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Qualitative Health Research and the IRB: Answering the "So What?" with Qualitative Inquiry

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Abstract Qualitative inquiry is increasingly used to foster change in health policy and practice. Research ethics committees often misunderstand qualitative inquiry, assuming its design can be judged by criteria of quantitative science. Traditional health research uses scientific realist standards as a means-to-an-end, answering the question "So what?" to support the advancement of practice and policy. In contrast, qualitative inquiry often draws on constructivist paradigms, generating knowledge either as an end-in-itself or as a means to foster change. When reviewers inappropriately judge qualitative inquiry, it restricts the ways health phenomena can be understood. Qualitative inquiry is necessary because it enables an understanding not possible within scientific explanation. When such research illuminates, it can also shed light onto the "So what?" In order to ensure an appraisal of qualitative inquiry congruent with its paradigmatic premises, we suggest the "Illumination Test," met when findings foster rich understanding of phenomena, resulting in a reflective "aha!"

Keywords Qualitative inquiry · Ethics · Rigour · REB/IRB

Introduction: Clinical research

In a conventional health research milieu, clinical research is understood to have a very specific purpose: The goal of this research is a means-to-an-end; that is, to support the advancement of clinical practice and policy. Clinical Research is designed primarily to answer the question: "So what?"

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Nursing research, for instance, is generally oriented at understanding a problem such that an intervention can be designed to address that problem. For example, physiological research has recently discovered that sucrose on an infant's tongue can help decrease painful sensations. "So what?" clinical research has since been designed to intervene, to determine how much sucrose, or when the dosage should be administered, the goal being to maximize outcomes (i.e., to reduce pain for newborns).

In the clinical setting, "research" is defined in congruence with applied scientific principles. As a result, qualitative inquiry researchers find themselves up against a major challenge if they want to build a respected niche in the clinical setting. Coming from different epistemological and ontological traditions, qualitative inquiry does not fit the conventional idea of "research" or "applied science."

Yet, qualitative inquiry can offer two major contributions to clinical practice. First, qualitative inquiry can also be a means-to-an-end, generating knowledge to foster changes in policy and practice and thereby addressing and answering the "So what?" This position can be a hard sell, and even more so as we move further into the age of "evidence-based medicine," in which the definition of "evidence" is premised on positivist science.

A second thing qualitative inquiry has to offer can be an even harder sell. Qualitative inquiry can also be an end-in-itself, offering conceptually rich analysis for the sake of the advancement of knowledge. For instance, philosophical interrogation and anthropological reflection in conjunction with qualitative research can enrich our understanding of a phenomenon yet while not aiming to control or intervene upon it. For example, Carnevale's work in philosophy and ethics integrates conceptual reflection on ethical understandings of moral agency in children (Carnevale 2005). Similarly, Macdonald and colleagues' work on pediatric death and dying offers anthropological and ethical reflection for clinicians working with families in the intensive care unit (Macdonald et al. 2005). Such conceptual work stimulates discussion and contemplation regarding both research questions and design and offers a framework for re-thinking conventional views. While not directly prescribing specific change, this work can inform "So what?" applied research and practice.

Research Ethics Committees

Research ethics committees[1] act as gate-keepers for many domains of health research and knowledge transfer. While qualitative inquiry is slowly being afforded more of a place in health policy and clinical practice, regrettably many clinical research ethics committees continue to misunderstand interpretive[2] forms of inquiry. Research ethics committees are mandated to ensure institutions produce "good research" in order to answer the "So what?" To do so, reviewers use positivistic rigour to ensure that the answers are achieved in standardized objective ways.

Although not always the case, in our experience reviewers often review qualitative protocols with one of four approaches:

1. Reviewers assume qualitative studies should be assessed as if simply another kind of quantitative research and so submit the research projects to the rigour criteria of quantitative science (e.g., generalizability, reliability, validity).

[1] Commonly called Research Ethics Boards (REBs) in Canada, Institutional Review Boards (IRB) in USA.

[2] We use 'interpretive' as a descriptive term and not to necessarily imply the hermeneutical paradigm.

2. A second approach that is becoming more common is that reviewers see qualitative researchers as "guilty until proven innocent". Reviewers allow the possibility that qualitative researchers are innocent (i.e., that they can coherently justify their methods and support the "So what?"), however they require that the researchers sit before a (frequently) positivist panel where the researchers must explain and/or convince the reviewers, in positivistic language, about how reviewers *should* have reviewed the protocol. This becomes a session in the defence of qualitative inquiry, the education of committee members, and not a genuine 'peer-review.'
3. Third, qualitative studies are often approached as if 'handmaidens' to quantitative inquiry. Qualitative research is seen as useful only as a means to quantitative ends; e.g., designed to generate measurable hypothesis and instruments for future quantitative studies. Quantitative research is retained as the definitive way to advance knowledge.
4. A final way qualitative studies are often approached is one that is contested cogently in the literature by authors such as Barbour (2001) and Eakin and Mylekovskiy (2003). More and more, research ethics committees (as well as research journals) are using a universal checklist of standardized qualitative criteria (e.g., saturation, inter-rater coding) thereby minimizing the complexity of tailoring these criteria for each study.

'Peer review' is intended to ensure the production of ethical, rigorous health research, a worthy goal. Where this goal breaks down, however, is when the scientific realist standards and measures required by conventional health research are used to assess *all* methodological rigour. This sort of review perpetuates the privileging of a conventional scientific epistemology and thereby restricts the other ways health phenomena can be researched and understood. As Segal (1997) argues following Frankford (1994), when a positivist model is used to study a positivist system, the very efforts to analyze the system will reproduce that same system, reproducing what Frankford calls a "treadmill constituted in scientism."

