Ethical issues in using data from quality management programs

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Abstract Since the advent of formal, data-driven quality improvement programs in health care in the late 1980s and early 1990s, there have been questions raised about requirements for ethical committee review of quality improvement activities. A form of consensus emerged through a series of articles published between 1996 and 2007, but there is still significant variation among ethics review committees and individual project leaders in applying broad policies on requirements for committee review and/or written informed consent by participants. Recent developments in quality management, particularly the creation and use of multi-site disease registries, have raised new questions about requirements for review and consent, since the activities often have simultaneous research and quality improvement goals. This article discusses ways in which policies designed for local quality improvement projects and data bases may be adapted to apply to multi-site registries and research projects related to them.

Keywords Ethics · Spine surgery · Quality management

Most current policies about ethics committee review and written informed consent by research subjects can be traced to the Declaration of Helsinki [1] and the Belmont Report [2]. These two landmark statements laid the foundation for a set of policies in both Europe and the United States that require ethics committee review for virtually all research activities involving human subjects, and written informed

consent from research subjects except for a defined set of minimal-risk types of research. For purposes of these policies and associated regulations, research was defined as: “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” [3].

In the 1980s, the publication of seminal research articles on small-area variations in medical practice, the high prevalence of medical errors in hospital settings, and the absence of solid scientific evidence for most medical practices challenged the traditional ways in which medicine was taught, practiced, and evaluated. New initiatives under names like “outcomes research” [4], “evidence-based medicine” [5], and “comparative effectiveness research” [6] began to reshape the field of both medicine and surgery. Among the new initiatives taken up at that time was the application of formal quality measurement and quality improvement concepts from manufacturing industries to health care. These programs, usually called either “Continuous Quality Improvement” [7] or “total quality management”, emphasized the careful analysis of work processes by those most directly involved in those processes on a daily basis. The careful analysis, in turn, involved formal collection and analysis of data on key process and outcome characteristics in order to identify statistical associations between either process and outcome variables or between changes in processes and subsequent changes in either process or outcome variables.

Because these activities had the surface appearance of research, and could occasionally be published in peer-reviewed journals [8, 9], ethics committees charged with reviewing research began to question whether they also had responsibility to review and approve quality improvement activities, and journal editors began to question whether reports of such activities, when submitted for publication,

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should include attestations about ethics committee review and approval [10]. These questions were not frequent or problematic as long as quality improvement projects were purely local initiatives carried out by doctors, nurses, and managers who did not generally write articles for publication, but became both frequent and problematic when academic physicians became involved in quality improvement and wished to publish results of that work in order to meet requirements for academic advancement. The fundamental conceptual question was whether, or when, quality improvement activities were research and, therefore, subject to policies about ethics committee review and informed consent.

Donald Berwick [11], in his 1996 article entitled “Harvesting Knowledge from Improvement” pointed out that useful information about medical care can be obtained from activities that are not research, but rather are quality improvement projects whose goal is measurable improvement in a process or outcome of care in one or more specific, local environments. In making this observation, he drew a distinction between research activities whose primary aim is the creation of generalizable knowledge, and quality improvement activities whose primary aim is something else.

Other authors addressed this question and drew different conclusions about the applicability of policies governing research to quality improvement. Some authors emphasized the intent or actual fact of publication in peer-reviewed journals as the major defining characteristic of research, so that any quality improvement activity that included either the intent to publish or the actual fact of publication at some later point should be subject to ethics committee review and perhaps requirements for written informed consent by participants [12]. Others emphasized the concepts of risk or novelty, arguing that any quality improvement activity involving some change in clinical practice that would involve some element of risk for patients under care should be classified as research and, therefore, be subject to policies governing research [13–15]. A common theme in many of these arguments was the idea that almost any form of knowledge is at least potentially generalizable, and that a definition of research primarily based on the presence or absence of the intent to create generalizable knowledge was “subjective” and impossible to enforce in practice [16].

Still other authors argued against this view, pointing out that the intent to create generalizable knowledge was the essence of the definition of research upon which the entire body of applicable policies and regulations had been based, and that it would be possible to distinguish research activities from quality improvement activities based on checklists or algorithms that could clarify primary purpose or intent in situations where that intent was not obvious

[17]. These authors concluded that most local quality improvement initiatives were not research, and not subject to regulations governing research. They did point out, although, that other forms of protection might be required for quality improvement projects involving some element of risk to patients whose care might be affected by those projects [18]. The idea of distinguishing research from quality improvement and the use of checklists to distinguish in “gray area” situations has been successfully applied in some jurisdictions [19].

Nearly 10 years after Dr. Berwick’s “Harvesting Knowledge” article, a series of articles in *Quality and Safety in Health Care* expanded on this idea by discussing a proposed set of guidelines for reporting the results of quality improvement projects in peer-reviewed journals [20–22]. The key underlying presumption of these proposed guidelines was that there is a fundamental difference between research and quality improvement activities, but that both types of activities can produce useful information and may be worthy of publication in peer-reviewed journals. This fundamental difference, articulated again by Berwick in his article in this series [23], is the distinction between activities designed to produce universal, generalizable knowledge (research), and activities designed to produce local knowledge and local quality improvement. This latter activity, which has also been called “pragmatic science” [24], relies on rich knowledge of local circumstances and careful tracking of data over time to identify the cause and effect relationships in those local environments that yield improvements in key dimensions of quality of care. Those cause and effect relationships and their impacts on quality may or may not be found in other settings; knowledge gained in this type of activity is not inherently generalizable, although it may be, depending on similarities between the circumstances in which the initial project was done and other circumstances in which similar effects might be desired.

