Contextualising the Use of Qualitative and Quantitative Research Methodologies in Chinese Medicine: Epistemological & Ethical Issues

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ABSTRACT

Research into the effects of medical interventions is one of the oldest traditions of any medicine, as is the study of its ethical dimension. In this paper, we briefly describe and recount the history of both quantitative and qualitative methods in clinical research. We discuss key theoretical, methodological and practical features of both methodological perspectives and consider some of the central ideas of medical ethics. We sketch a theory of the relationship between the quantitative and qualitative as essentially complementary and interdependent. The theory is illustrated by reference to the placebo effect and a research 'case study' from within the Chinese medicine community. We conclude that despite the challenges, combined research methodologies in Chinese medicine offer both scientific and ethical benefits.

KEYWORDS qualitative research, quantitative research, ethics, Chinese medicine research, philosophy of medicine, philosophy of science.

Evidence in medicine: background

Concepts of knowledge and evidence evolve over time and sometimes generate vigorous controversy. Quantitative research encompasses a wide range of methods and techniques. In the Western medicine and Chinese medicine (CM) setting, key features include: the quantification of phenomena arising in experimental settings, in which several variables are measured while specified conditions are controlled; and the use of often complex statistical methods in order to derive meaning from the measured results.[1] The use of such an approach to assess the efficacy and effectiveness of particular techniques and treatments is now referred to as 'evidence based medicine' (EBM). The linking of clinical decision making with systematically compiled data is a rapidly evolving component of medicine that is widely regarded as central to the current practice of Western medicine. Its rise to recent importance is due to developments in the field of epidemiology since the 1950s and the formation of the EBM working group in 1992, which argued that the information of most value for clinical medicine is that derived from large scale, appropriately controlled population studies.[2]

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Along with the success of EBM, awareness developed of the importance of the patient experience in both clinical practice and research and this led to an increasing utilisation of qualitative research methods. The latter had first been developed alongside quantitative population studies in the middle of last century, as researchers began attempting to investigate, and philosophers grappled to understand, the phenomenology of illness and caring. Philosophical insights into the nature of perception and judgment were applied in the development of both quantitative and qualitative approaches, especially those elements of the philosophy of Immanuel Kant that dealt with the nature of knowledge and our ways of thinking about things, not just our observation or experience, and how they contributed to the generation of understanding of the world.[3] The recognition of interpretation as inherent in the concepts of knowledge and evidence is consistent with classical epistemologies and emphasises the unexceptional nature of qualitative knowledge within the Western framework of reason.

Qualitative research, which seeks to fill the epistemological gaps within quantitative research, encompasses a wide range of philosophical perspectives, methodologies and techniques. Despite this heterogeneity, there are several common key features that may help elucidate the nature of the field. These include: an emphasis on a continuity between theoretical frameworks and research methods; recognition of the importance of participants' frames of reference and of close contact between participants and researchers in the data collection phase, with the ability to explore emerging questions and issues that arise; and rich and copious data that are analysed using techniques that facilitate the description of emerging concepts and patterns.

A number of theoretical standpoints, with their own methodologies, can be employed under the rubric of qualitative research, including, among others, ethnography, phenomenology, grounded theory, narrative study, feminism, and postmodernism.[4] These different approaches may be distinguished by their use and interpretation of one or more of the following data collection techniques: observation, one to one interviews, group discussions, and examination of written, visual, audio, historical and documentary data. A unifying feature is that all qualitative research provides 'an in-depth and interpreted understanding of the social world of research participants by learning about their social and material circumstances, their experiences, perspectives and histories'.[5]

Challenges in the use of pure methodologies

The relationship between the quantitative and qualitative research domains is complex. On the one hand, the quantitative is embedded within some qualitative research methods, such as the identification of themes in thematic analysis, while conversely, the qualitative is observable in the quantitative, such as in the development of descriptive statistics.[5] The two approaches stand in an interdependent, overlapping and dialectical relationship, with the quantitative giving rise to hypotheses which are in turn extended and made meaningful by the qualitative interpretations generated from the results. Similarly, in the deployment of statistical methodologies the significance obtained from numbers, initially a quantitative result, gives rise to a qualitative process of interpretation, and consideration of relevant social implications. This qualitative methodology may then generate further quantitative hypotheses to be tested, and so on. This process of making sense between the quantitative and qualitative domains, and vice versa, is itself subject to a variety of interpretations and provides a rich field of exploration.

An appreciation of the depth and complexity of experience is one of the most important features of qualitative research. The idea that individuals come from environments that both form and are formed by them[6] has been largely absent from the ideology of quantitative research in medicine since its identification with science[7] and the promotion of the medical gaze in the last century.[8] The objectivist perspective favoured by medicine places emphasis on the role of a particular kind of observer who is separate from the conceptual conditions of knowledge. The challenge with this approach, however, is that there is still a subject and object, which thereby occupy an uncertain status in the prevailing paradigm. The denial of the role and influence of the researcher, the research environment, financial and competing interests, and the role of practitioners in fixing both the questions raised within the clinical encounter and answers that are considered to be valid, have led to researcher effects and bias that continue to play significant roles in the outcomes of research, let alone in the formation of the research questions themselves. Some of these controversies are exemplified in contemporary discussions about the nature and role of the so-called 'placebo effect'. It may be said that the attempt to extract not only the practitioners, but also the patients themselves, from the practice of medicine, is the source of the opacity of the nature of the placebo from the viewpoint of the quantitative field.

