

Ethical Issues in Patient Safety Research: A Systematic Review of the Literature

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Abstract: As many as 1 in 10 patients is harmed while receiving hospital care in wealthy countries. The risk of health care–associated infection in some developing countries is as much as 20 times higher. In response, in many global regions, increased attention has turned to the implementation of a broad program of safety research, encompassing a variety of methods. Although important international ethical guidelines for research exist, literature has been emerging in the last 20 years that begins to apply such guidelines to patient safety research specifically. This paper provides a review of the literature related to ethics, oversight, and patient safety research; identifies issues highlighted in articles as being of ethical relevance; describes areas of consensus regarding how to respond to these ethical issues; and highlights areas where additional ethical analysis and discussion are needed to provide guidance to those in the field.

Key Words: research ethics, patient safety, quality improvement, informed consent, health services research

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Patient safety concerns are prevalent among health-care systems worldwide. Preventable harms result in pain, suffering, and even death for patients and lead to increased costs for medical systems.¹ Patient safety concerns are now regarded as a serious public health threat. The World Health Organization (WHO) Research Priority Setting Working Group states that “understanding the magnitude of the problem and the main contributing factors that lead to patient harm is essential to devise effective and efficient solutions for different contexts and environments and to build safer health systems.”²

Many health systems and facilities engage regularly in activities referred to as quality assurance, quality improvement, or audit (Although quality assurance and audit are terms used to refer to practices that aim to review how care is being delivered and compare it with a set of explicit criteria to determine how it can be improved, *quality improvement* is a term that is meant to encompass both prospective and retrospective activities that are meant to improve care by determining why preventable harms or systematic inefficiencies occur and by designing techniques

to improve them.³) to monitor and improve the care they provide to patients. In addition, growing awareness of these concerns and possible strategies to address them has led to a significant increase in the amount of *research* being conducted related to patient safety. Such research is designed to document the extent, nature, and possible determinants of patient safety incidents and to understand the effectiveness of interventions designed to prevent or reduce them. Patient safety research is often included under the broader category of quality improvement, and more generally of health services research. In fact, methods used to conduct patient safety research are similar to those used in these other broader quality improvement and research activities, including, for example, retrospective review of medical records, prospective observational data collection, and randomized controlled trials.⁴ Patient safety research ideally results in interventions and strategies that can be implemented in health care settings as a means of safety improvement actions.

International ethical guidelines for research require third party oversight of research by an ethics review committee (REC) and also outline both principles and actions that should be implemented as part of the ethical conduct of human research. As patient safety research has become more widespread, ethics literature related to quality improvement and patient safety activities and research has also grown. It is the purpose of this paper to review the literature related to ethics oversight and patient safety research, aiming to synthesize the existing literature in this field. The paper is organized around a series of topics relevant to ethics and patient safety research that emerge in the literature as well as several topics that are absent in the literature but that are central to the ethics of patient safety research. Topics identified through the literature include when patient safety activities that collect data should be considered research for the purposes of ethical review, what type of oversight is necessary, and when informed consent is needed from patients. Topics that are largely absent from the literature and that require additional guidance include when informed consent should be sought from providers, how best to protect privacy and confidentiality, when to intervene when a potentially unsafe activity is observed or identified, and under what circumstances deception is acceptable as part of patient safety research.

SYSTEMATIC REVIEW METHODOLOGY

The methodology for this systematic review was laid out in a protocol document, available upon request, developed by 2 authors (J.K. and K.H.) and reviewed by all other authors (D.W., N.K., C.A., M.B., I.L., and A.S.). The review followed the Meta-analysis Of Observational Studies in Epidemiology Group (MOOSE) guidelines,⁵ the IOM standards for systematic reviews and guidelines,⁶ and the Cochrane Handbook.⁷

Potentially relevant citations were identified using a systematic search strategy within the PubMed and EMBASE electronic databases from January 2000 to April 2012 (Please refer to Appendix A for the complete PubMed, EMBASE, Web of

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Knowledge search strings.). This time frame was chosen based on the date of publication of the first seminal report on patient safety in 1999. Given that the MeSH term, “Patient Safety”, was only introduced in 2012, the specific search strategy used for this work built upon a published and validated search strategy for patient safety papers indexed in PUBMED and EMBASE.⁸ A review of the gray literature published within the last 3 years was also performed using the Web of Knowledge, through multiple simple combinations of search terms, complemented with a manual review of the titles and abstracts of a subset of professional societies meetings (Appendix A). Based on this search strategy, 6,948 citations were initially identified, which were reduced to 6,101 after removal of duplicates with EndNote X5 (Fig. 1).

