

# Confronting and Resolving an Ethical Dilemma Associated with a Practice Based Evaluation Using Observational Methodology of Health Information Technology

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## Keywords

Testing and evaluation, clinical information systems, ethics

## Summary

As the adoption of health information technology (HIT) has escalated, efforts to evaluate its uptake have increased. The evaluation of HIT often requires direct observation of health care practitioners interacting with the system. When in the field, the evaluator who is not a trained health care provider may observe suboptimal use of the technology. If evaluators have plans to share the results of the evaluation at the conclusion of the study, they face a decision point about whether to disclose interim results and the implications of doing so. To provide HIT evaluators with guidance about what issues to weigh when observing the implementation of HIT, this paper presents a study of an actual case and discusses the following considerations: (1) whether the evaluation of HIT is considered to be human subject research; (2) if the evaluation is human subject research, whether the Institutional Review Board will consider it exempt from review or subjected to expedited or full review; and (3) how interim disclosure to the clinic management impacts the research study. The recommendations to evaluators include use of a protocol for interim disclosures to patients, clinicians, and/or clinical management for both quality assurance initiatives and human subjects research.

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## 1. Introduction

As health information technology (HIT) matures, evaluation of HIT has increased [1, 2] and moved from technical and laboratory studies to studies undertaken in clinical settings where the HIT is implemented. These *in situ* evaluations focus on human and organizational issues [1, 3-5] and the impact of HIT on the quality of patient care processes and patient care outcomes [2]. To foster the acceleration of HIT adoption, professionals in the field can anticipate more studies that evaluate organizational process changes, contextual factors, and patient outcomes [1]. These evaluations of health systems in their contexts of use have been described by ethicists as a moral imperative [6].

Evaluations of HIT often include direct observation where the observer may be a clinician with or without an informatics background, or the observer may be an informatician with or without a clinical background. Informed by their background, the evaluator may observe the suboptimal use of HIT [7-9]. In the absence of a plan to report such use, the evaluator is left to consider the risks and benefits of disclosure in the midst of conducting the study. This situation is an ethical dilemma: an apparent conflict between two or more morally prescribed values [10, 11].

A review of published HIT evaluations was performed to determine whether and how dilemmas about suboptimal use of HIT had been addressed in the past. This review failed to provide any helpful guidance [7, 8, 12-15]. Only one HIT evaluation report indicated that feedback for iterative system improvements was provided during the study [16], but no discussion of the ethical considerations were included in the report. In this paper, the term “*consideration*” refers to the ethical principles’ relevant guidelines referenced to identify possible resolutions to an identified ethical dilemma. Examples of considerations include the ethical principles presented in the Belmont Report, professional guidelines, and Institutional Review Board (IRB) policy and procedures [17-19].

The issue of whether and how to address observed suboptimal use of HIT during an HIT evaluation will grow in importance as EHR adoption and accompanying evaluations increase. This paper was undertaken to provide insight and offer recommendations regarding this moral quandary. It is the goal of this paper to describe a particular ethical challenge in the conduct of HIT evaluation studies in the clinical practice setting, consider different approaches to addressing this challenge, and make recommendations to address this challenge in future studies.

## 2. Background

The obligation to evaluate the implementation of HIT in clinical practice settings has been previously discussed in response to the United States Food and Drug Administration’s 1996 call to regulate clinical information systems as medical devices. The authors proposed that systems that were safe for patients would not produce any “measurable harm,” would demonstrate outcomes that met or exceeded the status quo, and would support incurring the investment of time and money [20]. The methods for this assessment, whether observational or otherwise, were not discussed.

To obtain an in-depth understanding of HIT in the clinical practice setting, qualitative (or mixed methods using qualitative and quantitative methods) evaluations are often used [21]. Depending on the research design and goals, the researcher may plan to inform the research site during the course of the evaluation study or only at the conclusion of the study. Evaluation studies that are designed to provide feedback during the evaluation are formative studies. Formative evaluation takes place during development or deployment of the information. Feedback may be provided during the formative evaluation to offer information for decisions made during the development process or after deployment to improve the information resource. An example of a formative evaluation in the context of HIT would be the use of a method referred to as member checking which reports results to those managing and implementing HIT in clinical practice for their feedback and which enhances the validity and transferability of the study’s conclusions [22, 23]. In contrast, summative evaluation studies are designed to provide feedback at the conclusion of the study for the purpose of assessing how effectively the resource performed, after the information resource is deployed and relatively stabilized in its envisioned environment [22] (p.26). An example of summative evaluation

in the context of HIT would be providing iterative feedback to those managing and implementing HIT two years after the clinical information system had been adopted in clinical practice [24].

