliographies that will be searched, and the search terms that will be used.
- 5 Critical appraisal of the studies retrieved is important to assess the quality of the research, minimising the risk of an inconclusive review with excessive variation in study quality. The protocol must therefore describe how the quality of primary studies will be assessed and any exclusion criteria based on quality considerations.

6 It is necessary to extract data from the primary research regarding the participants, the intervention, the outcome measures and the results.

7 Statistical analysis (meta analysis) may or may not be used and will depend on the nature and quality of studies included in the review. Although it may not be possible to state exactly what analysis will be undertaken, the general approach should be included in the protocol. When statistical analysis is not possible, current practice is to develop a narrative summary.

Pearson, in arguing that evidence-based practice includes an interest in research on clinical effectiveness but is not confined to this interest, says:

... randomised trials are the gold standard for phenomena that we are interested in studying from a cause and effect perspective, **but clearly they are not the gold standard if we are interested in how patients and nurses relate to each other**, or if we are interested in how patients live through the experience of radiotherapy when they have a life threatening illness. We have yet to work out how to assess the quality of alternative approaches to research other than the RCT.¹¹

He goes on to suggest that '...evidence-based practice is not exclusively about effectiveness; it is about basing practice on the best available evidence'.¹¹

The diverse origins of problems in health care require a broad interpretation of what counts as valid evidence for practice and the utilisation of a diverse range of research methodologies to generate appropriate evidence. Methodological approaches in this area need to be eclectic enough to incorporate classical, medical and scientific designs and the emerging qualitative and action-orientated approaches from the humanities and social and behavioural sciences. The development of interdisciplinary research and a greater understanding of the relationship between medical, nursing and allied health interventions are also fundamental to the creation of research methodologies that are relevant and sensitive to the health needs of consumers.

There is a small, but growing amount of literature addressing the role of qualitative research in evidence-based practice, which recognises a need to move beyond the effectiveness of interventions to consider their appropriateness and practical feasibility.

Lemmer *et al.*, in attempting to conduct a systematic review in an area of health visiting, focusing on the RCT as a 'gold standard', report on a paucity of trials in this field and argue that clinical complexity demands a need to integrate qualitative methods into systematic reviews. They argue that '...the comprehensiveness and synthesis of a systematic review are more important to emphasise than

whether the literature is outside the clinical remit of an RCT'.¹²

The need to more fully integrate the results of qualitative research into the systematic process is well stated by Popay and Williams, who suggest that '...there are many proponents of evidence-based decision making within healthcare who cannot and/or will not accept that qualitative research has an important part to play ...'.¹³

Popay and Williams assert that the results of qualitative research do more than simply enhance those of quantitative studies and suggest that qualitative research is capable of generating evidence that:

- explores taken-for-granted practices;
- increases understanding of consumer and clinical behaviour;
- develops interventions;
- illuminates patient's perceptions on quality/appropriateness;
- gives guidance to understanding organisational culture and change management; and
- evaluates complex policy initiatives.¹³

Green and Britten stated that:

Qualitative research may seem unscientific and anecdotal to many medical scientists. However, as the critics of evidence based medicine are quick to point out, medicine is more than the application of scientific rules.¹⁴

Green and Britten go on to argue that qualitative research findings provide rigorous accounts of treatment regimens in everyday contexts. They also contend that there is an increasing need within the evidence-based practice arena to raise awareness of the fact that different research questions require different kinds of research. They are unequivocal in their assertion that 'good' evidence goes further than the results of meta-analysis of RCTs.

The Cochrane Qualitative Methods Group, established in 2002, is currently exploring the scope for incorporating qualitative research into Cochrane reviews. There are still no internationally reviewed guidelines for assessing the quality of specific qualitative methods and no established procedures for ranking or rating qualitative research findings reported in the literature. There have been, however, a number of attempts to synthesise (as a form of meta-analysis) the results of similar qualitative studies, and these are well described by Sandelowski *et al.*; these authors have also developed an in-depth theoretical approach to the systematic metasynthesis of qualitative findings that maintain the integrity of individual studies.¹⁵ Drawing on the work of Sandelowski *et al.*, Popay and Williams, and Lemmer *et al.*, an approach to qualitative meta-analysis, quality assessment

and the development of a quality rating scale for qualitative research results could be used to add appropriateness and feasibility dimensions to the current effectiveness-orientated systematic review process.^{12,13,15}

There are signs that the evidence-based practice movement is beginning to develop a more comprehensive view of evidence. There are research initiatives attempting to construct approaches to assessing and synthesising the results of interpretative and critical research, so that these forms of evidence can become an integral part of systematic reviews and, thus, inform practice. Several authors have reported on the systematic review of evidence elicited through interpretative and critical approaches to inquiry.^{16–}

¹⁸ An approach to the meta-synthesis of qualitative findings, and the problems associated with synthesising the findings of studies that are essentially context-bound, is described by Jensen and Allen and Popay and Roen overview a wide range of current initiatives focusing on methods to appraise and synthesise qualitative research within the framework of the systematic review process.^{19,20}

Developing sound and acceptable methodologies to appraise the findings of qualitative research and to synthesise the findings of two or more similar studies is both complex and challenging. Interesting developments in this area have been reported by several authors.^{17,21–24} Such evolving approaches to evidence-based practice represent a growing body of work supporting the appropriate use of relevant evidence in the systematic review process that will help practitioners to perform well in practice and to use their professional judgement in the use of appropriate evidence.

Including qualitative data in systematic reviews

Over a period of two years, a project utilising participatory processes at three consensus workshops has explored the review of qualitative evidence, and an electronic package has been designed to enable reviewers to systematically review qualitative evidence. The purpose of this project was to determine how evidence generated through qualitative research could be systematically reviewed and to identify how evidence of appropriateness and feasibility could augment evidence of effectiveness in evidence-based health care.

Project design

The project consisted of four phases.

In Phase 1, acknowledged experts in qualitative and action-orientated approaches were invited to attend a con-

sensus workshop, with a view to working with the researcher to develop instruments to evaluate, and extract data from, qualitative research reports.

In Phase 2, acknowledged experts in qualitative and action-orientated approaches were invited to attend a consensus workshop, with a view to working with the researcher to develop a systematic process of extracting and synthesising data from qualitative research reports.

In Phase 3, the researcher worked with a software developer to develop an electronic system to review qualitative evidence.