Lynn et al. [25] published what might be considered a “consensus statement” on this issue in 2007, bringing together many of the authors who had previously published on the topic along with representatives of many national organizations in the US involved in either funding or conducting clinical research. The authors started by identifying quality improvement as an essential, ongoing part of regular health-care operations, focused on improving one or more aspects of care in specific, local settings. By this definition, most quality improvement is not research as defined by the Common Rule in the US. It is, therefore, not subject to requirements for ethics committee review and written informed consent by patients, although it may be subject to other forms of independent oversight and approval. They went on to point out that any activity that combines both research and quality improvement is

research and, therefore, subject to research regulation. To help clarify the distinction between types of activity, they proposed a revised definition of research: “activities that are designed to increase enduring knowledge about the nature and function of human beings and their environment.” Finally, they argued that activities with both quality improvement and research aims be treated as research for purposes of decisions about ethics review and consent.

This article might be viewed as having settled the issue of ethics committee review and consent issues for research versus quality improvement, at least in the US, so far as any issue with much ambiguity can be settled. However, the relative settling of issues as embodied by the Lynn article appears to be not the final word. Johnson et al. present results from a study of the criteria used by a sample of US IRBs to distinguish between research and quality improvement. They argue, on the basis of these results, that no clear consensus yet exists in practice on the criteria with which to distinguish research and quality improvement. Their results show a great deal of variation among IRBs in using specific criteria to distinguish research from QI, suggesting that a level of consensus in the published literature does not directly translate into similar consensus among IRBs actually responsible for overseeing research [26]. Similar variation among IRBs in approving procedures for a national registry of fatal asthma cases is described by Clark et al. [27].

The lack of practical consensus was also illustrated by a recent case in which a multi-hospital quality improvement project that involved grant-funded evaluation by a group of faculty researchers in another part of the United States was judged by the federal Office of Human Research Protections (OHRP) to have proceeded without adequate IRB review and approval, and without adequate opportunity for participants to have provided informed consent [28]. OHRP subsequently said that the hospitals could continue to use the QI intervention (a checklist for reducing infections in ICU settings) without IRB review since it had become “standard practice”, but the question of whether the university-based evaluation was research seems to have been left somewhat unsettled. Kass et al.’s description suggests that such activity is indeed research, albeit research that may be declared “minimal risk” and therefore exempt from requirements to obtain informed consent from participants. From the perspective of participating hospitals, the key question would seem to be whether they were engaged in the activity primarily, or even partially, to produce generalizable knowledge. If so, they were engaged in research and should have followed research regulation procedures. If, though, their intent was to produce local process improvement and were generating and analyzing data only for that purpose, then the activity (at the individual hospital level, not the university level) could have

been fairly characterized as quality improvement and not research. The simultaneous participation of multiple hospitals in a single protocol, and the involvement from the onset of the project of university-based researchers clearly carry the implication that a main goal of the project was the production of generalizable knowledge and that the activity, at both hospital and university levels, was research [17].

QI programs that involve data collection and analysis, but not process improvement

A number of quality management, quality reporting, or quality improvement programs are active that do not easily fit into the paradigms of either local quality improvement or research. They probably do fit the category of “overlap projects” described by Lynn et al., but they are different in some meaningful ways. These programs might be regional or national quality improvement programs, or regional or national disease registries organized by a variety of specialty groups. There are also data collection and analysis initiatives under labels of either “public reporting” [29] or “pay for performance” [30] that can involve individual-level patient data and can be used for both quality improvement and research purposes, in addition to their primary purpose of comparing performance among providers. The features of all these programs that make them difficult to classify include: multi-site data collection according to standard protocols (as opposed to purely local data collection designed and managed by local clinical teams); a combination of stated goals that include both quality improvement and research; and data analysis objectives (comparison of individual providers or hospitals) that are neither quality improvement per se nor the production of generalizable knowledge that is the hallmark of research.

The relatively clear distinction between research and local quality improvement, albeit hard-won, is not yet a clear guide to how to proceed in projects, like multi-site clinical registries, that have simultaneous research, quality improvement, and comparative performance objectives. The remainder of the paper will be devoted to analysis of the issues raised by these types of projects in spine surgery and back pain, and in medicine and surgery more generally, and how recent thinking about the distinction between quality improvement and research may serve as a guide to policies about these newer initiatives.

Terminology

The term “registry” is usually used to refer to an organized, structured data base that includes clinical and demographic

information on a specific group of patients [31]. Cancer registries were among the first patient registries to be established, but prominent clinical registries have been in place for many years for stroke, acute myocardial infarction, heart failure, fatal asthma, and low back pain, as well as for many other diseases or conditions. Many of the early registries were established with a public health purpose in mind; that is, the ability to accurately identify incident cases of an important disease and track incidence, prevalence, and outcomes of that disease over time.