HIT evaluations in the clinical practice setting have reported HIT design issues including ineffective implementation of policies and procedures in HIT [9], HIT functionality that does not match clinical workflow [7], and 'bugs' in medication ordering functionality. Use of HIT systems with design issues can lead to unintended adverse consequences that have the potential to affect patient safety. Examples include: problems ordering a medication that resulted in an adverse drug event [25]; changes in workflow that delayed medication administration [26]; or a bar code scanner that did not scan which contributed to a medication administration error [27]. While using HIT in the clinical process and waiting for these design issues to be addressed, clinicians employ work-arounds as they deliver care [7], that is, they go to extraordinary lengths to get past a perceived frustration with the system, which may sometimes lead to undeserved negative consequences such as loss of job and suspension [27]. However, there is an absence of consensus literature establishing what is either an optimal or sub-optimal use of HIT. Examples of suboptimal use of HIT include: entering information in free text fields when it should have been collected elsewhere; too much copying and pasting of verbiage; and not entering clinical information in a timely manner.

HIT evaluators and ethicists may look to the experience of independent data monitoring committees (DMC) used in clinical trials for a model for additional oversight. These boards analyze quantitative data related to adverse events and clinical outcomes during the course of the clinical trial to ensure the safety of participants. The ethical dilemma is whether to stop a trial early in the event when data indicate subjects receiving the investigational intervention are faring better or worse than expected. The DMC must weigh the benefit and/or risk to subjects with the benefit that may accrue to future patients if the trial is completed. Rationale for non-disclosure of interim analysis to investigators is that the interim results may not be conclusive, and their disclosure to clinicians could jeopardize the successful completion of the clinical trial. In the context of HIT, a committee independent of the clinicians under observation and clinic management could be created to monitor instances of suboptimal use and decide whether the use ought to be disclosed to clinic management and/or clinicians prior to the completion of the evaluation.

### 3. Case Report: Evaluation of Electronic Health Record (EHR) in Clinical Practice Setting

The case study that follows will serve as an example that highlights common scenarios and dilemmas that may be observed and ethical considerations involved. This actual case is offered to provide HIT evaluators with guidance about what issues to weigh when observing the implementation of HIT

In 2009, an evaluation was conducted to assess the uptake of a commercially available EHR created to improve and streamline clinic operations in an ambulatory geriatric day center environment where interdisciplinary care teams provide direct patient care. The objective of the study was to assess the EHR's impact on clinician satisfaction with clinical process. The evaluation began 11 months after the EHR system was implemented. An evaluator, who was a social scientist with expertise in the implementation of clinical information systems, observed clinicians directly during 8 half-day visits over 6 weeks. Observations were focused on individual clinicians randomly selected to represent each clinical team and clinical role. The observer recorded in field notes what, where, and when clinicians documented patient care information and the types of work-arounds clinicians adopted. During the data collection period, clinicians were observed utilizing the system in a number of suboptimal ways. For example, clinicians were observed failing to consult the EHR before the patient visit, and when seeing patients, they made notes on paper without referring to the EHR. In addition, clinicians were observed entering clinical information from memory or paper into the EHR, often after the patient had left the day center, rendering the data (e.g., vital signs, fasting blood sugar results) unavailable to other clinicians seeing the patient on the same day. Patient clini-

cal data in the EHR six months old were observed to be intermixed with current entries in the chronological patient record.

## 4. Discussion

### 4.1 The Ethical Dilemma

An ethical dilemma may occur when, for example, the investigator had designed an HIT evaluation to share results at the conclusion of the study. This summative evaluation included a direct observation component in the course of the study during which the investigator observed actions that compromised the optimal HIT technology uptake. When the observer/evaluator has professional credentials of those being observed, there may be an affirmative obligation to take action. This is clear in the context of an evaluation of *direct* patient care, where the investigator observes delivery of suboptimal care or a risk to patient safety. If the observer is a trained health care provider, there is a professional obligation to intervene and/or report the concern to the medical director in charge of the care provided in the setting where the evaluation is taking place [22]. When there is potential for observation of actions that may result in direct harm to patients, advance planning for disclosure during the conduct of the study is warranted.