Thereafter, 2 authors (J.K. and K.H.) independently undertook full title and abstract review of all selected citations and identified articles that warranted a full text review, based on the following criteria: articles were retained if they were related to safety or quality improvement and the abstract included the term *ethical issues* or *ethics issues* or referenced specific ethical issues including but not limited to issues of conflicts of interest, informed consent/waivers of consent, privacy or confidentiality, deception, and/or possible “duty to report.” Articles were also included if they discussed criteria for ethics oversight of patient safety or quality improvement activities or defined where patient safety improvement activities lie in the spectrum of

research and practice. Articles were excluded if they exclusively reported results of patient safety projects, or if they pertained exclusively to health-care quality.

All articles identified for full text review (61) were retrieved and reviewed independently by J.K. and K.H. using a standardized data abstraction form containing the following items: reviewer initials, article identifiers (study ID number, author, year of publication, country where participants lived), category under which the article fell (i.e., ethics oversight of patient safety practice activities, informed consent/waivers of consent, intervention in unsafe practices, etc), funding source and key author conclusions. These independently completed data forms were then reconciled by K.H., and a doubly verified final consensus data abstraction form was created for each included full text article.

The final qualitative synthesis of this work was undertaken by a third author (D.W.), who had access to the final data abstraction forms as well as the full text of the selected articles. D.W. ultimately excluded 12 articles, as they did not meet the aims of this current work on final review.

RESULTS AND DISCUSSION

Based on our systematic review, we identified a final sample of 49 articles. Of these, 45 were policy papers, and 4 were studies involving human subjects. After a review of the articles,

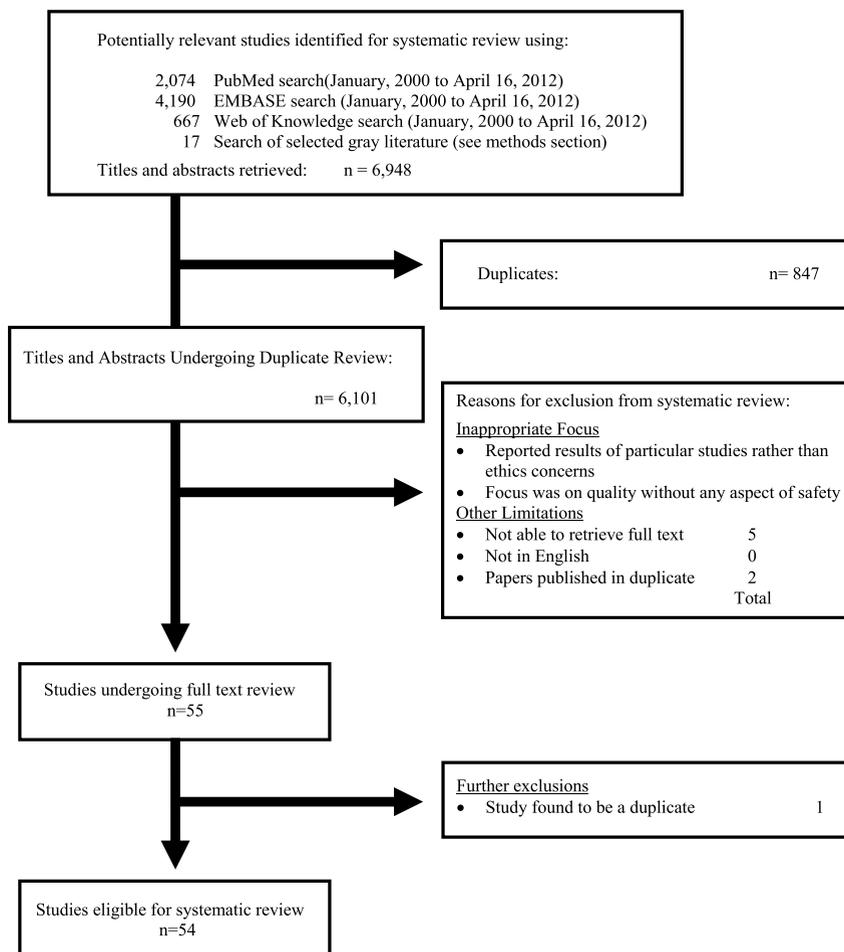


FIGURE 1. Flow chart of study identification, rejection, and selection according to MOOSE⁴² (Meta-analysis Of Observational Studies in Epidemiology) guidelines.

