All Comments

Names	American Academy of

McInerny, Thomas K., MD, FAAP

Comment ID

23

Organization

Org Typ1	Org type	Categories
		1. Reporting, 18. Other, 2. Vendor Engagement (CoC, etc), 3. PS

1 Reporting

• AHRQ's Common Formats should be rapidly improved to include the ability to handle images, including screen shots, photos, and videos.
• The AAP recommends that workflow friendly reporting tools be developed for all health IT systems and tools. For example, the "green button" from an EHR standardizes key information and sends it to the appropriate reporting body (eg, Patient Safety Organizations).

2 Vendor Engagement (CoC, etc)

• Voluntary reporting by developers may fail to result in a meaningful safety reporting system, because there is little to no incentive for developers to report. The AAP recommends that developers be provided PSO legal protection for reporting since this form of protection does not currently exist.

3 PSO

• PSOs need more resources: the capabilities, strategy, and funding of these organizations widely vary. Additional funding and technology resources as well as programmatic re-direction are necessary to build strong and effective safety reporting systems from the current PSO structure.

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

• Although the AAP is pleased with the breadth of the plan, we urge the inclusion of greater detail around specific activities and concrete delivery dates and deliverables.

Names

Coli, Bob, MD

Comment ID

103

Organization

Org Typ1	Org type	Categories
		8. MU, 9. Cert

1 Reporting

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

One practical way to immediately begin achieving these important Meaningful Use goals would be to implement a standard format for reporting the results of clinical lab tests and imaging results by leveraging the pilot teams and production deployments of the LRI+LOI+eDOS Initiatives and the Automate Blue Button Initiative (ABBI).
The basic problem confronting physicians and their patients is that the user interfaces of EHR, PHR and HIE platforms are using variable reporting formats to display results as incomplete and fragmented data. The adverse patient safety, workflow and redundant testing effects of this user interface problem have existed since medical information system development began over 60 years ago. (2) However, while they are familiar to clinicians and nurses, until recently, the negative effects of poorly displayed test results data have remained hidden from most policy makers and health IT system vendors.

9 Cer

One practical way to immediately begin achieving these important Meaningful Use goals would be to implement a standard format for reporting the results of clinical lab tests and imaging results by leveraging the pilot teams and production deployments of the LRI+LOI+eDOS Initiatives and the Automate Blue Button Initiative (ABBI).
The basic problem confronting physicians and their patients is that the user interfaces of EHR, PHR and HIE platforms are using variable reporting formats to display results as incomplete and fragmented data. The adverse patient safety, workflow and redundant testing effects of this user interface problem have existed since medical information system development began over 60 years ago. (2) However, while they are familiar to clinicians and nurses, until recently, the negative effects of poorly displayed test results data have remained hidden from most policy makers and health IT system vendors.

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

Names

Austin, Myslin

Comment ID

102

Organization

Org Typ1	Org type	Categories
		10. Testing, User Tools, best practices

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices

I applaud the direction to ensure safety in health IT and would recommend a more prescriptive approach regarding human factors element that impact the environment of care. The environment, irregardless of setting need to consider complexity reduction as a strategy for safer use of technology. The impact of implementation of each change must be evaluated in terms of the holistic impact. I am currently conducting a human factors usability assessment of a clinical decision support tool using studies and tools provided through AHRQ and was taken aback by the missed opportunities to leverage lessons learned from other industries. The fact remains that safety risk posed by distractibility, fatigue, faulty user interface may not be readily apparent to a reviewer as outlined in this plan.

• Instead of relying on errors of using faulty human centered design principles lets leverage lessons learned from other industry to utilize technology in a way that complements or at least is not counter productive to human performance. How about asking IT vendors if they are using specifications guidelines from the aviation or automotive industry to design screen displays, alerts etc.

11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

Names

Craven, William D.

Comment ID

101

Organization

Org Typ1	Org type	Categories
		18. Other

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

The plan needs to clearly spell out how patients can opt out of the use of the Electronic Health Records System either completely or in part. The right of Americans to opt out was clearly promised to patients by HHS Secretary Kathleen Sebelius and HHS National Coordinator for Health information technology Dr. David Blumenthal. The current draft does not adequately explain how, specifically, a patient exercises their right to opt out.

Names

Talarico, Laurie , MS, RN, NP

Comment ID

99

Organization

Org Typ1	Org type	Categories
		16. State Governments

1 Reporting

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

As a safety measure, inclusion of jurisdictional statue/regulation adherence in particular with ambulatory practice setting medication ordering practices must be addressed. Many HIT software programs allow for CPOE functions to include non-prescriber authorization of renew/refill or extension a prescription that has expired without first consulting the prescriber. This is not allowed in many jurisdictions, including MA.

17 Private Sector Leadership

18 Other

Names

Lorance, L. Murray

Comment ID

90

Organization

Org Typ1	Org type	Categories
		18. Other

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

I do not see where EMS/Fire agencies & ambulance entities, even volunteer rescue entities (who create patient incident forms which accompany pt. to medical treatment) are included in this important policy change, nor received notice to comment by deadline. It might result in unfunded mandates which will adversely affect local rescue agencies, who are limited by fixed operating budgets. We cannot continue to tag on additional regulations and responsibilities or limitations on every aspect of life. The authors and proposers must be identified, exposed /held accountable for excessive requirements as well as unwanted added circulations of personal information. There could also be other unintended consequences for these entities which need full consideration.

Names

Kross, Dean, MD

Comment ID

26

Organization

Org Typ1	Org type	Categories
4	4. Clinician Provider Organization	1. Reporting, 14. Publish Report on strategy and recommendation

1 Reporting

• I urge that the Plan publicly assure confidentiality for those reporting the deaths or other injuries caused by HIT.
• I urge that the Plan specify a mechanism whereby all users, nationally, are notified of where to report an adverse event, near miss, or the dysfunction of the HIT device.
• I urge that the Plan require that there be a mechanism to preserve the screen shot of the EHR, CPOE, or CDS device at the time of dysfunction and send it to the central safety organization when deemed necessary by the user.
• I urge that the Plan specify to whom the user reports the adverse event(s).