This question of the placebo effect — what it is, how we account for it — is at present the subject of vigorous investigation[9–11], although no authoritative consensus on its underlying mechanisms is yet available.[12–13] The ethical appropriateness of including a group that is administered a placebo in clinical research has long been questioned and remains a topic of intense debate.[14–15] What can be said, however, is that the 'effect' refers to a range of behaviours, attitudes and physiological and psychological responses that cannot be described in mechanistic terms but can nonetheless be broadly encompassed as a general

numerical effect on measurable variables. The placebo effect does not exist in the qualitative realm of enquiry but is ever-present in quantitative research as an inextinguishable trace of the qualitative world.

Recognition of the problems raised by the exclusion of individual patients from active roles in medical research has given rise to a number of compensatory innovative responses, such as the use of increasingly complex trial designs, increased attention to exclusion characteristics, adjustments to outcome measures, ever-increasing conditions required by ethics committee, and the elaboration of refined methodologies such as comparative effectiveness research. In acupuncture research, the use of protocols such as CONSORT and STRICTA, are being encouraged.[16] Pragmatic trial design is an example of another response to the challenge of accounting for individual patient and practitioner effects.[17] That the importance of the placebo has been built into the conventions of quantitative medical research suggests an increasing anxiety associated with the exclusion of qualitative knowledge. This anxiety, qualitative in very nature, is generated by, and at the limits of, the quantitative paradigm.

In clinical medicine itself, approaches are emerging that also renew the emphasis on the human experience of illness and caring. These include personalised medicine, individualised care, integrative medicine, and patient centred care, all of which have encouraged the conduct of qualitative studies examining the patient viewpoint and understanding.[18–20] Qualitative studies have also investigated practitioner and student attitudes,[21–3] including awareness of and attitudes towards ethical issues.

Ethics in medical research

Ethical issues are at the centre of both clinical and research practice. Both fields of activity require complex negotiations involving values, preferences, opinions and beliefs, in different and sometimes changing social and cultural environments. Supposed 'principles' of medical ethics — such as the right to autonomy or self-rule and the duty to act in the best interests of patients or research participants — may have different weights and significance depending on the context. For example, a patient's 'right to choose' may be overridden in a variety of circumstances, such as those involving decisions about access to, and the judicious distribution of, resources, or they may be compromised or attenuated by lack of time, competing interests or other influences. Voluntary and mandatory codes of practice can enhance awareness of the importance of ethical considerations and guide the behaviour of both clinicians and researchers. In the field of research the Australian National Statement on Ethical Conduct in Human Research[24] provides a broad framework for ethical discourse which places emphasis on the values of research merit and integrity, justice, beneficence, and respect. For example, the statement specifies that for research to be ethically acceptable the potential benefits should outweigh the likely harmful outcomes and that, except in clearly defined circumstances, the consent of the participants must be freely obtained. Adherence to such ethical values and principles is not a secondary or supplementary aspect of medical research but is now recognised to stand at its very core.

The two clusters of methodologies share common ethical issues, such as respect for participants and recognition of the importance of consent and privacy. However, they also raise their own distinctive questions. In the quantitative realm, for example, ethical questions generally refer to specific instrumental or operational aspects of a study, especially questions about techniques and protocols. In the qualitative field, ethical issues arise from the deconstructed, self-reflexive nature of the researcher and the endeavour to engage in evolving, meaning-generative relationships with participants and their field of experience as, for example, in participatory research in communities. In quantitative research the fundamental ethical requirement is to demonstrate that the dignity and rights of the individuals involved are being upheld. Where the approach taken is a qualitative one, the key issue is to recognise and respect the experiences of the participants and to acknowledge the meaning generating capacity of the relationships between them and researchers.

The methodological diversity underlying qualitative research represents a response to the complexity of the processes just referred to of meaning generation in relation to personal experience. Quantitative research is inherently objectivist, in the sense of presupposing a radical independence between the subject and object of knowledge. By contrast, qualitative methodologies draw attention to the dependence of knowledge and truth on the process of observation itself and the cultural and theoretical context within it occurs. Some qualitative frameworks, such as those of feminism and postmodernism, explicitly include the observer as a key variable. However, these are the exception, and many other qualitative approaches retain a commitment to the separation of the research process from that of action and change, thereby preserving fundamental features of the dominant epistemological paradigm of medical research.

The ethical discourses about quantitative research have developed out of this tension between the objectivism of science and dialogue between researchers and research participants: that is, they are a response to the inherently non-reflexive nature of quantitative thinking. In the latter, the removal of the agency of the research participant at the level of knowledge acquisition requires its re-insertion in the form of

supplementary 'principles' of ethics, such as the principles of respect, beneficence and justice. As a result of its evolution as an extension of the quantitative paradigm which nonetheless preserves the basic structure of objectivistic knowledge, qualitative research seeks to follow the same ethical principles, even if the ways in which they are realised sometimes differs: for example, in the more active, participatory versions of qualitative methodologies the distinction between 'researcher' and 'research participant' becomes somewhat blurred, thereby changing the nature of conversations about consent, risk etc.