Although a registry can be established as a purely local effort, most registries are larger in scope, involving multiple institutions within a single country or even across countries. The multi-institutional scope may be a reflection of a public health goal, or it may reflect the impetus for the project coming from a national specialty society, a large, multi-institutional health care system like the Veterans Administration in the US, a disease advocacy group, or a medical device or pharmaceutical company [32]. Multi-institutional scope may also be a reflection of one or more research aims for the registry, with the ability to produce generalizable knowledge being enhanced by a large sample of patients representative of both the larger universe of patients with a condition and the larger universe of institutions in which those patients receive care.

There is an important distinction between registry projects and quality improvement projects as discussed by previous authors addressing the quality improvement—research distinction. Even though the term “quality improvement” may legitimately be used to describe an aim or a benefit of a registry, the means by which registry activities produce quality improvement are different from those by which local quality improvement initiatives produce their effects. The distinction might be thought of as reflecting “indirect” versus “direct” effects, or perhaps “distal” versus “proximal” effects on care processes actually delivered to patients in local settings. There is also an important distinction in terms of the role played by a project data base. Table 1 summarizes some of these distinctions.

Ethical issues in multi-site registry projects

The challenging ethical issues involved in registry projects include the following:

- If the project has both research and quality improvement aims, is it necessary to determine which aims are primary in order to apply policies about review and consent, or does the presence of research objectives make the project research and not different in any way from purely research projects?

- If a registry project is treated as research because it has research aims, should there be any distinction made in the ethics committee review process between such a project and a traditional hypothesis-testing research project?
- Are there any distinctions that should be made between registry projects and traditional research projects in terms of requirements for written informed consent by participants? If a registry may support multiple research projects, many of which are not known at the time of the establishment of the registry, how can participants provide truly informed consent for research at the time of registry enrollment?
- Do the quality improvement or public health aims of a registry project supersede the research policies regarding informed consent, so that the requirements for written informed consent would not apply in some registry initiatives, even those with clear research aims?

In the United States, the recent passage of the Health Insurance Portability and Accountability Act (HIPAA), along with associated regulations about privacy protections for patients' health information, has created both additional complexity in creating policies about patient protections and opportunity to create review and consent processes for registry projects that recognize multiple project objectives. HIPAA regulations are primarily about protections of patient information from inappropriate disclosure, not about protection from physical harm related to research or about requirements for written informed consent. On the one hand, these regulations have added a degree of complexity for research investigators as they have had to pay more attention to issues of data security and privacy, and have had to develop more stringent agreements and policies when personally identifiable information is shared among investigators at different institutions. On the other hand, though, an explicit focus on breaches of confidentiality as a form of risk to patients allows for a review focusing on those issues at the time of the initial establishment of a registry, with subsequent reviews focusing on other forms of risk (if any) as specific research projects are developed involving use of registry data. A “two-phase” review process for registry projects is then possible, with initial review for the registry *per se* focusing on privacy and confidentiality issues, and later, multiple, specific research project reviews focusing on the typical range of potential research risks.

In a “two-phase” review process, the initial review focuses on the registry's procedures for collection and maintenance of individual patient data, with most of the attention paid to procedures in place to protect patient privacy and confidentiality of personal information. This review may be conducted at all hospitals or other medical facilities participating in the registry. At this stage of

Table 1 Characteristics of local quality improvement projects and of larger-scale registry projects

Attribute	Local QI project	Registry project
Leadership	Local clinicians or support staff who actually provide care	Project Director or Principal Investigator at either a “lead site” or a separate institution
Primary aim	Improvement in one or more specific processes or outcomes of care	Collection of defined set of data on large sample of patients
Number of patients involved	Can be large or small, depending on the setting and the difficulty of collecting data	Usually large
Frequency of data analysis	Constant in some cases, frequent in others as improvement is carried out through frequent cycles of process change and analysis	Relatively infrequent, at least until a minimum target sample size has been achieved
Importance of data base(s)	Relatively unimportant—tracking of a small set of key process indicators over time may replace a traditional data base	Crucial—the data base is the essence of the project
Focus of data analysis	Changes in key process or outcome variables over time, and in response to changes in local processes	Statistical associations between various treatment and outcome variables; comparison of outcomes across sites or providers within sites
Staff involved in data analysis	Members of QI project team, employing basic time series analysis methods	Dedicated, specialized statistical analysts, employing sophisticated multivariable analysis methods
Temporal association between data analysis and process change	Data analysis may either precede or follow process change; time lags between analysis and process change typically very short	Data analysis may also either precede or follow broader process changes; time lags between analysis and process change typically many months to years
Research objectives	Usually absent, although project leaders may elect to publish descriptions of QI projects	Usually present, with either general analytic aims or specific questions or hypotheses stated at the start of the initiative
Research products	Generally none, even if some description of project is published	Often multiple research projects and published articles, many of which were not specifically planned in advance

review, there is no review or approval of specific research projects and associated risks, since in many cases, specific research projects will not yet have been designed. A second phase of review is initiated whenever one or more specific research projects using the registry data are proposed. In the second phase of review, the usual criteria for review of research projects are applied, including discussion of potential risks of harm to research subjects. Projects involving only analysis of existing registry data may be reviewed through an expedited process and granted a waiver of requirements for individual patient consent, on the principle of their involving minimal risk to participants. On the other hand, though, some research projects involving followup contact with patients or some other feature creating some added risk or discomfort to patients may go through a process of full committee review and a requirement for written consent on the part of individual study participants. Participants would be asked to consent to the procedures involved in a specific project, not to the basic activities of the registry or to any future quality improvement or research activities of the registry.