In Phase 4, the software developed was piloted with the expert groups and other health professionals attending systematic review training workshops.

Outcomes

At the workshops a group of leading Australian qualitative researchers were invited to participate in a consensus workshop to consider how a systematic process of extracting and synthesising qualitative data can occur to reflect a rigorous process equivalent to the existing processes applied to the results of RCT and other quantitative research, while maintaining sensitivity to the contextual nature of qualitative research.

More specifically, participants were asked to:

- design appropriate data extraction tools;
- design appropriate data synthesis tools; and
- draft a position statement.

Nine of those invited attended the workshops. Workshop attendees were: Professor Mary FitzGerald, University of Newcastle; Associate Professor Jane Stein-Parbury, University of Technology; Professor Colin Holmes, James Cook University of Northern Queensland; Professor Michael Clinton, Curtin University; Professor Desley Hegney, University of Southern Queensland; Dr Ken Walsh, The University of Adelaide; Dr Karen Francis, Charles Sturt University; Mr Matt Lewis, La Trobe University; and Ms Cathy Ward, La Trobe University.

Consensus workshops

Expected outcomes were agreed upon at each workshop. It was also agreed that the workshop outcomes would need to accommodate the nature of qualitative approaches to research, rather than replicate existing formats. The participants emphasised the complexity of interpretative and critical understandings of phenomena, but were also aware of the need to ensure that outcomes would be practical and usable. Participants were also mindful of the complexity of the types of research under consideration, and wanted to

balance the utility of the outcomes with the complexity of the material.

‘Meaning’ was identified as a unifying theme of qualitative research. A list of methodological frameworks was generated and these were then grouped in relation to their orientation (Appendix I). Judgements were made about the value of each methodological position in relation to specific criteria of meaningfulness, appropriateness, feasibility and effectiveness.

The participants recognised that they were working with a wide range of methodologies, each with its own strengths and weaknesses. They agreed to develop a ‘matrix’ approach, which was considered to be more appropriate than a simple hierarchy of evidence. With regard to the centrality of contextual issues in interpretative and critical research, the group suggested that this be taken into account by including statements in the summary about the scope of applicability.

The group agreed that an overall matrix and the context statement should generate a summary statement describing the strengths and weaknesses of the available evidence and the associated levels of confidence.

Workshop outcomes statement

Consensus was reached on an ‘outcomes statement’ developed collaboratively by the group (Appendix II).

Drawing on this consensus summary statement, prototype components for a qualitative assessment and review instrument were developed. This was named the Qualitative Assessment and Review Instrument (QARI).

Appraising and synthesising qualitative data

Critical appraisal

The central concern in critically appraising experimental or quantifiable data is to limit bias and thus establish the validity of a study. From a quantitative perspective, sources of bias include selection bias, performance bias and attrition bias, and validity is assessed by establishing the extent to which a study’s design and conduct address potential bias.

This focus on limiting bias to establish validity is antithetical to the philosophical foundations of qualitative approaches to inquiry. Emden and Sandelowski suggest that validity, in quantitative terms, measures those things that it purports to render generalisable. In social inquiry, however, they argue that validity is perceived as criteria of rigour for qualitative research.²⁵

There is much dissent in the literature on the appropriateness of establishing criteria to assess the validity of qualita-

tive research. However, Pearson takes the view that a transparent approach to appraising qualitative research is central to its ongoing credibility, transferability and theoretical potential.²⁶ Denzin and Lincoln concur with this conclusion and highlight the need for development of a set of validity criteria sensitive to the nature of the qualitative research and its basis in subjectivity.²⁷ Popay *et al.* are unequivocal in their assertion that the development of standards for assessing evidence from qualitative research is both possible and desirable.²⁸ They provide the following as a guide to common standards:

- evidence of responsiveness to social context and flexibility of design;
- evidence of theoretical or purposeful sampling;
- evidence of adequate description;
- evidence of data quality;
- evidence of theoretical and conceptual adequacy; and
- potential for assessing typicality.²⁸

There is a growing amount of literature that examines the appraisal of qualitative studies and a large number of formats are available. Drawing upon this literature and an extensive process of development and piloting, Averis and Pearson describe a general set of criteria for appraising the validity of interpretative and critical research.²⁶ These criteria were incorporated into the critical appraisal scale of the QARI software, which was developed by the project.

The critical appraisal scale was piloted and refined in three systematic review training workshops. The checklist in Appendix III provides the essential framework for the critical appraisal of interpretative and critical studies.

Data extraction

Data extraction aims to reduce the findings of many studies into a single document and summarise:

- methods;
- interventions; and
- outcomes.

Data extraction involves transferring data from the original paper using an approach agreed upon and standardised for the specific review. An agreed format is essential to minimise error, to provide a historical record of decisions made about the data in the review, and to become the data set for analysis and synthesis. A data extraction instrument, drawing on the literature and input from a panel of experts, was developed, extensively piloted, refined and incorporated into the QARI software (Appendix IV). Based on the standard approach promoted by the Cochrane Collaboration and adopted by the JBI, two reviewers are expected to independently extract data, and then confer.

Meta-synthesis

The most complex problem in synthesising textual data is agreeing on and communicating techniques to compare the findings of each study. Meta-synthesis relates to the combining of separate elements to form a coherent whole. This involves reasoning from the general to the particular using a process of logical deduction. An approach to the meta-synthesis of qualitative data, which draws on the literature and input from a panel of experts, was developed for QARI. This involves:

- translating themes, metaphors or concepts;
- transferring actual text or summarised text that illustrates the theme, metaphor or concept; and
- re-categorising the data obtained to arrive at a synthesis.

In order to pursue this, reviewers need to establish the following before carrying out data synthesis:

- their own rules for setting up categories;
- how to assign findings to categories; and
- how to write narrative summaries for each category.

The reviewers need to document these decisions and their rationale in the systematic review report. This process is incorporated into the QARI software.

The analysis and synthesis of qualitative studies is commonly termed meta-synthesis, and like meta-analysis, it is based on processed data. There are major differences between the approach used to synthesise the findings of RCT and the approach used for qualitative studies. Reality for the qualitative researcher, and reviewer, is viewed as multiple and constructed, and so undertaking meta-synthesis means that no two reviewers will produce exactly the same results. Although meta-synthesis provides only one interpretation, it aims to capture the essence of the phenomenon interest.

When engaging in the synthesis of the results of qualitative studies, differing research methods, such as phenomenology, ethnography or grounded theory, are not mixed in a single synthesis of all qualitative studies.