2 Vendor Engagement (CoC, etc)

• The vendors must be held accountable to a central body, as they are to the FDA
• The "Code of Conduct" is decidedly naïve and has little role in the Plan. Big business, ie big pharma or big HIT vendor, as repeatedly witnessed, can not police itself and wield too much self serving influence.
• Thus, the authority should be vested in either the FDA or the organizational structure recommended by the IOM

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

• I urge that the Plan assure that the reports collected be put on a public database with anonymity, like MAUDE, as an example.
• Since each of the three HIT components (EHR, CPOE, and Clinical Decision Support) meet the F D and C Act's definition of a medical device, the FDA should be central to any such program. Yet, to the detriment of the patients and device users, the Plan ignores the FDA.
• The FDA is organized to assure the safety, efficacy, and usability of these devices, yet the Plan left the FDA out of the process, entirely.
• I urge you to reverse course and keep the FDA actively involved in the HIT Safety Plan, and to simplify the Plan to assure the safety of HIT devices.

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

• The vendors must be held accountable to that central body, as they are to the FDA
• Thus, the authority should be vested in either the FDA or the organizational structure recommended by the IOM.
• The FDA is organized to assure the safety, efficacy, and usability of these devices, yet the Plan left the FDA out of the

process, entirely.
• I urge you to reverse course and keep the FDA actively involved in the HIT Safety Plan, and to simplify the Plan to assure the safety of HIT devices.

15 ONC Safety Program

• As designed and described, the Plan is convoluted, decentralized, and user unfriendly.
• The responsibility for the safety, efficacy and usability of HIT should be vested in one organization, and not diffusely distributed amongst several, especially when they have zero experience in matters of medical device safety. That central organization should provide accountability, transparency, and integrity to the critical process of surveillance of the safety of HIT devices.
• The Plan creates excess complexity, for what should be a simple program, by using organizations that are not currently equipped to handle matters of device safety and adversity.
• The truth about the near misses, injuries, and deaths as well as the EHR crashes, EHR freezes, and other EHR unavailability should not be concealed in a morass of new bureaucracy.
• I urge that the Plan specify a mechanism whereby all users, nationally, are notified of where to report an adverse event, near miss, or the dysfunction of the HIT device.

16 State Governments

17 Private Sector Leadership

18 Other

• As designed and described, the Plan is convoluted, decentralized, and user unfriendly
• The basic premise of your HIT Safety Plan ("Plan"), "shared responsibility", sounds enticing, but is intrinsically flawed and dangerous, violating the recommendations of the IOM, as you show in your "crosswalk".
• I urge that the Plan place particular emphasis on EHR outages of any duration, EHR freezes, interface failures, and other dysfunctions that endanger large populations at one time.
• It fails to address matters of recalling an HIT device, or matters of warning letters to the vendor requiring mitigation of its device's dangers.

Names

Bright, Roselie A., ScD, MS, PMP

Comment ID

84

Organization

Org Typ1	Org type	Categories
		1. Reporting, 15. ONC Safety Program, 18. Other, 4. ACB, 6. QSR

1 Reporting

Confusion on the part of health care providers regarding *what* to report

Just for EHRs, the Plan has a long list of entities to which providers should report EHR AEs:

- ONC
- ONC-Authorized Certification Bodies (ONC-ACBs)
- Health IT developers
- Patient Safety Organizations (PSOs) (a provider could be involved with more than one, since some are based on geography and others are based on other criteria, such as type of condition being treated)
- State, if living in one of the 26 states that collect AE reports
- State CMS surveyor or accreditor

In addition, a provider could reasonably conclude that an EHR is a medical device, and send the AE report to FDA. This large

list of to-whom-to-report will cause confusion on the part of would-be reporters. HHS has been trying to consolidate all reporting, for patient safety, FDA-regulated products, and significant diseases, to one entity, which would then triage the reports to the appropriate entity for review. We strongly encourage the Plan to join or incorporate this effort to offer "one-stop reporting" to providers.

Confusion on the part of health care providers regarding *how* to report

Many organizations, including AHRQ, in HHS have been cooperating with each other and non-HHS entities to develop standard electronic formats for AE and disease reports. One of the efforts, the Public Health Reporting Initiative, is overseen by ONC. Contrary to these efforts, AHRQ's Common Formats (for providers to use when reporting to Patient Safety Organizations (PSOs)) are incompatible with any of the electronic formats, and are paper-based. Presumably, AHRQ was under a tight statutory deadline to craft types of reports that are conceptually additional to those already used by HHS. We recommend that AHRQ begin work with its sister agencies and the appropriate standards bodies to convert the Common Data Formats to the modern electronic standards, which have been designed to readily accommodate new types of information on each report, as well as new types of reports. All of the organizations that have been designated to receive AE reports from providers should become technically capable of receiving, storing, analyzing, and forwarding reports that are sent in the modern electronic format.

Our understanding of PSOs is that they have been established to "[encourage] clinicians and health care organizations to voluntarily report and share quality and patient safety information without fear of legal discovery." It seems likely to us that most providers are not yet members of a PSO. Educating providers about reporting EHR AEs will be a large undertaking; even after decades of the medical device reporting program, provider knowledge that medical device AEs are reportable is inadequate.

We are also concerned that confusion on the part of providers might result in the same report being sent to more than one PSO, and to other types of organizations as well as PSOs. When the data are combined, it will be difficult to detect whether apparent duplicates are truly duplicative, since the PSO reports will have had identifying information removed.

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

ONC-ACB de-identifies AE reports before passing them to ONC

On page 30 of the plan, Recommendation 7.a., Actions column, second paragraph, "ONC-ACBs will … provide de-identified reports to ONC". We recommend that ONC receive them with full identification for two reasons: to recognize duplicate reports from different sources, and to facilitate further inquiry about the AE with the reporter. Both recommendations can be crucial to efficient ONC review and analysis.

ONC-ACB analysis of AE reports

On page 13, figure 2, ONC-ACBs box, ONC will direct the analyses to be done per ONC's view of which EHR issues have the potential to cause the greatest patient harm. We agree that prior hypotheses may drive analyses of AE reports. We also strongly encourage "open-minded" analyses, by each of the AE analysis entities (not just ONC-ACBs), to allow unanticipated patterns and problems to be noticed.

5 CMS

6 QSRS

We support using the Quality & Safety Review System and Medicare Patient Safety Monitoring System to study the impact of the automation of health records on ease of AE reporting.

We recommend considering additional ways of studying this issue:

- Form 2 groups of hospitals (it would probably be more efficient to focus on hospitals for the first study of this type) that are comparable, except one group still uses paper health records and the other uses EHRs.
    - Examine all the billing claims (or a convenient subset, such as Medicare and Medicaid) from all the hospitals that indicate any of a predefined set of AEs occurred.
    - Search for the corresponding AE reports among the relevant databases.
    - For the possible AEs that were not reported, ask the provider to verify that an AE did occur and was reportable (reasons for billing to falsely indicate an AE include simple coding error, or a set of tests were ordered to rule out a particular diagnosis).

