

Quality Measures and Quality Indicators

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Overview

1. My perspective
2. Historical overview
3. Questions & observations from ethics and accounting
4. Conclusions

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1. My perspective

- ▶ Involvement in research ethics policy
- ▶ Research Ethics scholarship
 - Centring the human subject project
 - Law Commission of Canada Report
 - Canadian Network for the Governance of Ethical Health Research Involving Humans: Evidence, Accountability and Practice
- ▶ REB involvement
 - Canadian Blood Services, OCREB Governance
- ▶ Accounting ethics: CGA Canada

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2. Historical overview

- ▶ “There is an urgent need for empirically informed and ethically sensitive research on the effects of research on human subjects as well as on the effectiveness of governance procedures. There is little point in experimentation ... without careful research-based assessments of processes and results.”
 - McDonald (2000) Law Commission of Canada

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What is missing now

- ▶ “The current system does not systematically assess performance or outcomes”
 - the Consortium to Examine Clinical Research Ethics, Emmanuel et al. Annals 2004

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Evidence-based ethics

- ▶ “The time is ripe for evidence-based ethics. Similar to evidence-based medicine, an evidence-based ethics would emphasize the importance of data in informing discussions and decision-making about the ethical issues inherent to clinical medicine and research.”
 - Sugarman JAMA 2004

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A paradox

- ▶ “It is paradoxical that those in the health professions base their practice on evidence-based standards *except* in the case of ethical review.”

- Beagan & McDonald HLR 2005

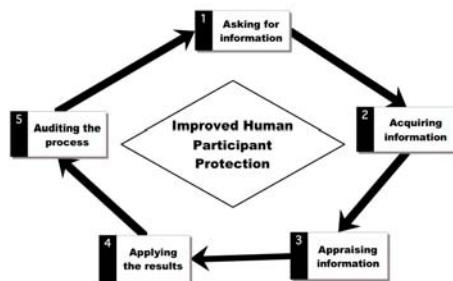
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FIGURE 1



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FIGURE 2



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Centring the human subject in health research:

- ▶ Understanding the meaning and experience of research participation
 - Susan Cox, Michael McDonald, Joe Kaufert, Patricia Kaufert, & Anne Townsend
 - CIHR operating grant
 - 3-stage project involving individual interviews, case studies, and knowledge translation and exchange

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Goals of research

- Explore the meanings and experiences of being a research subject from the standpoint of subjects.
- Compare and contrast the perspectives of research subjects with the perspectives and practices of researcher professionals, REB members, scholars, and policymakers.
- Assess the ethical and other implications of recent and emerging changes in the context and design of health research.
- Pilot methods for implementing new understandings of the experience of being a research subject in research design, the process of ethical review and the governance of research ethics.

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2. Questions & Observations: ethics and accounting

- ▶ What counts as success for institutional systems of human participant protection and how would we show it?
- ▶ What are the right quality measures/indicators for human participant protection?
- ▶ Assumption: we should measure quality in terms of what is meaningful rather than what is merely convenient or expedient.

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Lessons from Accounting Theory

1. Measures should track what is important to information users.
2. Not all information users are alike: they may well have different needs and capacities.
3. There are trade-offs between accuracy/comprehensiveness and timeliness.
4. It is essential to recognize the strengths and weaknesses of specific measurements.
5. Measuring has its costs.

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Information Users: roles & needs

- ▶ Those with a stake in participant protection
 - Actual & potential participants (below)
 - REBs, HPP staff/admin, institutional officials
 - Regulatory compliance, institutional reputation, acting responsibly
 - Researchers, research workers, coordinators, & sponsors
 - Speed/costs of review; effects of research quality/productivity; reputation
 - Regulators
 - Oversight effectiveness and cost; political & social accountability; reputation

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Level-specific needs

- ▶ Macro – policy formation and oversight
 - Numbers & kinds participants, comparison with animal research
- ▶ Meso – institutional management and oversight
- ▶ Micro – project and participant specific issues
 - REB review level
 - DSMB
 - Research team

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Research Participants

- ▶ Diversity of experiences, perspectives & motivations, e.g., altruism/egoism
- ▶ Still common themes – examples:
 - Importance and fragility of trust
 - Concern with the quality of research
 - Wanting to know research results
 - Practical costs often trump more abstract ideals
 - Acute insights into researcher behaviour
 - Impact of research on their lives

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4. Conclusions

1. Process indicators are important, but fairly straightforward, e.g., OCREB, CGSB
2. Substantive indicators are essential but harder:
 - Have to drill down to effects on participants
3. Combine research & practice – the evidence-based medicine model
4. Performance indicators are an important part of “virtuous learning loops”

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