The aim of meta-synthesis is to portray an accurate interpretation of a phenomenon, and to compare and contrast the constructs of individual studies to reach consensus on a new construction of that phenomenon.

Meta-synthesis involves:

- identifying findings;
- grouping findings into categories; and
- grouping categories into synthesised findings.

Findings: Findings are conclusions reached by the reviewer(s) after examining the results of data analysis (e.g. themes, metaphors), consisting of a statement that relates

two or more phenomena, variables or circumstances that may inform practice.

Categories: Categories are groups of findings that reflect similar relationships between similar phenomena, variables or circumstances that may inform practice.

Synthesised findings: Synthesis refers to the combining of separate elements to form a coherent whole, using logical deduction and reasoning from the general to the particular. In QARI, a synthesised finding is defined as an overarching description of a group of categorised findings that allow for the generation of recommendations for practice.

Categorising findings

In order to pursue this, reviewers need to establish their own rules for the following before carrying out data synthesis:

- setting up categories;
- assigning findings to categories; and
- writing narrative summaries for each category.

Reviewers need to document these decisions and their rationale in the systematic review report. This process is incorporated into the QARI software.

The primary reviewer then categorises findings.

Synthesised findings

When categorisation is complete, the reviewers then study the categories and synthesise these to form a set of synthesised findings.

Levels of evidence

Current approaches to evaluating evidence utilise a hierarchy of evidence designed to assess the validity of recommendations for clinical guidelines. These approaches focus on the effectiveness of treatment and rank only quantitative evidence according to the rigour of the research designed to limit bias. An approach to categorising the validity of qualitative evidence, which draws on the literature and input from a panel of experts, has been developed for QARI. This approach is based on three levels of qualitative evidence:

Unequivocal: The evidence is beyond reasonable doubt and includes findings that are factual, directly reported/observed and not open to challenge.

Credible: The evidence, while interpretative, is plausible in light of the data and theoretical framework. Conclusions can be logically inferred from the data but, because the findings are essentially interpretative, these conclusions are open to challenge.

Unsupported: Findings are not supported by the data and none of the other level descriptors apply.

These three levels of evidence are incorporated into the QARI software.

Levels of applicability

There is little point in accumulating evidence to answer a question if it cannot then be used to benefit patients. Evidence-based practice involves integration of the best available evidence with clinical expertise. When it comes to deciding whether or not to incorporate a particular activity or intervention into practice, some or all of the following considerations will be relevant:

- Is it available?
- Is it affordable?
- Is it applicable in the setting?
- Would the patient/client be a willing participant in the implementation of the intervention?
- Were the patients in the study/studies that provided the evidence sufficiently similar to your own to justify the implementation of this particular intervention?
- What will be the potential benefits for the patient?
- What is the potential harm to the patient?
- Does this intervention allow for the individual patient's values and preferences?

In addition to the requirement to define levels of evidence for practice, there is also a need to establish levels of applicability. The QARI project group developed the 'Feasibility, Appropriateness, Meaningfulness and Effectiveness' (FAME) scale,²⁶ a hierarchy of applicability of evidence that is incorporated into the QARI software.

The QARI levels of applicability of evidence are shown in Table 1.

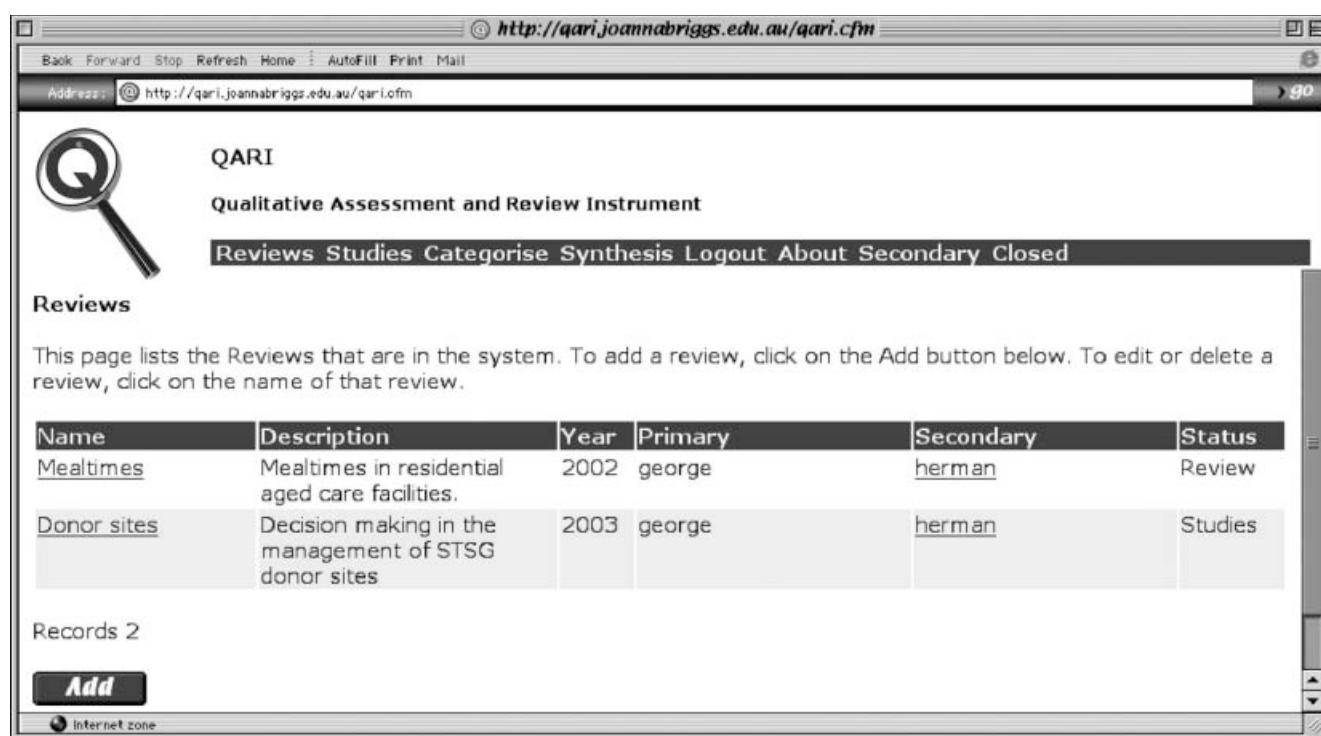
The QARI software

The QARI attempts to establish the results of non-quantitative research as appropriate evidence for health-care practitioners. It was designed to create a system that would enable health scientists and health practitioners to review evidence from an inclusive position. The purpose of the QARI developmental process was to determine how evidence generated through qualitative research could be systematically reviewed, and identify how evidence of appropriateness, meaningfulness and feasibility could augment evidence of effectiveness in evidence-based health care.