we identified 3 broad topic areas that were discussed in the literature. These include the following: defining where patient safety improvement activities lie on the clinical practice–research continuum, oversight of patient safety activities, and when informed consent should be sought from patients. Each of these broad categories is broken down into subcategories that describe those issues that were raised in the articles identified through this systematic review. In addition, we defined 4 topics that we felt were important ethical issues related to patient safety research but that did not receive much attention, if any, in the literature identified through this systematic review. More specifically, these topics were either not discussed in any of the articles identified through the systematic review or were discussed in no more than 1 article. We felt it was important to mention these topics as these are areas where additional ethical and policy work is needed. These include the following: when informed consent should be sought from providers or the health-care team, how to best protect patient confidentiality and privacy, whether patient safety researchers have duties to report errors to patients or to the authorities and when, and whether it is ethically acceptable to use deception as part of a patient safety research project. For several of these topics, we supplemented the information found in the articles identified through the systematic review with additional articles we identified in the literature that provided information that we felt was pertinent to understanding that topic but that was not unique to the literature on patient safety research. All articles identified through the systematic review appear in bold text in the reference list at the end of this paper, whereas the additional articles we cite but that were not identified through the systematic review appear in plain text. For each topic we identified, we present a summary of the ways in which the topic was discussed in the literature as well as the controversies that exist, and we describe areas where additional guidance is still needed. In this paper, we do not provide information on the number of articles that make a particular claim because there are several influential papers that are cited numerous times in the patient safety and quality improvement literatures. As a result, the ideas proposed in those papers tend to appear frequently in the literature, not because they are necessarily more important than other ideas but rather because they have been proposed in one or more high visibility articles. Given this, we do not feel that providing information on the number of articles that make a particular claim would add value to the paper. Instead we have developed a robust methodology for identifying papers and have provided a summary of each of the issues in order to give an overview of where the field currently stands.

We first describe those topics discussed in the patient safety literature and then discuss those topics that are mentioned less often or not at all. This is not to suggest that the issues that are mentioned less often are less relevant or less important, but it seems that additional ethical guidance is needed in these areas.

Topics Frequently Discussed in the Patient Safety and Quality Improvement Literature

The Clinical Practice–Research Continuum: Defining Where Patient Safety Improvement Activities Lie

Much attention in the literature focuses on which patient safety projects require ethical oversight. This has been a particularly challenging area because of the confusion that exists regarding when a patient safety activity counts as research.⁹ Several scholars note that in the United States regulations, research is defined as an activity that involves systematic collection of data for the purposes of developing or contributing to generalizable knowledge,¹⁰ whereas “clinical practice is an exchange of information between and individual patient and

members of a healthcare delivery team.”¹¹ Several articles in the literature describe how ethical guidelines and regulations require additional oversight for activities considered research (such as third-party prior review of the research and informed consent to ensure that participants’ welfare or rights are not unduly compromised) but not for those considered routine practice.^{12,13} As such, at least according to existing ethical guidance and regulations, being able to distinguish which activities count as research from activities that do not become an important responsibility.^{14,15}

However, the definitions of research provided in ethical guidelines and regulations^{14,15} result in confusion for patient safety professionals¹⁶ as many patient safety/quality improvement activities are carried out to improve the quality of care within a given health-care setting and yet may also produce information that is generalizable or publishable.^{17,18} Furthermore, they collect data in a systematic manner, always to improve care of future patients in that facility¹⁹ and sometimes to improve care of patients more broadly.^{4,17} As such, ethics literature related to patient safety has devoted attention to when patient safety activities should be considered research for the purposes of requiring ethical oversight, outlining various criteria that can be helpful for making such a determination. These criteria fall into several broad categories including the purpose of the project, the design of the project, whether those directing and/or funding the project are internal or external to the institution where the project will be implemented, and the generalizability of the project’s results to other settings or future patients. Each of these criteria has been recommended as a useful indicator of whether a project constitutes research and whether it must be reviewed by a REC.

Purpose of the Project: Generation of New Knowledge Versus Implementing Practices Based on Existing Knowledge

Many scholars assert that understanding the purpose of a patient safety activity—whether the project is intended to generate new knowledge or is intended to implement practices based on existing knowledge—is relevant in determining whether a project should be considered research.^{20–23} If the stated purpose of a project is to generate new knowledge and if it is designed with the scientific rigor to be able to actually produce such knowledge, then, consistent with the guidance provided by the Office for Human Research Protections (OHRP), that project likely would be considered research requiring ethical review.²⁴ By contrast, patient safety activities designed to measure compliance with recommended strategies, such as hand washing, or to improve compliance in individual settings, generally would not be considered research.^{11,16,25–30}

Design of the Project: Flexibility of the Protocol and Feedback of the Project Results

Several aspects of the design of a patient safety activity have been cited as relevant to determining whether the activity constitutes research. Many authors assert that research projects commonly rely on strict protocol designs, whereas patient safety activities are generally more flexible because the objective of these projects is often to bring about immediate improvements in care.^{19,23,25,26,31–33} Mary Ann Bailly and colleagues, for example, state that “Instead of a fixed protocol implemented for a time period that may last for years [as generally required in research], QI [quality improvement] methods often require repeated modifications in the initial protocol as experience accumulates over time and as the desired changes engage the local structures, processes, patterns, habits, and traditions.”²⁵ A closely related criterion, suggested by several scholars, is

whether the project involves randomization, as projects involving randomization are generally less flexible than other evaluation designs.^{18,21,23,25,31,34}

