

**HIT Policy Committee
Adoption/Certification Workgroup**

Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC
Thursday, February 25, 2010, 9 a.m. to 3:00 p.m./Eastern Time

Panel 1: Identifying the Issues (09:15 hours)

Alan Morris, MD Intermountain Healthcare and Univ. of Utah [invited]

PROPOSITIONS:

- A. Electronic health records organize and archive data to make them available to appropriate human decision-makers.**
- B. The reason for acquiring data in any format, including an electronic health record, is to influence human decision-making.**
- C. Human decision-making is context dependent.**
- D. An electronic health record will produce context-dependent outcomes.**
- E. Decision-support protocols are tools that aid human decision-makers and can make human decision-makers less context dependent.**
- F. Like any tool, electronic health records and decision-support protocols can be used appropriately or inappropriately, and lead to favorable or unfavorable outcomes.**
- G. Bottom-up, clinician driven, problem solving with detailed patient-clinician encounter decision-support protocols, complements and informs the primarily top-down, systems HIT approach of the biomedical informatics community. Both approaches, conducted in parallel and with knowledge of the other strategies imperatives assure a more successful national HIT venture.**
- H. Decision support is too general a term. One must distinguish guidelines from protocols, and distinguish inadequately explicit protocols from adequately explicit protocols that lead to consistent and uniform clinician decision-making. One must also distinguish adaptive protocols that generate patient-specific recommendations that reflect changes in patient state.**

QUESTIONS:

- 1. What are patient-safety risks that may be introduced inadvertently through the use of electronic health records (EHRs) or other HIT products?**
 - a. Inaccurate electronic medical record.
 - i. Wrong patient.
 - ii. Erroneous data.
 - b. Failure to use the electronic medical record data to drive clinician decision-support protocols.
 - i. Merely transferring the clinical care process of today to an electronic format
 - ii. Imbalance between top-down (IT and Administratively driven) and bottom-up (clinician driven) development contributions.

1. Absence of on-site clinical use and input that would drive iterative refinement
 2. Parochial, site-specific, developments.
 - a. Overlooking vetting from multiple clinicians at multiple institutions
 - iii. Overlooking the patient-clinician encounter scale
 1. Confounding different scales of inquiry
 - a. Improperly assuming that reductionist science results, global IT considerations, or administrative imperatives will adequately inform clinician decisions at the patient clinician encounter scale.
 2. Fail to leap forward and change the way medicine is practiced.
 - iv. Underestimating clinician decision limitations (human limitations)
 1. Inadequately tested, and validated decision-support protocols.
 - a. Failure to appreciate the importance of reproducible and exportable clinical decision-support methods.
 2. Thoughtless acceptance of decision-support protocol instructions.
 - c. Outdated decision-support protocols
 - i. Failure to systematically maintain validated protocols.
 1. Absence of academic support from Deans and Department Chairpersons for young faculty interested in this T3 Translational research challenge.
 - d. Failure to aim for multi-institutional application
 - i. A focus on parochial, site-specific, development.
 - e. Web services architecture.
 - i. Failure to systematically archive validated protocols.
 - ii. Interface improperly with different systems
 - iii. Await extensive distribution of electronic medical records before linking systematically with multiple systems.
- 2. Are there specific types of risks that are more common than others?**
- a. Failure to use the electronic medical record data to drive clinician decision-support protocols
 - b. Outdated decision-support protocols
 - c. Data inaccurately entered in electronic medical record.
- 3. What are the causes of those risks?**
- a. Failure to use the electronic medical record data to drive clinician decision-support protocols.
 - i. Support clinician-driven bottom up evaluations of reproducible decision-support, informed by the best top-down general IT recommendations.
 - ii. Link payment to process control with validated and vetted decision-support tools at the patient-clinician encounter.

