

## RESEARCH REFLECTIONS

## Exploring the challenges of ethical conduct in quality improvement projects

by Steven Hall, Virginia Lee, and Kristen Haase

## INTRODUCTION

Quality improvement (QI) and clinical research projects both play increasingly important roles in healthcare to improve and enhance patient care. Quality improvement projects in healthcare are critical for improving internal organizational systems and processes to enhance outcomes and deliver safer, cost-effective, and efficient healthcare (Hagen et al., 2007; Newhouse, Pettit, Poe, & Rocco, 2006). Clinical research projects use the scientific method to systematically investigate a health-related problem or phenomenon to lead to generalizable knowledge and potentially lead to new discoveries to impact patient care and healthcare systems. As rigorous QI projects and clinical research projects become the norm in driving healthcare improvements, the binary of research versus QI has become less clear (Newhouse et al., 2006). The intent to publish is no longer sufficient for determining whether a QI activity is research (Casarett, Karlawish, & Sugarman, 2000).

A common question for clinicians and researchers is whether or not authorization from a research ethics board

(REB) is required prior to conducting their project with participants. The role of the REBs is to ensure research is planned and conducted in a manner that protects the rights and welfare of a project's participants (Page & Nyeboer, 2017). Research ethics boards make recommendations and provide direction for the ethical conduct of a research project. In Canada, the Tri-Council Policy Statement (TCPS) establishes fundamental ethical principles and dictates standard ethical conduct for research (Ezzat et al., 2010). Tri-Council Policy Statement guidelines clearly indicate that REB approval is required when conducting research and is not required when executing QI or program evaluation projects (Research, 2005). Therefore, there is a gap in the literature regarding the ethical oversight of QI projects (Ezzat et al., 2010). Health researchers are often left without clear guidelines about the approaches warranted to protect QI participants. A debate exists in the literature as to whether or not ethical oversight is necessary in QI projects and, if so, how it should be provided and who should guide this process (Fiscella, Tobin, Carroll, He, & Ogedegbe, 2015; Layer, 2003; Lynn, 2007; Nerenz, Stoltz, & Jordan, 2003; Thurston, Vollman, & Burgess, 2003).

The purposes of this paper are to (1) describe how to determine if a project is QI or research, and (2) describe the minimum considerations to ensure the ethical oversight of QI projects.

## DISTINGUISHING QI FROM RESEARCH

Research and QI have previously been considered to be fundamentally different activities (Mold, 2005). However, they have become increasingly difficult to distinguish. Not all clinical issues and questions are amenable to research (Beyea & Nicoll, 1998), and both QI and research may address

clinical, administrative or educational problems (Shirey et al., 2011). "QI" is a generic term for activities that have the desired effect of improving an aspect of the healthcare process (Nerenz et al., 2003), and QI protocols have typically been informal and subject to change throughout a project (Shirey et al., 2011). An example of this is the Plan, Do, Study, Act (PDSA) cycle, wherein interpretation and implementation of data into practice is an ongoing evaluative process (Shirey et al., 2011). Research is defined as a scientific process that generates new knowledge or validates and refines existing knowledge (Mold, 2005; Shirey et al., 2011), and adheres to strict research protocols to control for extraneous variables. To add further complexity, some are hybrid projects, which are research projects on the QI process and are recognized to be a legitimate means of generating new knowledge across clinical settings, as it is a direct route to improving outcomes and delivery of services (Morner & Stevans, 2019).

One distinguishing criterion used to decipher the difference between QI or research is to review the project's purpose. If the project aims to generate new knowledge that would be relevant to future beneficiaries such as patients, families, staff, or to the broader scientific community, it would be classified as research. If the intent is to improve current work-flow processes and enhance efficiency within an organization, it is considered QI (Beyea & Nicoll, 1998; Shirey et al., 2011).

