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Including qualitative evidence in clinical guidelines

Qualitative evidence syntheses offer insights into patients' experiences, views, beliefs, and priorities. Christopher Carroll calls for bodies such as NICE to include this type of evidence when developing clinical guidelines.

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As Sackett and colleagues wrote almost 20 years ago, evidence-based practice involves the use of the "best external evidence" to inform clinical decision-making.[1] The published evidence used to underpin clinical guidelines, including those produced by NICE in the UK, is almost exclusively quantitative. This is understandable as the principal focus is efficacy and safety: the aim is to establish what works. However, Sackett and colleagues were also clear that clinical practice should take account of patients' preferences.

Indeed, it is accepted that clinical guidelines need to access and use evidence of patients' views and experiences. This is currently achieved not only by patient involvement in the process[2] but also by using primary qualitative research, which employs techniques such as interviews to explore how and why patients make the decisions they do.[3;4] A synthesis of such qualitative research studies can paint a rich, subtle and extremely useful picture of patients' experience, views, beliefs and priorities. This article makes a case for integrating this type of evidence into the development of clinical guidelines. It does so by highlighting how its use has led to more detailed, practical recommendations in the example of the long-term management of stroke, and by explaining how it could potentially enhance the clinical guidelines on type 2 diabetes and cardiac rehabilitation.

What is qualitative evidence synthesis?

Currently, clinical guidelines, where possible, base their recommendations not on single studies but on the statistical synthesis of multiple studies (the pooling of quantitative studies in meta-analysis). The urge to combine such studies and their findings, to synthesize, is driven by the promise of achieving greater power, more precise results and the possibility of generalizing from statistically representative samples.[5] The basic rationale behind the synthesis of qualitative evidence is similar: to make the most of single studies for the purposes of policy and practice.[4] The synthesis of a number of relevant studies of qualitative evidence can offer multiple perspectives, as well as providing evidence of contradictory viewpoints, all of which might otherwise be missed when considering a single study alone.[4] Qualitative evidence synthesis also enables researchers to "go beyond" the findings of such primary research studies, by producing something that is more than their simple

sum.[6] The criticism often levelled at qualitative research, with its small samples, is its lack of generalizability. However, this is to view such studies as if they had the same purpose and were measuring the same outcomes as their quantitative equivalents. They do not. Rather they are filling some of the gaps left by the quantitative evidence. The type of generalizability they offer is different. For example, qualitative study samples can be "informationally" rather than statistically representative, in the sense that they can offer information that is applicable to many other people with a similar condition or receiving similar treatments.[4] Qualitative evidence and its synthesis therefore does not often seek to offer an alternative to quantitative evidence in terms of measuring efficacy and safety, but principally offers something that the quantitative evidence often does not, such as identifying and explaining patient behaviours. It is arguable whether evidence-based practice can really exist without taking into account such evidence.

The synthesis of this evidence can be undertaken using a range of approaches, and standards already exist for the conduct and reporting of qualitative evidence synthesis.[7] Approaches to synthesis can be aggregative (such as narrative or framework synthesis or meta-aggregation, which summarize studies' findings), interpretive (such as meta-ethnography or critical interpretive synthesis, which seek to generate completely original conceptualizations and theories based on the evidence), or a combination of the two (such as thematic synthesis).[6;8] Methods such as framework, narrative and thematic synthesis are seen as being particularly useful for answering questions about the uptake of interventions and for integrating quantitative and qualitative findings.[6;8;9] These methods are therefore potentially the most appropriate for use in developing clinical guidelines. In the UK, NICE public health guidance already often uses a form of thematic synthesis, and integrates quantitative and qualitative evidence using a narrative approach.[10]

Given that the value of qualitative evidence and its synthesis has been recognized in the field of public health guidance, and arguably should be a key part of any evidence-based practice, it makes sense to consider how this evidence might contribute to clinical guidelines also.

What can qualitative evidence syntheses add to clinical guidelines?

Qualitative evidence synthesis has several potential benefits for clinical guidelines[4], but this brief paper will focus on the topic of patient preferences, in particular the issue of shared decision-making, that is, the principle of "Nothing about me without me".[11] This principle requires that clinical decisions be consistent with the elicited preferences and values of the patient. It is an end in itself.[11] It is known that the failure to take into account a patient's needs and views can contribute to lower levels of adherence to treatments and poorer clinical outcomes[12], while well-conducted shared decision-making is known to have positive benefits in terms of patient satisfaction and a willingness to follow treatment plans.[13] These are key outcomes of interest for any policy maker who wants to see research having its intended effect in practice. A current NICE Quality Standard and clinical guideline details how patients and, where applicable, family and other representatives, should be actively involved in negotiating treatment decisions.[14;15] However, this guidance is obviously quite generic. By contrast, a qualitative evidence synthesis of multiple relevant studies can provide specific information about what needs to be done, and the many issues that need to be taken into account, when conducting shared decision-making with particular groups of patients. This type of synthesis can therefore potentially offer a valuable supplement to the experiences of patient representatives on guideline panels.

