Innovations in the Ethical Review of Health-Related Quality Improvement and Research: The Alberta Research Ethics Community Consensus Initiative (ARECCI)

La Alberta Research Ethics Community Consensus Initiative (ARECCI) : des innovations dans l'examen déontologique de l'amélioration de la qualité et de la recherche dans le domaine de la santé

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Abstract

The Alberta Research Ethics Community Consensus Initiative (ARECCI) is a unique Canadian initiative that addresses the ethical oversight of two main categories of health-related investigative projects: research and quality improvement (including quality assurance and program evaluation). ARECCI was formed as a result of discussions arising from health regions, health researchers and the Alberta Committee of Research Ethics Boards (REBs) Chairs, who all desired a clearer and more consistent approach to the ethical oversight of investigative health projects. The Alberta Heritage Foundation for Medical Research (AHFMR) established and supported ARECCI in 2003 in response to this need. ARECCI is unique in its ongoing efforts to bring together a wide-ranging group of stakeholders to develop consensus on a set of pragmatic recommendations and tools for the ethical review of research and quality improvement, and to get extensive consultation on those recommendations. This paper presents the ARECCI context and process, recommendations and tools produced by ARECCI and lessons learned from the ongoing ARECCI process.

Résumé

La *Alberta Research Ethics Community Consensus Initiative* (ARECCI) est une initiative canadienne unique qui aborde le suivi déontologique de deux grandes catégories de projets de recherche dans le domaine de la santé : la recherche et l'amélioration de la qualité (y compris l'assurance de la qualité et l'évaluation de programme). L' ARECCI a été créée à la suite de discussions tenues dans les régions sanitaires et parmi les chercheurs en santé et les présidents de l'*Alberta Committee of Research Ethics Boards* (REBs), qui souhaitaient tous voir une approche plus claire et plus uniforme dans le suivi déontologique des projets de recherche dans le domaine de la santé. En 2003, la *Alberta Heritage Foundation for Medical Research* (AHFMR) a établi et appuyé

l'ARECCI en réponse à ce besoin. L'ARECCI est unique dans les efforts soutenus qu'elle déploie pour réunir un large éventail d'intervenants en vue de parvenir à un consensus relativement à un ensemble de recommandations et d'outils pragmatiques pour assurer un examen déontologique de la recherche et de l'amélioration de la qualité, et de tenir des consultations poussées au sujet de ces recommandations. Cet article présente le contexte de l'ARECCI et le processus connexe, les recommandations et les outils découlant de cette initiative et quelques importantes leçons apprises en cours de route.

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Quality improvement (QI) activities in healthcare settings are commonplace throughout Canada and the rest of the world, and are employed to improve the process, outcomes and efficiency of healthcare services (Casarett et al. 2002; Murphy et al. 1998; Reinhardt and Ray 2003). While no single definition for QI exists, QI projects are generally defined as those that collect data in ongoing cycles of monitoring, evaluation and action. The importance of QI projects is widely recognized, and they are instrumental in helping to make healthcare better, safer, more cost-effective and more productive (Casarett et al. 2000; National Health Medical Research Council 2003; Reinhardt and Ray 2003). QI, sometimes also called continuous quality improvement, shares many characteristics with the processes of quality assurance (QA) and program evaluation (PE) (Casarett et al. 2000). Therefore, for the purposes of simplicity and brevity, the terms quality improvement, quality assurance and program evaluation are grouped together in this paper under the umbrella term "quality and evaluation" projects (Q/E). We make this simplification, however, with the recognition that there are subtle but important distinctions between QI, QA and PE, and some have suggested that these different activities should receive distinctive ethical treatment (Thurston et al. 2003).

There is increasing recognition that as the number, scope and sophistication of Q/E projects increase, they are becoming progressively more difficult to distinguish from traditional research projects (Casarett et al. 2000; Doezema and Hauswald 2002; Nerenz et al. 2003; Reinhardt and Ray 2003; Wade 2005). This blurring of the boundaries between Q/E and research is important for several reasons. To begin with, while all health-related research projects require ethical review by research ethics boards (REBs), no such requirements exist for ethical review of Q/E initiatives in Canada or most other countries (CIHR 2005; Casarett et al. 2002; Horsfall and Cleary 2002; Layer 2003; National Health and Medical Research Council 2003). There is also a growing realization that Q/E initiatives can impose additional risks and burdens to healthcare clients, such as potential loss of autonomy and confidentiality (Anderson 1996; Bellin and Dubler 2001; Casarett et al. 2002; Horsfall and Cleary 2002; Nerenz et al. 2003). Furthermore, the lack of clear distinctions between

Q/E and research – combined with the general lack of any requirements for the ethical review of Q/E – may lead some researchers, consciously or unconsciously, to "package" their particular research project as a Q/E project to avoid the normal ethical review process required of research, which many perceive as bureaucratic, time-consuming and cumbersome (Casarett et al. 2000, 2002).