In Europe and elsewhere outside the US, these may not be separate domains, but there may be some value in preserving the distinction as a basis for designing a comprehensive approach to ethics committee review and individual participant consent in registry projects.

Research as primary versus secondary aim

In the United States, current policies require Institutional Review Board (IRB) review and approval of virtually all research projects, but allow for “expedited review” and a waiver of requirements for written informed consent for projects involving “minimal risk”. An example of a type of project involving minimal risk is a retrospective review of information collected for other purposes; e.g., a retrospective study involving a review of medical records or analysis of insurance claims data. A multi-site registry whose primary intent is feedback of information to surgeons for purposes of quality improvement would be classified in the domain of quality improvement, and research use of the data would be “secondary use of existing data” as far as US IRB rules are concerned.

This approach has been used successfully in the National Surgical Quality Improvement Program (NSQIP), a large registry initiative that started in the 1990s in the Veterans Administration but has recently been expanded to include a large number of private-sector hospitals [33, 34]. The NSQIP data base has been used for a large number of research studies, focusing on both specific processes of care and larger health policy issues like the relationship between hospital volume and surgical outcomes [35]. The project involves prospective enrollment of eligible surgical

cases, concurrent review of medical records by trained nurse abstractors to obtain a finite set of clinical, intra-operative, and demographic data at the time of surgery, then tracking of patients to identify deaths within a finite period of time post-surgery. Because the project is defined primarily as a quality improvement initiative, though, and because data on care processes and outcomes are indeed fed back on a regular basis to participating surgeons for quality improvement purposes, the project does not require written informed consent by patients. Similarly, patients who are enrolled in local and state tumor registries typically are not asked to consent, because the activities are deemed to have primary aims of either public health reporting or quality improvement.

In many registry projects, the initial classification of the project as quality improvement is then carried forward to eliminate the requirement for written informed consent by patients in the registry as specific research projects are carried out later. Examples include multiple studies from the NSQIP data base, studies involving the Surveillance Epidemiology and End Results (SEER) cancer registries, studies using the Acute Decompensated Health Failure National Registry (ADHERE) [36], and studies using the New York Cardiac Surgery Reporting System (NY-CSRS) [37].

Exceptions to this general pattern are easy to find, though. The Paul Coverdell National Acute Stroke Registry is an example of a registry with the stated primary intent of quality improvement [38]. Participating hospitals' IRBs reviewed and approved the project; most decided that it was actually exempt from requirements for review because its primary purpose was quality improvement and because no direct patient contact was involved. However, the absence of individual patient consent made it impossible to collect follow-up outcomes data after discharge, presumably because such activity would "cross the line" into the realm of direct patient contact, in spite of the registry's primary intent of quality improvement. The concern may be well-justified; Sugarman et al. [39] document patients' privacy concerns when approached for participation in a specific research project at some time after their enrollment in a tumor registry.

Littenberg and MacLean [40] describe an example of a registry initiative that is both QI and research, and that uses a passive consent/opt-out model to deal with the consent, IRB, and HIPAA issues. This process kept participants in the registry and subsequent studies unless they specifically asked to be excluded. As a result, fewer than 3% of the potential registry participants were excluded. The authors present a compelling argument for why it is important for QI projects and registries to have all eligible patients included, including a large number of those who may not agree to voluntary participation in research. This argument

is central to considerations about possible ethics review and consent differences between QI, registry projects, and research. The bias produced by non-response in QI or registry projects may be greater than the bias produced by non-response in biomedical and clinical research. If everyone has more or less the same physiology, a 50% participation rate in a clinical trial does not matter, especially if it is a prospective, randomized controlled trial. For projects having to do with issues of compliance, treatment choice, process–outcome relationships, or comparative performance, though, the biases associated with a 50% participation rate may be fatal.

Another interesting example is provided by Schwartz et al. [41] who describe a cognitive rehabilitation registry whose primary purpose is "facilitating access to patients for cognitive rehabilitation research". In this case, given the explicit primary research aim, written informed consent from individual participants was required before registry enrollment, although project staff were allowed to review medical records of potential registry participants in order to identify patients who would be invited to participate. The participation rate among those invited to participate was 58%, with significant differences in some important demographic and clinical variables found between those who consented to be in the registry and those refusing.