- For the 2 groups, compare the rates of AE reporting per total reportable AEs.
- Further analyses could be done by subdividing the AEs by categories that correspond to factors that have already been published to be related to AE reporting rates, hospital characteristics, patient characteristics, provider (the person) characteristics, and event characteristics.

Consider adding information about the provider's EHR system to the standard format for all AE reports. This will allow AE report reviewers and automated review software to notice patterns involving EHER

7 MAUDE

Overlap of responsibility for medical devices that incorporate software

As mentioned elsewhere in this document, the Plan includes ONC efforts to analyze AEs associated with medical devices that include software. AE reports for these products are already collected by FDA. FDA experience has shown that access to all relevant reports is important for detecting patterns of AEs. We recommend allowing FDA to have access to all the Health IT reports that ONC collects.

ONC analysis of MAUDE reports

We agree that monitoring MAUDE for EHR AE reports makes sense. We invite ONC to also use the expertise of the FDA reviewers of all reports related to software in medical devices, as well as the FDA scientists and engineers who focus on Health IT interoperability and interference.

We invite AHRQ and ONC analysts to learn from FDA analysts.

8 MU

9 Cer

We suggest that ONC also obtain the authority, under medical device law, to revoke certification and order EHR manufacturers to issue recalls of their products.

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

We recommend that a central database be formed to which each group has as much access as legally allowable, so that patterns and signals will be more readily perceived. The overlap of EHRs with software embedded in medical devices suggests that relevant MAUDE AE reports should also be available to the central database, and MAUDE analysts should have access to the central database.

We encourage reviewers of AE reports to consult with FDA and NIST experts on EHRs, medical devices with software, and interoperability and interference issues.

16 State Governments

17 Private Sector Leadership

18 Other

Four areas related to health IT are brought up as being in the scope of the Plan:

- electronic health record (EHR) AEs
- AEs for medical devices that incorporate software (Plan page 10, first paragraph; Plan page 32, Recommendation 7.c., Actions column, first paragraph)
- Impact of EHR vs paper health records on overall AE reporting
- Impact of health IT on patient safety

- Which of the above aspects is addressed with each of the specific parts of the plan is unclear

1. **Minor errors that have been identified in the Plan**

Page 12, Figure 1, NPSD box: should "Network of Patient Safety Database" be "Network of Patient Safety Databases", as named on the AHRQ website?

Page 12, Figure 1, and page 39: the box in figure 1 is the same as the box "PSO/AHRQ" on page 39. However, the name of

the figure on page 12 is “AHRQ/PSO”. The names should be consistent. Furthermore, Figure 1 could benefit from a more descriptive title, and page 39 should have a figure identifier and title.
Page 13, Figure 2, and page 39: the box in figure 2 is the same as the box “ACBs” on page 39. However, the name of the figure on page 13 is “ONC-ACB”. The name on page 39 should be “ONC-ACB” to be consistent with figure 2 and the rest of the document. Furthermore, Figure 2 could benefit from a more descriptive title. Third, on both pages, inside the inner box named “ONC-ABCs”, second inner bullet, there is an extraneous “s” between the words “developers” and “receives” that should be removed.
Page 14, Figure 3, and page 39: On both pages, inside the inner box named “Surveyors and Accreditors”, “Conduct surveys and accredits” should be “Conducts surveys and accredits”. Furthermore, Figure 3 could benefit from a more descriptive title.
Page 20, #1, first paragraph: should “larger context patient safety” be “larger context of patient safety”?
Page 21, #3, title: should “the implementation the Health IT Safety Plan” be “the implementation of the Health IT Safety Plan”?
Page 25, Recommendation 1.c., Actions column, last sentence: “and validate a sample of the complaints HER technology developers” seems to be missing one or more words.
Page 31, Recommendation 7.b., Actions column, second paragraph: the first sentence is unclear (“AHRQ is already developing the Quality & Safety Review System (QSRS) to facilitate retrospective, surveillance of harm from all causes, health IT safety events.”). A suggested rewording, if it captures the intended meaning, is: “AHRQ is already developing the Quality & Safety Review System (QSRS) to facilitate retrospective surveillance of harm from health IT safety events of all causes.”
Page 32, Recommendation 7.c., Actions column, last paragraph, last clause: Should “is can be” in “EHR technology is can be used to report safety events in AHRQ’s Common Formats” be “is” or “can be”?
Page 38, under “Develop Safety measures and targets”: should “with that larger context general patient safety” be “with the larger context of general patient safety”?

Names

Hoggle, Lindsey, MS RD PMP

Comment ID

51

Organization

Academy of Nutrition and Dietetics

Org Typ1	Org type	Categories
9	9. Allied Professional Organization	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 13.

1 Reporting

• As with quality measures, there is a need to align safety reporting processes across all reporting programs as this would allow for increased efficiency, reduced redundancy and greater overall potential for improvement.
• In past discussions by the HIT Standards Committee, the recommendation for a “button” to report risks and events immediately within the framework of the EHR was suggested. This option, while undeveloped, would provide a “real time” capture and reporting process for busy providers who may want to report but are challenged with competing tasks and time restraints. It seems logical that a third party reporting process (concurrent with the EHR vendor) would provide the best framework for quality improvement and risk adjustment across all vendors. As with quality measures, there is a need to align safety reporting processes across all reporting programs as this would allow for increased efficiency, reduced redundancy and greater overall potential for improvement.

2 Vendor Engagement (CoC, etc)

• Patient safety should take precedence over company IP and data collection should be accomplished such that this problem does not occur. In particular, the Academy requests clarification on how the ONC will monitor EHR vendor safety mitigation compliance in commitments to a culture of safety.
• Previous assertions that EHR Intellectual property is compromised by reporting such instances of potential harm should not

be endorsed. Patient safety should take precedence over company IP and data collection should be accomplished such that this problem does not occur. In particular, the Academy requests clarification on how the ONC will monitor EHR vendor safety mitigation compliance in commitments to a culture of safety.