Therefore, although the current Canadian Tri-Council Policy Statement defines research as "… a systematic investigation (involving human research subjects) to establish facts, principles or generalizable knowledge" (CIHR 2005: article 1.1), and clearly states that QI does not need ethical review and approval by an REB, there is growing recognition that Q/E cannot always be easily distinguished from research, and that many Q/E initiatives may require some kind of ethical review. However, there are currently no clear guidelines in Canada for situations in which ethical review of Q/E might be warranted, or the kinds of processes that might be appropriate for such ethical review.

Animal, Vegetable or Mineral? Suggestions for Distinguishing Projects

One of the debates at the core of this issue is how to distinguish clearly between research and Q/E for the purpose of deciding whether a particular project needs ethical review. Unfortunately, such clear distinctions have remained elusive (Casarett et al. 2000; Layer 2003), although a number of authors have proposed various criteria. Reinhardt and Ray (2003), in their review of the literature, have noted that many authors propose that the purpose or focus of the study is an important distinguishing criterion for ethical review. Nerenz et al. (2003) have also stated that purpose or intent should be the main determining criterion, and have offered several "test questions" to clarify the intent of those conducting a particular project and the need for ethical review. As Casarett et al. (2002) have noted, however, assessing the intent of those conducting a given Q/E project can often be difficult, as many such projects may have more than one purpose, and the purpose(s) of some Q/E projects can change over time.

Given these inherent difficulties, other models for determining the need for ethical review of Q/E projects have been proposed. Casarett et al. (2000) have suggested alternative criteria based primarily on whether patients are expected to benefit directly from the information gathered by the project – arguing that if not, it is most likely research and probably needs to be reviewed. Alternatively, Lo and Groman (2003) advocate that the level of risk a particular project poses should determine the extent to which that project receives ethical review. Nerenz et al. (2003) have also proposed that level of risk is an important determinant of the appropriate level of review, but that the particular intervention, the intended audience for the findings and the data source(s) also need to be equally considered. The National Health and Medical Research Council of Australia (2003) has suggested criteria of even broader

scope, and has offered at least nine questions that need to be asked in determining whether a project needs ethical review. Given the myriad of suggested criteria to distinguish between research and Q/E, it is not surprising that the US Veteran's Health Administration has stated that "… QI cannot always be meaningfully differentiated from other activities … notably treatment and research" (Casarett et al. 2002: 45), and has instead provided some general recommendations for the ethical conduct of QI (Casarett et al. 2002; Layer 2003).

Concerns and Cautions

While there is growing consensus that Q/E projects may require some type of ethical review, there is obviously much less consensus on how to determine when Q/E requires the level of review that research currently receives. There are also significant concerns over the possible implications of ethical review of Q/E. First and foremost, the REB ethical review process is seen by many as potentially complex, time-consuming and idiosyncratic (Ahmed and Nicholson 1996; Alberti 2000; Dal-Re et al. 1999; Jamrozik 2004; Jamrozik and Kolybaba 1999; Oliver 2006; Redshaw et al. 1996), and many fear that subjecting Q/E to REB review would overwhelm the already taxed REB process (Layer 2003; Nerenz et al. 2003). Even if REBs had unlimited resources to review Q/E projects, REB membership generally does not include expertise on Q/E methodology, purposes and outcomes. A closely related worry is that any kind of REB-like process might create a perceived barrier to the conduct of Q/E projects (Cretin et al. 2000; Lo and Groman 2003; Lynn 2004).

Ethical Review of Quality and Evaluation Projects: If Yes, How and By Whom?

Determining whether or not quality and evaluation projects require ethical review is only the first piece of the puzzle. Equally important is ensuring that if and when Q/E projects are subject to some kind of ethical review, the review process is more expedient than that offered by many research ethics committees, which can typically take months to conduct a review (Ahmed and Nicholson 1996; Dal-Re et al. 1999). Thus, several authors have proposed that the majority of REBs, in their typical configuration, may well have difficulty providing an appropriate review process that meets the unique needs of Q/E projects (Layer 2003; Nerenz et al. 2003), although Thurston et al. (2003) have recommended that some PE projects could be sent for REB approval.