In all these examples, there has been some requirement for IRB review at participating sites. In almost all examples, each participating hospital or clinic's IRB had to review and approve the project; different projects may have had different decisions made subsequently about "exempt" versus "expedited" and whether written consent from participants was required. The requirement for IRB review and approval from all participating sites almost inevitably creates problems for multi-site registry projects, as different IRBs may reach different conclusions about the essential nature of registry initiatives, and therefore make different requirements about operational issues that could include requirements for written consent [42]. In some cases, the differences can be resolved with some additional time and effort, but in the end, the registry and subsequent analyses can be implemented as planned in all participating sites. In other cases, though, the differing IRB interpretations can create fundamental problems in project design, such as a requirement for written consent in some sites but not in others.

"Quality Improvement Research" versus research in general

When the primary purpose of a project is ambiguous, or if the primary purpose of the project is "quality improvement research", US policies will create a requirement for IRB

review and approval. There may or may not also be a requirement for written informed consent by patients whose data goes into the project or who are involved in the project in some other way. From this perspective, there is no meaningful distinction between “quality improvement research” or “outcomes research” and research in general [12, 43]. The rules about ethics committee review and participant consent do not distinguish between different research topic areas. It really does not matter whether a research project has some connection to quality improvement or not; if the activity is research, then it is regulated by existing policies about research.

Chaney et al. [44] describe an interesting approach to issues of IRB review and informed consent in the context of the Veterans Administration’s QUERI program—a body of work that they label as “implementation science”. The fundamental goal of the activity is quality improvement, but its nature is research, and it is conducted and regulated as research. The projects are typically multi-site projects with challenges of IRB review and consent procedures, but there is little controversy over whether the projects are research. The challenges here are similar, but not identical, to the challenges faced by multi-site registry or quality management projects that are either primarily for research or include clear research aims at the outset.

Informed consent: if and when?

Bhatt et al. [45] describe a quality improvement initiative that involved creation of a registry of some 18,000 patients with acute coronary syndromes at 248 US hospitals. A declared research aim of the project was the identification of relationships between early invasive management and in-hospital mortality among high-risk patients. The findings about such relationships, obtained from a large number of community hospitals, were the key quality improvement aspects of the project. The registry and subsequent analyses went forward without a requirement for individual patient consent because the IRBs at participating hospitals agreed that the initiative was fairly characterized as quality improvement, and because the procedures for data collection and transmission involved removal of patient identifiers as soon as the original abstraction of data was complete. The registry, then, involved individual patient-level data, but not identifiable patient data. This approach was adequate for the analytic aims proposed, but would not have supported any future studies requiring follow-up contact with individual patients.

To the extent that ethics committee requirements for individual patient consent are based on the presence or absence of patient identifiers in the data set, this approach may be helpful for projects that do not require any patient

identifiers to achieve quality improvement or research aims. The ADHERE heart failure registry is another example of a project that avoids the necessity of individual patient consent by only transmitting de-identified information from participating clinical sites to the central coordinating site [36]. (Another rationale for the absence of a consent requirement is the fact that the initiative does not involve any alterations to existing clinical practice patterns—it is an observational study only, with quality improvement presumably following as a local initiative based on analyses of the de-identified data.)

There may be agreement that a particular registry project has research aims for which individual patient consent is required, but if so, when, and for what range of purposes? Does the type of consent vary depending on the range of possible research uses to which the registry will be put? Does it matter if the research activities are always going to be led by one institution or investigator versus led by multiple investigators at different institutions in the future? In the former case, one might imagine a “blanket consent” in which patients agree to participation in a class of research projects with similar features rather than one specific project; in the latter case, the projects may be different enough from each other that a “blanket consent” would not be feasible.

Obtaining individual patient consent from registry participants can easily be a costly and difficult process. An article by Tu et al. [46] provides important evidence on the extent to which requirements for written informed consent in a national stroke registry project had two significant adverse effects. The first was the creation of significant biases in the recruitment of patients to the registry, resulting in a registry sample that was not representative of the underlying patient population on several key clinical and demographic characteristics. The second was additional cost related to staff time requirements related to obtaining consent at participating hospitals. The funds could conceivably have been better spent on other aspects of the registry, or on other important quality improvement or research projects. Requirements for IRB review and/or informed consent do not come at no cost; advantages to patients and the larger society should be weighed against harms to patients and the larger society related to erroneous or biased information in registries, longer time to complete important QI or research projects, and studies or QI projects that were never done.

Vates et al. [47] present an excellent example of how one clinical department has been able to create and manage a local patient registry that was established before the passage of HIPAA but has had to become HIPAA-compliant. The registry is explicitly identified as a research registry, with the ability to support both retrospective data analysis studies and studies involving direct patient

contact. A form of “blanket consent” is used to authorize use of patient data in retrospective studies and to enable contact of patients for future prospective studies. The consent is written to extend to all physicians in the department, so separate consents are not required for projects by different investigators. New patients are asked to fill out consent forms at the time of clinic visits; patients in the registry before the advent of HIPAA were either asked to fill out consent forms at clinic visits (if they were still under care) or sent consent forms in the mail. Virtually all patients who have been asked in clinic settings for consent have given consent, but responses to mailed requests for consent have yielded a lower proportion of consent, mainly because no response to the mail request was received. Where no explicit consent is given, the department still has procedures for sharing of patient information among physicians as a preliminary step to inviting patients to participate in specific research projects.