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

• Future stages of Meaningful Use should require HL7 Standards that support this area [Transition of care]: HL7 Nutrition/Diet Orders Domain Analysis Model 2 and HL7 Nutrition/Diet Order Clinical Messaging Project.3

• Given the present burdens on individual practitioners regarding MU reporting, it seems that guidance on the process and measures for conducting such a study should be provided to any participating providers. It seems this would be better suited to inclusion prior to implementation and as part of the training process for all providers who have rights to use the EHR system. A similar requirement that would provide more consistent results as certification criteria which includes multi-disciplinary input into the development and implementation process would be helpful. The Academy agrees with present ONC focus on patient safety, human factors, a safety culture and user-centered design. In addition, continued progress on the usability testing criteria under development by National Institutes of Standards and Technology (NIST) should continue to reinforce safety components of health IT.

9 Cer

• A similar requirement that would provide more consistent results as certification criteria which includes multi-disciplinary input into the development and implementation process would be helpful. The Academy agrees with present ONC focus on patient safety, human factors, a safety culture and user-centered design

10 Testing, User Tools, best practices

• In addition, continued progress on the usability testing criteria under development by National Institutes of Standards and Technology (NIST) should continue to reinforce safety components of health IT.

11 Edu

• The Academy recommends inclusion of both training prior to health care professional access and use of EHRs and routine training on safety measures for proper use of orders and documentation of care. While training is generally a component of EHR implementation, great variations exist as to the extent of training and user requirements prior to the end-user using the system for patient care.

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

• The IOM 1999 report, To Err is Human12, identified “automated order entry, clinical reminders, drug-drug interaction and drug-allergy checking” as components of HIT that can improve patient safety. To date, these areas have limited implementation in comparison to the potential they provide. Additional research and development in these areas are needed.

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

• The Academy agrees with the creation of a Health IT and Patient Safety Plan to support the evolution of health care’s focus of a culture of safety which is understood and upheld by patients, providers, and all stakeholders of the health care system.

• The Academy recommends that EHR should incorporate features related to nutritional health, but never give a mechanism (e.eg., MU) for how ONC should ensure nutrition is incorporated into EHRs

• The Academy recommends inclusion of safety related questions in patient satisfaction surveys to promote improved awareness an input on patient generated safety comments

Names

Sama, Andrew E. MD, FACEP

Comment ID

20

Organization

ACEP (American College of Emergancy Physicians)

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

• Mere reporting alone is not enough. ACEP recommends requiring analysis of reported issues and accountability by vendors to address deficiencies in a timely manner be incorporated into the ONC certification process.
• ACEP would strongly encourage a tracking system that not only collects reports of adverse event data or patient safety issues, but also what action has been taken, when upgrades will be installed, and what steps are being taken by the developer to mitigate a similar event or condition in the future. This is a critical component of the continuous performance improvement cycle.

2 Vendor Engagement (CoC, etc)

• ACEP recommends requiring accountability by vendors to address deficiencies in a timely manner be incorporated into the ONC certification process.
• Mere reporting alone is not enough. ACEP recommends requiring analysis of reported issues and accountability by vendors to address deficiencies in a timely manner be incorporated into the ONC certification process.
• EDIS vendors should learn from local patient safety improvements and ensure timely distribution of necessary changes to all installation sites.
• “Hold harmless” or “learned intermediary” clauses should be removed from all vendor software contracts.6

3 PSO

• PSOs may be ill-equipped to handle the volume and may not have ready access to the necessary expertise to do this analysis. ACEP supports enhanced dedicated HIT resources for PSOs to:
o Collect, aggregate and analyze user reports
o Work with providers to mitigate risks
o Work with vendors to mitigate risks
• ACEP recommends requiring analysis of reported issues
• ACEP recommends that the EHR certification process incorporate enhanced standards of usability, clinician end-user testing, design, and functionality be met for individual departmental use (ED, OR, ICU, etc).
• ACEP notes that the diagram in Appendix D: ONC Program, that reports to the PSO’s will be de-identified and aggregated by AHRQ before submission to the ONC or vendors. This lacks a basic performance improvement feedback loop.
• A review process should be in place to monitor ongoing patient safety issues with EDIS. ED providers and other stakeholders should be encouraged to submit safety concerns for review. In addition, prospective risk assessments should be conducted regularly.

4 ACB

5 CMS

6 QSRS

• ACEP also supports the proposed Quality & Safety Review System (QSRS), however, this system, is being designed for use on a voluntary basis, which may limit its effectiveness.

7 MAUDE

8 MU

9 Cer

• However, it is equally important that the interface for alerting users to real dangers must not disrupt workflow from lifesaving care. Therefore, ACEP urges ONC to reduce clinically insignificant CDS alerts, as defined by the clinicians and pharmacists who will be receiving them, during the vendor product certification process. Furthermore, ACEP urges ONC and vendors to test and certify usability for emergency department modules with emergency department clinicians from a variety of settings including academic, community, rural, and urban settings as each may differ in practice patterns. Although these comments are largely related to the practice of emergency medicine, ACEP recognizes that it may be beneficial to other hospital departments as well.
• ACEP supports the concept of incorporating safety into certification criteria for HIT products and further recommends the development of departmental specific criteria to enhance the functionality of the ED.
• ACEP recommends that the EHR certification process incorporate enhanced standards of usability, clinician end-user testing, design, and functionality be met for individual departmental use (ED, OR, ICU, etc).

10 Testing, User Tools, best practices

• ACEP encourages user-centered development processes for EDIS modules focused on safety and facilitating the design of EHR interfaces with good usability in the academic, community, urban, and rural ED settings prior to ONC certification or marketing.

11 Edu

• ACEP objects to the emphasis on end-user training as a mechanism to achieve this objective. Current systems already rely too heavily on training for use of overly complicated workflow and processes as a solution for “workarounds.”

12 Investigate Corrective Action

• ACEP also supports investigating and taking corrective action to address serious adverse events or unsafe conditions involving EHR technology. ACEP notes that ONC’s plan states “when necessary”. For our members it is always necessary to take corrective action to address a serious adverse event or unsafe condition to prevent that event or condition from happening again.

13 Priority areas, Measures, Targets

• ACEP recommends enhanced standards for usability, clinician end-user testing, design, and functionality for specific departmental use (e.g. ED, OR, ICU, Peds, etc.).

