

## The Development and Implementation of a Quality Improvement Review Committee (QIRC): An Ethical and Pragmatic Imperative

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### Article abstract

**Background:** In complex academic healthcare systems, quality improvement (QI) projects designed to improve care and enhance learning proliferate, yet there is considerable variation with respect to how, or even whether, these projects receive ethical oversight. As a result of a high volume of projects that were submitted to one of our research ethics board (REB) panels, but deemed not-research and therefore not eligible for review, questions at our organization began to surface with respect to how the ethical dimensions of QI projects might be assessed, and which institutional approvals might be required to ensure compliance with emerging normative standards. **Methods:** A mixed-methods environmental scan led to a retrospective quantitative analysis of our organization's QI projects coupled with in-depth qualitative consultations with staff, physicians, and learners across our health network. REB exemptions were analyzed via run charts to assess baseline QI project volumes and thematic analyses were conducted on field notes from 133 stakeholder consultations. **Results:** During a 34-month period, 117 REB exemption letters were issued for QI projects. Consultations identified the need for: a clearly defined ethical review process for QI projects, appropriate governance structures, and opportunities to identify and mitigate risk. Respondents also spoke to the ethical imperative to conduct QI initiatives. This paper discusses how these themes contributed to the development and implementation of our Quality Improvement Review Committee (QIRC). **Conclusion:** Since 2020, over 840 projects have been reviewed by our QIRC, with a view toward mitigating risks for patients, staff, and QI project teams across UHN.



ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

# The Development and Implementation of a Quality Improvement Review Committee (QIRC): An Ethical and Pragmatic Imperative

Sarah E. McMillan<sup>a</sup>, Sarah Tosoni<sup>b</sup>, Kerry-Ann Smith<sup>a,c</sup>, Betty Chau<sup>a</sup>, Paul Oh<sup>a</sup>, Catriona Steele<sup>a</sup>, Lucas B. Chartier<sup>b,d</sup>, Ann Heesters<sup>e,f,g,h</sup>

## Résumé

**Contexte :** Dans les systèmes de santé universitaires complexes, les projets d'amélioration de la qualité (AQ) destinés à améliorer les soins et l'apprentissage prolifèrent, mais il existe des différences considérables quant à la manière dont ces projets sont supervisés sur le plan éthique, voire même s'ils le sont. À la suite d'un volume élevé de projets soumis à l'un de nos comités d'éthique de la recherche (CER), mais considérés comme n'étant pas de la recherche et donc non éligibles à un examen, des questions ont commencé à se poser au sein de notre organisation sur la manière dont les dimensions éthiques des projets d'AQ pourraient être évaluées et sur les approbations institutionnelles qui pourraient être nécessaires pour garantir la conformité avec les normes émergentes.

**Méthodes :** Une enquête environnementale à méthodes mixtes a conduit à une analyse quantitative rétrospective des projets d'AQ de notre organisation, associée à des consultations qualitatives approfondies avec le personnel, les médecins et les apprenants de l'ensemble de notre réseau de santé. Les exemptions de CER ont été analysées à l'aide de diagrammes d'exécution afin d'évaluer les volumes de base des projets d'AQ, et des analyses thématiques ont été menées sur les notes de terrain de 133 consultations avec les parties prenantes.

**Résultats :** Au cours d'une période de 34 mois, 117 lettres d'exemption du CER ont été émises pour des projets d'AQ. Les consultations ont mis en évidence la nécessité d'un processus d'évaluation éthique clairement défini pour les projets d'AQ, de structures de gouvernance appropriées et de possibilités d'identifier et d'atténuer les risques. Les personnes interrogées ont également évoqué l'impératif éthique de mener des initiatives d'AQ. Le présent document explique comment ces thèmes ont contribué à l'élaboration et à la mise en place de notre comité d'examen de l'amélioration de la qualité (CEAQ).

**Conclusion :** Depuis 2020, plus de 840 projets ont été examinés par notre CEAQ, dans le but d'atténuer les risques pour les patients, le personnel et les équipes de projet d'AQ dans l'ensemble de l'UHN.