The obligation is less clear when the observer is not a trained health care provider. In general, it is not the role of the evaluator to intervene in absence of any evidence of direct harm to patients. In this case, the observer/evaluator is not observing direct patient care. Under some extreme circumstance, an evaluator with no medical training could observe a clinician taking an action that might harm the patient (e.g., clinician is about to trip over a cord that may result in his/her collision with a patient that may result in harm); however, such observations are unlikely in the context of the observation of clinicians in their workspace outside of patient rooms. For this case study, the observer watched clinicians interact with an electronic system and did not view the details of the patient (either directly by observation or reviewing the information on the screen with any specificity). For this case study, the observer had neither sufficient knowledge, nor role responsibility to intervene or report on an action related to standard patient care.

On the other hand, an expert in HIT who observes the utilization of technology may observe an action where the potential harm to a patient is unknown and/or unclear. Examples of such situations include the observation of clinicians not using the HIT as it was intended (e.g., as a primary communication mechanism between clinicians reducing face-to-face communication) [28], or adopting work-arounds (e.g., affixing patient identification barcodes for medication administration to computer carts and scanners to eliminate the step involving scanning the barcode attached to the patient) [7]. It is possible that inefficient use of technology by a clinician observed by the evaluator may result in harm to the patient. For instance, if the clinician is observed struggling with the system, it is possible that time spent struggling is time that should be directed to patient duties. However, it is hard to trace whether the time away from patient duties results in direct harm to a patient. Presented with a situation where potential for harm to patients is unknown or unclear, the evaluator may consider the reasons to take action or not. To illustrate, an example of an actual case is discussed.

The goal of this case example was to assess the impact of the HIT on the clinical process and to specifically look at the accuracy and timeliness of the entry of clinical information. The HIT being evaluated was designed for real-time input as the clinician cares for the patient. However, clinicians were accumulating data for input (e.g., writing documentation notes on paper) after patient visits were complete.

#### Dilemma

Does the evaluator ever have an affirmative obligation to disclose the suboptimal use of EHR system to clinic management before the evaluation is complete? Relevant considerations to the resolution of this dilemma include: (1) whether the evaluation of HIT is considered to be human subject research; and (2) the integrity of the evaluation process and outcome.

## 4.2 Relevant Considerations Regarding Observer Actions

### 4.2.1. Human Subject Research Consideration

The following discussion is based on regulations in the United States: this should not prevent international readers from applying similar considerations and recommendations in their own country's context. According to the Federal regulations that guide the conduct of human subject research,

“[r]esearch means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (102(d)) [29].

A human subject is defined as,

“a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual or identifiable private information” (102(f)) [29].

The question as to whether the evaluation of HIT should be considered human subject research places it in the middle of an ongoing controversy about whether quality improvement initiatives ought to be considered human subject research and what attributes ought to be used to distinguish one from the other [30-35]. One could argue, for example, that an HIT evaluation is human subject research because the evaluation involves the observation and systematic data collection about identifiable clinicians interacting with a novel technology. On the other hand, one could argue that because evaluation is meant to improve the implementation of a novel technology in a particular setting and the data collected will be used to improve site specific performance, the evaluation is a local quality improvement initiative. The debate can be further confounded if the evaluator is affiliated with an academic institution where the common understanding is, that in order for the results of any project conducted by an affiliate of the institution to be published in a high quality academic journal, it must be reviewed by an IRB.

In the event an HIT evaluation is submitted to an IRB for review, the IRB may decide that the evaluation is exempt from IRB review, or that the evaluation ought to be reviewed, either in an expedited fashion (by the Chair of the IRB or an experienced member of the IRB), or by the full IRB. As to whether the evaluation is exempt from IRB review, the IRB would consider whether the evaluation meets the following criteria:

“Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation” (101(b.2)) [29].

An IRB might decide the behavior under observation is a “public behavior” and consider the HIT evaluation exempt from review, as long as the evaluator agrees to record observations without personal identifiers *and* is satisfied that if a disclosure occurred, the clinician under observation would not suffer any damage related to “financial standing, employability or reputation.” On the other hand, the IRB may decide that the observation of clinicians is not technically “public behavior,” as the members of the general public are not routinely given access to the work space of clinicians, and therefore, the project would not qualify as exempt from IRB review. It is also possible, though unlikely, that the IRB could decide that, even without personal identifiers attached, the recording of clinician behavior could result in some harm. For example, if the clinicians are observed failing to utilize HIT in the way it was meant to be used, such recordings could result in some harm to their employability status or reputation and therefore not qualify as exempt from IRB review.