- iii. Address the need to change current processes and deal directly with information overload.
 - 1. Balance the current “expert” paradigm with some “process control” paradigm
 - 2. Deal directly and nationally with what is reasonable to provide and what cannot be justified.
 - iv. Reduce regulatory burdens for those developing the data required for progress.
 - 1. Experience with regulatory Agencies (OHRP and FDA)
 - v. Absence of immediate clinician benefits from use of decision-support protocols and electronic medical records.
 - b. Outdated decision-support protocols
 - i. Absence of an archival site.
 - ii. Absence of academic support for young faculty interested in maintaining/updating protocols. They cannot easily develop academic careers with this activity.
 - c. Data inaccurately entered in electronic medical record.
 - i. Clinician factors
 - 1. Overworked
 - a. Inadequate time allocated to patient visit.
 - 2. Data acquisition and recording interferes with workflow
 - a. Clinicians know that most data will never again be examined. This can lead to inattention to data because they usually do not lead to decisions
 - 3. Inadequate processes for correcting errors
 - ii. Laboratory factors
 - 1. Automatic data acquisition time/date stamp differences
 - 2. Synchronizing data is imperfect
 - 3. Correcting erroneous data
 - d. Web services architecture.
 - i. Failure to systematically archive validated protocols.
 - ii. Absence of standard interfaces and terminology.
 - iii. Need to develop linking applications that map local terms to those of web-based decision-support protocols.
- 4. What are ways to prevent and/or mitigate those risks?**
- a. Inaccurate electronic medical record.
 - i. Clinician factors
 - 1. More clinicians
 - 2. Automated systems and clinician extenders to enhance workflow
 - 3. More time allocated to patient visit.
 - 4. Error correction processes

5. When data are used for decision-support clinicians pay more attention to data accuracy, because they know the data will influence decisions (clinicians know that most data will never again be examined. This can lead to inattention to data that do not lead to decisions).
 - ii. Laboratory factors
 1. Automatic nation time synchronization scheme
 2. Correcting erroneous data
 - b. Emphasize the importance of electronic medical record data to drive clinician decision-support protocols.
 - i. Support clinician-driven bottom up evaluations of reproducible decision-support, informed by the best top-down general IT recommendations.
 - ii. Link payment to process control with validated and vetted decision-support tools at the patient-clinician encounter.
 - iii. Address the need to change current processes and deal directly with information overload.
 1. Balance the current “expert” paradigm with a “process control” (evidence-based) paradigm that is, when possible, reproducible
 2. Deal directly and nationally with which clinical and health care elements are reasonable to provide and which cannot be justified.
 - iv. Reduce regulatory burdens for those developing the data required for progress with electronic medical records and decision-support.
 - c. Maintain and update decision-support protocols
 - i. Establish an archival site for validated, safe, reproducible computer protocols.
 - ii. Begin a program to support young faculty interested in maintaining/updating protocols.
 - iii. Approach the organizations of Deans and Department Chairpersons to address the academic advancement needs of young faculty members committed to this T3 Translational research..
 - d. Web services architecture.
 - i. Await extensive distribution of electronic medical records before linking systematically with multiple systems.
- 5. How would you weigh the benefits and risks of using EHRs in patient care?**
- a. Evaluate Electronic Health Records experimentally
 - i. Study units within organizations
 - ii. Evaluate data quality before and after introduction of decision-support protocols
 - iii. Before / after designs
 - iv. Organization level randomization with before / after designs
- 6. How might data on risks best be identified as greater HIT adoption occurs?**
- a. Capture patient-clinician encounter data in real time.

- i. Aggregate risk / error data
 - ii. Feed back to clinician in real time, the patient-specific instructions that are the output of adequately explicit decision-support protocols.
 - b. Design decision-support protocols and other applications so clinicians derive immediate benefits from their use.
 - i. Data capture from physician extenders
 - 1. Patient (Computer screen interaction with or without assistance from someone in 2 below).
 - 2. Assistant (RN, PA, Clerk)
 - ii. Computer Physician Order Entry
 - iii. Automatic billing
 - iv. Automatic note templates
 - v. Automatic continuing medical education credit for clinician review of reasons or source information within the decision-support protocols.
- 7. **What are the factors that might impact an organization from reporting adverse events or known concerns about HIT products?**
 - a. Punitive actions
 - i. Regulatory agency oversight burdens
 - ii. Reimbursement penalties
 - b. Image concerns
 - i. Inadequate appreciation of human decision-making limitations
 - ii. Inadequate appreciation of medical care delivery limitations.
 - c. Inadequate time to manage clinical and data processing challenges.
 - i. Inefficiencies linked to reduced income
 - ii. Clinical needs will trump accurate data acquisition needs.