## Mots-clés

amélioration de la qualité, comité d'éthique de la recherche, examen éthique, réduction des risques

## Abstract

**Background:** In complex academic healthcare systems, quality improvement (QI) projects designed to improve care and enhance learning proliferate, yet there is considerable variation with respect to how, or even whether, these projects receive ethical oversight. As a result of a high volume of projects that were submitted to one of our research ethics board (REB) panels, but deemed not-research and therefore not eligible for review, questions at our organization began to surface with respect to how the ethical dimensions of QI projects might be assessed, and which institutional approvals might be required to ensure compliance with emerging normative standards.

**Methods:** A mixed-methods environmental scan led to a retrospective quantitative analysis of our organization's QI projects coupled with in-depth qualitative consultations with staff, physicians, and learners across our health network. REB exemptions were analyzed via run charts to assess baseline QI project volumes and thematic analyses were conducted on field notes from 133 stakeholder consultations. **Results:** During a 34-month period, 117 REB exemption letters were issued for QI projects. Consultations identified the need for: a clearly defined ethical review process for QI projects, appropriate governance structures, and opportunities to identify and mitigate risk. Respondents also spoke to the ethical imperative to conduct QI initiatives. This paper discusses how these themes contributed to the development and implementation of our Quality Improvement Review Committee (QIRC). **Conclusion:** Since 2020, over 840 projects have been reviewed by our QIRC, with a view toward mitigating risks for patients, staff, and QI project teams across UHN.

## Keywords

quality improvement, research ethics board, ethical review, risk mitigation

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## INTRODUCTION

The pressing need for Quality improvement (QI) in healthcare is evidenced by consistently high rates of hospital-acquired patient harm. A recent New England Journal of Medicine article noted that adverse events were identified in one in four hospital

admissions, with 25% of these being described as preventable (1). In Canada, one in seventeen hospital admissions in 2022-2023 involved at least one harmful event related to health care including medication errors, infections, procedure-related harms, or accidental injuries such as patient falls (2). QI has been defined as “a broad range of activities of varying degrees of complexity and methodological and statistical rigour through which healthcare providers develop, implement and assess small-scale interventions, identify those that work well and implement them more broadly in order to improve clinical practice.” (3, p.2). As is the case with most hospitals, a high percentage of our institution’s QI initiatives were, and are, focused on reducing avoidable patient harm.

Despite the potential benefits of QI initiatives, and the widespread assumption that they constitute low-risk, commonplace, aspects of health care activities, some commenters have cautioned that non-research knowledge-generating activities may contribute to harm inadvertently when considerations around conflict of interest, consent, power relationships, inequities, and coercion are given insufficient attention (4). Given the varying degrees of complexity and risk inherent in QI initiatives, it is reasonable to argue that ethical review of these projects can help to prevent or mitigate harm.

When the Institute of Medicine of The National Academies (IOM) published its landmark proceedings, *The Learning Healthcare System*, in 2007 (6), it became evident that new ways of conceptualizing the ethical review of knowledge-generating initiatives ought to accompany the embrace of so-called learning healthcare systems. Indeed, as Faden et al. noted in an influential introduction to a special issue of the Hastings Center Report in 2013 (7), while there is an ethical imperative to improve healthcare by embracing the opportunities presented by learning healthcare systems, such initiatives must be accompanied by efforts to incorporate ethical thinking into knowledge-generating activities if institutions are to deliver on their promise to respect the rights and dignity of patients, respect clinician judgments, provide optimal care, avoid imposing inappropriate risks and burdens on patients, address health inequalities, enhance learning, and contribute to the common good of enhancing care at the individual and system level.