Several scholars have also indicated that whether or how quickly results are reported back to the health-care organization(s) or teams where the project was implemented is relevant, suggesting that patient safety activities may be more likely to provide direct feedback (and implement changes) to those who were involved than research projects are.^{26,33,34} In many patient safety activities, the results are continuously reported back to clinicians and clinical managers and changes to the protocol can be made quickly, based on the data that are being fed back.^{18,19,25,31,35,36}

Project Funding Source: External Versus Internal

A few scholars have also suggested that funding source is a relevant criterion for determining whether a project constitutes research. We are aware of several scholars who have suggested that patient safety activities funded by external sources are more likely to be research, whereas activities funded through internal institutional sources are more likely to not be research.^{23,25,31,33} However, others have argued that a project's funding source is not a relevant criterion. Kass and colleagues state that "What makes a project research rather than exclusively quality assurance, however, is not who funds it but, rather, the project's intentions and goals."³⁷

Generalizability of the Study Findings

Several scholars, as well as various regulations and guidelines, describe research as being predominantly to benefit future patients or patients in other settings rather than the participants involved with the project.^{17,31} Generalizable knowledge refers to the applicability of the results to other settings, other practitioners, and other patients as well as to the enduring nature of the knowledge gained.^{24,25,27} However, in the literature, disagreement exists regarding the point at which knowledge generated should be considered generalizable. One scholar has suggested that intent to generalize refers to any situation in which the physician-investigator intends to apply the results from an interaction with a patient to other patients or to other situations,³⁸ whereas another scholar has suggested that generalizability implies that the results of a project are applicable across settings—to other organizations outside of those involved in the study.²⁵ Another challenge related to generalizability, highlighted in the literature, is whether it is possible to know when a project is initiated how generalizable results will be.^{10,16–18,39} Projects initially designed to improve care at a local setting may have results that could be applied to other settings as well.

Because it may be difficult to define the point at which the results of a project count as generalizable knowledge, other scholars have suggested several criteria that they believe are indicators of intent to produce generalizable knowledge. For instance, David Nerenz and colleagues suggest that one way to determine who is intended to benefit from a patient safety activity is to review the project's hypothesis. If the hypothesis is worded more generally, they assert, the findings of the study likely are meant to be broadly applicable to society and future patients.⁴⁰ If a project's hypothesis clearly specifies a time and place where the results are meant to apply, then the project is less likely to be viewed as a research project.

Another proposed criterion for determining when a project is intended to produce generalizable knowledge, suggested by Bellin and Dubler, is the number of sites participating in a patient safety activity. Bellin and Dubler suggest that research is commonly conducted in a number of settings to improve the

generalizability of the results, whereas patient safety practice, meant to bring about immediate change to improve the care within an organization, are generally restricted to the organization or organizations where the results are meant to apply.³⁴ As previously stated, many patient safety activities are meant to inform local practice. These projects are implemented in particular localized health-care settings, and the project is designed to incorporate specific features of that setting. Projects such as these are less likely to be viewed as research than projects that involve multiple institutions. However, Mary Ann Bailly and colleagues warn that the involvement of multiple institutions does not necessarily mean that a project ought to be considered research since the results of that project can still be tied to the time and place where the project was implemented. These authors state that "the fact that the organizations cooperate to share insights about the process of change within each organization would usually make any research component an instance of research on organizational behavior, not research on human subjects."²⁵

Other scholars have suggested that intent to broadly disseminate the results of a project can be considered a proxy for the intent to produce generalizable knowledge.^{19,21,29,31,32,41,42} Molly McNett and colleagues state that "the initial intent when designing a QI (quality improvement) project should not be to disseminate the information to a larger audience. If this is the case, then the purpose is no longer to improve internal processes but rather to contribute to generalizable knowledge and thus should be treated as a research activity."²⁹ Others have rejected the intent to disseminate as a valid criterion for defining research.^{35,43} Specifically, several scholars note that journals publish numerous articles that are not a result of research, such as editorials, letters to the editor, and case reports.^{17,40} Davidoff and Batalden further suggest that including this as a criterion may discourage patient safety professionals from disseminating the results of their projects, which would effectively slow progress on improving patient safety standards.⁴⁴

What is apparent from this review is that currently, there is considerable disagreement regarding the importance of these different criteria in distinguishing which patient safety activities should be considered research. No criterion on its own was mentioned by all authors, and even where there is some agreement regarding the importance of a particular criterion, such as generalizable knowledge, there still exists disagreement regarding the threshold at which production of generalizable knowledge, or intent to produce the same, makes an activity research.