As opposed to having REBs review Q/E projects, it has been recommended that healthcare organizations should proactively seek ethical conduct of Q/E projects (Casarett et al. 2002; Thurston et al. 2003) by establishing a review process of their own. This ethical review process could take several forms, such as a pre-existing QI or ethics committee (not an REB), or a group especially convened for this purpose

(Casarett et al. 2002; Lo and Groman 2003; National Health and Medical Research Council 2003). As opposed to rigidly assigning a "one-size-fits-all" legislative approach to these QI review groups – as has been the case with REBs – Casarett et al. (2002) have argued that the QI ethical review process should be governed by general guidelines, and that approaches may have to be tailored to address local needs. There is also some debate about whether the ethical review process of Q/E needs to be kept independent of the person(s) actually conducting the Q/E project (Lo and Groman 2003).

Establishment and Purpose of ARECCI

In response to growing recognition of the aforementioned issues, the Alberta Research Ethics Community Consensus Initiative (ARECCI) was established and supported by the Alberta Heritage Foundation for Medical Research (AHFMR) in 2003. This initiative brought together representatives from numerous stakeholders with the purpose of establishing a consensus about the types of investigative health projects (involving persons) that require ethical review, as well as the appropriate process for the ethical review of various types of projects.

The initial group consisted of representation from the six major REBs in the province of Alberta (designated under the *Alberta Health Information Act*), representatives of the Regional Health Authorities (Alberta has been divided into nine health regions governed by independent health boards), the government ministry Alberta Health and Wellness and AHFMR, with additional expertise added as required. All ARECCI decisions were made by consensus.

Goals of ARECCI

As the working group's discussions began and a literature search on the ethical review of QI was conducted, it became clear that Q/E projects involving ethical issues appeared to be "falling through the cracks," or receiving review from REBs on an ad hoc basis. Therefore, the following primary goals of ARECCI were identified:

- to develop a common understanding and broad consensus on issues of ethics review
- to increase the clarity, consistency, transparency and efficiency of ethics review processes in Alberta
- to develop recommendations on an approach to answer the following questions:
  - What kind of investigation or project is it?
  - What process of ethics review should be used for each kind of project?
  - What level of review is appropriate for different kinds of projects?

- to develop guidelines and tools for Alberta's health researchers, managers, ethics boards and other stakeholders to implement the ARECCI recommendations
- ultimately, to influence regional, provincial and federal policy related to ethics review processes.

A phased approach to ARECCI

As the work of ARECCI progressed, it became apparent that the enterprise the group had embarked upon was a longer-term undertaking. The initiative has thus come to be characterized to date by at least two phases, with the main activities and accomplishments of each phase highlighted below.

PHASE I: DEVELOPMENT OF ASSUMPTIONS AND GUIDELINES

This phase occurred from approximately January 2003 to November 2004. A year of in-depth work by the entire group and four subgroups resulted in a set of underlying assumptions, recommendations for determining the appropriate process and level of ethical review for a variety of projects and some practical tools to support the implementation of the recommendations. The subgroups developed screening tools to determine the kind of project, a series of risk filters to determine the level of risk and case studies to illustrate the application of these guides. Publication guidelines and capacity building needs within health authorities were also defined.

In the early summer of 2004, the ARECCI draft principles and recommendations were presented at three stakeholder consultation meetings for feedback. The first stakeholder consultation was with the provincial committee of REB chairs from all six designated REBs in Alberta. The second consultation was provincial in scope, and involved comprehensive representation from administrators and practitioners from the nine health authorities throughout urban and rural Alberta, as well as representatives from the continuing care sector, Alberta Health and Wellness, the Alberta Mental Health Board and the Alberta Cancer Board. Finally, the third consultation was designed to engage expertise from outside Alberta and from a range of perspectives. This consultation included representatives from major Canadian health research funding agencies, Health Canada, the Canadian College of Health Service Executives, the National Quality Council and bio-ethicists from Canada, the United States and Australia. All stakeholder groups were generally very positive about the draft ARECCI documents, although many helpful clarifications and revisions to the documents were recommended. In addition, there was strong support for pilot testing of the recommendations and tools in selected health regions and REBs. Based on the input received from both these consultation processes, the initial recommendations

and tools were revised into a second version, and ARECCI began to make plans for piloting these recommendations and tools.