A number of screening tools have been developed in an attempt to “maintain accountability and appropriate risk oversight” (8, p.1). Two notable examples are A pRoject Ethics Community Consensus Initiative (ARECCI) (9) and the Public Health Ontario screening tool (8). Healthcare organizations’ Research Ethics Boards (REBs) within the Toronto Academic Health Sciences Network (TAHSN) frequently have used these tools to deem projects “not research” and some have issued research waivers exempting eligible projects from existing institutional ethical review mechanisms. The practice of relying solely on distinguishing research from non-research activities (with the latter attracting no formal arm’s length ethical review) can foster a tendency to overlook important vulnerabilities and ethical risks (10). We have observed that projects which do not contribute to generalizable knowledge, therefore deemed exempt from REB review, may still present risks to participants (e.g., patients, staff, or others), violate healthcare workers’ rights, or pose risks to institutional reputations (11).

Interest and engagement in QI work has grown exponentially in the past several years at our institution which is the largest academic health sciences centre in Canada. For the purposes of understanding the broader contextual drivers of quality improvement work in our province, it should be noted that the Ministry of Health and Long-term Care (MOHLTC), and other professional bodies, require ongoing evidence of improvement in the quality of care delivery. Health Quality Ontario is a government agency that requires organizations to submit quality improvement plans (QIPs) with indicators measuring system performance on an annual basis (12). QIPs, and increasing QI educational opportunities, have sparked corporate initiatives focused on domains of quality from which staff members develop their own local projects to address gaps observed in their day-to-day practice. Given that participation in many quality improvement activities is a government-mandated requirement, organizations must consider how to fulfill their obligations to improve and innovate whilst preventing potential harms.

As our own QI community of practice continued to expand, questions began to surface with respect to how the ethical dimensions of QI projects might be assessed, and which institutional reviews or approval processes might be required to ensure compliance with normative standards. Our scoping project was initiated to: (a) characterize the volume and nature of the QI work being done at our organization, (b) determine how to support these efforts at an institutional level, and (c) develop and implement processes to identify and mitigate risks associated with QI activities. In this paper we present the results of the review which provided foundational guidance for the development and implementation of our QIRC.

## METHODS

A mixed-methods approach was employed whereby a quantitative analysis of REB exemption volumes was coupled with in-depth stakeholder consultations using a negotiated interactive observation approach (13) to learn from staff, learners, and physicians about their experiences and needs related to QI. The aim of the investigation was to make recommendations that would inform future planning activities at our organization, as well as provide real-time navigation with respect to ethical concerns, risk-reduction, privacy, scientific merit and/or feasibility. An advisory committee with representation from Clinical and Organizational Ethics, Clinical Practice, Research Ethics, Research Quality, and Education was struck to provide feedback and assist with access to, and interpretation of, the data.

## Quantitative REB Exemption Volume Analysis

Quantitative data were collected from our REB to determine the number of QI exemptions issued and the time elapsed between submission and the provision of an exemption letter. Specific data points were the REB number, project title, project lead role, location, exemption letter date, as well as the date that an exemption was requested.

## Qualitative Stakeholder Consultations

Consultations were conducted via in-person meetings, emails, and telephone calls. Stakeholders were reached via word of mouth, email advertisement, and self-referral. The Centre for Quality Improvement and Patient Safety (CQIPs) at the University of Toronto provided us with the names of all institutionally-affiliated individuals who completed a QI certificate course from 2013 to 2018, and staff members who were still employed by our hospital network were contacted directly. Stakeholders were stratified by program to sample across the network. Consultations were not audio recorded and detailed fieldnotes were taken.