Oversight of Patient Safety Practice Activities

Several scholars question whether it is useful to try to make a distinction between patient safety research versus practice, suggesting instead that ethical protection should be in place for all such activities.^{4,22,31,33,44–46} Davidoff and Batalden assert, for example, that "The critical issue here is not whether they are doing research; it is whether staff engaged in the improvement have taken the appropriate steps to protect those people who participate in their efforts to improve care."⁴⁴ Similarly, Christine Grady and colleagues state that "The guiding principle should be that activities whose goals extend beyond the immediate interests of patients should undergo independent review to ensure that patient interests are protected."⁷⁴ Also asserting that all patient safety projects should be submitted for ethical review, Doezema and colleagues argue that those directing patient safety programs should not be the ones to determine whether projects are ethically acceptable because those who designed the project may have a conflict of interest.³⁸

Countering this view, however, is literature suggesting that requiring all patient safety projects that collect systematic data to undergo review by RECs may become a disincentive for clinicians, administrators, and other health-care staff to collect rigorous data around patient safety questions.^{28,47}

Other scholars suggest that ethical oversight should not be required for all patient safety projects but also disagree that the defining criterion for review should be research versus practice. Rather, these authors argue that ethical oversight should be required for patient safety or quality improvement research projects where the risk of harm to participants is greater than minimal risk, where minimal risk is defined as the amount of risk inherent in clinical practice, and where reliable confidentiality measures are in place.^{42,48,49}

Several authors also suggest that if ethics oversight were to be expanded to all patient safety activities (rather than those strictly defined as research), current RECs may not be appropriate bodies of oversight.^{4,22,25,26} First, many RECs are already overburdened with reviewing research protocols.^{22,50} In addition, methods used in patient safety research projects often differ from those used for research of health technologies or health-care interventions. Protocols for patient safety research are often more flexible and more closely integrated with clinical care than other research, and members of RECs may be less familiar with the methods used to conduct these activities.²⁵ Furthermore, even when projects are submitted to RECs for review, there is significant confusion among RECs regarding whether a patient safety research project should undergo expedited or full committee review. Several scholars note that when multisite patient safety projects are reviewed by RECs, different RECs can vary widely in their review of those projects.^{9,51,52}

As a result, some scholars have put forward models they think would be more appropriate forms of oversight for patient safety and quality improvement efforts. Baily and colleagues recommend 3 levels of oversight for different types of quality improvement projects²⁵—professional responsibility of quality improvement such as minimal risk activities that “are simple in design, so there is no need for methodological review,” and whose effects “are very local, in the sense that their success or failure will have no repercussions on other parts of the organization”; local management review and supervision of quality improvement for “activities designed to improve care in the local setting that require at least some monitoring by management” and research involving human subjects that ought to be reviewed by a REC. In regard to this third level, Baily and colleagues recommend that RECs devoted specifically to quality improvement be established.²⁵

Although no other published reports have recommended this 3 level system of oversight, other scholars agree with the recommendation that RECs specifically devoted to reviewing patient safety and quality improvement research are needed both to ensure that these projects are implemented and conducted in an ethically appropriate manner but also to have review be targeted to this type of work.^{10,17,45,50,53} In fact, 2 surveys conducted by Taylor and colleagues found that currently in the United States, quality improvement projects are reviewed by a variety of internal oversight processes including review by “the QI management team/office; clinical leadership conducting QI; and an advisory board (or equivalent) created for the purpose of reviewing QI,”⁵⁴ but they are not generally reviewed by RECs.^{54,55}

However, Kass and colleagues believe that it is not appropriate to create completely separate RECs for these projects: “the development of a completely separate review and oversight mechanism would raise questions about what other types of

human subjects research (public health practice research, qualitative behavioral research) would also benefit from an alternate system. From a practical perspective, it may be more sensible to identify the arenas where current regulations are an awkward fit and try to address those specifically.”³⁷ Nevertheless, at least one organization has had success in implementing a REC that focuses exclusively on reviewing quality improvement protocols.⁵⁶ Some members of this REC are also members of the institution’s general REC, but all of the members have expertise in both quality improvement methods and research. In an article about this new REC, Lowell Wise claims that the introduction of this REC has effectively made those involved in quality improvement feel “less isolated from the greater body of the organization.”⁵⁶ A final model, which was implemented by the U.S. Army Institute of Surgical Research and Brooke Army Medical Center, is to form a committee to review QI projects to determine whether the project should be considered research and should therefore be submitted to a REC.³⁵