If the IRB decides that the HIT evaluation is not exempt from IRB review, it will next determine whether the evaluation can be reviewed in an expedited fashion. To make this determination, the IRB will consider whether the evaluation meets the following two criteria:

1. research activity presents “no more than minimal risk to human subjects,” and
2. the activity proposed is “[r]esearch on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies” [36].

As to whether the activity presents no more than minimal risk, the IRB will likely consider risk to the clinicians under observation as well as whether their failure to use the novel HIT of interest appropriately could result in any distal harm to their patients. As noted just above, an IRB could decide that the disclosure of a particular clinician’s failure to utilize HIT in the way it was meant to be used could result in some harm to that clinician’s employability status or reputation. Therefore, the disclosure would be an activity that presents more than minimal risk to the clinicians under observation. If so categorized, the HIT evaluation would be reviewed by the full IRB committee which would likely require that the evaluator obtain informed consent from each clinician to be observed. The IRB may further require that the evaluator include a plan for reporting any such disclosure as an adverse event. If the reporting of such events becomes more frequent than anticipated, the IRB may ask that the consent form be revised to further clarify the likelihood of disclosure or decide that the benefits of the evaluation no longer outweigh the risks to the clinicians under observation and stop the evaluation.

An IRB may also consider whether the inappropriate use of HIT could result in predictable harm to a patient. If the IRB determines that harm to a patient is predictable, it will need to determine whether the magnitude of the predictable harm to patients outweighs the benefits from the evaluation that may accrue to future patients. In the evaluation of HIT, the potential risks to patients are possible, but usually distal to the phenomenon under observation. It is therefore difficult to quantify and/or predict the magnitude of such risks. On the other hand, a clinician who fails to appropriately use a bar code reader intended to reduce medication administration errors may compromise patient safety [27]. If the evaluation has been reviewed as human subject research and the risk to patients identified prior to evaluation is considered to be more than minimal, the IRB may suggest that additional protections be implemented. These protections may include, for example, the systematic disclosure to all the patients who may be seen by a clinician in the practice that the utilization of a novel HIT is under observation and there is a potential risk to the quality of the care they may receive. These protections could include patients being informed that measures have been taken to minimize the likelihood of harm, and the adoption of the novel HIT will be halted if any patient experiences direct harm shown to have been a direct result of inappropriate use of the technology. While patients may have little choice to seek care elsewhere, the IRB may consider the disclosure a reasonable step, given that obtaining informed consent from all potential patients in advance of the implementation of HIT may be infeasible.

Finally, if the risks to either clinicians under observation or their patients are unlikely but possible, the IRB may ask the evaluator to report any harm encountered as an unanticipated event. Most IRBs will likely have a policy regarding the reporting of unanticipated events. One of our local IRBs (The Johns Hopkins Medical Institutions Institutional Review Board), for example, currently defines unanticipated problems as, “involving a risk to participants or others” that is unexpected in terms of frequency, severity, or nature given what was described in the research protocol and informed consent documents, or characteristic of the subject population; and “participants or others are at greater risk of harm than was previously known or recognized.” The researcher is to report in writing unanticipated problems to the IRB within 10 working days [19]. It is unclear whether the suboptimal implemented HIT itself would qualify as an unanticipated event, as it may or may not be a predictably common event depending on the HIT.

#### 4.2.2. Integrity of Evaluation Process and Outcome Considerations

Providing feedback to the clinic management team prior to the completion of the evaluation may compromise the evaluator’s relationship to the clinicians under observation or bias the outcome of

the evaluation. Interim disclosures may compromise the collegial relationship between the evaluator and the clinicians under observation. Clinicians may be less cooperative when observed after the disclosure which may compromise the quality of subsequent attempts to collect data.

Interim disclosure may bias the evaluation findings and/or limit the reliability and the generalizability of the findings [37] (p.30). The health services research literature points out that the act of studying human performance may alter the behavior of those being observed [22, 38] (p. 212). In this case, clinicians knew they were being observed and continued to use technology suboptimally, that is, observation did not alter their behavior.