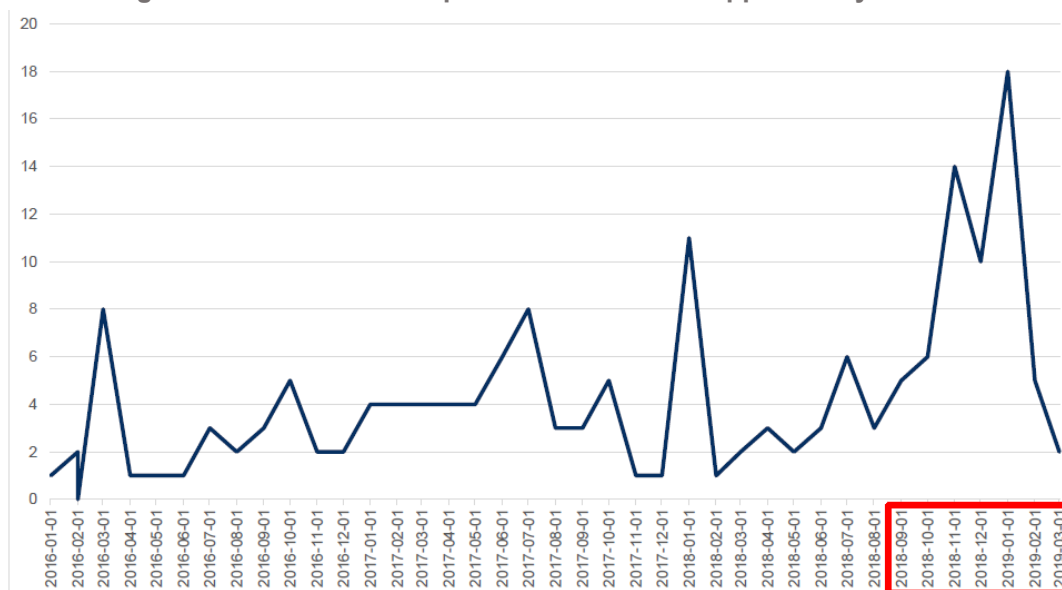
A total of 133 consultations were included in the analysis: 85 were held with point-of-care clinicians (63%), and 17 with key decision makers (i.e., Directors or Vice-Presidents). The most represented professional group was nurses (n=43), followed by physicians (n=17), occupational therapists (n=7), pharmacists (n=6), social workers (n=6), physiotherapists (n=3), technologists (n=2), and radiation therapists (n=1). Field notes were taken and analyzed for common themes using a thematic analysis approach (14,15).

## RESULTS

### REB Exemption Volumes

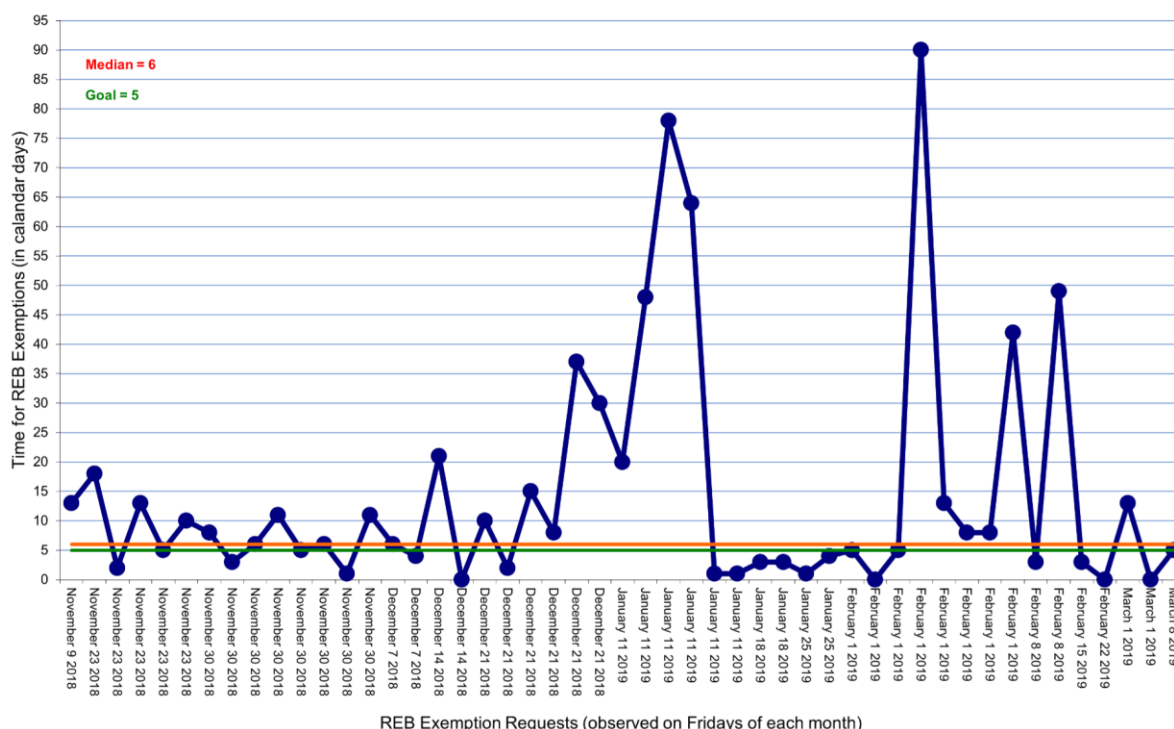
Data collected prior to this project's initiation revealed that 117 exemption letters were issued by the REB between January 2016 and October 2018 (an average of 3.4 per month, with a range of 0 to 11 per month; see Figure 1). We anticipated that the number of requests for REB research exemption letters would increase as our consultations proceeded. A spike in exemption letters was noted in November 2018 (n=14) and January 2019 (n=18). The time between request and exemption letter between November 2018 and March 2019 is represented in a run chart (Figure 2). The median was six calendar days with two astronomical points (these are significantly increased data points compared to the other data). We cannot be sure why this occurred, but suspect the longer turnaround time was due to delays in categorizing projects where it was unclear whether they were more appropriately classified as QI or research. These projects may have required additional discussion or information in order to come to a determination.