A second distinguishing feature to consider is the type of question underlying the study. Research uses systematic problem-solving approaches that are inquiry-driven; QI also uses a systematic, problem-solving approach, but is data-driven, rather than inquiry-driven (Shirey et al., 2011). The third distinguishing feature is the data

## AUTHOR NOTE

Steven Hall, BSc, BSN Candidate, University of Saskatchewan, College of Nursing, Saskatoon, SK  
[steven.hall@usask.ca](mailto:steven.hall@usask.ca)

Virginia Lee, N, PhD, Senior Nursing Research Consultant (interim), Nursing Directorate, Professional Practice, Education, Workforce Organization and Research, McGill University Health Centre (MUHC), Montreal, QC  
[virginia.lee@mcgill.ca](mailto:virginia.lee@mcgill.ca)

Kristen Haase, RN, PhD, Assistant Professor, College of Nursing, University of Saskatchewan, Saskatoon, SK  
[kristen.haase@usask.ca](mailto:kristen.haase@usask.ca)

collection process. Whereas QI projects collect data in iterative, short, rapid cycles to provide immediate improvements, research projects rely on controlled data collection approaches, as detailed in research protocols. Quality improvement projects are typically conducted with patients who are inducted into the study with few or no eligibility

restrictions to enhance external validity (Layer, 2003; Duke University, 2016). In contrast, research participants often must meet inclusion and exclusion criteria to be eligible to enter the study. A number of algorithms are available to facilitate this distinction. However, few provide guidance on how to maintain ethical conduct (see Table 1).

## ETHICAL CONDUCT IN QI

Upholding the ethical principles of autonomy, beneficence, non-maleficence, and justice in QI projects should be as stringent as what is expected in clinical research. Whether intentional or unintentional, QI projects can expose participants to risk or burden,

**Table 1: QI versus Research Distinguishing Tools**

Distinguishing Tool	Reason(s) to Seek REB Approval	Checklist / Requirements	Specific Recommendations for Ethical Conduct in QI Projects
Quality Improvement Activities in Health Care Versus Research (Duke University Human Research Protection Program, 2016)	REB defines project as research or QI	Purpose, scope, evidence, clinicians/staff, methods, sample/population, consent, benefits, risk	No clear recommendations
Quality Improvement vs. Research (University of Tennessee Chattanooga, 2018)	Knowledge generation; risks greater than minimal, delayed implementation of results	-	No clear recommendations
Determining Quality Improvement vs. Research Activity (Marcus Institute for Aging, 2017)	Knowledge generation	Purpose, design, flexibility, deviation from standard care, future data use, clinicians/staff, funding, previous REB appraisal	Request REB review when funded by research grant
Checklist for quality improvement/quality assurance/program evaluation/curriculum development studies requiring ethical review (University of British Columbia, n.d.)	Knowledge generation	Audience, funding, sampling techniques, recruitment, comparison, risks/benefits, methodology	No clear recommendations
Quality Improvement or Research Worksheet (Nosowsky, n.d.)	Comparison or control groups used	Randomization, goals, clinicians/staff, protocol, timely return of results, funding	Consult REB if unsure
Quality Improvement vs. Research - Do I Need IRB Approval? (Virginia Commonwealth University, n.d.)	Untested clinical intervention, multi-site implementation	Knowledge generation, implications, goals, funding, randomization, location, existing evidence, deviation from standard care	No clear recommendations
Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research (Western University, 2017)	Disciplined inquiry or systematic investigation	Funding, purpose, local policies, design, bias, comparison, generalizability, burdens, confidentiality, data collection, beneficence, publication potential	Suggests guidance from alternate body
Research Versus Quality Initiative Screening Tool (McGill University, 2018)	Difficult to distinguish	Purpose, funding, generalizability, design, controls, risks, sample size, goals, timely return of results, publication potential	Seek guidance from MUHC Centre for Applied Ethics (Designated for QI)
Is your project Research or Quality Improvement? Guideline & Checklist (Ottawa Hospital Research Institute, 2016)	Elements of research	New intervention, randomization, blinding, prospective evaluation, purpose, funding, design, consent process, risks, publication potential	No clear recommendations
ARECCI Ethics Screening Tool (Alberta Research Ethics Community Consensus Initiative, 2017)	Risk level for participants	Funding, local policies, generalizability, burdens, publication potential, intentions, location, data collection, confidentiality, COIs, topic sensitivity, deviation from standard care, deception, safety, effectiveness	Comply with local policies
Quality Assurance (QA) and Quality Improvement (QI) Studies (Queen's University, 2018)	Data proposed for research purposes	Refer to ARECCI Screening Tool	Respect free and informed consent, voluntary participation, privacy and confidentiality
Research Versus Quality Improvement Guideline & Checklist (St. Joseph's Health Centre Toronto, 2014)	Elements of research	Funding, randomization, controls, design rigour, participant burden, sampling techniques, deviation from standard care, publication potential	Refer to "SQUIRE 2.0" (Standards for Quality Improvement Reporting Excellence) guidelines
Guidance: When Does Your Project Warrant Review By A Research Ethics Board? (Vancouver Coastal Health Research Institute, 2009)	Knowledge generation, multi-organization projects	-	Follow institutional policies re: privacy / risk