Informed Consent

Ethics literature related to patient safety research also addresses whether and when informed consent should be obtained from patients and, to a far lesser degree, clinical staff participating in patient safety research. The objective of informed consent in this setting—as in any other clinical research setting—and as described by various scholars is to inform potential participants about the research, including the potential risks and benefits and to respect individuals’ rights to make autonomous decisions.^{46,57} Most current ethics guidelines allow exceptions to this requirement if the risks of the research are low, and it is not feasible to obtain consent from participants.^{14,15} These notions are reiterated in the patient safety research literature.^{37,45,57} Available literature suggests that patient safety research activities expected to include greater than minimal risk should obtain informed consent from patients, although the literature in general is silent about what types of studies count as greater than minimal risk research in the context of patient safety. Further challenges emerge regarding consent and patient safety research because interventions are sometimes directed at systems rather than individual patients⁵⁷ and because many projects collect data about how best to implement proven strategies rather than testing an intervention with uncertain clinical efficacy,¹¹ many of which do not impose more than minimal risk to patients.^{58,59} For all of these reasons, ethics literature related to informed consent has asserted that requiring written informed consent from patients would be overly burdensome or is unnecessary for many patient safety research projects^{11,57–59} or that consent procedures for patients should be significantly modified to allow for opt out rather than opt in mechanisms of authorization³³ or broader systems of disclosure rather than formal, individual level consent.^{31,52}

Consistent with this logic, Miller and Emanuel suggest that REC members and investigators need to consider whether any of the interventions are experimental, whether the introduction of the protocol increases risks to patients, as well as whether the interventions could have been introduced in to clinical care without doing research. If all of the interventions are based on evidence-based standards and present no additional risk beyond standard clinical care and if the intervention could have been introduced in to clinical care without the specific informed consent of patients, then, according to Miller and Emanuel, the rights of patients are not violated if informed consent is not obtained.⁵⁷ Baily, Lynn, and colleagues suggest that patients should be prohibited from opting out of minimal risk quality

improvement activities, given the importance of such activities for ongoing high-quality patient care,²⁵ recommending that “Consent to receive care should include consent to participate in routine, minimal-risk QI [quality improvement], whereas activities that entail more than minimal incremental risk... should require specific informed consent and a more formal review, potentially including a reviewer from outside of the organization.”²⁶ Laura Tapp and colleagues define projects that impose greater than minimal risk to patients and therefore require informed consent to be obtained as those that provide less care than is standard in that particular setting, those using untested interventions, where patients are assigned to a study arm based on the protocol—not the physicians’ best judgment, projects that aim to reduce costs, and projects where confidential data are shared.⁶⁰

Although there is some discussion of a professional obligation on the part of health-care providers to take part in quality improvement and patient safety projects,⁶¹ largely excluded from the literature is guidance on when or whether to seek informed consent from individual health-care providers or from entire health-care teams when these health-care professionals are the subjects of the research. Patient safety research may include chart reviews or observation of health-care interactions, and documenting the decisions and actions of health-care providers, and anecdotally, we are aware of some RECs that do require informed consent to be obtained from health-care providers. However, we are only aware of one article that discusses whether formal consent or broad disclosures about ongoing patient safety research should be required from health-care providers. Baily and colleagues state that because health-care providers have an obligation to work to improve the quality of care delivered to patients, they also have an obligation “to cooperate with their organization’s QI program.”²⁵ Therefore, specific informed consent should not be required from health-care workers for minimal risk projects. However, Baily and colleagues also recommend that informed consent should be obtained from health-care professionals when, as part of a quality improvement or patient safety activity, these individuals are exposed “to more than minimal additional risk of physical or mental harm compared to their current working conditions (exposure to radiation or toxic chemicals, for instance) or [when the activity] collected information about workers that was outside the category of information employers are normally entitled to have about their employees (such as their use of tobacco, alcohol, or illegal drugs outside of the workplace). Consent is not required, however, for QI that is risky to the worker simply because it might generate evidence of incompetence on the job or lead to a reduction in force for efficiency reasons.”²⁵

Although this guidance from Baily and colleagues is helpful, there is a need for additional guidance on the necessity of and/or best practices for obtaining consent when entire clinical teams are the subject of patient safety research. Patient safety checklist studies, for example, sometimes document whether the team, as a whole, attended to certain activities, or projects review medical charts revealing an entire team’s interactions with a patient. We are aware of no literature that addresses whether teams should be consulted individually or as a whole, and whether refusal by one member of the team requires nonenrollment of the entire team.

Unaddressed Challenges Related to the Ethics of Patient Safety Research

In addition to needing more guidance on when informed consent should be obtained from health-care teams and how, we now discuss several topics that are rarely mentioned, if at all, in the patient safety or quality improvement literatures and for

which additional ethics guidance is needed. These topics include best practices for protecting patient and provider confidentiality and privacy, whether there is a duty to report errors to patients and authorities, when it is acceptable to use deception as part of patient safety research projects, and whether there exists a duty to relieve the stress of clinical staff participating in patient safety projects and how best to report back the results of those projects.