The ideas and concepts that are subject to the processes of measurement, including the hypotheses that are tested, clearly precede quantitative assessments of them; qualitative thinking is in this respect more fundamental than quantitative thinking. Furthermore, because not all aspects of experience can be expressed quantitatively there are irreducible residues of qualitative experience that perdure within the quantitative domain.

Case study

The above points can be illustrated by a study currently being undertaken by the authors which utilises quantitative and qualitative methodologies to characterise the attitudes, beliefs and behaviours of CM practitioners in Australia. The overall aim of the study intends to provide a comprehensive description of CM practice which conveys both the large scale cultural structures and local values and attitudes of individual practitioners. Quantitative data obtained from a nationwide survey are being analysed using descriptive statistics in the form of frequencies and percentages, to provide an overall quantitative description of eight domains within CM practice in Australia: demographics; clinical practice; evidence; registration; education; professional development; professional associations; and the future of CM in Australia. In addition to this, qualitative, semi-structured interviews are being conducted to provide a deeper characterisation of CM practitioner and key stakeholder attitudes and values. Data from the interviews and qualitative survey responses are being analysed using established qualitative techniques, including thematic analysis. In the research design the qualitative and quantitative data complement each other: the qualitative data are analysed for recurring topics and themes, which are used to generate quantitative hypotheses, while conversely, the quantitative information obtained from a national survey is tested and interpreted in the medium of qualitative dialogues. The results and discussions based on the findings will be published in upcoming journal articles. It is hoped that knowledge of the clinical and cultural dynamics of CM will contribute to the development of both clinical practice and policy recommendations.

Each methodology clearly provides its own insights and evokes its own theoretical interpretations. The combination of methodologies, however, also raises some contentious issues. These include that of population sampling, which is understood differently by the two perspectives. The quantitative paradigm demands that sufficiently large numbers be included to constitute a 'representative' sample, while the qualitative one focuses not on statistical arguments but on the inclusion of all relevant substantive demographic factors. The contrasting approaches go to the heart of the differences between the two methodological perspectives: quantitative research is concerned with abstract representations of phenomena across whole populations while qualitative approaches seek to provide inventories of the full range of concrete variables that manifest themselves in the complex and differentiated array of social life worlds. As a descriptive study, our project seeks to pierce the qualitative unknown by investigating a population that has not hitherto been investigated in this manner, in spite of previous limited workforce studies.[25–6] It is our hope that the use of both quantitative and qualitative methodologies will allow the complex array of ethical, social and cultural factors to be identified so that effective policies and educational strategies can be developed.

What does this mean for CM?

Like other social practices, CM embraces a complex array of discourses, techniques and ethical standpoints. It has its own body of knowledge and standards of truth and validity, its own professional networks, and its own approaches to clinical praxis and education. The current research project has posed the question of the specific nature of the practitioner-patient relationship in CM. The encounter between practitioner and patient is the central dynamic force underlying all clinical practice, including that of Western medicine, and the characterisation of a particular practice must seek to identify any features that are unique to or distinctive of it. Our research suggests that CM can be distinguished precisely in these terms, by the quest of the practitioner and patient collectively and jointly to re-discover wellness, that is, through the distinctive ethical project underlying CM.

It may be argued that one of the defining principles of both scientific research and clinical medicine is the proliferation of viewpoints, of the fostering of competing and evolving theories of phenomena and experience which can be tested in varying degrees by experiment. The fecundity of ideas and concepts in fact emphasises most trenchantly the crucial role of qualitative ways of thought, which resist limiting the plenum of creative possibilities to a single standard of judgement. The qualitative domain allows us to consider and engage actively with participants' views and experiences about their sickness and

healing, which are infinitely variable. The conversations that may thereby be generated cannot be reduced to mere reporting, but invariably evoke ethical engagements, as participants and researchers together seek to deepen their understanding of the research question, the research activity, and their experience of the research topic. Ideally, participants may feel empowered to engage with the research process as active subjects. They may feel more included in the research experience, in the investigation of their experience, and in the reporting of the findings and subsequent decisions.

CM practitioners may understand that these are some of the reasons their patients may choose to participate and prosper within the CM framework. Research in CM involves a level of complexity inherent in an internally reflexive system. We suggest that research in CM is not only well suited to qualitative methodologies, but that the inclusion of such methodologies in studies investigating the use and effectiveness of CM is essential not only to enhance understanding of CM but also to ensure its ethical conduct.

Clinical Commentary

The relationship between research and clinical practice is increasingly emphasised within the Chinese medicine (CM) field. This paper attempts to outline the two broad methods of research, quantitative and qualitative, and to examine their ethical dimensions and comparative features, as highlighted in the placebo effect. The benefits and challenges of combining both methodologies are exemplified by reference to a current study into the nature of CM practice in Australia. We conclude that the use of combined methods in CM research offers both scientific and ethical benefits.

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