may present an unequal distribution of benefit across participants, and can present conflicts of interest in the prioritization of projects (Duke University, 2016). Although the TCPS lacks clear guidelines for maintaining ethical conduct in QI projects, some guidance exists in the literature (Hagen et al., 2007; Government of Canada, 2005). In essence, the ethical principle of non-maleficence (protecting patients from harm) must be observed and appropriate action to avoid causing harm must be taken in QI studies (Dixon, 2017). A favourable risk-benefit balance must be achieved by limiting risks such as patient harm and breaches in confidentiality, as well as maximizing benefits to patients and patient care (Dixon, 2017). The social and scientific value for the project, resources spent, and risks imposed on participants should be justified in QI activities (Lynn, 2007). Furthermore, appropriate safeguards for security and confidentiality are critical in these projects (Ezzat et al., 2010).

To aid researchers and clinicians, we propose a minimum set of considerations in the ethical oversight of QI activities: (1) purpose, (2) informed consent, (3) participant confidentiality, and (4) withdrawal from activity.

### 1. Review the purpose and design of the activity

When QI projects are poorly designed or not properly conducted, it would be unethical to proceed with the activity, as the project would be unlikely to lead to healthcare improvements. To ensure the goal of QI projects produces relevant knowledge that will be useful to the host organization, the Institute of Medicine (IOM) (Wolfe, 2001) suggests that QI projects align with six aims:

1. *Safety*: Care is intended to help patients; therefore, injuries are avoided.
2. *Effectiveness*: Services are provided based on scientific knowledge to patients who are likely to benefit from them.
3. *Patient-centred*: Care is respectful and responsive to individual preferences, needs, and values.
4. *Timely*: Interventions should reduce wait-times for patients requiring care.

5. *Efficiency*: Avoiding waste, such as equipment, supplies, energy, and funds.
6. *Equity*: Care does not vary in quality, regardless of gender, ethnicity, geographic location, or socioeconomic status.

### 2. Consider the need for informed consent

The main rationale for informed consent is to respect the autonomy and protect participants from exposure to project risks that they have not agreed to accept (Miller & Emanuel, 2008). However, QI initiatives are routinely adopted in hospital settings. For example, a hospital seeking to implement evidence-based interventions could establish a QI project to evaluate the implementation and, in this case, the consent to treatment would also imply consent to the intervention and inclusion in the QI project (Miller & Emanuel, 2008). Moreover, it is often impractical to obtain informed consent from all participants enrolled in QI projects (Miller & Emanuel, 2008). Wide-spread QI projects implemented across a large organization do not logistically allow for each participant to go through a consent process. Obtaining explicit signed consent from healthcare professionals may be less relevant when the QI project is conducted as part of activities that are expected in one's job description. Quality improvement participants should be asked for informed consent if the QI initiative poses more than a minimal risk, and those risks should be compared with the relative risk of receiving standard healthcare (Lynn, 2007).