This paper will consider the topic of shared decision-making in three NICE clinical guidelines: stroke, type 2 diabetes and cardiac rehabilitation. The aim is to demonstrate the potential value of integrating the findings of qualitative evidence into their recommendations. These clinical guidelines have been chosen because they have all been recently updated and there are also relevant, published qualitative evidence syntheses. They therefore offer an appropriate "test case".

The long-term management of stroke

The issue of goal-setting for stroke rehabilitation provides an example of how the synthesis of qualitative evidence has already enhanced recommendations. The influence is quite transparent when cross-referencing the full guideline detailing the

methods and evidence used[16] with the final NICE clinical guideline (CG162).[17] The full guideline identified a relevant synthesis of qualitative and quantitative evidence[18], but essentially performed its own thematic synthesis of 17 qualitative studies, by which relevant themes were identified and the supporting evidence listed. This published evidence suggested that patients and family members felt the issue of goal-setting was not only viewed as relatively unimportant, but was seen as being wholly the remit of the health professional: decision-making on this aspect of care was not being shared. Together with the relevant quantitative evidence, these findings informed a series of evidence statements (6.2.3), which in turn informed the recommendations (6.2.5). These recommendations then appeared in the final guideline (CG162), which required that goal-setting be conducted at specific meetings and be meaningful, relevant, challenging but achievable, time sensitive (reviewed regularly), and involve ample input from the patient and their family and/or carers (**Figure 1**). In other words, the qualitative evidence synthesis stressed the importance of shared-decision making, and the specifics of how it should be conducted, and these were integrated in detail into the recommendations.

<Insert Figure 1>

Figure 1 also shows how the quantitative and qualitative evidence were integrated using a thematic approach: how the evidence statement was developed and the recommendation formed. The influence of the qualitative evidence and its synthesis is quite clear: the quantitative evidence only noted that standard procedures were not conducive to shared decision-making; the qualitative evidence indicated exactly what needed to be done. This offers a rare but informative example of how this evidence has enhanced a NICE clinical guideline.

Type 2 diabetes

In section 1.3 on diet, the recently published NICE clinical guideline on type 2 diabetes (NG28) constantly recommends that health professionals, “provide … advice”, “emphasise advice …”, “discourage” or “encourage” certain actions.[19] Strategies emanate from the relevant health professional alone. Yet a recent

qualitative evidence synthesis of 37 studies stressed the importance of shared decision-making because patients with type 2 diabetes and their families felt that communication with health professionals was often difficult and their opinions were not acknowledged.[20] The evidence synthesis indicated that a shift from "advice" to negotiation was needed: effort should be made to elicit the concerns, needs and preferences of patients and their families. A new, possible, revised recommendation is given in **Figure 2**.

<Insert Figure 2>

Long-term cardiac rehabilitation

As with type 2 diabetes, evidence on patients' views and experiences is arguably lacking from the NICE clinical guideline on cardiac rehabilitation (CG172).[21] Two of the key findings from a qualitative evidence synthesis of 90 studies looking at patients' views of cardiac rehabilitation are, first, patients' sense of lacking any control over their condition and, second, their being unconvinced that the interventions on offer would actually produce positive outcomes.[22] A number of included qualitative studies reported that some cardiac rehabilitation patients focus only on the avoidance of stress as their perceived means of reducing the chance of another heart attack (for example) rather than modifying diet, physical activity or smoking - three key points of the guidance (CG 172). Given that attendance on rehabilitation programmes is a known problem[22], a decision-making process that explicitly addresses patients' potential mind-sets might lead to greater patient satisfaction with agreed treatment plans, and improved clinical outcomes (**Figure 3**). This offers another example of how general recommendations about shared decision-making can be clarified and made more specific by using the findings of a qualitative evidence synthesis, and how they can provide more explicit guidance on the best approach for reaching decisions with patients.