The QARI software is designed to manage, appraise, analyse and synthesise textual data as part of a systematic review of evidence. QARI has been designed as a web-based database and incorporates a critical appraisal scale, data extraction forms, a data synthesis function and a reporting function.

Table 1 Qualitative Assessment and Review Instrument (QARI) levels of applicability of evidence

Feasibility	Appropriateness	Meaningfulness	Effectiveness
Immediately practicable	Acceptable and justifiable, within ethical guidelines	Provides a rationale for practice development	Effectiveness established to a degree that merits application
Practicable with limited local training or modest additional resources	Acceptable after minor revision	Provides a rationale for local, regional or national reform	Effectiveness established to a degree that suggests application
Practicable with extensive additional training or resources	Acceptable after major revision	Provides a rationale for practice-relevant research	Effectiveness established to a degree that warrants consideration of applying the findings
Practicable with significant national reforms	Acceptable after development of new ethical guidelines	Provides a rationale for advocating change	Effectiveness established to a limited degree
Impracticable	Ethically unacceptable	Evidence unlikely to make sense to practitioners	Effectiveness not established

**Figure 1** Reviews screen listing the reviews available to the logged on reviewer.

The software has been internationally peer reviewed. It has been tested by a group of international systematic reviewers and is currently being piloted by evidence review groups in Canada, Australia, England and Scotland.

The QARI software can be accessed by those who hold a licence by entering the JBI website (<http://www.joannabriggs.edu.au>) and then clicking on the SUMARI logo.

An overview of how QARI is used is presented here to demonstrate the process of appraisal and meta-synthesis.

When QARI is opened, the main menu is always across the top of the screen (Fig. 1).

Reviews

Reviews are the projects to which Studies, Extractions and Findings relate. The reviews screen lists the reviews available to the logged on reviewer (Fig. 1).

Before a Reviewer can work on a project they must be assigned to the Review, either when the Review is first cre-

ated or when it is edited later. The Primary Reviewer must appoint a Secondary Reviewer when a new review is added. A Study is related to a Review. Extractions and Findings are written for a single Study.

The Studies screen allows users to view, add, edit and delete Studies (Fig. 2). A Study goes through a process of being Assessed and Extracted before Findings are made against it. Assessment of a Study determines whether a Study is to be 'included' or 'excluded'. For a study to be used in the Review it must be assessed. Both the Primary and Secondary Reviewer perform the assessment process independently.

Assessment

If a Study is found to be 'excluded' a reason for the exclusion must be entered. During this process the Primary Reviewer would review each Study to determine a final Assessment status (Fig. 3). If a Study's Assessment status is in dispute the Primary Reviewer would need to resolve any conflicts.

In the case of both Assessments on the Study being 'excluded', a final exclusion reason would need to be created. This reason would default to the original exclusion reason given by the Primary Reviewer but could be modified before being saved.

Once any assessment conflicts are resolved, the Primary Reviewer would complete the final assessment. The Study's status would then be updated to 'extraction' and the Review's status to 'open'.

Filtering

This function will filter the view so that only unassessed studies are displayed. The 'Assessment' column indicates what is required to complete the assessment.

None: No assessment has been preformed by the primary or secondary reviewer.

Primary: The primary assessment has not been completed but secondary assessment has been completed.

Secondary: The secondary assessment has not been completed but primary assessment has been completed.

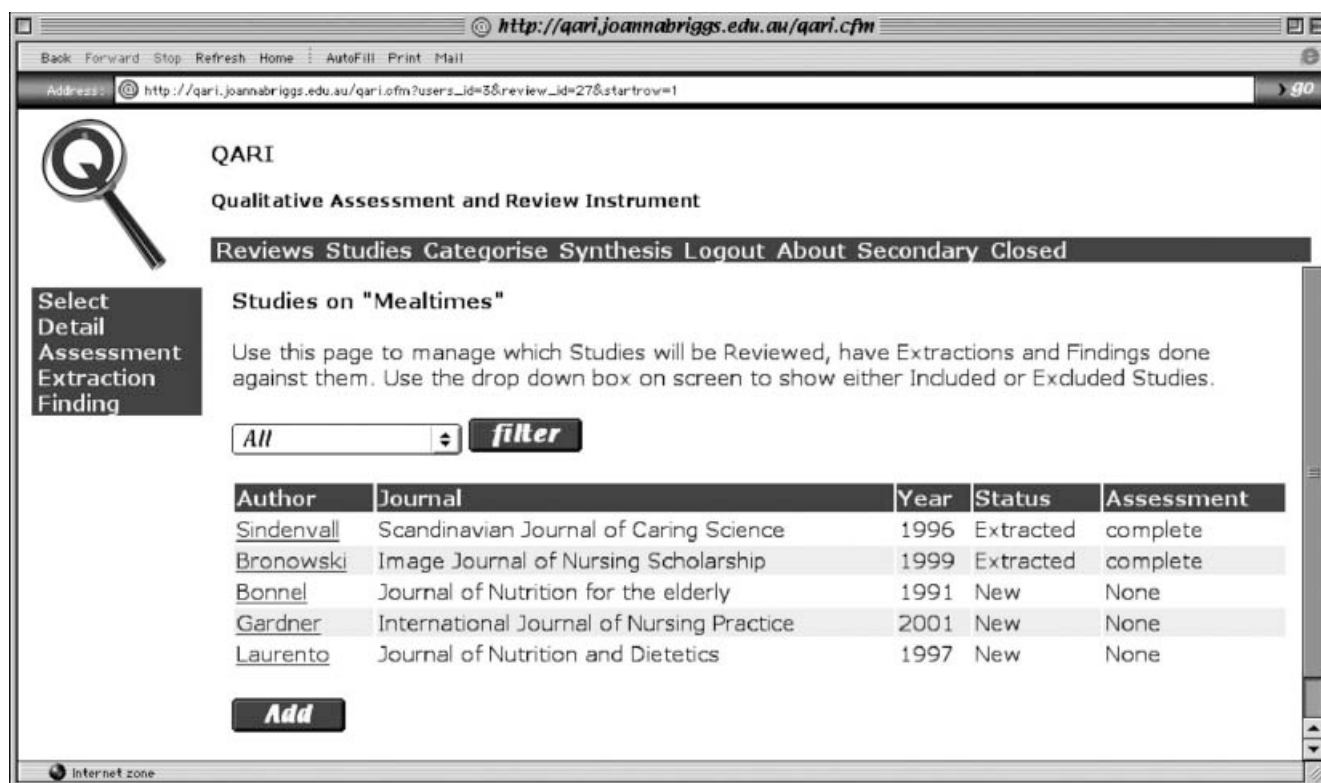
Final: Final assessment by the primary reviewer is required.