### 3. Consider how participant confidentiality is protected

While QI activities often pose minimal physical, psychological, social, or financial risk to participants, the threat to privacy and the loss of confidentiality of health information are important considerations (Baily, Bottrell, Lynn, & Jennings, 2006). Confidentiality extends to everything a member of the QI team can learn about a patient in the medical records or by observation in conducting the project. Participant information can be unintentionally transmitted if QI data is left unattended on desktops,

computer screens, or discussed in corridors or elevators. To mitigate participant risk and maintain participant confidentiality, QI projects typically undergo some level of internal review. However, the quality of this review can vary, as there is no clear definition of requirements (Fiscella et al., 2015; Taylor, Pronovost, & Sugarman, 2010).

### 4. Consider whether the right of participant withdrawal from project is necessary

When people participate in research, they have the reserved right to withdraw from a project at any time, and are entitled to the same 'standard of care' throughout their treatment, regardless of their actions (Edwards, 2005). However, because informed consent is not always obtained in QI initiatives, participants may not have explicitly volunteered nor have been aware of their participation in a QI activity, so it may not be possible to allow participants to withdraw (Miller & Emanuel, 2008). In this case, we recommend revisiting the concept of informed consent and providing strong, concise education on all options that are available for treatment. Participants require clear, concise information on all options that are available to them. In cases where the QI activities involve risks beyond standard of care, the concept of informed consent may become relevant.

### REB Exemption

If a project is deemed to be QI, it is good practice to request an exemption letter from the institution's REB, as most journals require this prior to publication (Bauchner & Sharfstein, 2001; Eccles, Weijer, & Mittman, 2011). If the nature of risk in the QI study seems elevated beyond what is expected under routine care, a REB review may be requested to determine what sort of minimal criteria to apply to protect the participant (Nosowsky, n.d.).

## CONCLUSION

Quality improvement projects can span a wide range of projects of differing complexity where potential benefits and risks to participants can vary (Lo & Groman, 2003). Although the need for a REB review is presently deemed unnecessary for QI projects, it is not

justification for less rigour or less attention to the protection of study participants. Project leaders are responsible to maintain ethical oversight and

protect the safety and dignity of study participants (Government of Canada, 2005). An important future directive for QI initiatives is ensuring practical,

user-friendly ethical guidelines for QI projects that do not stifle the projects, and provide the adequate safeguards for QI participants.