Interim disclosure of suboptimal use of the EHR system made to clinic management could result in at least three possibilities. First, management could decide to take no action and the evaluator would continue to collect data as planned. Second, management could chide the clinicians for their suboptimal use of EHR and hope for improvement. The clinicians may or may not change their behavior; if they do, their efforts to change may diminish over time. The fact that the clinicians under observation by the evaluator adopted and utilized work-arounds to the EHR indicates that chiding on behalf of management would not likely result in stable behavior change that would bias future data collection. On the other hand, management may decide to intervene in order to remedy the situation in real-time. This management intervention may influence clinician behavior, and ultimately, the findings of the completed evaluation, whether a summative or formative approach.

### 4.3. Ethical Dilemma Recommendations

The following are three recommendations for evaluators considering the real time observation of clinician behavior as a component of an evaluation of HIT implementation:

1. During the design of the evaluation or in advance of the implementation of the evaluation, evaluators, in collaboration with the relevant members of the clinic management team, consider whether there are any circumstances under which suboptimal implementation of HIT could result in direct patient harm. If any circumstances are identified, a protocol for interim disclosure can be adopted prior to implementation. If none are identified, the clinical management team will receive the results when the evaluation report is completed. However, if the evaluation is considered to be human subject research, the plan for interim disclosure, or lack thereof, will need to be included in the proposal submitted for review by an IRB.
2. If circumstances under which the clinical management team will receive interim results are identified, these circumstances will need to be disclosed to the clinicians who will be under observation. If the evaluation is considered to be human subject research, the circumstances under which interim disclosure would occur will need to be included in the consent form provided to clinicians who will be under observation.
3. If the evaluator observes an unanticipated event that has the potential to result in direct patient harm, he/she should disclose the event to the clinic management for the consideration. Clinic management will need to make a decision for disclosure to the clinicians under observation. If the evaluation is considered to be human subject research, the evaluator will need to disclose the event to the local IRB, and in consultation with the IRB, consider whether interim disclosure to the clinical management team is warranted.

Details for considering the decisions are described further in ► Figure 1, and recommendations are further detailed in ► Table 1.

## 5. Conclusion

The systematic informatics evaluation of HIT interventions may include the observation of functionality and workflow of the HIT. Field researchers conducting HIT evaluations would benefit from considering in advance the circumstances under which interim results will be disclosed to clinic management teams. The potential risks and benefits of interim disclosure can be considered in advance of data collection and in collaboration with the clinic management team. These risks

and benefits of disclosure need to be made transparent to the clinicians under observation. Consideration of the goals of the research, research design, research ethics, impact on the host site, and possible bias effects, all contribute to decision-making regarding the interim disclosure of observations. Advance planning for disclosure simplifies the decisions researchers need to make once an evaluation is up and running. More evaluations that describe when and how evaluators provide interim feedback to clinical management teams and the effect of disclosure on the subsequent behavior of clinicians under observation would be informative.

#### **Implications of Results for Practitioners**

Field evaluators of HIT would benefit from considering in advance the circumstances under which interim results related to observed suboptimal use of HIT will be disclosed to clinic management teams. The potential risks and benefits of interim disclosure (1) can be considered in collaboration with the management team in advance of data collection, and (2) need to be made transparent to the clinicians under observation.

#### **Conflict of Interest**

Neither author has a conflict of interest.

#### **Institutional Reviews**

The Institutional Review Boards of the researchers' academic institution and of the research site approved the study in the case example.