Do public health or quality improvement aims ever prevail?

In the context of back pain or spine surgery, it is unlikely that a public health interest would supersede a registry’s purpose as either quality improvement or research (The situation is different in the case of serious infectious illnesses like HIV/AIDS or hepatitis where there is a compelling public health interest in preventing disease transmission, or in the cases of organ or tissue donation registries where an important purpose of the registry is matching of donors and recipients.). In the United States, though, there is a relatively recent phenomenon in which major public or private purchasers of health care (e.g., the Center for Medicare and Medicaid Services—CMS) are requiring participation in registries as a condition for payment for expensive clinical services [48]. In 2005, for example, CMS expanded its coverage for positron-emission tomography (PET) scans in patients with cancer on the condition that patients participate in one or more PET registries (e.g., the National Oncologic PET Registry). Local IRBs reviewing the registry activity made a narrow distinction between the coverage and payment aspects of the registry and the research aspects of the registry. They decided that patients and hospitals participating in the registry were not engaged in research, and therefore not obliged to seek local IRB review nor to obtain written consent from individual patients. They did, though, decide that the registry staff and investigators affiliated with the registry were engaged in research, and that individual patient data in the registry could only be used for research if that patient had consented to that use [49]. IRB review and approval is presumably required at the home

institution(s) of registry-affiliated investigators. Research using the registry, then, is only carried out on a subset of data in the registry involving patients who have consented to that use. The CMS goal of linking coverage decisions to research on effectiveness is met in part, and is met to greater or lesser degree depending on the proportion of patients who actually agree to have their data used in the research that CMS deems essential for informing future coverage decisions.

If future back pain or spine surgery registries may be used for multiple purposes that include research, this model may be applied to those registries. That is, all patients meeting basic eligibility criteria would be entered into the registry, and data from all patients might be used for a variety of non-research purposes, including quality improvement or comparative performance analysis. The use of a patient’s data for research, though, would require an explicit consent from that patient.

Summary

Published articles between 1996 and 2007, up to and including the Lynn et al. article, have created a workable basis for distinguishing between local quality improvement and research activities, and for applying appropriate oversight and consent policies to activities in the two different categories. In general, projects with objectives of both types should be treated as research for purposes of ethics committee review and requirements for participant consent.

Multi-site registry initiatives, which are an increasingly popular form of quality improvement activity, but which differ in several important ways from local process improvement activities, create some new ethical challenges. Models for ethics committee review and consent have been developed and applied successfully to such projects; many of these involve a “two-stage” review and consent process. In a first stage, the registry project is reviewed primarily from the perspective of patient privacy and protections for confidentiality of data. This phase of review may not address any specific research projects, since in some cases, no specific research projects will have been designed at the time the registry is established. Patient consent is typically not required in situations where quality improvement is the primary stated aim of the registry, and/or when no specific research projects have been identified in advance. The second phase of review comes when specific research projects are proposed. If a project involves only secondary analysis of the registry data that have already been collected, the project may be approved through an expedited process, with no patient consent required. If, however, the project involves some follow-up contact with patients in the registry (e.g., administration of

a health status survey), or if there is concern about possible complaints from patients who learn about use of their data in research, investigators may be required to obtain consent from individual registry patients before using their data in research. The two-stage approach seems to represent an appropriate and feasible compromise between two competing concepts—the inclusion of all eligible patients in registries used for quality improvement or analyses of comparative performance; and the right of research subjects to participate on a voluntary basis.