DISCUSSION OF SELECTED QUESTIONS:

- 1. **What are patient-safety risks that may be introduced inadvertently through the use of electronic health records (EHRs) or other HIT products?**
 - a. **Failure to use the electronic medical record data to drive clinician decision-support protocols.**
 - i. **Overlooking the patient-clinician encounter scale**
 - 1. **Confounding different scales of inquiry**
 - a. **Improperly assuming that reductionist science results, global IT considerations, or administrative imperatives will adequately inform clinician decisions at the patient-clinician encounter scale.**

Both the quality of data stored in clinical repositories (4) and the quality of clinical trials (5-7) are widely believed to be low, reflecting the largely recognized inadequacy of our clinical research enterprise to meet the clinical scientific and efficacy needs of our community (8, 9).

The medical scales of inquiry (10), like those of the physical sciences (11), vary. Inquiry scales range from the reductionist focus on the behavior of the parts of a system to the holistic focus on the integrated behavior of the intact system. The many parts of the patient system include biochemical, cellular, organ and physiologic elements. For medical questions, the intact system consists of the patient within the clinical environment, with all of the interactions and foibles that occur during the patient-clinician encounter (10, 12, 13). For medical decision-making, the concept of the scale of inquiry is important both to clinician decision-makers and to clinical researchers. Definitive answers about decisions at the patient-clinician encounter scale frequently require definitive studies at the patient-clinician encounter scale, because extrapolation of results from other scales, such as the cell biology or epidemiologic scales, is frequently inadequate (10).

iv. Underestimating clinician decision limitations (human limitations)

1. Inadequately tested, and validated decision-support protocols.

a. Failure to appreciate the importance of reproducible and exportable clinical decision-support methods.

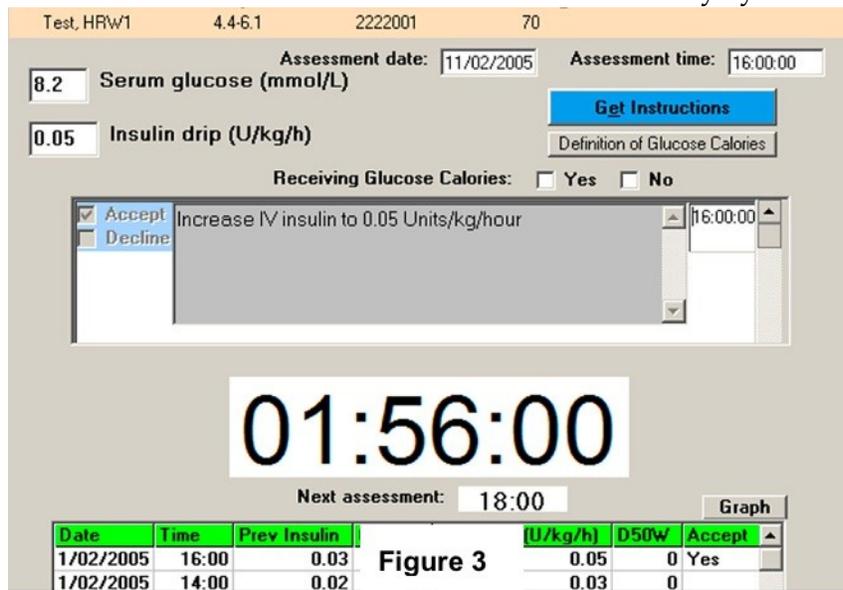
Observations in usual clinical practice can be confounded by unnecessary variation (14), and by error (15) that includes both random and systematic noise (10). Clinical care and research interactions are, therefore, commonly non-reproducible. The NIH has recognized our need to reengineer clinical research and clinical care through the Roadmap program and its successor, the Clinical Translational Science Award program (8, 9). Current efforts by the NIH Clinical Research Policy Analysis and Coordination Program (NIH Roadmap, Office of Science Policy, Office of the Director) to harmonize Federal Government interpretations of regulations reflect the widespread distribution of unnecessary variation and its deleterious impact on our community (16).