**Figure 1. Number of Exemption Waiver Letters Approved by Month**



The above graph shows the number of QI exemption waiver letters issued by the REB from January 2016 to the beginning of March 2019. The X axis represents the number of waiver letters. The Y axis represents the month/year. The red box shows the months the QI Review Process Project was in effect.

Figure 2. UHN REB QI Exemption Run Chart: Time for REB Exemption vs. REB Requests



## Themes from Consultations

### Theme 1: Clearly Defined Processes

Stakeholders expressed a desire for greater organizational clarity around the institutional structures and processes that could support QI work. They made requests for education, navigational support, and a defined approval process with transparent policies and accountabilities. Respondents commonly expressed confusion about whose approval (both departmentally or organizationally) was needed to initiate projects. Consultations also captured discussions with neighbouring academic hospitals to learn about their approaches to the review and approval of QI projects. We liaised with a neighboring institution which has had a QI review process in place for over a decade. We were struck by the framing of their QI review process as an oversight function as well as an educational and consultative service (4). Given our stakeholders' requests, we noted that the addition of an optional education and consultation service could help to prompt reflection and guidance on ethical considerations at the earliest stages of project conception and development.

### Theme 2: Appropriate Governance Structures

Discussions with stakeholders uncovered a worrying outcome of efforts to enforce research/non-research boundaries. While an REB exemption letter did not provide any assurances about the quality of a project or a warrant of its ethical disposition, we discovered that project leads, potential QI project participants, publishers, conference organizers, and others were interpreting exemption letters as evidence that initiatives had obtained de facto institutional seals of approval. On the other hand, REB staff were insistent that it was not within the REB's mandate to provide a comprehensive ethical review of non-research related activities. Our stakeholders expressed confusion and concern when they learned an REB exemption letter did not imply that a project had received an ethical review. They also relayed the significance that the REB exemption letter held for them when it came to disseminating their academic work. Journals and conference organizers expected them to provide evidence of REB approval or its equivalent. Without an organizational home for the independent review of quality improvement projects taking place across our network, project leaders were left to rely on existing processes that were ill-suited to their needs.