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References

- Carlson RV, Boyd KM, Webb DJ (2004) The revision of the Declaration of Helsinki: past, present and future. *Br J Clin Pharmacol* 57(6):695–713. doi:[10.1111/j.1365-2125.2004.02103.x](https://doi.org/10.1111/j.1365-2125.2004.02103.x)
- Fischer BA (2006) A summary of important documents in the field of research ethics. *Schizophr Bull* 32(1):69–80. doi:[10.1093/schbul/sbj005](https://doi.org/10.1093/schbul/sbj005)
- Lynn J (2004) When does quality improvement count as research? Human subject protection and theories of knowledge. *Qual Saf Health Care* 13:67–70
- Marwick C (1993) Federal agency focuses on outcomes research. *J Am Med Assoc* 270(2):164–165. doi:[10.1001/jama.270.2.164](https://doi.org/10.1001/jama.270.2.164)
- Evidence-Based Medicine Working Group (1992) Evidence-based medicine. A new approach to teaching the practice of medicine. *J Am Med Assoc* 268(17):2420–2425. doi:[10.1001/jama.268.17.2420](https://doi.org/10.1001/jama.268.17.2420)
- Horn SD, Gassaway J (2007) Practice-based evidence study design for comparative effectiveness research. *Med Care* 45(10 Suppl 2):S50–S57
- Kritchevsky SB, Simmons BP (1991) Continuous quality improvement. Concepts and applications for physician care. *J Am Med Assoc* 266(13):1817–1823. doi:[10.1001/jama.266.13.1817](https://doi.org/10.1001/jama.266.13.1817)
- Goldberg D et al (2004) Mailings timed to patients' appointments: a controlled trial of fecal occult blood test cards. *Am J Prev Med* 26(5):431–435. doi:[10.1016/j.amepre.2004.02.009](https://doi.org/10.1016/j.amepre.2004.02.009)
- Smith R (2000) Quality improvement reports: a new kind of article. They should allow authors to describe improvement projects so others can learn. *Br Med J* 321(7274):1428. doi:[10.1136/bmj.321.7274.1428](https://doi.org/10.1136/bmj.321.7274.1428)
- Valji K (2002) IRB approval—who needs it? *J Vasc Interv Radiol* 13(3):225–226. doi:[10.1016/S1051-0443\(07\)61714-X](https://doi.org/10.1016/S1051-0443(07)61714-X)
- Berwick DM (1996) Harvesting knowledge from improvement. *JAMA* 275(11):877–878
- Armstrong D et al (2005) Potential impact of the HIPAA privacy rule on data collection in a registry of patients with acute coronary syndrome. *Arch Intern Med* 165(10):1125–1129. doi:[10.1001/archinte.165.10.1125](https://doi.org/10.1001/archinte.165.10.1125)
- Casarett D, Karlawish JH, Sugarman J (2000) Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications. *J Am Med Assoc* 283(17):2275–2280. doi:[10.1001/jama.283.17.2275](https://doi.org/10.1001/jama.283.17.2275)
- Bellin E, Dubler NN (2001) The quality improvement-research divide and the need for external oversight. *Am J Public Health* 91(9):1512–1517. doi:[10.2105/AJPH.91.9.1512](https://doi.org/10.2105/AJPH.91.9.1512)
- Thurston NE, Watson LA, Reimer MA (1993) Research or quality improvement? Making the decision. *J Nurs Adm* 23(7–8):46–49. doi:[10.1097/00005110-199307000-00013](https://doi.org/10.1097/00005110-199307000-00013)
- Casarett D, Karlawish JH, Sugarman J (2000) Should patients in quality-improvement activities have the same protections as participants in research studies? *J Am Med Assoc* 284(14):1786–1788. doi:[10.1001/jama.284.14.1786](https://doi.org/10.1001/jama.284.14.1786)
- Nerenz DR, Stoltz PK, Jordan J (2003) Quality improvement and the need for IRB review. *Qual Manag Health Care* 12(3):159–170
- Diamond LH et al (2004) Commentary: quality improvement projects: how do we protect patients' rights? *Am J Med Qual* 19(1):25–27. doi:[10.1177/106286060401900105](https://doi.org/10.1177/106286060401900105)
- Hagen B et al. (2007) Innovations in the Ethical Review of Health-Related Quality Improvement and Research: the Alberta Research Ethics Community Consensus Initiative (ARECCI). *Healthc Policy* 2(4):1–14
- Davidoff F, Batalden P (2005) Toward stronger evidence on quality improvement. Draft publication guidelines: the beginning of a consensus project. *Qual Saf Health Care* 14(5):319–325. doi:[10.1136/qshc.2005.014787](https://doi.org/10.1136/qshc.2005.014787)
- Stevens DP (2005) Why new guidelines for reporting improvement research? And why now? *Qual Saf Health Care* 14(5):314. doi:[10.1136/qshc.2005.016311](https://doi.org/10.1136/qshc.2005.016311)
- Thomson RG (2005) Consensus publication guidelines: the next step in the science of quality improvement? *Qual Saf Health Care* 14(5):317–318. doi:[10.1136/qshc.2005.015727](https://doi.org/10.1136/qshc.2005.015727)
- Berwick DM (2005) Broadening the view of evidence-based medicine. *Qual Saf Health Care* 14(5):315–316. doi:[10.1136/qshc.2005.015669](https://doi.org/10.1136/qshc.2005.015669)
- Brock WA, Nolan K, Nolan T (1998) Pragmatic science: accelerating the improvement of critical care. *New Horiz* 6(1):61–68
- Lynn J et al (2007) The ethics of using quality improvement methods in health care. *Ann Intern Med* 146(9):666–673
- Johnson N, Vermeulen L, Smith KM (2006) A survey of academic medical centers to distinguish between quality improvement and research activities. *Qual Manag Health Care* 15(4):215–220
- Clark S et al (2006) Feasibility of a national fatal asthma registry: more evidence of IRB variation in evaluation of a standard protocol. *J Asthma* 43(1):19–23. doi:[10.1080/00102200500446896](https://doi.org/10.1080/00102200500446896)
- Kass N et al (2008) Controversy and quality improvement: lingering questions about ethics, oversight, and patient safety research. *Jt Comm J Qual Patient Saf* 34(6):349–353
- Fung CH et al (2008) Systematic review: the evidence that publishing patient care performance data improves quality of care. *Ann Intern Med* 148(2):111–123
- Rowe JW (2006) Pay-for-performance and accountability: related themes in improving health care. *Ann Intern Med* 145(9):695–699
- Drolet BC, Johnson KB (2008) Categorizing the world of registries. Elsevier, Amsterdam
- Deer T et al (2004) Intrathecal drug delivery for treatment of chronic low back pain: report from the National Outcomes Registry for Low Back Pain. *Pain Med* 5(1):6–13. doi:[10.1111/j.1526-4637.2004.04011.x](https://doi.org/10.1111/j.1526-4637.2004.04011.x)
- Khuri SF (2005) The NSQIP: a new frontier in surgery. Elsevier, Amsterdam, pp 837–843
- Khuri SF et al. (1998) The Department of Veterans Affairs' NSQIP: the First National, Validated, Outcome-Based, Risk-Adjusted, and Peer-Controlled Program for the Measurement and Enhancement of the Quality of Surgical Care, pp 491
- Khuri SF et al (1999) Relation of surgical volume to outcome in eight common operations: results from the VA National Surgical Quality Improvement Program. *Ann Surg* 230(3):414–429. doi:[10.1097/0000658-199909000-00014](https://doi.org/10.1097/0000658-199909000-00014)
- Adams KF Jr et al (2005) Characteristics and outcomes of patients hospitalized for heart failure in the United States: rationale, design, and preliminary observations from the first 100,000 cases in the Acute Decompensated Heart Failure National Registry (ADHERE). *Am Heart J* 149(2):209–216. doi:[10.1016/j.ahj.2004.08.005](https://doi.org/10.1016/j.ahj.2004.08.005)