## REFERENCES

- Alberta Research Ethics Community Consensus Initiative. (2017). *ARECCI Ethics Screening Tool*. Retrieved from <http://www.aihealthsolutions.ca/arecci/screening/439683/917a010525b36969679477bd3ee91f7>
- Baily, M. A., Bottrell, M. M., Lynn, J., & Jennings, B. (2006). Special report: The ethics of using QI methods to improve health care quality and safety. *Hastings Center Report*, 36(4), S1–S40. doi:10.1353/hcr.2006.0054
- Bauchner, H., & Sharfstein, J. (2001). Failure to report ethical approval in child health research: Review of published papers. *BMJ*, 323(7308), 318–319. doi:10.1136/bmj.323.7308.318
- Beyea, S. C., & Nicoll, L. H. (1998). Is it research or quality improvement? *AORN Journal*, 68(1), 117–119.
- Casarett, D., Karlawish, J. H. T., & Sugarman, J. (2000). Determining when quality improvement initiatives should be considered research. *JAMA*, 283(17), 2275. doi:10.1001/jama.283.17.2275
- Dixon, N. (2017). Guide to managing ethical issues in quality improvement or clinical audit projects. In: *Healthcare Quality Improvement Partnership*. Retrieved from <https://www.hqip.org.uk/wp-content/uploads/2017/02/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects.pdf>
- Duke University Human Research Protection Program. (2016). *Quality improvement activities in health care versus research*. Retrieved from <https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/QI%20policy%20and%20checklist.pdf>
- Eccles, M. P., Weijer, C., & Mittman, B. (2011). Requirements for ethics committee review for studies submitted to Implementation. *Science*, 6(1), 32. doi:10.1186/1748-5908-6-32
- Edwards, S. J. L. (2005). Research participation and the right to withdraw. *Bioethics*, 19(2), 112–130. doi:10.1111/j.1467-8519.2005.00429.x
- Ezzat, H., Ross, S., Von Dadelszen, P., Morris, T., Liston, R., & Magee, L. A. (2010). Ethics review as a component of institutional approval for a multicentre continuous quality improvement project: The investigator's perspective. *BMC Health Services Research*, 10(1). doi:10.1186/1472-6963-10-223
- Fiscella, K., Tobin, J. N., Carroll, J. K., He, H., & Ogedegbe, G. (2015). Ethical oversight in quality improvement and quality improvement research: New approaches to promote a learning health care system. *BMC Medical Ethics*, 16(1). doi:10.1186/s12910-015-0056-2
- Government of Canada. (2005). *Tri-Council Policy Statement: Ethical conduct for research involving humans. Interagency Secretariat (or Panel) on Research Ethics*. Retrieved from [https://ethics.gc.ca/eng/policy-politique\\_tcps2-eptc2\\_2018.html](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)
- Hagen, B., O'Beirne, M., Desai, S., Stingl, M., Pachnowski, C. A., & Hayward, S. (2007). Innovations in the ethical review of health-related quality improvement and research: The Alberta Research Ethics Community Consensus Initiative (ARECCI). *Healthcare Policy*, 2(4), e164.
- Layer, T. (2003). Ethical conduct recommendations for quality improvement projects. *Journal for Healthcare Quality: Official Publication of the National Association for Healthcare Quality*, 25(4), 44–46.
- Lo, B., & Groman, M. (2003). Oversight of quality improvement. *Archives of Internal Medicine*, 163(12), 1481. doi:10.1001/archinte.163.12.1481
- Lynn, J. (2007). The ethics of using quality improvement methods in health care. *Annals of Internal Medicine*, 146(9), 666. doi:10.7326/0003-4819-146-9-200705010-00155
- Marcus Institute for Aging. (2017). *Determining quality improvement vs. research activity*. Retrieved from <https://www.marcusinstituteforaging.org/sites/default/files/files/QIvsResearch%281%29.pdf>
- McGill University. (2018). *Research versus quality initiative screening tool*. Retrieved from <https://muhc.ca/sites/default/files/users/user181/QI%20vs%20Research%20screening%20tool-FINAL.doc>
- Miller, F. G., & Emanuel, E. J. (2008). Quality-improvement research and informed consent. *New England Journal of Medicine*, 358(8), 765–767. doi:10.1056/nejmp0800136
- Mold, J. W. (2005). Primary care practice-based research networks: Working at the interface between research and quality improvement. *The Annals of Family Medicine*, 3(Suppl. 1), S12–S20. doi:10.1370/afm.303
- Morner, E., & Stevans, J. (2019). Clinical quality improvement and quality improvement research. *Perspectives of the ASHA Special Interest Groups*, 4(1), 27–37. doi:10.1044/2018\_pers-st-2018-0003
- Nerenz, D. R., Stoltz, P. K., & Jordan, J. (2003). Quality improvement and the need for IRB review. *Quality Management in Healthcare*, 12(3), 159–170.
- Newhouse, R. P., Pettit, J. C., Poe, S., & Rocco, L. (2006). The slippery slope: differentiating between quality improvement and research. *JONA: The Journal of Nursing Administration*, 36(4), 211–219.
- Nosowsky, R. (n.d.). *Quality improvement or research worksheet*. Retrieved from [https://www.med.umich.edu/NURSING/research/HowToInfo/IRBMED\\_for\\_Nursing.pdf](https://www.med.umich.edu/NURSING/research/HowToInfo/IRBMED_for_Nursing.pdf)
- Ottawa Hospital Research Institute. (2016). *Is your project research or quality improvement? Guideline & Checklist*. Retrieved from <http://www.ohri.ca/ohsnreb/forms/Checklist%20Research%20or%20QI%20-%20revised%20November%2020202016.pdf>
- Page, S. A., & Nyebøer, J. (2017). Improving the process of research ethics review. *Research Integrity and Peer Review*, 2(1). doi:10.1186/s41073-017-0038-7
- Queen's University. (2018). *Quality assurance (QA) and quality improvement (QI) studies*. Retrieved from [https://www.queensu.ca/urs/sites/webpublish.queensu.ca/urswww/files/files/GREB/Nov/Quality%20Assurance%20and%20Quality%20Improvement%20Studies%20Guidelines%20v\\_2018JUN07.docx](https://www.queensu.ca/urs/sites/webpublish.queensu.ca/urswww/files/files/GREB/Nov/Quality%20Assurance%20and%20Quality%20Improvement%20Studies%20Guidelines%20v_2018JUN07.docx)
- Shirey, M. R., Hauck, S. L., Embree, J. L., Kinner, T. J., Schaar, G. L., Phillips, L. A., ... McCool, I. A. (2011). Showcasing differences between quality improvement, evidence-based practice, and research. *The Journal of Continuing Education in Nursing*, 42(2), 57–68.
- St. Joseph's Health Centre Toronto. (2014). *Research versus quality improvement guideline & checklist*. Retrieved from [CANADIAN ONCOLOGY NURSING JOURNAL • VOLUME 30, ISSUE 1, WINTER 2020  
REVUE CANADIENNE DE SOINS INFIRMIERS EN ONCOLOGIE](https://www.stjoestoronto.ca/wp-content/uploads/2016/01/SJHC-</a></p>
</div>
<div data-bbox=)