14 Publish Report on strategy and recommendations

15 ONC Safety Program

• EDIS-related patient safety concerns identified by the review process should be addressed in a timely manner by ED providers, EDIS vendors, and hospital administration. Each of these processes should be performed in full transparency, specifically with openness, communication and accountability.
• Lessons learned from performance improvement efforts should be measured and shared publicly, including with other EDs using the same EDIS.5

16 State Governments

17 Private Sector Leadership

18 Other

• ACEP supports ONC’s stated patient safety goals regarding the use of health information technology to:
o • Increase clinicians’ awareness of potential errors and adverse interactions;
o • Improve the availability and timeliness of information to support treatment decisions, care coordination, and care planning;
o • Make it easier for clinicians to report safety issues and hazards; and

o • Give patients the opportunity to more efficiently provide input on data accuracy than what paper records might allow.
• While ACEP supports these goals, many of our members find it difficult to be optimistic about the realization of these goals for EDIS. While HIT vendors have enjoyed the boon in EHR adoption resulting from the HITECH Act, to date little of these incentives have translated into the kinds of technology necessary to deliver on the stated aspirations. We therefore encourage the ONC to focus more on how to incentivize vendors to deliver innovations and basic user interface design to the emergency department (and all departments of the hospital), in order to fulfill the promise of technology not just the increased overhead created by ineffectually designed systems.

Names

Binzer, Peggy C.

Comment ID

62

Organization

Alliance for Quality Improvement and Patient Safet y (AQIPS)

Org Typ1	Org type	Categories
13	13.. Safety Organization	18. Other, 2. Vendor Engagement (CoC, etc), 3. PSO support, aggr

1 Reporting

• AQIPS supports ONC's conclusion that there may be a need for regulatory changes to permit PSOs, providers and developers to work together to deliver high quality care safely. Importantly, no legislative changes will be necessary to achieve this expanded culture of safety.
• AQIPS applauds the HIT developers who have committed to the Health Information Industry Code of Conduct or other Industry Commitment Statements to protect patients by affiliating with a PSO to report all patient safety-related events to that PSO, and work proactively with providers to identify and resolve the causes of any issues.

2 Vendor Engagement (CoC, etc)

• AQIPS strongly supports ONC's plan to support PSOs to identify, aggregate, and analyze health IT safety event reports. As you know, the PSOs' nonpunitive learning system accelerates the speed with which tactical real world solutions can be identified to continuously improve the quality of patient care and patient outcomes. Indeed, PSOs not only identify, aggregate and analyze various types of safety events related to HIT but also design interventions, best practices, clinical protocols, systems changes and work flow recommendations to prevent any such safety events from reoccurring and to improve the quality of patient care. AQIPS member PSOs enhance patient safety throughout the health care continuum as part of a learning system that establishes a "culture of safety". As recognized by the Institute of Medicine (IOM) in its 1999 landmark report "To Err is Human", a shame and blame culture encourages errors to be hidden, and thus, the errors are repeated over and over again. To prevent this cycle with HIT safety events, AQIPS strongly supports evaluating such events within the culture of safety.
•
• AQIPS applauds the HIT developers who have committed to the Health Information Industry Code of Conduct or other Industry Commitment Statements to protect patients by affiliating with a PSO to report all patient safety-related events to that PSO, and work proactively with providers to identify and resolve the causes of any issues.

3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership

• AQIPS stands ready to work with our members, as well as ONC and AHRQ, to support the implementation of HIT event reporting to PSOs and to work to continually evaluate and improve the health care delivery system. We also urge ONC to give careful consideration to the comments of our member PSOs and partners, including the Bipartisan Policy Center (BPC).

18 Other

Names

Burchell, Leigh

Comment ID

96

Organization

Allscripts

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 13. Priority areas, Measures, & Targets, 15. ONC Saf

1 Reporting

We need to roll out – on a broad basis – a simplified reporting mechanism using standardized terminology. In fact, we have been espousing support for the Patient Safety Organization model for close to two years. It builds on a model already supported by legislation, and it offers legal protections for providers to encourage their participation in the process.

• It should be clearly stated that certain HIPAA standards will need to be waived in order for providers to be able to report useful data. Patient name may not have to be reported, but can the combination of treating doctor, date and time of safety event, circumstances of the event, and event location constitute Personal Health Information (PHI)? If so, the final policy should be clear that HIPAA liability is waived when reporting a real or potential safety event identified in the care of the patient.

• Additionally, we ask that it be clarified that all reported data is deemed a "potential" patient safety issue and not made public in any way until the point at which the event has been analyzed and it is clear that it was truly associated with the health IT system and not user error or some other cause.

Lastly, we request that there be consideration of calling events in this area something other than "adverse events," as the term is already associated with the FDA adverse event reporting process for pharmaceutical companies. Such a process as that would be overly burdensome and not called for based on the lack of demonstrated data around patient safety and health IT, so using different terminology would avoid confusion or inadvertently drawing parallels where they should not be drawn.

2 Vendor Engagement (CoC, etc)

The entities covered by the protections does need to be extended to include others in the healthcare ecosystem who must be incited to participate, including software developers – this was correctly described in the ONC proposed plan – as it is vital to create a "no fault" reporting process regardless of whether an issue is identified by an end user or the developer. The fundamentals of the PSO model, however, are sound.

- We believe strongly that such a **Code of Conduct is the responsibility of the vendors** and that ONC has no jurisdiction over the development, enforcement or ongoing maintenance of such a Code. Precedent for other similar Codes shows responsibility for such work to reside squarely with the affect body (bodies).
- Many of the ideas suggested by ONC as appropriate for inclusion in a Code of Conduct or other such document are ones we support. The one exception to this about which we feel strongly is the suggestion that there be some formalized effort to compare user experiences across different EHR systems. Any comparative analysis associated with this new system around Patient Safety should not be implemented until that new process is up and running for at least five years to allow non-biased data to be reported, analyzed and aggregated.
- Any Code of Conduct should review the strength and limitations associated with using the data reported in statistical analysis. Statistics based on self-reported data have inherent biases, which greatly affect how the data can be interpreted and used.

The idea that CMS **surveyors would have responsibility for investigating potentially deficient practices by providers or suppliers is one we do not support**. This area of CMS is hugely overwhelmed already in their work with provider organizations, and the corrective process they lead people to is arduous. We do not believe this type of model is appropriately applied to health IT developers, as this is well outside the experiences or skillsets or the surveyors and would be inefficient, costly and likely unsuccessful. Additionally, it requires clarification that should any model similar to this be adopted despite counsel to the contrary, it is critical that a corrective action plan targeted at the software developer be suggested only after a thorough root cause analysis has demonstrated that the event is actually attributed to the health information technology.

3 PSO

The aggregation of data reported into individual PSOs by providers and vendors up into a national learning system is very important, as most of the individual PSOs will not have enough data to do statistically valuable analysis of trends on their own.