PHASE II: PILOTING THE RECOMMENDATIONS AND TOOLS

This phase occurred from approximately January 2005 to November 2005. During this phase, the ARECCI recommendations and tools were piloted in seven provincial health regions, three Alberta REBs and two out-of-province REBs. The purpose of the pilot projects was to assess the feasibility of the ARECCI recommendations and tools in practice. Based upon the feedback received during the pilot projects, the ARECCI recommendations and tools were revised into their final version (see ARECCI Recommendations and Tools, below). Overall, the results from the pilots were quite positive, and many valuable lessons were learned. Because the pilot projects were incorporated into a larger research project, the detailed methods and results of the pilot projects will be presented separately in a forthcoming paper.

ARECCI recommendations and tools

ARECCI ASSUMPTIONS

In developing the recommendations and tools, the ARECCI working group strove for an appropriate balance between protecting people in healthcare settings and avoiding an increased burden to healthcare organizations, which might arise with an expanded scope of ethics review. The following three assumptions underlie the ARECCI recommendations and tools:

- If an investigation or project is determined to require ethics review, it should be reviewed using an appropriate process of ethics review, by a body having appropriate jurisdiction and capacity (e.g., REB or structures within a health region or organization).
- Although REBs currently provide the highest level of ethics review across the province, there is no reason, in principle, that a similarly high level of ethics review should not be developed and provided by other processes for investigations or projects that are deemed to be Q/E for purposes of ethics review.
- Each individual institution will comply with applicable legislation, regulations and policy (e.g., Tri-Council Policy Statement, *Alberta Health Information Act*, etc.).
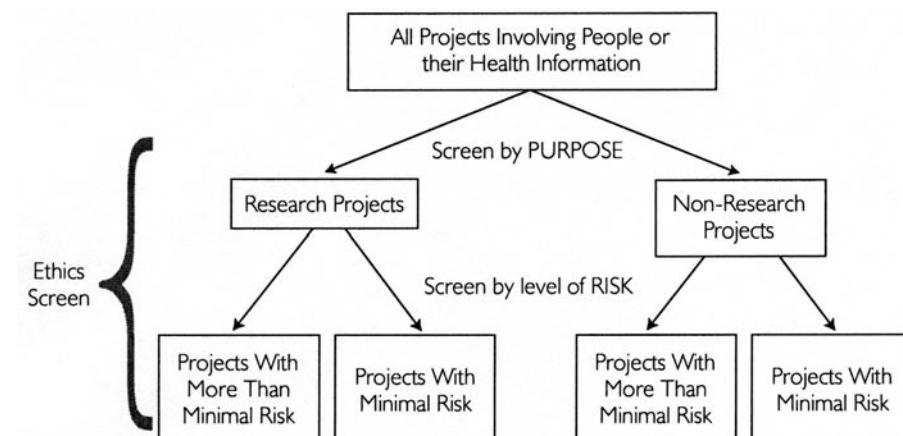
ARECCI RECOMMENDATIONS

The ARECCI working group arrived at five final recommendations regarding the ethical review of investigative health projects. In turn, some of the recommendations were accompanied by "tools" designed to help implement them. The recommendations are as follows:

1. *Screen all projects to determine whether ethics review is needed:* All projects that involve people or their health information would benefit from ethics screening to determine whether they need ethics review, and if so, what kind and level of ethics review.
2. *For the purposes of screening, first screen projects according to purpose:* For the purposes of the ethical review of projects involving people or their health information, it is helpful to distinguish projects by their primary purpose. If the purpose is to contribute to the growing body of knowledge regarding health and/or health systems that is generally accessible through standard search procedures of academic literature, then the investigation is best classified as research. If the project is something other than this, then the project is best classified as non-research (Q/E).
3. *After screening by purpose, subsequently screen projects according to level of risk:* For each project (research or otherwise) determined by ethics screening to require review, the determination of whether it should be subject to full or expedited ethics review should be based on the degree of risk to all those involved – including, without limitation, risk to the privacy or to the physical, mental, psychological, emotional or spiritual health of individuals or communities.
4. *Build capacity and build on existing practices:* Capacities and resources for ethics screening and review of non-research projects should be developed throughout the province. Ethics screening and review processes should build on existing organizational structures for the design, implementation and evaluation of these types of initiatives.
5. *Progressive implementation:* These recommendations should be implemented in all organizations engaged in knowledge building projects involving people or their health information, and should be accompanied by evaluation and improvement initiatives at all levels of the system.

