Expanding the evidence within evidence-based healthcare: thinking about the context, acceptability and feasibility of interventions

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Abstract

The evidence-based model is crucial to contemporary healthcare. It is dependent on systematic review methodology modelled on an arguably out-dated hierarchy of evidence. There has been a significant increase in medical and health research using qualitative and mixed method designs. The perspective taken in this article is that we need to broaden our evidence base if we are to fully take account of issues of context, acceptability and feasibility in the development and implementation of healthcare interventions. One way of doing this is to use a range of methods which better fit the different aspects of intervention development and implementation. Methods for the systematic review of evidence other than randomized controlled trials are available and there is a readiness to incorporate these other types of evidence into good-practice guidance, but we need a clear methodology and to translate these advances in research into the world of policy.

Delivering evidence-based healthcare is a complex interpersonal process

Evidence-based healthcare (EBHC) depends on collating research evidence, communicating findings, and translating findings into best practice guidance which can be implemented in real-world practice. Cochrane's definition of EBHC highlights the centrality of the clinician-evidence relationship to bridge the gap between research and practice (see: http://www.cochrane.org/about-us/evidence-based-health-care#REF1). How clinicians feel about evidence can impact on the degree of fidelity with which healthcare interventions are implemented.[1] As such there are critical differences between evidence of *efficacy* and *effectiveness*. All evidence based interventions, whether biomedical, social or structural, involve interpersonal processes and are *"delivered in the context of an encounter between a health professional and a patient, making healthcare professional clinical behaviours an important proximal determinant of the quality of care that patients receive"*.[2]

Thus, interpersonal relationships and communication are fundamental to implementation science. This jars with most understandings of the role of evidence within guideline formation which disproportionately privileges large-scale population based studies. Such studies are

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vital tests of efficacy and cost-effectiveness, yet poor at understanding implementation. The current evidence hierarchy used to help shape guidance production (e.g. by NICE and SIGN[1]) struggles to incorporate qualitative and mixed methods research, and thus lacks systematic analyses of the context and experience of implementing interventions. Clinicians and commissioners[2] need to understand the interactions, relationships and sociocultural contexts which shape the acceptability and meaningfulness of healthcare interventions. To complete the cycle of translating findings into 'practice-ready' guidance it is necessary to consider the human systems within which an intervention is to be implemented. This is an iterative process, as described in the Medical Research Council's (MRC) framework for developing complex behavioural interventions (see: http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871).

A *complete* evidence-base must inform healthcare guidance. This should: develop from a pluralistic model of research; address translational and implementation questions; draw upon different methods for different questions; provide diverse evidence on which to base best practice guidance.

What's missing from conventional accounts of how 'best evidence' informs practice?

We know that within the hierarchy of evidence systematic reviews of randomized controlled trials (RCTs) sit at the top as the 'gold standard' and are key to informing guidance.[3] This is unsurprising because they report on efficacy and/or cost-effectiveness of interventions in terms which provide clear messages for policy makers. However, as Sackett's discussion of evidence-based medicine made clear, when faced with an individual patient, an RCT may not provide coherent advice.[4] Instead, Sackett emphasised the need for both clinical expertise *and* current best evidence because without both, practice will suffer to the detriment of patients. Balancing insights from cumulative knowledge and taking a negotiated and tailored approach to each patient represents the best approach.

Whilst the traditional hierarchy of evidence is vital in understanding cumulative knowledge and healthcare delivery, it is not without its shortcomings. The vital focus on objective, measurable and controllable ways of looking at healthcare at a population level mean that social context and individual experience are stripped away; the patient *and* the clinician are both reduced to cyphers. To be useful, best-practice guidance must be adaptable to real-world practice scenarios, i.e. take account of the cultural and psychosocial context. This is the job of translational research which emphasizes working within real-world environments, partnerships, stakeholder consultations, and often involves qualitative and/or mixed methods designs.[5,6]

Incorporating experience and context into healthcare evidence

There has been a substantial rise in the use qualitative and mixed methods research in medical and healthcare settings in the last 20 years which has provided great insight into the

[1] These denote the National Institute for Health and Care Excellence and the Scottish Intercollegiate Guideline Network.

[2] UK healthcare is devolved to member states. In England healthcare services are commissioned by the NHS Commissioning Board whose role it is to allocate funds to deliver the best possible care to patients. This is supported by regional Clinical Commissioning Groups made up of local practitioners whose responsibility it is to ensure that local services meet local needs (see: http://webarchive.nationalarchives.gov.uk/20130805112926/http://healthandcare.dh.gov.uk/system/).

value and accessibility of healthcare services.[7,8] Furthermore, it has shown us how patients make sense of their own health, whether health information provided is clear and appropriate, and whether healthcare professionals feel competent when explaining complex risks associated with diagnosis or treatment regimes.[9,10]

Some ground has been gained in recent moves by funding bodies, particularly the UK government funding programme - National Institute for Health Research (NIHR) - to foreground patient perspectives in designing and conducting research through patient, carer and public involvement (PCPI; e.g.:http://www.crncc.nihr.ac.uk/about_us/stroke_research_network/in_your_area/south_west/Patients_carers). A review of patient involvement has demonstrated that it can be cost-effective and has been adopted in a range of research designs including RCTs, naturalistic studies, participatory and political action research.[11,12] As such, PCPI has sanctioned the utility of patient and carer perspectives. Nevertheless, it remains an initiative to involve patients in the research *process*, rather than expanding the types of methods used in designing services. Patient perspectives remain absent from the process by which evidence becomes guidance. Although patients increasingly help set research agendas, unless their perspectives are turned into high quality peer reviewed papers they will not shape guidance production.