Included: The study has been fully assessed and is included in the review.

Excluded: The study has been fully assessed and is excluded from the review.

Initial assessment

To add an initial Assessment, the reviewer clicks the Author's Name on the Studies Screen and then clicks the <select>



QARI
Qualitative Assessment and Review Instrument

Reviews Studies Categorise Synthesis Logout About Secondary Closed

Select Detail Assessment Extraction Finding

Studies on "Mealtimes"

Use this page to manage which Studies will be Reviewed, have Extractions and Findings done against them. Use the drop down box on screen to show either Included or Excluded Studies.

Author	Journal	Year	Status	Assessment
Sindenvall	Scandinavian Journal of Caring Science	1996	Extracted	complete
Bronowski	Image Journal of Nursing Scholarship	1999	Extracted	complete
Bonnel	Journal of Nutrition for the elderly	1991	New	None
Gardner	International Journal of Nursing Practice	2001	New	None
Laurento	Journal of Nutrition and Dietetics	1997	New	None

Figure 2 Viewing the studies.

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Assessment for : Sindenvall - Scandinavian Journal of Caring Science (1996)

Type Primary
User george

- 1) There is congruity between the stated philosophical perspective and the research methodology. Yes
- 2) There is congruity between the research methodology and the research question or objectives. Yes
- 3) There is congruity between the research methodology and the methods used to collect data. No
- 4) There is congruity between the research methodology and the representation and analysis of data. Yes
- 5) There is congruity between the research methodology and the interpretation of results. Yes
- 6) There is a statement locating the researcher culturally or theoretically. Yes
- 7) The influence of the researcher on the research, and vice-versa, is addressed. No
- 8) Participants, and their voices, are adequately represented. Yes
- 9) The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body. Yes
- 10) Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of the data. (Undefined) Yes No Unclear

Include Yes

Reason

Update Cancel

Internet zone

Figure 3 Assessment edit screen.

button. When 'Assessment' is clicked in the menu to the left of the screen, the Assessment Summary screen will be displayed. If the Primary Reviewer clicks the <Add Primary> button, the Assessment Edit screen will appear. The reviewer then answers each of the 10 questions by selecting from the drop-down menus to the right of the questions (see Assessment Edit screen at Fig. 3). The reviewer then includes or excludes the Study by using the drop-down menu at the bottom of the questions. If the study is excluded, an explanation is entered in the reason field.

The Secondary Reviewer can now assess the study. The Secondary Reviewer will follow the same steps as the Primary Reviewer, but click the <Add Secondary> button.

Final assessment

Once both initial assessments have been completed, the Primary Reviewer can perform the final assessment.

When both assessments are designated 'included', final answers for the 10 questions must be decided, as the responses may not be the same. When the final assessment is to 'exclude' the study, the Exclude Reason fields must be combined.

Data extraction is then performed on included studies (Fig. 4). The Primary Reviewer can add their Extraction on a Study. An Extraction must be done on a Study before the Findings can be associated to it.

A methodology usually covers the theoretical foundations of the research. A list of methodologies appears in Appendix I. This list is not exhaustive and where possible more details should be added (e.g. ethnography may be critical or feminist).

Method is the way that the data is collected and a list of methods, again not exhaustive, is provided below. It is important to be as specific as possible. For example, if inter-

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Select Detail Assessment Extraction Finding

Extraction Details : Sindenvall - Scandinavian Journal of Caring Science (1996)

Methodology	phenomenology
Method	interview
Interventions	Nurse aid to provide meal service
Setting	American Nursing Home
Geographical	Kansas Urban
Cultural	Anglo-Saxon
Participants	50 male residents
Data Analysis	Thematic analysis
Authors Conclusion	mealtimes provide a major opportunity for communication
Reviewers Comments	Authors conclusions are supported by the data reported

Complete

Figure 4 Extraction details screen.

view is selected, it is important to specify what type of interview: open-ended, semistructured, face-to-face or telephone.

- interview;
- media analysis;
- field notes;
- discourse analysis;
- observation;
- survey;
- questionnaire.

An intervention is a planned change made to the research situation by the researcher as part of the research project. For example, an intervention could be serving lunch at 10 am in a nursing home, or providing an education intervention. However, there will not necessarily be an intervention in qualitative research and this field may either refer to an activity or phenomenon, or be left incomplete.

Setting and Context refers to the specific location where the research is conducted. For example, the setting could

be a nursing home, a hospital or a dementia specific ward in a subacute hospital. Some research will have no setting at all (e.g. discourse analysis).

The Geographical Context refers to the specific location of the research. For example, Poland, Austria or rural New Zealand.

The Cultural Context refers to the cultural features of the study setting, such as time period (e.g. 16th century), ethnic groupings (e.g. indigenous Australians), age groupings (e.g. older people living in the community) or socio-economic groups (e.g. professional). These data should be as specific as possible and might also identify employment, lifestyle, level of functionality and gender factors, as well as participation rate. Information entered in this field should relate to the inclusion and exclusion criteria of the research. Ambiguous terms or group names should also be defined in this section (e.g. a carer is a personal care attendant).