A Moral Imperative

Any approach to health research that excludes or misunderstands qualitative inquiry – as either a means-to-an-end or an end-in-itself – is morally flawed. The limitation of qualitative inquiry threatens the advancement of health knowledge: qualitative inquiry is necessary for the development of health practice and policy *because* it enables an understanding of phenomena that is frequently not possible within a framework of scientific explanation.

All researchers (and especially those paid by public monies in public institutions) have a moral imperative to do the best research they can with the tools and knowledge they have. Similarly, research ethics committees have the responsibility to encourage ethical research that can further the understanding of the human condition. When research ethics committees misunderstand or inappropriately judge the value of qualitative inquiry, this threatens the advancement of health knowledge. By misjudging qualitative inquiry, research ethics committees are often impede ways of knowing and understanding that have the potential to favourably impact health, health policy, health intervention and health outcomes.

The Illumination Test

In order to ensure an appraisal of qualitative inquiry congruent with its paradigmatic premises, we argue that research ethics committees should not rely on conventional

measures of quantitative rigour nor seek standardized checklists of qualitative rigour. Instead, in order to adequately assess the potential worth of qualitative inquiry, projects should be measured against two basic standards:

1. Qualitative inquiry must indeed be "research." By "research" we do not mean the quantitative definition that requires a fixed structure (e.g., hypothesis, objective, methods, measures). Instead, we mean simply that while qualitative projects may be unconventional, creative and/or artistic in premise, design and intent, they still must be ethically sound, logically coherent, and directly answer a valid and worthwhile question if they are to be considered "research."
2. Second, qualitative inquiry should pass what we call the "Illumination Test." Quantitative research generally seeks *explanation*. Drawing on the natural sciences paradigm, quantitative research is judged in terms of how well it can provide an explanatory account of a phenomenon, ideally through measured casual relations among variables and ultimately putting forth predictive propositions in which particular outcomes can be instrumentally controlled. In contrast, qualitative inquiry does not generally seek such explanation. Rather, through the lens of an interpretive framework, explanation is believed to be incomplete. Instead, qualitative inquiry aims to foster a greater *understanding* of a phenomenon.

Through an interpretive lens, representations of phenomena are necessarily drawn from a network of meanings which are embedded in complex configurations of social systems. The experience and significance of any phenomenon is necessarily influenced by these systems. For example, although physics can *explain* colour differences in terms of variable light absorption, colour differences for most people cannot be reduced to their physical properties. Instead, such things as our moods, customs, or cultural significations affect how color is experienced.

To return to the pain example sited in the introduction, pain research has devoted substantial attention toward the reliable and valid measurement of pain, the identification of determinants of pain, as well as strategies for controlling pain. Relying on an exclusively positivist paradigm presumes pain is a tangible phenomenon that can be measured and manipulated to produce certain outcomes (i.e., less pain). The prevalent use of parametric statistical operations for such research insinuates that when a patient, upon a clinician's request, rates their pain as 8 out of 10, this is twice as great as a score of 4. Rather, given that most pain measures provide ordinal data (rather than interval or ratio data), this is conceptually flawed. Despite its many important contributions to comfort in clinical settings, this primarily quantitative approach to pain research is incomplete. Many patients are puzzled by the request to represent their pain in terms of a number on a scale of 1–10. Further, hearing a patient *explain* that their pain is 7 will not help a clinician to *understand* what that 7 means to the patient. Pain is linked to social phenomena that affect how pain is experienced, expressed, inflicted and comforted. Pain at 7 expresses many things, including experiential phenomena.

Research aimed at the *understanding* of a phenomenon requires a rigourous process of analysis of that phenomenon embedded in its surrounding contexts and significations. This analysis must seek to advance the coherence and completeness of prior understandings, with the aim of enriching our current understandings. At the same time, we must recognize that such understandings are always provisional, in need of further inquiry and analysis. How we achieve this improved understanding will vary from phenomenon to phenomenon and context to context. Sometimes it will call for a comprehensive social analysis, other times an experiential study or historiographical inquiry. A standardized set of criteria or a checklist will never adequately determine the strength and value of any analysis.

How to Operationalize the Illumination Test

What we are calling the "Illumination Test," is met when research findings enlighten and foster a rich understanding of a phenomenon, resulting in the readers' reflective "aha!". Thus, the genuine evaluation of a qualitative inquiry project by a research ethics committee cannot be achieved without addressing the following two elements:

1. Reviewers must have a significant understanding of qualitative inquiry. This understanding would have to include such elements as the philosophical premises, merits and limits of various data collection techniques, and ethical considerations particular to qualitative research.
2. Reviewers must have more than a superficial understanding of the phenomenon in question. Without a good grasp of the phenomenon (for example, cancer pain), a reviewer cannot know the potential a study has to push an analysis forward. Indeed, we propose that to operationalize the Illumination Test, the research ethics committee must solicit the opinion of an expert. An expert on the phenomenon in question is required to engage the project at a level that can really assess the degree to which the study does enlighten (or to which a proposal has the potential to enlighten) their understanding of the phenomenon. Such assessment should ask: Does this study answer existing questions? Does it address conceptual gaps or speculations? Does it add a new dimension to our conceptualizing of this phenomenon? Does it relate the phenomenon to other phenomena in novel ways?

Conclusion

When qualitative inquiry illuminates, it enriches the sophistication of our understandings of complex health issues. In turn, this sheds light onto and helps address the "So what?" required for applied health research, either direct or indirectly. Using the Illumination Test to assist the evaluation of qualitative inquiry will also contribute to the countering of the epistemic authority currently attributed to by the scientific paradigm. As well, it will enable a diversity of methodological perspectives to address the moral imperative that health researchers have to the advancement of health knowledge.

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