### Theme 3: Risk Identification

At the time of our evaluation, the Terms of Reference of the UHN Quality of Care Committee (16) defined risk as "the exposure to any event which may jeopardize the health, safety, or property of patients, visitors or staff; or the property or reputation of the facility." Various perceptions of the risks associated with QI projects emerged from the consultations. Some stakeholders expressed worries about their personal or professional liability whilst accessing personal health information for their projects. Others identified risks associated with patients' physical safety. Yet others wanted reassurance that they were not violating any institutional conflict-of-interest provisions and appreciated an opportunity to have an independent review of their projects. Common concerns were that the QI intervention might not fall within the current standard of care or would threaten QI project participants' emotional or psychological safety (for example, via surveys or interviews that explored phenomena that were sensitive in nature or that touched on the needs of vulnerably-situated or equity-deserving populations). Concerns arose related



to the reputation of the institution or with respect to its relationship to the communities it serves. These include circumstances where participation in multi-site projects might lead to release of sensitive information or unknowing breaches of legal or regulatory standards (e.g., violations of the Quality of Care Information Protection Act (17)). Additional areas of concern included worries about a failure to demonstrate good stewardship of financial or other resources (e.g., via unjustified duplication or overlap of projects), value-based conflicts (e.g., such as the tension between a patient's right to privacy and a professional's duty to improve care). Finally, there were concerns related to the lack of clear organizationally-defined QI review structures.

#### ***Theme 4: An Ethical Imperative to Conduct QI***

Although QI work is not without risk, our stakeholders frequently reminded us that reluctance or unwillingness to systematically improve care may be viewed through a risk lens as well. Several of our stakeholders described barriers to QI work as having direct consequences for patient health and safety, and they suggested that a failure to engage in improvement initiatives can negatively affect staff morale and satisfaction, and contribute to burnout and moral injury. Healthcare professionals have well-established duties of beneficence, to show respect for persons, and to steward resources well. Stakeholders spoke of feeling overburdened by change and bemoaned the loss of momentum and waste which resulted when redundant projects were being conducted across the organization or when change efforts were not sustained. These findings brought to light some of the risks associated with an ill-defined QI oversight and review pathway.

#### ***Theme 5: Strategies for Risk Mitigation***

Strategies for risk mitigation emerged during the consultation process. These included suggestions relating to project conceptualization, data collection, and screening for risk. With respect to project conceptualization, key strategies included consulting with necessary departments at early project stages (e.g., Privacy, Patient Education, Decision Support); ensuring that measures used are appropriate for the aim and population; considering the feasibility of taking on specific QI-related roles (by considering the project's scope and the resources needed to bring it to completion); and conceptualizing multiple evidence-based interventions at an early project stage. With respect to data collection, recommended strategies included seeking early consultation from our organization's Privacy Office (especially if the project is multi-site and data will be shared externally); reflecting on questions in surveys that could pose psychological or emotional harm to QI project participants; understanding legislation related to responsibilities that accompany access to patients' charts and participant data; avoiding the collection of individual-level data unless absolutely necessary and reporting only aggregate level data; mitigating power relationships whenever possible (e.g., by ensuring de-identification or anonymity); and by obtaining informed consent for surveys, focus groups, and interviews. In terms of screening for risk, suggested strategies included highlighting the fact that while eliminating all risk is not generally possible, an awareness of risks and mitigation of risks remains essential. It was noted that risk mitigation could include identifying when an experienced mentor or third party might be needed to provide direction and oversight, and avoiding terminology that induces project participants to infer that a project is research rather than QI. (Terms like 'study', 'hypothesis' and 'Principal Investigator' suggest that an activity is research and, therefore, subject to the rigorous review and oversight of an institutional research protection program.)

## **DISCUSSION**

In general, we found that our stakeholders would benefit from a clearly defined process that would include ethical review of QI projects, an appropriate governance structure, a proportional approach to project review, and identified strategies for risk mitigation. As we noted earlier, under existing TCPS2 guidelines, quality improvement falls outside the purview of REBs (18, art. 2.5). This has had the unfortunate consequence of reinforcing an artificial – and sometimes untenable – distinction between research and QI, and has made it common for knowledge-generation projects that fall outside of REB jurisdiction to elide any form of mandatory or systematic ethical review.