Data analysis refers to the techniques utilised to analyse the data. A list of examples is provided below. This list is not

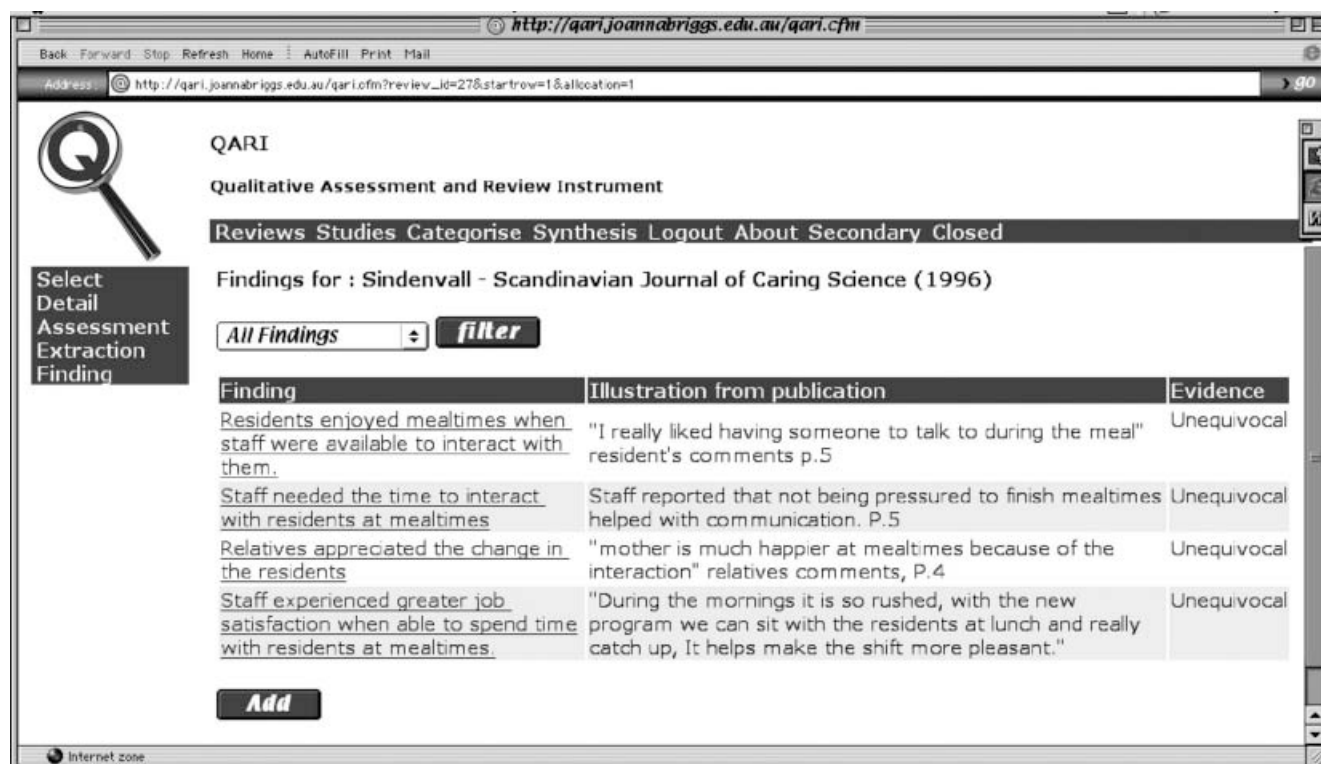


Figure 5 Add findings to a study.

exhaustive and should be supplemented with specific information where appropriate:

- named software programs;
- contextual analysis;
- comparative analysis;
- thematic analysis;
- discourse analysis;
- content analysis.

A Reviewer can add Findings to a Study, but only after an Extraction is completed on that Study (Fig. 5). If a Study's status changes to 'excluded', then the related Findings will also be excluded (but not deleted).

Once all of the information on a Review is collected in the form of Findings and Extractions, the Findings can be allocated to user-defined categories (Fig. 6). To develop categories <Categorise> is selected in the main menu. A screen will appear that lists all of the Findings that have been created for the review. A category should be established for those Findings that can be naturally grouped.

Once all of the Findings have been 'categorised', the categories can then be designated to user-defined Synthesised Findings (Fig. 7). To develop Synthesised Findings <Synthesis> is selected in the main menu. A screen will appear that lists all of the findings that have been created

for the review. This will be grouped by the categories allocated to the findings. A Synthesised Finding should be established for those categories that can be naturally grouped.

Discussion

This project set out to elicit whether or not it would be possible to integrate qualitative research findings into the systematic review process, and, if it was possible, to develop a system to do so. The outcome is a prototype system designed to enable systematic reviews to follow a rigorous process in appraising and synthesising qualitative data. This development augments a larger project currently in progress: a System for the Unified Management of the Assessment and Review of Information (SUMARI). SUMARI is designed to enable reviewers to incorporate a wider range of findings than those currently accommodated within an emerging review orthodoxy. The QARI forms one module of SUMARI.

The Comprehensive Systematic Review (CSR) is predicated on the view that the results of well-designed research studies – grounded in any methodological position – provide more rigorous evidence than anecdotes or personal

Figure 6 Finding details screen.

opinion, but that, in the absence of such results, opinion deriving from experience and expertise can still legitimately be regarded as the 'best available' evidence.

The CSR is an approach to evidence review that enables reviewers to consider evidence of Feasibility, Appropriateness, Meaningfulness and Effectiveness in the form of a focused review of one, two or more evidence types.

SUMARI

SUMARI has been developed to enable systematic reviewers to take an inclusive view of what counts as evidence. SUMARI is a developing software package designed to assist health and other researchers and practitioners to conduct systematic reviews of evidence of Feasibility, Appropriateness, Meaningfulness and Effectiveness and to conduct economic evaluations of activities and interventions. The package consists of five modules (Fig. 8).

Module 1: Comprehensive Review Management System (CReMS)

This module includes the review protocol, search results and a reporting function. It is designed to manage a systematic review and captures the results generated through the four analytical modules and formats them into a final report.

Module 2: Qualitative Assessment and Review Instrument (QARI)

This module is designed to facilitate critical appraisal, data extraction and synthesis of the findings of qualitative studies.

Module 3: Meta Analysis of Statistics Assessment and Review Instrument (MAStARI)

This module is designed to conduct the meta-analysis of the results of comparable cohort, time series and descriptive studies using a number of statistical approaches.