National guidelines by important organizations such as the Institute for Healthcare Improvement, the Agency for Healthcare Research and Quality, the American Heart Association, and others do not include the level of detail and complexity required for reproducible methods. Guidelines generally consist of broadly defined suggestions for care, and may contain inexact descriptions of patient state, which requires clinician judgment and allows variable clinician decision-making. For example, consider the following published guideline for managing a patient supported with mechanical ventilation: "Try to return to 40% oxygen breathing and positive end-expiratory pressure of 5 centimeters of water as soon as possible." It does not include the details of what should be done. In contrast, a reproducible clinical-decision method generated the following individualized treatment recommendations for a patient supported with mechanical ventilation: "Reduce oxygen breathing by 10%, from 60% to 50%; Maintain positive end-expiratory pressure at 8 centimeters of water; Reassess oxygen partial pressure in the arterial blood in 30 minutes, at 15:40 hours." Reproducible clinical-decision methods (computer protocols) involve complex and multiple decisions within one protocol. The reproducible clinical-decision methods contain enough detail to theoretically have the computer control the intervention (e.g., mechanical ventilator, intravenous drugs) but

we always retain clinician oversight, in which a bedside clinician reviews and decides to accept or decline the computer protocol recommendation.

My colleagues and I define a protocol as adequately explicit (leads to reproducible clinician behavior) when it's patient-specific instructions are accepted and executed by clinician's at least 90% of the time. An adequately explicit protocol can elicit the same decision from different clinicians when they are faced with the same clinical information. Paper-based protocols can contain enough detail to be adequately explicit (17) but they are difficult to use. Adequately explicit computer protocols are easier to use, can contain the greatest detail (18), and may lead to the upper limit of achievable uniformity of clinician decision-making short of closed-loop control (19-21). Inadequately explicit protocols omit important details (22-24) and elicit variable clinical decisions from different clinicians, who must fill in the gaps in protocol logic. Humans are inconsistent, and any single clinician may produce different choices at different times, even though faced with the same patient data. Judgment, background and experience vary among clinicians and so will the choices they use to fill in the gaps of inadequately explicit protocols (and guidelines). We have used adequately explicit computer protocols to achieve a previously unattainable level of scientific rigor and credibility in multiple clinical investigative sites and in usual clinical practice (1-3, 10). We use a point-of-decision-making display of computer protocol recommendations to clinicians.

Several adequately explicit computer protocols (eProtocols) address some limitations of current clinical trial and usual clinical care delivery systems (25-27). These eProtocols lead