While the PSO's can and should play a central role in this process, they do not have the depth of knowledge to analyze all reports that will be submitted given the complexity of the healthcare delivery environment and the software that is used. They should be expected to do initial triage upon receipt of a report and decide if it may be health IT-related, but PSOs should be advised to partner with the vendor or vendors involved in the event to do the analysis and validate that the interpretation of the event is correct. This will ensure an accurate analysis of the event while ensuring the right level of expertise is involved in the evaluation process.

4 ACB

5 CMS

The idea that CMS surveyors would have responsibility for investigating potentially deficient practices by providers or suppliers is one we do not support. This area of CMS is hugely overwhelmed already in their work with provider organizations, and the corrective process they lead people to is arduous. We do not believe this type of model is appropriately applied to health IT developers, as this is well outside the experiences or skillsets or the surveyors and would be inefficient, costly and likely unsuccessful. Additionally, it requires clarification that should any model similar to this be adopted despite counsel to the contrary, it is critical that a corrective action plan targeted at the software developer be suggested only after a thorough root cause analysis has demonstrated that the event is actually attributed to the health information technology.

6 QSRS

7 MAUDE

It's worth noting that there is not much about health IT that is reported to that database so the value of doing that analysis may be minimal and not worth the public investment. We would not expect that any expectation of reporting to that database be added to any patient safety process, either, and request clarification to that effect. Reporting requirements for manufacturers who are actively covered by the MAUDE requirements (pharma and device manufacturers, for example) live with burdensome, limiting compliance requirements, and the health IT industry would suffer enormously in continued

advancement of adoption and utilization if they were to be expanded to us.

8 MU

There should be infrastructure in place that protects patient privacy and allows for dynamic distributed population queries – this enables the health system to continually refine their understanding of outbreaks and diseases. These are very important attributes of a truly learning health system. Along these lines, there's some good work being convened by CDISC and ONC's S&I Query Health that contribute to this, and those efforts should be integrated into 2016 Edition Standards and Stage 3 of Meaningful Use. Despite the focus on the elements included in the Action and Surveillance Plan, these other "external" opportunities yield the highest possible impact for the overall safety of the healthcare system and should be included in any final recommendation coming out of ONC.

9 Cer

We are doubtful about the benefits of incorporating "safety" into certification criteria beyond attestation that there is a patient safety process in place, such as a QMS or user-centered design evaluation. The stringent testing scenarios inherent to the certification process would not be flexible enough to account for the many different use cases that are of concern within the patient safety conversation; additionally, such a focus would direct development efforts to "passing the test" – the narrow test developed within the test scripts rather than the many broader scenarios reflected in reality – and would not actually ensure the safety of the processes they have developed.

The work done in the area of Usability by both The National Institute for Standards and Technology (NIST) and the Strategic Health IT Advanced Research Projects - C (SHARP - C) Program have fallen short of expectations and not provided extensive value to date, as widely acknowledged. Thus, the suggestion that this work will strengthen safety-enhanced certification criteria is very concerning to us. As stated, we do not believe this type of topic can be accurately tested in a certification environment, but should any work move forward along these lines despite this feedback, it is imperative that health IT vendors should have sufficient input into the process.

10 Testing, User Tools, best practices

We commend ONC for the attention paid to patient matching in the Plan and strongly suggest rapid work in this area. The inability of providers to accurately match patients is potentially the largest risk to patient safety currently in existence today.

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

Safety priorities

As it relates to the concept of developing safety priorities, we support the theory but note that it will be enormously difficult to set them for the many, many different use cases that now and will soon exist. We also do not have adequate data on what the baseline is at this time, making it difficult to set even initial data targets. Rather, as described previously, once we have a centralized reporting process, we will better be able to understand the actual extent of the problem and then define the priorities and targets.

14 Publish Report on strategy and recommendations

15 ONC Safety Program

We thus strongly suggest that it should be the role of the public stakeholders to lay out directional markers and identify the end goal that we're trying to reach but not to try to define the actual path. We should all be required to work towards the same overriding goals but have the room to allow market needs to ultimately define how we each reach them.

- Inevitably, this web of involved regulators will lead to confusion and an extremely heavy regulatory burden on all stakeholders. Rather, the primary goal of this plan should be – above all else – to develop a single, straight-forward process for the reporting, analysis and learning from patient safety issues related to the use of health information technology that is fair, thorough and transparent.

Ultimately, we must collectively make an effort to deliver progress in the area of patient safety risk management in such a way as to avoid interfering with the efficiency of the organizations relying on the system. The risk for this interference is higher the more "cooks there are in the kitchen," so we ask that Secretary Sebelius ensure that all of the agencies currently touching health IT be winnowed down to a clearly defined, simplified ownership system.

16 State Governments

We are entirely opposed to State-specific regulations and unequivocally state that all standards in this area need to be at a Federal level.

17 Private Sector Leadership

We thus strongly suggest that it should be the role of the public stakeholders to lay out directional markers and identify the end goal that we're trying to reach but not to try to define the actual path. We should all be required to work towards the same overriding goals but have the room to allow market needs to ultimately define how we each reach them.

18 Other

- Because the ONC has within its mandate oversight and regulation of software companies, however, the Action & Surveillance Plan leans more towards discussion of and proposal of ideas related to vendors than the admittedly more complex but nonetheless critical provider role in the safety system. The ultimate patient safety plan that is developed to comprehensively ensure a safe healthcare environment must comprehensively address not only falls and bedsores and health IT but do it in a cohesive manner that is easy for all stakeholders to comply with
- Any requirements for the program must allow sufficient time for changes not only in the software world but also by the providers themselves.

Names

Stream, Glen, MD, MBI, FAAFP

Comment ID

95

Organization

American Academy of Family Physicians (AAFP)

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	1. Reporting, 18. Other, 3. PSO support, aggregation, and analysis

1 Reporting

Reporting requirements must occur in a non-punitive environment and be compatible with the task and time constraints of ambulatory care delivery.