Protecting Patient and Provider Confidentiality and Privacy

Participant privacy and participant confidentiality are two separate but related issues. Privacy has been defined as “having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others,” whereas confidentiality is “treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.”⁶² Currently, there exists a significant amount of guidance that describes best practices for maintaining privacy and confidentiality in the context of research. Both Council for International Organization of Medical Sciences (CIOMS) and the OHRP provide guidance on best practices for maintaining patient confidentiality when information from patients’ medical records is used for research purposes.^{15,62}

However, this literature is not specific to patient safety research. This is significant because there are several issues that are particularly challenging for this field such as how to manage review of patients’ medical records, observation of physicians’ behavior while care is being provided, observation of patients to see if the care physicians or nurses provided is appropriate, and what to do if and when interview or focus group respondents suggest deficiencies in the health care system. Therefore, additional guidance is needed on whether, for example, special protections should be in place related to health-care providers’ actions being documented such as whether permission should be sought in surgical suites where an unconscious, naked patient is undergoing surgery and an observer who is not part of the health-care team is completing a checklist on whether providers are following recommended infection control practices. Because patient safety research projects observe providers, in addition to or instead of patients, the need to protect confidentiality may extend to providers as well.

Related, future guidance should address whether confidentiality is better protected by having an insider or outsider review charts and conduct observations. It may be that patient confidentiality is better protected by having someone from inside the institution review medical charts, whereas provider confidentiality is more readily protected when someone external to the organization conducts reviews or observations, as it may be troubling to have colleagues observing one another.

Duty to Report Errors to Patients or Authorities

Apart from determining when to obtain informed consent and how best to protect patient and provider privacy and confidentiality, another issue that is relevant to patient safety research is whether it is appropriate for researchers to disclose information about things such as specific errors recorded or observed as part of research to third parties because these errors could negatively impact the health and well-being of patients. If it is deemed appropriate, a further issue that should be considered is how to report such errors. Unfortunately, we were

again unable to identify literature that describes when or whether there is a duty to intervene when errors are observed either prospectively or as part of medical chart reviews. Such questions emerge for example, when a research team member is abstracting information from medical records about errors and comes across an error that may be significant and, perhaps, previously unnoticed. In this case, there is a need for guidance about whether either patients or hospital authorities should be informed that an error may have occurred. Similar questions might emerge during observations of medical procedures, where researchers must have guidance regarding whether, when, and how to report any particularly problematic observations to third parties or, indeed, when, to intervene in order to prevent an impending error from occurring. Also relevant is whether any local regulations create duties to report substandard care of health care providers (and whether researchers might be immune from such reporting requirements). We are not aware of any literature that addresses these questions. However, two bodies of literature may have some indirect relevance to these questions of reporting. Although this literature was not identified through our systematic review, we felt that it was relevant to mention it here.

First, there is literature related to when researchers should disclose “incidental findings” to patient-subjects. Such might occur if, for example, a researcher is examining radiologic scans in order to explore a particular scientific question but, in the process, identifies an irregularity on the scan that may have clinical relevance to the patient, but about which the patient may be unaware. Although it is well recognized that if incidental findings arise during the course of clinical care, clinicians have an obligation to inform patients if those findings are thought to have clinical relevance, how to respond to incidental findings in research is less clear.^{63–65} Franklin Miller and colleagues suggest that researchers have a duty to intervene or inform patient-subjects of incidental findings when these findings may be of clinical relevance.⁶³ They suggest this duty derives from the nature of physicians’ and researchers’ professional responsibilities as well as from the principles of beneficence and nonmaleficence.⁶³ Susan Wolf and colleagues agree that there is a duty to report incidental findings, and further argue that before reporting an incidental finding, investigators also have a duty to validate and confirm the finding, possibly by consulting a colleague.⁶⁴

Leading perhaps to a different approach regarding disclosure might be literature on the “no fault” philosophy of patient safety work. This approach argues that to reduce errors in health-care settings, one must ensure that there is an open and non-punitive system for documenting and reporting errors and then identifying strategies to address them.^{66–69} Such approaches would suggest that reporting of individual errors found through medical records, particularly with the goal of bringing any type of punitive action to an individual health-care provider, would be counterproductive to longer term goals of improving patient safety outcomes overall. On the other hand, while developing a nonpunitive environment is important generally, there is also recognition that certain types of errors or problems may require intervention or attention by clinicians or hospital leadership. This dilemma has been solved to some extent by at least 2 groups conducting patient safety research. Investigators of the Canadian Adverse Events Study formulated a “safety committee” or recognized experts who agreed to review data and make a decision about possibly informing the hospital or relevant personnel about potential risks or unsafe providers (Personal Communication with Ross Baker, 2012). A similar solution was also adapted by the French Adverse Event Study (Personal Communication with Philip Michael, 2012). Not addressed in the

literature, at least to our knowledge, is whether action should ever be taken in informing families about possible errors, including those where subsequent clinical intervention might still be possible, and how.