REB-Research-vs.-QI-Guideline-Checklist-July-24-2014-2.doc

- Taylor, H. A., Pronovost, P. J., & Sugarman, J. (2010). Ethics, oversight and quality improvement initiatives. *BMJ Quality & Safety*, 19(4), 271–274.
- Thurston, W. E., Vollman, A. R., & Burgess, M. M. (2003). Ethical review of health promotion program evaluation proposals. *Health Promotion Practice*, 4(1), 45–50. doi:10.1177/1524839902238290
- University of British Columbia. (n.d.). *Checklist for quality improvement/quality assurance/program evaluation/curriculum development studies requiring ethical review*. Retrieved from <https://med-fom-fmprpostgrad.sites.olt.ubc.ca/files/2016/02/>

BREB\_ChecklistForResearchRequiringEthicsReview.pdf

- University of Tennessee Chattanooga. (2018). *Quality improvement vs. research*. Retrieved from <https://www.utc.edu/research-integrity/pdfs/irb-qi-qivsresearchguidance.pdf>
- Vancouver Coastal Health Research Institute. (2009). *Guidance: When does your project warrant review by a research ethics board?* Retrieved from <https://www.vchri.ca/when-does-your-project-warrant-review-research-ethics-board>
- Virginia Commonwealth University. (n.d.). *Quality improvement vs. research—Do I need IRB approval?* Retrieved from <https://research.vcu.edu/>

human\_research/research\_qi\_guidance.pdf

- Western University. (2017). *Distinguishing between quality assurance/improvement, program evaluation & research*. Retrieved from [https://www.uwo.ca/research/\\_docs/ethics/hsreb\\_guidelines/H\\_S\\_R\\_E\\_B\\_%20Guidance%20-%20Distinguishing%20Between%20QA%20and%20Research.pdf](https://www.uwo.ca/research/_docs/ethics/hsreb_guidelines/H_S_R_E_B_%20Guidance%20-%20Distinguishing%20Between%20QA%20and%20Research.pdf)
- Wolfe, A. (2001). Institute of Medicine Report: Crossing the quality chasm: A new health care system for the 21st century. *Policy, Politics, & Nursing Practice*, 2(3), 233–235. doi:10.1177/152715440100200312