- Though evidence-based content and processes for adverse event reporting exist in the inpatient setting, the AAFP urges ONC to carefully consider how the outpatient setting presents a different set of workflows and potential event cascades leading to unique patient safety events and risk.
- Current Agency for Healthcare Research and Quality (AHRQ) Common Formats are inpatient specific and are more likely to be completed by support staff after the incident rather than by clinicians at the point of care. The AAFP calls for the adoption of a streamlined, clinical workflow compatible mechanism that provides consistency in reporting across multiple, independent end-user physicians who may not have deep domain knowledge of patient safety event and risk reporting.
- The AAFP remains concerned that protracted HIT product development cycles present a significant barrier to the application of knowledge collected by patient safety event and risk reporting, even when significant defects are identified. To enable the rapid development and implementation of software tools that decrease event reporting burden and improve patient safety, the AAFP calls on ONC to require EHR vendors to support the analysis of patient safety events and risks by allowing read-only access to their backend databases for independent evaluation and appropriate safety interventions.
- Acknowledgment of and response to patient safety events and risks might be significantly shaped by an organization's financial concerns, legal issues, or ingrained business practices. Reports of patient safety events and risks therefore should flow directly from physicians to independent third parties in addition to being channeled to product vendors and implementing health care organizations for evaluation and remedial action as appropriate.

The AAFP believes it will likely be several years before AHRQ's Quality & Safety Reporting System (QSRS) and its underlying Common Formats are applicable to the ambulatory care setting. The AAFP encourages more distributed efforts to more effectively bring the lessons learned from reported patient safety events and risk mitigation from the bench to all points of

care, be it in the hospital room, exam room, bedroom, or living room.

2 Vendor Engagement (CoC, etc)

3 PSO

In the draft ONC document, Figure 1 graphically represents information flow from patient safety organizations (PSO) to the AHRQ. The AAFP believes that another layer should extend down to the level of the HIT end-users themselves. In solo practices, those end-users are the "Providers" in the figure, but in larger health care organizations or in more complex vendor environments, there are likely to be complex sociotechnical relationships among "Providers" that must also be addressed (and diagrammed) to ensure appropriate understanding of patient safety event reporting and risk mitigation. As more family physicians chose health system employed positions, their ability to independently identify and report patient safety events and risks must be clearly understood and preserved.

4 ACB

EHR technology certification attempts to address an array of issues much broader than HIT patient safety. To date, the AAFP is unaware of any post-market surveillance performed as part of certification, any user complaint monitoring and redress, or any censuring or revocation of certifications by ONC-authorized certifying bodies, leaving significant gaps in our understanding of the effectiveness of the existing EHR certification process. Also, regarding the repurposing of existing evaluations, CMS surveyors audit only a small fraction of ambulatory practices annually. With a focus on fraud, they may not have the opportunity to interact with the practices that are in most need of patient safety evaluation and improvement.

5 CMS

6 QSRS

7 MAUDE

The Manufacturer and User Device Experience (MAUDE) device reports will unlikely be pertinent for some time to primary care ambulatory practices.

8 MU

Small practices will require extensive guidance in conducting health IT safety risk assessments given the current lack of evidence and best practices, particularly in the ambulatory care setting.

● Though the AAFP agrees with ONC that inaccurate, incomplete, and inaccessible clinical records are detriments to patient safety, we do not believe that improving the current process of bullet-based documentation for reimbursement will positively impact patient safety. Rather, the AAFP believes new reimbursement models and new clinical documentation expectations must be established to enhance a culture of patient safety and risk mitigation.

Individual experiences of AAFP members, many using EHR technology for over a decade, have not shown improvements in clinical care through upgrades to meaningful use stage 1 certified EHR technology (CEHRT). Some members have identified instances where implemented MU requirements have interfered with their ability to focus on clinical care.

9 Cer

EHR technology certification attempts to address an array of issues much broader than HIT patient safety. To date, the AAFP is unaware of any post-market surveillance performed as part of certification, any user complaint monitoring and redress, or any censuring or revocation of certifications by ONC-authorized certifying bodies, leaving significant gaps in our understanding of the effectiveness of the existing EHR certification process. Also, regarding the repurposing of existing evaluations, CMS surveyors audit only a small fraction of ambulatory practices annually. With a focus on fraud, they may not have the opportunity to interact with the practices that are in most need of patient safety evaluation and improvement.

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

As health IT and its expanding functionality are more broadly adopted across inpatient and ambulatory health care settings, it will become increasingly difficult to disambiguate health IT patient safety issues from general patient safety issues. An integrated approach to patient safety improvement that holistically evaluates products, processes, and people is imperative to sustained success.

Names

Zaroukian, Michael H., MD, PhD, FACP, FHIMSS

Comment ID

98

Organization

American College of Physicians (ACP)

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	1. Reporting, 15. ONC Safety Program, 8. MU

1 Reporting

We wish to emphasize our support for collaboration with PSOs that might perform some of the analyses/reporting based on data collected through the EHR.

- We support embedding reporting functionality in EHR systems but the reports and any data not already part of the legal medical record should be maintained separate from the legal medical record. The content must be segregated so that it remains private and undiscoverable.
- The plan does not acknowledge the substantial burdens on physician practices and healthcare organizations to administer and manage the reporting process, or how such burdens can be mitigated. The reporting burden should be monitored to ensure that it remains as light as possible, and reporting should remain optional. There should be continual oversight of the process by appropriate experts.
- Incident reporting needs to work within the established quality and safety processes of the healthcare organization.
- There will need to be intelligent filtering processes at multiple levels to ensure that the eventual reports are not given more credence than is warranted. More reporting volume is not necessarily a good thing if the quality of the initial reports is low.

For valid filtering to work effectively, there needs to be a generally held assumption that healthcare institution leadership can be trusted to appropriately filter, investigate, and act. For the increasing number of larger organizations that have Patient Safety Officers, involving such individuals can help ensure appropriate expertise, engagement and actionable reporting.

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

Perhaps “clinical safety measures” should be added to “clinical quality measures” in future iterations of Meaningful Use.

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

We have serious doubts that this activity will be adequately resourced. Appropriate aggregation and investigation activities should be conducted at multiple levels in the process, and this work will be expensive.

16 State Governments

17 Private Sector Leadership

18 Other

Names

Fishman, Linda E.

Comment ID

81

Organization

American Hospital Association (AHA)

Org Typ1	Org type	Categories
3	3. Provider Organization (Institutional)	10. Testing, User Tools, best practices, 15. ONC Safety Program, 18

1 Reporting

2 Vendor Engagement (CoC, etc)

The AHA supports the development of a voluntary code of conduct for EHR vendors with specific commitments to ensuring and promoting safety. The code of conduct should make clear that vendors are responsible for safe design and product development and will support safe use of their products. In addition, the code of conduct should discourage vendors from including in their contracts indemnity clauses or nondisclosure language that limit the ability of users to identify and raise safety concerns. The code of conduct also should address other areas, such as transparency in pricing and adherence to existing coding conventions for systems that support billing (see the AHA’s Nov. 12, 2012 letter to Secretary Sebelius and Attorney General Holder).