Given this, future efforts on ethics and patient safety research should focus on determining when, if ever, those involved in patient safety research should intervene if they observe in real time, or become aware through a medical records review, of an adverse event or medical error. Questions that should be addressed include whether patients or families should ever be informed, whether investigators should ever intervene if they observe something about to happen that they strongly believe is imminently or severely harmful (such as administering too large a dose of anesthetic), and whether investigators should ever intervene if medical records suggest the results of a crucial test were not communicated back to family, but the information is such that the patient or family might want to act on it. Future guidance should also consider scenarios where divulging information might result in litigation against the provider.

Finally, some patient safety research projects might use a method of interviewing patients and families about adverse events that may have happened to them while they were in the hospital to enquire further about the circumstances. In these situations, there is a need for further guidance as to how investigators should respond if patients or their families suggest they did not know previous to the research interview that a potential adverse event had occurred, including in the context of possible litigation.

Deception

In general, ethical concerns pertaining to the use of deception in patient safety research are closely linked to an ethical duty of truth telling and to foundational commitments to respect for persons.⁷⁰ Deception occurs when researchers “deliberately misinform subjects to study their attitudes and behaviour [sic].”¹⁵ Of particular ethical concern with regard to deception is that “covert methods can infringe on interests that people hold concerning research participation, and the sharing of private details.”⁷¹ Given this, the use of deception in research is still highly controversial. Although we were unable to find any literature that explicitly dealt with the ethical acceptability of deception in the context of patient safety research, we did find one article where deception was used as part of a quality improvement study.⁷² In this study, the authors employed professional patients to visit sexual health departments in London, England, to provide information on the quality of the services provided to them. The authors conclude that professional patients are useful for providing feedback to providers but also note several ethical issues with the use of deception in research. Namely, that professional patients use time that physicians could spend treating patients who are really in need of services, it is possible that professional patients could experience harm, and deception can result in a lack of trust between health-care professionals and researchers. To alleviate some of these issues, the research team asked for provider consent to be visited unannounced by professional patients and reported results in aggregate so no individual provider was identifiable.⁷² Looking past the patient safety literature to research guidelines, CIOMS adds that “Deception is not permissible... in cases in which the deception itself would disguise the possibility of the subject being exposed to more than minimal risk. When deception is deemed indispensable to the methods of a study the investigators must demonstrate to an ethics review committee that no other research method would suffice; that significant advances could result

from the research; and that nothing has been withheld that, if divulged, would cause a reasonable person to refuse to participate.¹⁵ The OHRP states that deception is more acceptable if it deals with actions that occur within the public sphere and also urges investigators involved in projects with mystery clients to consider what the project team will do if individuals deceived find out about the deception.⁶² The CIOMS guidelines also encourage investigators to consider whether and how they will debrief participants at the end of the study.¹⁵ Bryan Benham states that debriefing “includes (1) disclosing to the participant the nature and rationale for deception, and (2) identifying or mitigating any harms that the participants may suffer as a result of their involvement in the research. It is not uncommon to also (3) provide participants with the (explicit) opportunity to withdraw their data during the debriefing process”.⁷³ In the literature, debriefing has been seen as a method by which researchers who use deception can take moral accountability for their actions⁷² and can potentially reduce the long-term costs of deception.⁷⁴

Duty to Relieve Stress of Clinical Staff and Reporting Back Results

Implementation of patient safety research may cause considerable stress among the clinical staff if they feel that the goal of the study is to critique their current practice patterns or detect mistakes they have made. Unfortunately, we were not able to find any literature that discusses whether these projects have the potential to raise the level of stress staff experience and/or whether those involved in patient safety activities have a duty to relieve stress of the clinical staff. Given this, future attention should address whether implementation of patient safety research is particularly stressful to health-care providers and if so, whether individuals involved in patient safety research have a duty to implement procedures to mitigate any stress that the study might cause to health-care providers beyond their usual duties.

CONCLUSIONS

The public health threat of preventable harms, which compromise patient safety, is now well established within the literature. Given this threat, it is critical that health-care organizations and health-care systems establish best practices for improving patient safety and implement projects to demonstrate the effectiveness of interventions aimed at improving patient safety within their organization or system.

Although important scholarly work has laid the foundation for the critical ethical considerations for those involved in patient safety projects, there is still a significant amount of work to be done. The lack of well-established and trusted guidelines in this area as well as the lack of clarity as to how existing guidelines should be interpreted in the context of patient safety research creates uncertainty for both researchers and reviewers. This may result in projects being conducted or modified inappropriately or not being conducted at all either because of researchers shying away from proposals or ethics committees failing to approve them. Guidance on applying the well-established principles of ethics to the specific issues inherent to patient safety research is imperative to drive much needed progress in improving the safety and quality of care delivered to patients.

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