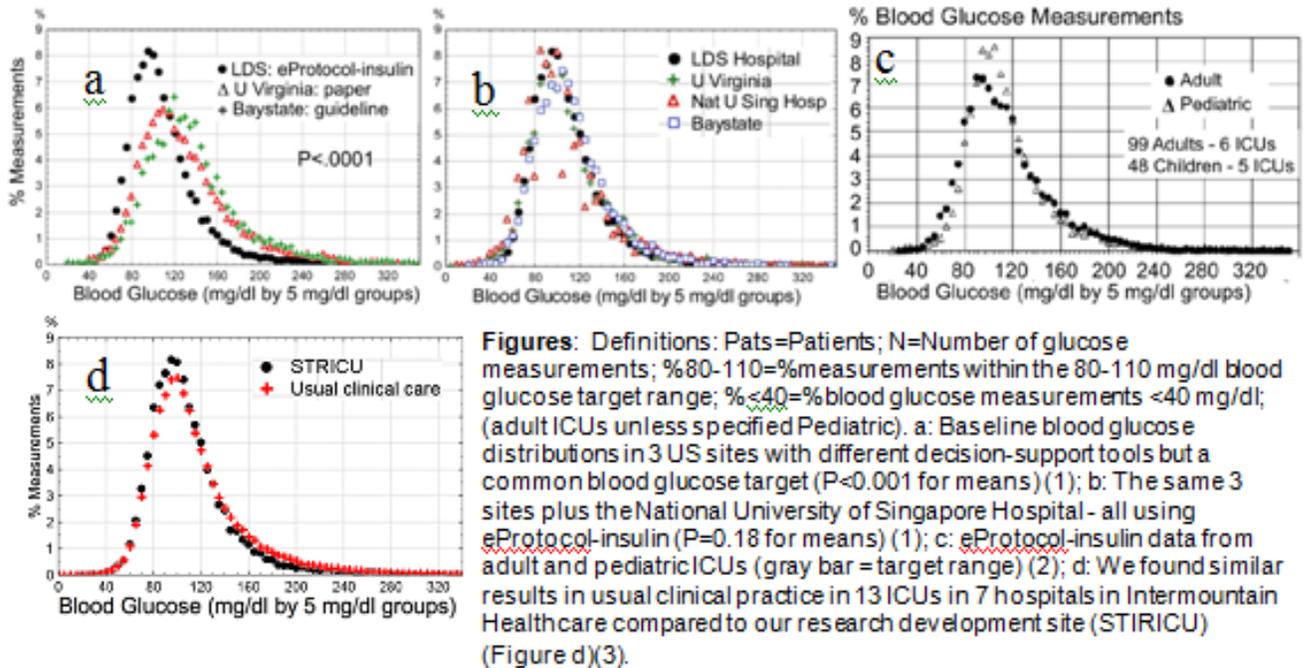
different decision-makers consistently to the same patient-specific decision and action, when dealing with the same patient state (10, 28, 29).

eProtocols allow an experiment to be replicated in a variety of clinical research and care settings (1-3). They have, to date, been used in limited settings (about 20 sites).

For example, consider blood glucose management with eProtocol-insulin (1-3).

Figure 3 provides one view of the single eProtocol-insulin bedside screen displayed to clinicians. After entering a blood glucose value, a bedside clinician receives an insulin infusion rate instruction. In the event of hypoglycemia, eProtocol-insulin generates instructions to discontinue insulin and administer intravenous glucose adjusted for patient weight. The clinician may accept or decline the instruction and enter an alternative treatment based on clinical experience or specific characteristics of a patient. If the instruction is declined, the clinician enters a reason captured by eProtocol-insulin. The computer then displays a digital

timer for the next recommended glucose measurement. In most instances, the recommended interval between blood glucose measurements is 2 hours.



Recent results using eProtocol-insulin demonstrate the potential of eProtocols to enable rigorous clinical research and consistent clinical practice (Figures a-c) (1). The decreases in mean glucose and the increase in the percentage of glucose measurements within the 80-110 mg/dl target range were statistically and clinically significant after replacement of usual care tools (Figure a) at the University of Virginia (Va) and Baystate Medical (Baystate) Centers with eProtocol-insulin (Figure b). Clinician compliance with eProtocol-insulin instructions was 91-98% for adults (Figure b) and 93% for children (Figure c). Blood glucose distributions with eProtocol-insulin in different adult ICUs and cultures (U.S. and Singapore (Nat U Sing)) and in pediatric ICUs were replicable (Figures b, c). The similar distributions in adults and children indicate our ability to join different medical specialties and enable replicable bedside clinician behavior with eProtocol-insulin (Figure c).