### **Constructing the QIRC**

Our initial recommendation for ethical oversight of QI at our organization was to build the review process outside of the existing quality structures in order to be at arm's length from those championing quality improvement projects as part of the Quality and Safety leadership team. In order to avoid dual roles, and challenges related to potential conflicts of interest, the QIRC reported through the Department of Clinical and Organization Ethics to our Executive Vice President of Education and Chief Medical Officer until very recently, when it moved into the Quality and Safety portfolio once an additional leadership role was filled and processes to manage conflicting interests and duties were more fully developed. A committee model was chosen for the QIRC to leverage expertise from individuals with clinical, ethical, quality improvement, and methodological expertise. The QIRC itself is a very lean team; its membership includes a dedicated chair and vice-chair, the medical director of quality, the senior director of clinical and organizational ethics, the director of quality and safety, two 0.5 FTE staff members, and a pool of ad hoc experts with content expertise related to the departments or programs in which the projects take place. The REB exemption volumes we tracked prior to the QIRC's formation (see Figure 1 and 2) helped to support our workforce planning, although we had to adjust our time-to-review estimates to account for the fact that the REB exemption process did not include an ethics review component.

Our consultation stakeholders expressed a strong desire for an approval document that journal editors and conference organizers would recognize as evidence that they had secured formal institutional authorization to undertake their projects. Furthermore, conversations between the REB Office and the QIRC revealed that determining whether a particular knowledge-generating project should be categorized as research or a quality improvement project is not always straightforward (7). This

led us to conclude that a close, collaborative, partnership between the REB and the QI oversight body must be built into our process. To ensure that this would be the case, our first QIRC Chair is someone who also has an REB Chair appointment and membership on the Research Executive Committee. Because ethics review is only one step in obtaining institutional authorization for conducting research or QI activities at our institution, further triage to additional departments (such as Privacy, Legal Affairs, or Digital Security) has also been integrated into our process.

Risk identification, mitigation, and triage to appropriate individuals or departments with expertise relevant to ensuring the quality and ethicality of QI initiatives are important components of our review process. However, it is a proportionate approach to the review of QI projects that allows for the duration and intensity of a review to be matched to the level of risk identified. This concept is not unlike the use of risk-based matrices in research ethics review which help reviewers to distinguish studies suitable for delegated as opposed to full board reviews. Ethical review of QI, which at its heart is about enabling improvements in clinical care, must be nimble and responsive to the clinical context. Furthermore, a dynamic review process such as the QIRC's can offer independent and personalized risk mitigation strategies that are specific to the project and sensitive to local needs, resources, strengths, and vulnerabilities.

## CONCLUSION

Since our Quality Improvement Review Committee was established in 2020, over 840 projects have been reviewed, thereby mitigating risks for patients, staff, and QI project teams across our organization. The QIRC also has established a searchable UHN QI Project Repository that reduces the prospect of redundant or needlessly duplicative efforts, and fosters connections and collaborations across the enterprise. Practical resources have been created as well, including an Introductory Consent Script Template (19) that offers guidance for consent language for surveys and focus groups, and model interview guides for use with staff or patients.

Although the QIRC has been well received, and we believe that we have accomplished a great deal in a short time with limited resources, we see significant opportunities for further development. Our next steps will include increasing the QIRC's organizational visibility and solidifying partnerships with key departments within our organization (including Legal Affairs, Privacy, and Data Governance) to enable the QIRC to move to a digitally-supported submission system. We are also hopeful that we will be able to add some additional staff to our modest team to ensure that our QIRC remains responsive and efficient. Future work will focus on evaluating the impact of the QIRC as it matures within our organization. It is our hope that by sharing these newly established structures, and the pressing needs and ethical considerations that underpin them, we will encourage other institutions to develop their own processes for the systematic ethical review of quality improvement work.

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### Conflits d'intérêts

Aucun à déclarer

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### Conflicts of Interest

None to declare

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