37. Hannan EL et al (2003) Provider profiling and quality improvement efforts in coronary artery bypass graft surgery: the effect on short-term mortality among Medicare beneficiaries. *Med Care* 41(10):1164–1172. doi:[10.1097/01.MLR.0000088452.82637.40](https://doi.org/10.1097/01.MLR.0000088452.82637.40)
38. Reeves MJ et al (2005) Acute stroke care in the US: results from 4 pilot prototypes of the Paul Coverdell National Acute Stroke Registry. *Stroke* 36(6):1232–1240. doi:[10.1161/01.STR.0000165902.18021.5b](https://doi.org/10.1161/01.STR.0000165902.18021.5b)
39. Sugarman J et al (1999) Ethical ramifications of alternative means of recruiting research participants from cancer registries. *Cancer* 86(4):647–651
40. Littenberg B, MacLean CD (2006) Passive consent for clinical research in the age of HIPAA. *J Gen Intern Med* 21(3):207–211. doi:[10.1111/j.1525-1497.2006.00339.x](https://doi.org/10.1111/j.1525-1497.2006.00339.x)
41. Schwartz MF et al (2005) A patient registry for cognitive rehabilitation research: a strategy for balancing patients' privacy rights with researchers' need for access. *Arch Phys Med Rehabil* 86(9):1807–1814. doi:[10.1016/j.apmr.2005.03.009](https://doi.org/10.1016/j.apmr.2005.03.009)
42. Stair TO et al (2001) Variation in institutional review board responses to a standard protocol for a multicenter clinical trial. *Acad Emerg Med* 8(6):636–641. doi:[10.1111/j.1553-2712.2001.tb00177.x](https://doi.org/10.1111/j.1553-2712.2001.tb00177.x)
43. Pronovost P, Wachter R (2006) Proposed standards for quality improvement research and publication: one step forward and two steps back. *Qual Saf Health Care* 15(3):152–153. doi:[10.1136/qshc.2006.018432](https://doi.org/10.1136/qshc.2006.018432)
44. Chaney E et al (2008) Human subjects protection issues in QUERI implementation research: QUERI Series. *Implement Sci* 3:10. doi:[10.1186/1748-5908-3-10](https://doi.org/10.1186/1748-5908-3-10)
45. Bhatt DL et al (2004) Utilization of early invasive management strategies for high-risk patients with non-ST-segment elevation acute coronary syndromes: results from the CRUSADE Quality Improvement Initiative. *J Am Med Assoc* 292(17):2096–2104. doi:[10.1001/jama.292.17.2096](https://doi.org/10.1001/jama.292.17.2096)
46. Tu JV et al (2004) Impracticability of informed consent in the Registry of the Canadian Stroke Network. *N Engl J Med* 350(14):1414–1421. doi:[10.1056/NEJMsa031697](https://doi.org/10.1056/NEJMsa031697)
47. Vates JR et al (2005) Protecting medical record information: start your research registries today. *Laryngoscope* 115(3):441–444. doi:[10.1097/01.mlg.0000157829.00509.e9](https://doi.org/10.1097/01.mlg.0000157829.00509.e9)
48. Lindsay MJ et al (2007) The National Oncologic PET Registry: expanded medicare coverage for PET under coverage with evidence development. *AJR Am J Roentgenol* 188(4):1109–1113. doi:[10.2214/AJR.06.1175](https://doi.org/10.2214/AJR.06.1175)
49. Hillner BE et al (2007) The National Oncologic PET Registry (NOPR): design and analysis plan. *J Nucl Med* 48(11):1901–1908. doi:[10.2967/jnumed.107.043687](https://doi.org/10.2967/jnumed.107.043687)