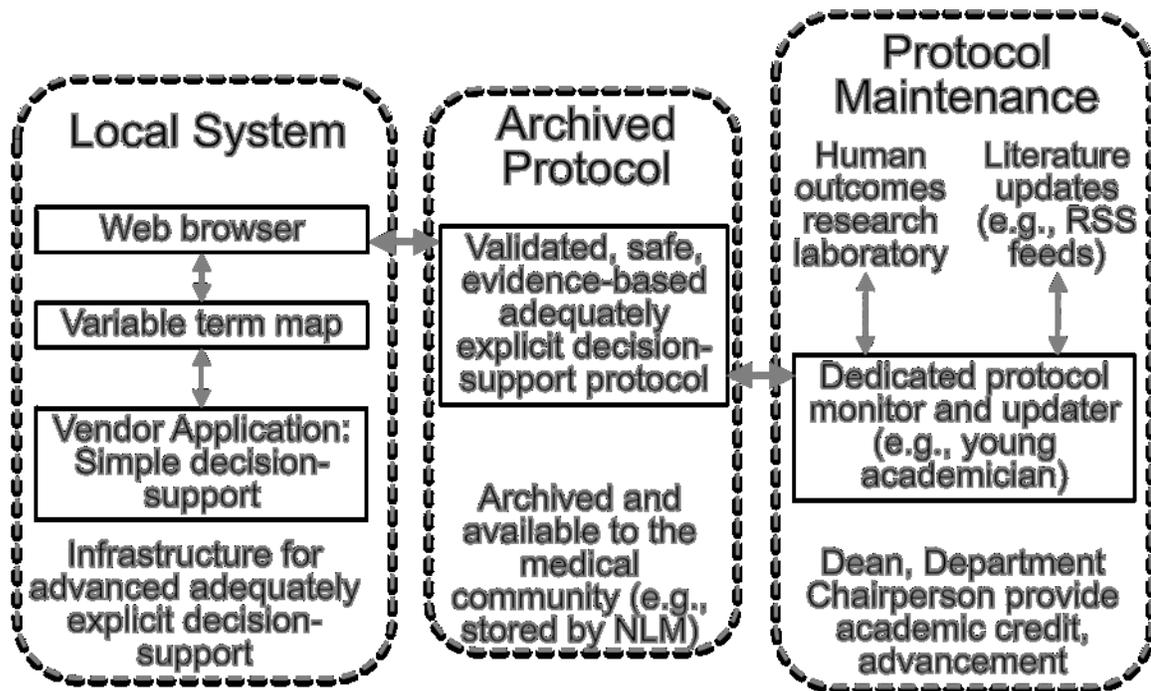
c. Outdated decision-support protocols

iii. Failure to systematically maintain validated protocols.

1. Absence of academic support from Deans and Department Chairpersons for young faculty interested in this T3 Translational research challenge.

Vendors are unlikely to assume the liability risks of open-loop servo-controlled adequately explicit evidence-based protocols that lead different clinicians to the same clinical decisions, when faced with the same patient data. Such protocols may be archived, for public access, by an institution like the National Library of Medicine (NLM). Maintaining the protocol (rules, logic, evidence-base) will be necessary to assure the protocol remains current.

This maintenance is unlikely to be assumed by either vendors or the government. The academic community will likely be the curators of protocols. This will require the commitment of a dedicated protocol monitor and updater with an interest in translational research, specifically T3 translation (30). I suspect persons will be young faculty members (academicians). The dedicated protocol monitor and updater will require a clinical environment that can function as a human outcomes research laboratory in order to properly and systematically evaluate the protocol changes in the clinical care context. This testing and validation should lead to publications in peer-reviewed journals. The updated protocol would, after formal validation and testing, replace the outdated version. Dedicated protocol monitor and updaters will require assurance from Deans and Department Chairpersons that they will be able to receive academic credit for this work and be able to advance academically. Finally, some institution will have to assume the responsibility of assuring continuity when the dedicated protocol monitor and updater changes positions or assumes new research interests. This function might be assumed by the agency that archives the protocol. The National Library of Medicine (NLM) would be a reasonable candidate.



d. Failure to aim for multi-institutional application

i. A focus on parochial, site-specific, development.

Attention to distributable (exportable) reproducible clinician decision methods that can be accessed by multiple institutions:

Some leading institutions consider decision-support functions of their electronic medical record systems primarily as a means of tailoring decision-support to the styles and needs of individual physicians or local clinical care units. For example, the American Thoracic Society-

Infectious Disease Society of America 2007 Community Acquired Pneumonia guidelines, while intending to standardize clinical decision making, called specifically for development and implementation of locally adapted guidelines. This could formalize the unnecessary variation in clinical care long decried by Dr. John Wennberg and would not produce methods that are reproducible across locations (10). Heart failure guidelines also depend on clinician judgment to identify issues like contraindications to angiotensin converting enzyme inhibitor use (31). My colleagues and I, in contrast, emphasize the importance of distributing a reproducible clinician decision method to multiple institutions. This would establish a distributed multicenter laboratory that could enroll many more subjects than currently possible in comparative effectiveness research, in a shorter time, and most importantly manage them all with the same reproducible clinician decision method. This constitutes a needed paradigm shift in clinical trial research that will allow rapid testing of innovations in care and rapid dissemination of research results to usual clinical practice.