Module 4: Narrative, Opinion and Text Assessment and Review Instrument (NOTARI)

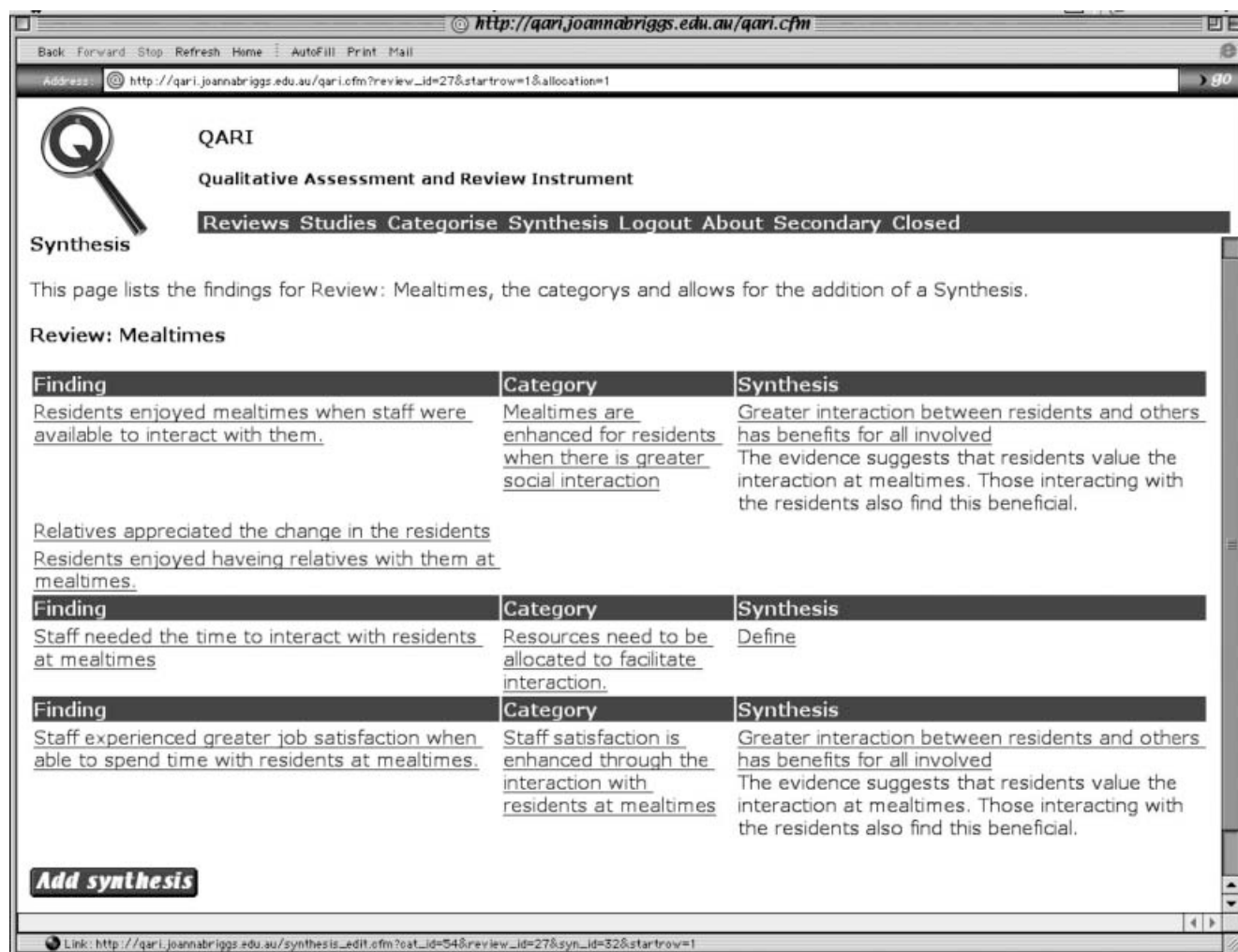
This module is designed to facilitate critical appraisal, data extraction and synthesis of expert opinion texts and reports.

Module 5: Analysis of Cost, Technology and Utilisation Assessment and Review Instrument (ACTUARI)

This module is designed to facilitate critical appraisal, data extraction and synthesis of economic data.

Using the package

The CReMS module is web based and, when downloaded on the user's server, can be accessed on the web by those



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Synthesis

This page lists the findings for Review: Mealtimes, the categories and allows for the addition of a Synthesis.

Review: Mealtimes

Finding	Category	Synthesis
Residents enjoyed mealtimes when staff were available to interact with them.	Mealtimes are enhanced for residents when there is greater social interaction	Greater interaction between residents and others has benefits for all involved The evidence suggests that residents value the interaction at mealtimes. Those interacting with the residents also find this beneficial.
Relatives appreciated the change in the residents Residents enjoyed having relatives with them at mealtimes.		
Staff needed the time to interact with residents at mealtimes	Resources need to be allocated to facilitate interaction.	Define
Staff experienced greater job satisfaction when able to spend time with residents at mealtimes.	Staff satisfaction is enhanced through the interaction with residents at mealtimes	Greater interaction between residents and others has benefits for all involved The evidence suggests that residents value the interaction at mealtimes. Those interacting with the residents also find this beneficial.

Add synthesis

Link: http://qari.joannabriggs.edu.au/synthesis_edit.cfm?cat_id=54&review_id=27&syn_id=32&startrow=1

Figure 7 Allocating synthesised findings to categories.

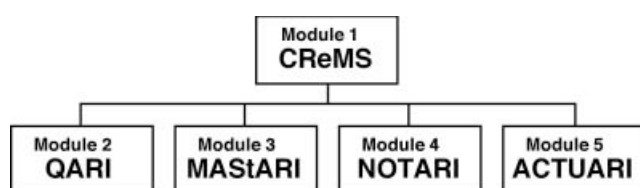


Figure 8 Modules in the System for the Unified Management of the Assessment and Review of Information (SUMARI).

authorised by the user. It can be used as a stand-alone program or in conjunction with other SUMARI modules.

Each of the other SUMARI modules are also web based and are designed to interface with CReMS and all other modules. Reviewers who wish to utilise the functions of a specific module can also use them as stand-alone programs.

The total package is designed so that each module interacts with the others and a reviewer can, at the point in the

review when critical appraisal, data extraction and data synthesis/meta-analysis is reached, select a pathway to manage RCT data, non-RCT quantitative data, qualitative data, textual data from opinion papers or reports or economic data. A single focus review (e.g. a review of effectiveness) would follow the RCT data pathway only and extract and analyse only results from RCTs. A review with more than one focus can select any number of pathways. For example, a review of effectiveness and feasibility may enter data from action research and evaluative studies into the QARI pathway and data from reports of learned bodies into the NOTARI pathway, as well as RCT results.