The added value of qualitative and mixed methods research

To incorporate experience and context into the evidence-base, alongside efficacy and cost-effectiveness, and thus to provide useful best-practice guidance that can deal with multiple formulations at the population, systemic and individual levels, we require a wider range of research questions and methods, and a more balanced view of their value. Mixed methods designs and qualitative research offer systematic ways of exploring the socio-cultural context within which healthcare services must be designed and delivered; they provide means of gathering and analysing patients' perspectives, features of interactions between patients and practitioners, language used in health information, and tools to understand patient expectations and satisfaction; and they can help us understand key relationships at the level of family, community, health and social care organisations, and government. NICE's conceptual framework puts the patients' *lifeworld* at the centre.[13] This refers to all of the socio-economic, cultural, and historical aspects of our lives; it includes our relationships, geography, and our ability to take control, or have agency, in our interactions with healthcare providers and policy makers. The centrality of the lifeworld requires that we are open to a broad range of research questions and designs and that we use the best-fit methods for the questions we are asking. This may involve multiple qualitative methods, qualitative and quantitative methods, or more than one quantitative method.[14] The outcomes of such research can help us to understand not only the role of experience and context in the implementation of interventions; they can also help us to develop future interventions, and future evaluations of the effectiveness of those interventions. They are therefore likely to be important to the users of research.[15] Critically then, the centrality of the lifeworld means that we must be open to including the outcomes of such research in syntheses of evidence, and in the development of guidance to inform best practice.

Systematic reviews of diverse evidence

The value of qualitative research is clear but there remains a gap between high quality primary qualitative research and its systematic review for inclusion in good-practice

guidance.[16] That is not to say that methods for systematically reviewing qualitative evidence do not exist.[17-] Furthermore, UK bodies NICE and SIGN have declared their commitment to qualitative evidence as essential, alongside more 'traditional' (i.e. quantitative) sources of evidence, in understanding healthcare and subsequently in producing guidelines for best clinical practice. For this work to be translated into the policy and practice world, we need a clear methodology. The work of the Cochrane Collaboration Qualitative Methods and Implementation Group in the UK (see: http://cqim.cochrane.org/) and the Patient-Centered Outcomes Research Institute in the US (see: http://www.pcori.org/) have begun this work. Significant advancements in appraisal tools for diverse evidence exist[18] but focused efforts are required to establish rigorous methods for *synthesis* of quantitative and qualitative data. Integrative and aggregative synthesis methods have been proposed.[17] The EPPI[3] approach involves the parallel synthesis of, for example, intervention studies (quantitative methods) and perspectives studies (qualitative methods). This is not an integrative approach because findings from studies with different designs are dealt with separately before being brought together in a 'mosaic' to answer the research question.[19] A recent proposal for 'best-fit' framework synthesis generates an a priori framework from literature describing conceptual models or theories. Next, deductive (using the framework) and inductive coding (data-driven) using principles of thematic analysis are used to perform the synthesis.[20] While currently proposed for the synthesis of qualitative evidence alone, there is potential to adapt this integrative method of synthesis for use with diverse evidence.

Once a rigorous methodology for systematic review *and synthesis* of diverse evidence is recognised, the next challenge is determining how such evidence will manifest in best-practice guidance. As indicated above, qualitative and mixed methods evidence will advise practitioners in their everyday encounters with patients in individual or group settings. Additionally, it will inform the development of strategies for desining interventions that are feasible in different contexts and that generate patient acceptance across a range of socio-economic and geographical groupings. In short, incorporating diverse evidence into EBHC will produce guidance encompassing best-practice at the population, systemic and individual levels.

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Contributors

Dr Shaw is a Health Psychologist and guarantor. Her expertise is qualitative methodology and evidence synthesis. Dr Larkin is a psychologist with expertise in mental health research and collaborative research methods, including experience-based design. Prof Flowers is an applied mixed-methods psychologist with extensive experience in the development of policy and practice. This article represents the authors' current thinking with regard to the development of systematic review methodology for diverse evidence. All are proponents of qualitative methods. Dr Shaw is Chair of the British Psychological Society's Qualitative Methods in Psychology Section (QMiP), but only when appropriate for the research question asked. The authors have been working together for several years to develop and encourage the use of mixed methods in psychology and healthcare studies. The message is not one of *either/or* but *both/and*. The evidence-base (i.e. systematic reviews and good practice guidelines) must fully represent the best available research, and thus must incorporate non-experimental, qualitative and mixed methods research.

Conflict of interest

The authors have no known conflict of interest.

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