3. What are the causes of those risks?

a. Failure to use the electronic medical record data to drive clinician decision-support protocols.

- i. Support clinician-driven bottom up evaluations of reproducible decision-support, informed by the best top-down general IT recommendations.
- ii. Link payment to process control with validated and vetted decision-support tools at the patient-clinician encounter.
- iii. Address the need to change current processes and deal directly with information overload.
 1. Balance the current “expert” paradigm with some “process control” paradigm
 2. Deal directly and nationally with what is reasonable to provide and what cannot be justified.
- iv. **Reduce regulatory burdens for those developing the data required for progress.**

3. Experience with regulatory Agencies (OHRP and FDA)

Accountability should apply to regulatory agencies, as it does to other groups and persons. One should consider the harm as well as the benefit that results from Agency activity. The OHRP damaged the NIH/NHLBI ARDS Network program with regulatory burdens. The FDA has almost halted an adequately explicit computer protocol activity due to regulatory burdens. The OHRP damages a scientific study of checklists being conducted in Michigan by Dr. Pronovost (Johns Hopkins). These recent activities should be considered, along with the dramatic protection conferred by disallowing Thalidomide treatment of pregnant American women so we can come to a balanced assessment of Agency contributions. The FDA could enable and enhance competent innovation of decision-support protocols by

reposting the 1989 Draft FDA Policy for the Regulation of Computer Products (32). This policy draft reflected the position voiced by the FDA director, Frank Young, MD (33)

5. How would you weigh the benefits and risks of using EHRs in patient care?

This will require systematic study and evaluation of electronic health records (34-36). Electronic health records may have both positive and negative effects (37) and may not achieve expected resolution of problems (38). The multiple possible impacts of reproducible clinical decision-support protocols illustrate, below, the difficulty of predicting the outcome of electronic medical records. Note particularly that 11 of the 14 listed impacts, in the Table below, have both favorable and unfavorable possible outcomes.

Possible impacts of reproducible clinical decision-support protocols	
Favorable	Unfavorable
Clarify the clinical decision making process and increase the clarity of thinking of clinical care team members by revealing the details of decision-making	Obscure the clinical decision making process and decrease the clarity of thinking of clinical care team members by hiding the details of decision-making
Reduce unnecessary variation in clinical care	
Link clinical care with evidence based medicine through validated, safe and reproducible protocols	Interfere with delivery of evidence based care by using inadequately validated protocols in clinical practice
Increase the quality of data acquisition, and care, because clinicians understand the data will lead immediately to prescriptions for patient care	Reduce the quality of care with thoughtless acceptance of protocol instructions by bedside clinicians
	Continue to deliver care according to outdated rules in protocols that did not receive required updating
Coordinate multiple sites with a common reproducible method	
Enable a distributed, geographically dispersed, laboratory for clinical research	
Provide nurses, therapists, and other physician extenders a surrogate physician (computer protocol incorporating the physicians' reasons for the decision) that operates around the clock	Reduce the role of physicians in clinical care
Train physicians to use technology and be more efficient	Reduce capacity of physicians to innovate
Reduce the frequency of calls to physicians at odd hours	
Enhance education of clinical trainees by articulating the rules for decision-making, including the details for the step changes, the assessment intervals, etc.	Reduce the quality of education of clinical trainees by distancing them from the decisions involved in clinical care
Automatically link inquiries during clinical care activities with Continuing Medical Education credit	Lead to abuse of Continuing Medical Education credit, through unnecessary inquiry into protocol logic behind instructions
Clarify the process of care, enabling better communication and understanding by all clinical care team members	Contribute to thoughtless care by making care rote

Possible impacts of reproducible clinical decision-support protocols	
Favorable	Unfavorable
Serve an exculpatory legal function in the event of poor clinical outcome	Serve an inculpatory legal function in the event of poor clinical outcome

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