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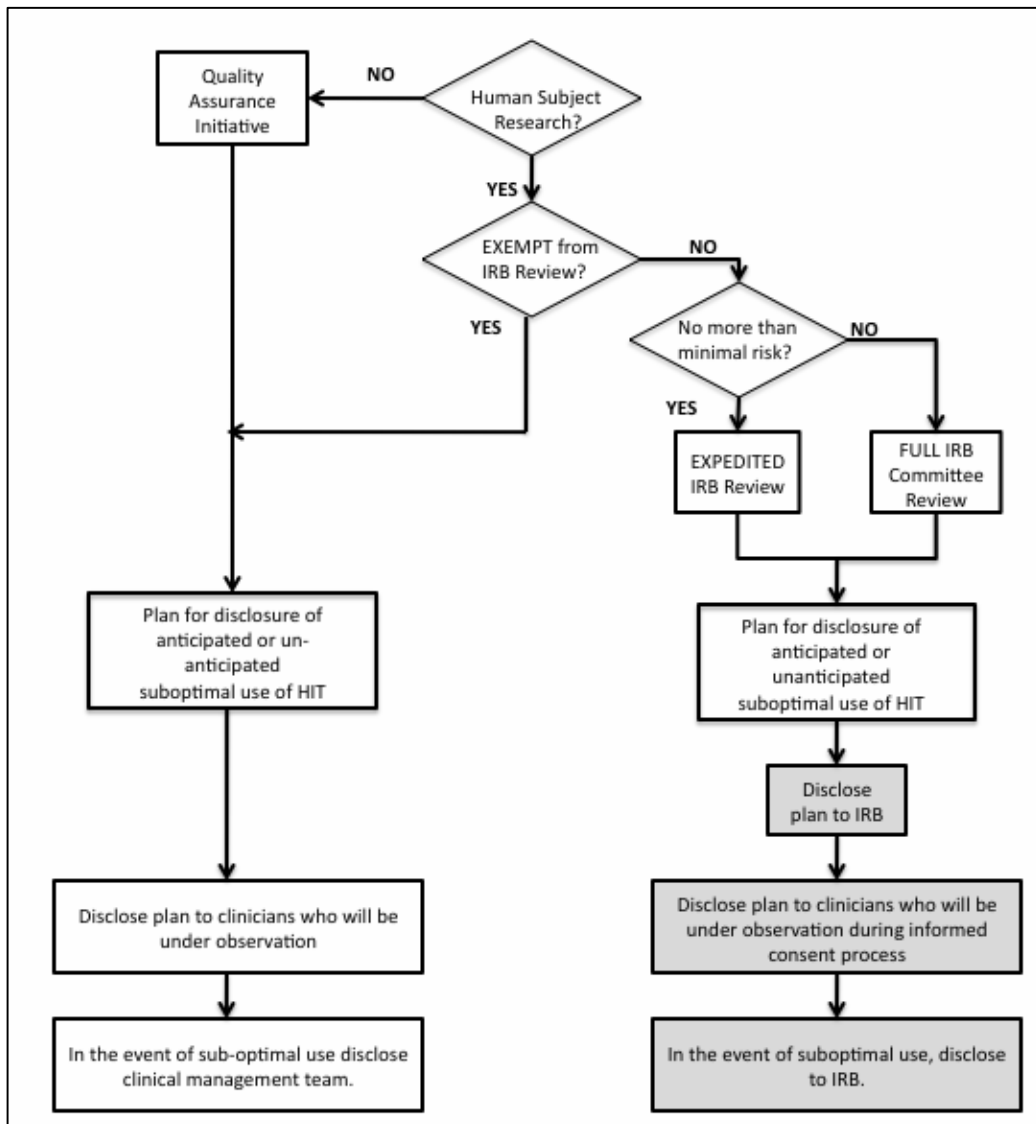


Fig. 1 Recommendations for evaluation design related to disclosure of clinical suboptimal HIT use (Note: Shading indicates action is required by regulation).

**Table 1** Summary recommendations for HIT evaluation

Types of Disclosure Decisions	Type of Evaluation Study	
	Not Human Subject Research	Human Subject Research
<b>1) Disclosure of suboptimal use of HIT</b>	In consultation with clinic managers, evaluators: a) adopt plan for interim disclosure, or b) adopt plan for disclosure when evaluation is complete.	In consultation with clinic managers, evaluators: a) adopt plan for interim disclosure, or b) adopt plan for disclosure when evaluation is complete.  Evaluator discloses plan to IRB.
<b>2) Disclosure to clinicians under observation</b>	If plan for interim disclosure is adopted, clinic management and/or evaluator disclose plan to clinicians under observation.	If plan for interim disclosure is adopted, evaluator discloses plan to clinicians under observation during informed consent process.
<b>3) Disclosure of unanticipated event that leads to direct harm to patient</b>	Evaluator discloses information about event to clinic management.  Regardless of plan for interim disclosure or disclosure when evaluation is complete, clinic management decide whether to disclose details of event to clinicians under observation and whether evaluation should continue.	Evaluator discloses information about event to IRB.  Regardless of plan for interim disclosure or disclosure when evaluation is complete, IRB decides whether to disclose details of event to clinical management and whether evaluation should continue.

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