Figure 1 provides an overview of recommendations 2 and 3, which state that projects be screened first by purpose and then by level of risk. Three single-page tools were developed to assist with the application of these two recommendations. To assist with the implementation of recommendation 2 (screening by purpose), a "Project Primary Purpose Checklist" was developed, which guides users (persons identified

by health organizations as having experience and expertise in research and/or Q/E) through a series of questions to help determine whether a particular project is most like research or most like Q/E. After users determine what kind of project they are reviewing, they then employ one of two "risk filters" (one for research, one for Q/E) to determine the level of risk and therefore the level of ethical review that may be appropriate for the project.

FIGURE 1. Ethics screening of health projects: screening by purpose and risk

These three ethical screening tools, in addition to more information on the recommendations and further documents pertaining to the ARECCI project, may be obtained for download at the ARECCI website at <http://www.ahfmr.ab.ca/arecci>, or by contacting the first author.

Conclusions

The ARECCI initiative represents a unique opportunity in Canada to assemble a wide variety of stakeholders to develop consensus on some pragmatic recommendations and tools for the ethical consideration of investigative health projects. In retrospect, the process of reaching consensus on the recommended approach has been a long and complicated one, and several of the recommendations may be seen as controversial. In general, however, we believe that this initiative has developed some important recommendations with strong potential to reduce some of the confusion and ambiguity surrounding the ethical review of various health-related investigative projects. In particular, we feel that the ARECCI recommendations and tools offer

both REBs and health organizations an important means by which to increase clarity, consistency and transparency in decisions regarding the kinds of projects that exist, whether such projects need an ethical review, where such review should occur and how to determine the relative risk of both research and Q/E projects. In addition, the complete ARECCI recommendations (available on the ARECCI website) have opened the door for discussion on the kinds of processes that might be appropriate for the ethical review of Q/E. Meanwhile, the ARECCI pilot projects have begun to provide valuable information about the ethical review processes that work best for a variety of healthcare and REB settings.

While we feel that ARECCI has been a considerable success, work remains to be done. For example, a third phase of collaboration is beginning, in which the stakeholders are focusing on dissemination of the current ARECCI recommendations and tools, refining the interpretation of the pilot project results and planning how to increase capacity throughout the system – both within healthcare organizations for ethics screening and review of Q/E projects, and also among REBs for increased consistency of decision-making on these issues. In addition, there is intent to continue the momentum gained with initial uptake of the ARECCI processes by supporting further implementation of the recommendations and tools. The focus of this work will be on exploring and evaluating how the ethical review of Q/E projects can be completed by healthcare organizations in a thorough and systematic manner, through fully accountable processes that are also flexible and that do not discourage the conduct of Q/E projects.

The ARECCI project focused primarily on decisions about the kinds of projects that require review, and in particular the appropriate avenue for ethically reviewing Q/E projects; less work was done on the actual processes of ethical review, including review of formal research projects. Although the REB review process is well established in Alberta, numerous stakeholders throughout the ARECCI process raised concerns about the transparency, efficiency, timeliness and consistency of the REB review procedures, as well as problems raised by multiple and inconsistent reviews – concerns that have been raised elsewhere in the literature (Ahmed and Nicholson 1996; Alberti 2000; Redshaw et al. 1996).

While there was clear consensus among the stakeholders in the ARECCI process that both risky research and Q/E projects should receive ethical review; however, there was no significant work done on how Q/E projects should be reviewed, the criteria that should be used and the process for review. Indeed, one of the main tasks of the next phase of ARECCI will be to work with health regions to develop the best model for health regions to review their Q/E projects with an eye to ethical considerations. At this point, however, there was widespread agreement among stakeholders (particularly among those in the health regions) that the REB model – which was described

by many participants as time-consuming, ponderous, bureaucratic and idiosyncratic – was not an appropriate model for conducting ethical review of projects other than formal research studies.

So, while the ARECCI recommendations regarding what gets reviewed, and at what level of scrutiny, should bring some measure of transparency and consistency to these particular aspects of ethics review, further work clearly needs to be done downstream, with respect to the internal workings of the ethical review processes themselves. An important focus of ARECCI phase III, therefore, will be to explore ways in which the ethical review of all projects can be achieved in ways that are transparent and consistent, as well as systematic, thorough, flexible and timely. This work will need to address concerns from both the REB and alternative ethical review perspectives as they develop and mature through regions and organizations.

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