<Insert Figure 3>

Putting evidence in to practice

Clinical guidelines and quality standards might stress the need for decision-making to be shared, but it is the synthesis of qualitative evidence that details what this negotiation should involve for any particular condition and its treatment.[14] By accessing and using evidence on patients' anxieties, beliefs and preferences, which can be highly condition-specific, clinical guideline recommendations can in turn be specified and enhanced. Treatment plans might have a greater chance of being followed if they are the result of a negotiation that specifically seeks to cover and address topics of known importance to particular sets of patients.[13]

However, the use of this evidence is not without its issues.[4] There are many hundreds of published qualitative evidence syntheses that can be used for clinical guidelines, but they might not be available for every indication. Fortunately, there are pragmatic and relatively rapid methods of qualitative evidence synthesis that could be used by guideline developers to fill that gap,[9] generic qualitative evidence synthesis reporting guidelines exist[7], others are being developed for particular methods[23], and standards are evolving to establish the level of confidence users can ascribe to the findings of such syntheses.[24] Also, despite the availability of methods for integrating quantitative and qualitative evidence[6;8], there is no ready-made toolkit for doing so. The NICE stroke guideline and public health programme[10] both offer relevant templates, but future work should seek to identify the most appropriate approach for clinical guidelines. The qualitative evidence might also come from settings that are not directly applicable to the NHS, so this needs to be taken into account too, though the same issue can apply to quantitative evidence. Nevertheless, as the examples described above suggest, such evidence, carefully considered and integrated with the quantitative evidence, can offer a highly useful addition to the expert and patient opinion currently used in the guideline development process.

Simply recommending the general principle of shared decision-making does not mean issues of importance to patients will be addressed. Such issues can be highly specific to a condition or set of patients. Qualitative evidence synthesis can help clinical guideline developers identify these issues and include them explicitly in their recommendations. It could be argued that practice cannot be truly evidence-based

without it. By making use of this evidence, clinical guidelines can be more informed, richer and context-specific. The potential benefits for patient satisfaction and clinical outcomes are obvious.

Figure 1: Long-term management of stroke: clinical guideline recommendations[16,17] **and findings from a relevant qualitative evidence synthesis**[18]

6.2.1: Table 27:
Summary of findings from the qualitative themes and quantitative evidence [16]

Quantitative and qualitative findings [18]	**Matching quantitative and qualitative evidence**
Inhibitory factors such as limited time, presiding professional routines and the single opportunity to meet clinicians post discharge for secondary risk management [150 252 200] (LOW to MODERATE CONFIDENCE IN STUDIES) Standard goal setting meeting which is held away from the patient and with standard documentation is not conducive to patient-centred goal setting [175] (MODERATE CONFIDENCE IN STUDY)	Quantitative evidence: Monaghan 2005 [175] Qualitative evidence: Leach 2010 [150]; Suddick 2006 [252]; Parry 2004 [200]; Cott 2004 [49]; Lawler 1999 [149]; Hale 2010 [100]

6.2.3: Challenges to patient participation in goal setting [16]

Five studies highlighted factors inhibiting patients from participating in goal settings. These factors include: limited time, presiding professional routines, goal setting meeting which is held away from the patient, single opportunity to meet clinicians post discharge for secondary risk management, stroke pathology with its highly unpredictable recovery prognosis and its effects such as aphasia and (LOW to MODERATE CONFIDENCE IN STUDIES)

NICE Clinical Guideline [17]

1.2.8 Ensure that people with stroke have goals for their rehabilitation that:
- are meaningful and relevant to them;
- focus on activity and participation; are challenging but achievable;
- include both short-term and long-term elements.

1.2.9 Ensure that goal-setting meetings during stroke rehabilitation:
- are timetabled into the working week;
- involve the person with stroke and, where appropriate, their family or carer in the discussion.

1.2.10 Ensure that during goal-setting meetings, people with stroke are provided with:
- an explanation of the goal-setting process;
- the information they need in a format that is accessible to them;
- the support they need to make decisions and take an active part in setting goals.

Figure 2: Type 2 diabetes clinical guideline: recommendations[19] **and findings from a relevant qualitative evidence synthesis** [20]