Conclusion

This paper reports on a system that presents a practical approach to developing, implementing and evaluating prac-

tice based on 'evidence' in its broadest sense. In addition to examining the concept of clinical effectiveness and the Cochrane Collaboration approach to the meta-analysis of quantitative research findings, other non-quantitative forms of evidence, and how they can be used as appropriate sources of evidence for practice, have also been considered. This has been done with a view to providing a practical process, using the QARI system, which will enable the comprehensive review of qualitative evidence for clinical practice. This project continues to evolve, with the primary aim of re-conceptualising the concept of evidence for practice, because health-care practices are often far more complex than they immediately appear.

The international interest in evidence-based practice, arising largely out of the work of the Cochrane Collaboration, is likely to accelerate given the global concerns about improving health care, increasing the effectiveness and appropriateness of health interventions, and containing the costs of delivering health services. Although the meta-analysis of the results of research into effectiveness is now highly refined, there is still much work to be done before this can be seen to be mirrored in regard to the results of qualitative research findings. A number of research groups are examining and developing ways to advance the incorporation of qualitative evidence into systematic reviews. The QARI software program is currently being used by groups in Canada, Scotland, England, Thailand and Australia and QARI licenses are now available. A number of completed reviews are currently being prepared for publication and it is anticipated that feedback from the readers of these reviews, the groups currently using QARI, and new QARI licenses will lead to further work and to the development of a more fully refined methodology and software program.

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Appendix I

Categorisation of methodological frameworks

Action/Description

- Ethnography
- Grounded Theory
- Action Research
- Case Studies
- Descriptive
- Programme Evaluation

Subjectivity (structures of consciousness)

- Phenomenology

- Ethnomethodology
- Hermeneutic
- Phenomenography

Analytical

- Conceptual/Analytical
- Historical
- Discourse analysis
- Biographical/textual/narrative
- Cultural/media analysis
- Deconstructive analysis

Appendix II

Group outcomes statement

- 1 In light of the emphasis placed on evidence-based approaches in contemporary health care, practitioners are increasingly required to recognise and assimilate the body of research literature relevant to their area of practice. Up to this point, the emphasis has been on determining effectiveness, with particular reference to quantitative research. This consideration should also extend to issues relating to Feasibility, Appropriateness, Meaningfulness and Effectiveness; this extension of inquiry requires that qualitative research should also be considered. Qualitative research yields distinct benefits that do not stem from quantitative research; this needs to be recognised in the context of a truly systematic and extensive review of the literature.
- 2 We have observed that there is currently a large amount of qualitative research available that is not being systematically utilised to inform practice. Until now, there has not been a process to incorporate this research into the development of clinical guidelines.
- 3 Consequently, a large amount of potentially important data has been ignored.
- 3 The challenges that were before the group referred to a range of issues specific to creating a concerted synthesis of qualitative research. Recent work by Evans and Pearson identifies the importance of incorporating both qualitative and quantitative research in systematic reviews, but suggests that there are potentially a range of issues that will arise from this development.²⁹ The nature of quantitative research makes a synthesis of data a relatively straightforward task. Data in the forms of means and standard deviations can be extracted from the research and entered into statistical tools, allowing for a meta analysis to be conducted, which in turn results in a clear indication of the effectiveness of the intervention. This reference back to primary data cannot be conducted for qualitative research as the nature of the data precludes this. Essentially, the aim of this process is to provide a system of evaluating the quality of qualitative research and to synthesise the body of research.

- 4 We envisage a tool – the Qualitative Assessment and Review Instrument (QARI). The model underlying QARI provides a systematic review process that mirrors that undertaken for quantitative research, while being sensitive to the nature of qualitative data. The model recognises the value of qualitative research, yet provides a mechanism to categorise the quality of original studies and the applicability of the findings to practice. A series of findings and concomitant narrative descriptions will be elicited from individual studies. The model views the majority of these research findings as fitting into four overarching categories: Political, Professional, Subjective and Clinical.
- 5 Political issues are those pertaining to the power relationships between people, people and ideas, people and organisations, and how these relate to society, including socio-economic concerns. (Belonging to, or taking, a side in politics; relating to a person's or an organisation's status or influence.) Professional matters include ethical, legal and regulatory concerns and issues relating to the organisations monitoring these aspects which are relevant to practice.
- 6 Subjective issues pertain to internal states, personal experience, opinions, values, thoughts, beliefs and interpretations. This category is distinct from factual reporting of past events.
- 7 Clinical concerns are related to care and treatment. This may refer to equipment, staffing or issues relating to clinical context.
- 8 It is recognised that a situation may arise where a given finding (narrative description) may fall into the domain of more than one category. In such cases it is recommended that the finding be addressed under each category deemed to be appropriate. These cases need to be verified by the second reviewer.
- 9 The questions addressed by qualitative research differ from those addressed by quantitative research; different perspectives are also provided. Currently there is no systematic approach to incorporate these into reviews of evidence-based practice. Qualitative research is important because it incorporates a service user's voice into the process of formulating evidence-based practice. At present, the only way this user's voice is heard is via interest groups.
- 10 There are currently no means to systematically review qualitative research. We believe best practice should reflect the whole range of evidence available, provided that this evidence is subjected to appropriate appraisal. We have reached consensus on a protocol for critically and systematically appraising a body of qualitative research that leads to summary statements and recommendations. Computer software will be developed to support this process.

Appendix III

Qualitative findings critical appraisal scale

Criteria	Yes	No	Unclear
1. There is congruity between the stated philosophical perspective and the research methodology.			
2. There is congruity between the research methodology and the research question or objectives.			
3. There is congruity between the research methodology and the methods used to collect data.			
4. There is congruity between the research methodology and the representation and analysis of data.			
5. There is congruity between the research methodology and the interpretation of results.			
6. There is a statement locating the researcher culturally or theoretically.			
7. The influence of the researcher on the research, and vice-versa, is addressed.			
8. Participants and their voices are adequately represented.			
9. The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body.			
10. Conclusions drawn in the research report appear to flow from the analysis or interpretation of the data.			
Total			

Reviewer's comments:

Appendix IV

Qualitative data extraction tool

Author: _____ Record number: _____

Journal: _____ Year: _____

Reviewer: _____

Method

Methodology

Data analysis

Setting & Context

Geographical context

Cultural context

Participants:

Number:

Description:

Interventions

Findings	Narrative description	Qualitative evidence rating (1,2,3)

Authors' conclusions

Comments