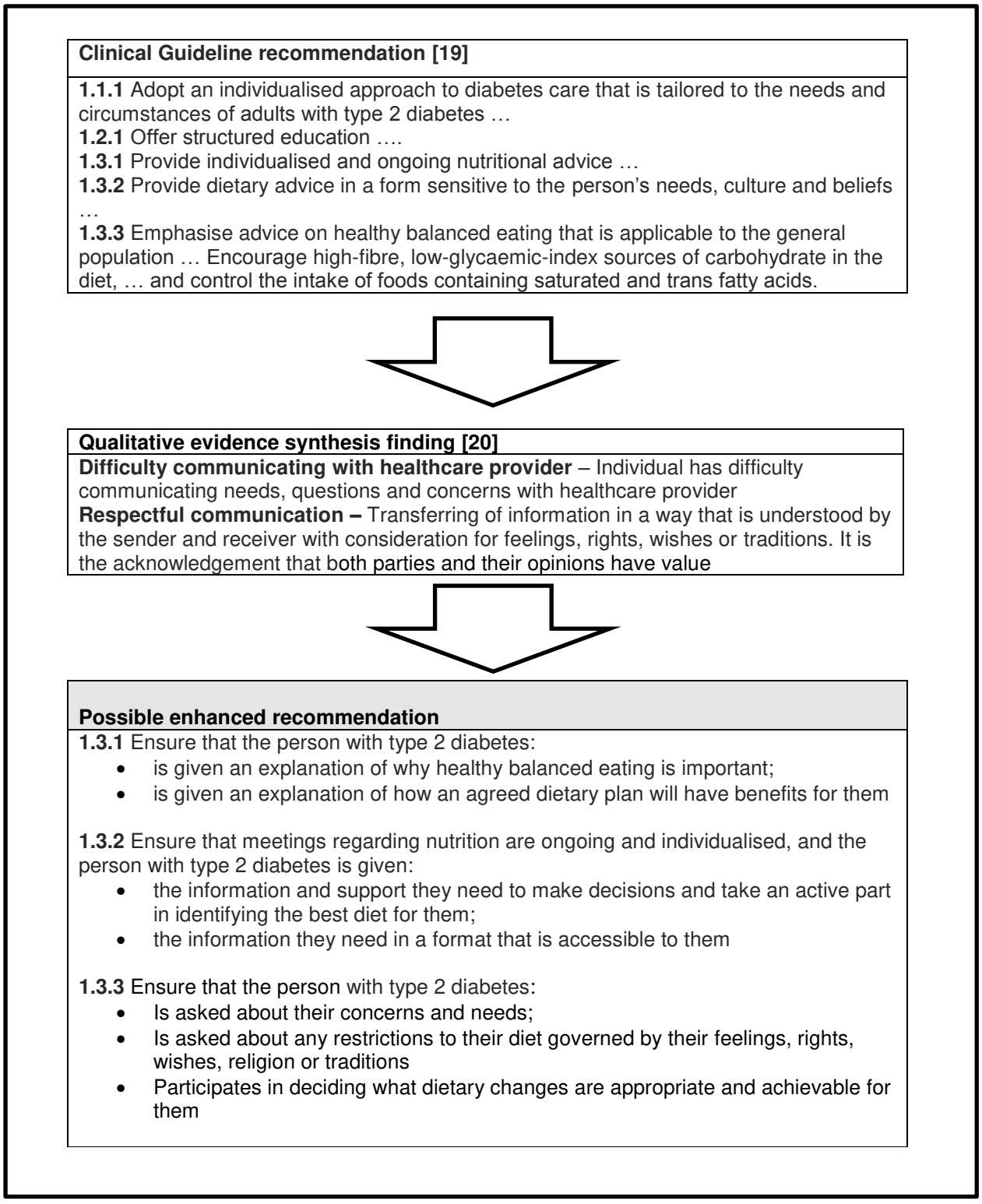
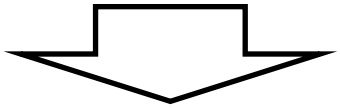


Figure 3: Cardiac rehabilitation clinical guideline: recommendations[21] **and findings from a relevant qualitative evidence synthesis**[22]

Clinical Guideline recommendation [21]

Encouraging people to attend

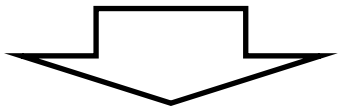
1.1.6 Establish people's health beliefs and their specific illness perceptions before offering appropriate lifestyle advice and to encourage attendance to a cardiac rehabilitation programme. **[new 2013]**



Qualitative evidence synthesis finding [22]

Theme: Beliefs about heart disease

In a number of studies, patients perceived heart disease as defying any attempts to reduce risk. Thus, attempts at risk reduction were perceived by patients to be futile. For example, risk of acute myocardial infarction was perceived to be unpredictable, inevitable, and uncontrollable, irrespective of whether the underlying heart condition was seen to be of low or high severity. Likewise, participants expressed a low sense of control over their future health.



Possible enhanced recommendation

1.1.6 Involve patients in decision-making by establishing their health beliefs and specific illness perceptions:

- Ask patients why they think they had a heart attack;
- Ask patients whether they think their condition can be controlled;
- Explain the relationship between lifestyle and heart disease;
- Explain how appropriate lifestyle behaviours and attendance at a cardiac rehabilitation programme can give the patient greater control over their condition;
- Agree appropriate and achievable lifestyle changes and rehabilitation programme attendance that is meaningful to the patient

KEY MESSAGES

NICE clinical guidelines make some use of qualitative research to inform recommendations, but there are no requirements to do so or any accepted standards for shaping its inclusion

Qualitative evidence synthesis, like the meta-analysis of quantitative evidence, represents a potentially valuable source of information to help develop enhanced recommendations for NICE clinical guidelines

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