3 PSO

4 ACB

5 CMS

Changes under the Conditions of Participation (CoPs) must be supported by clear evidence of what is essential safe practice and go through the rule-making process. If and when the CoPs for hospitals are updated, we encourage ONC to consider how corresponding safety standards could be built into certification requirements for electronic health records (EHRs) vendors.

6 QSRS

7 MAUDE

8 MU

9 Cer

The AHA supports the elements of ONC's 2014 edition certification criteria that support safety-enhanced design, including adherence to quality management principles and processes and user-centered design. As indicated in the safety plan, these elements of certification should be considered a starting place, and continue to evolve as we learn more about safe design and the interaction between usability of EHRs and patient safety. America's hospitals take very seriously their responsibility to ensure that care is safe, and bear ultimate responsibility when a patient is harmed. Therefore, it is very important to know that the tools deployed in hospitals also are safe, as developed, sold and used.

10 Testing, User Tools, best practices

Further, the AHA urges ONC to focus its efforts on a patient safety issue that received limited mention in the safety plan – a single, national approach to matching patients to their records that all parties can use to improve the accuracy and cost-effectiveness of patient matching. The issue of how to match patients with their medical records needs to be solved as we accelerate information exchange on regional and national levels. The inability to match patients across silos raises safety concerns about mismatches – incorrectly matching patients, or missing a match that should have been made. In addition, without a single, national approach to patient matching, hospitals and health systems are forced to expend significant resources on expensive, proprietary solutions to develop master patient indexes that apply only to that particular hospital or health system's patients.

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

We encourage ONC to assume a coordinating role in and caution against an approach that leads to duplicative efforts.

16 State Governments

17 Private Sector Leadership

18 Other

Finally, we note that the safety plan did not mention the key role of health information exchange to support the safety benefits of EHRs. To that end, we encourage ONC to focus considerable resources on advancing the more robust data exchange infrastructure necessary to support the sharing of health information. The full potential of health IT will not be realized until all relevant health information is easily accessible when and where it is needed to support clinical decisions and healthy behaviors. Key pieces of the exchange infrastructure are still missing, such as technical support for the adoption and use of standards, affordable exchange networks and widely accessible provider directories.

Names

Madara, James L., MD

Comment ID

89

Organization

American Medical Association (AMA)

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 18.

1 Reporting

We support ONC's recommendation to encourage health care providers to report health IT related patient safety events through the use of Patient Safety Organization (PSOs) and the Agency for Healthcare Research and Quality's (AHRQ) common formats. The use of PSOs and the common formats enables the voluntary, confidential reporting of health IT–related patient safety.
It should be clear to all parties that the information that would be collected and investigated by surveyors is reported separately from the patient safety work product submitted to PSOs. PSOs are the mechanism under federal law to ensure that information about errors that are submitted for purposes of evaluating and improving patient safety are legally protected and confidential, along with the identity of the reporter. We are concerned with the use of safety event and error reporting systems that do not have these federal protections, which would leave both patients and the subjects of their reports in extremely vulnerable positions.

2 Vendor Engagement (CoC, etc)

We believe that ONC should coordinate efforts with the public and private sectors, EHR vendors, physician and consumer advocates, and other stakeholders to discuss the recommended voluntary code of conduct for health IT developers in order to improve the safety of health IT products that physicians and other health care providers use.
It should be clear to all parties that the information that would be collected and investigated by surveyors is reported separately from the patient safety work product submitted to PSOs. PSOs are the mechanism under federal law to ensure that information about errors that are submitted for purposes of evaluating and improving patient safety are legally protected and confidential, along with the identity of the reporter. We are concerned with the use of safety event and error reporting systems that do not have these federal protections, which would leave both patients and the subjects of their reports in extremely vulnerable positions.

3 PSO

Careful attention needs to be paid to ensure that the reporting of patient safety events to PSOs via certified EHRs occurs in a manner that maintains the confidentiality and legal protections of the information reported.

4 ACB

5 CMS

It should be clear to all parties that the information that would be collected and investigated by surveyors is reported separately from the patient safety work product submitted to PSOs. PSOs are the mechanism under federal law to ensure that information about errors that are submitted for purposes of evaluating and improving patient safety are legally protected and confidential, along with the identity of the reporter. We are concerned with the use of safety event and error reporting systems that do not have these federal protections, which would leave both patients and the subjects of their reports in extremely vulnerable positions.

6 QSRS

7 MAUDE

8 MU

We are concerned that physicians do not have the necessary tools or resources to make a meaningful safety risk assessment. We seek clarification on this proposal. Without clear standards and guidance, this measure could be burdensome for health care providers, especially smaller practices, to meet.

9 Cer

10 Testing, User Tools, best practices

Disseminating and piloting interventions and tools aimed at improving health IT safety and evaluating the effectiveness of these tools in hospital and physician practice settings are also critically important.

11 Edu

Educating physicians on how to identify and report this type of patient safety event is also necessary. This will build physician understanding of the importance of reporting health IT events to advance the development of health IT systems that enhance safer performance. Knowing that they are contributing to health IT safety solutions might also serve as a catalyst for physicians to report these events, thus increasing physician participation in PSOs and voluntary reporting. In addition to physician education outreach efforts, we stand ready to work with ONC, AHRQ, and others to coordinate efforts to undertake a detailed and ongoing education program for the public to reinforce the importance and value of a voluntary, confidential reporting system working alongside other reporting systems.

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

The AMA believes more research is needed in the ambulatory setting to determine and monitor the effects of EHR use on patient safety.

Names

Weston, Marla

Comment ID

75

Organization

American Nurses Association (ANA)

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	10. Testing, User Tools, best practices, 11. Edu, 12. Investigate & C

1 Reporting

2 Vendor Engagement (CoC, etc)

• The text on page 11 proposes using a LHS consistent with that suggested by IOM. The absence of a feedback loop on the results of reporting and investigations considerably limits the value to learning that could be realized if such a feedback loop existed. Consider refinement of the objectives to delete “ensure” as a voluntary code of conduct can espouse but not ensure.

The *Actions* response to Recommendation 3 (page 28) states, “ONC will support and collaborate with the private sector to publish information on comparative user experiences.” ANA would appreciate additional information in order to be able to better understand the value of this action

3 PSO

4 ACB

5 CMS

The text on page 14 (last line of item 5) indicates, “CMS is currently educating its surveyors…” Readers would benefit from more information on the training program or a footnote indicating a resource where such information might be available.

6 QSRS

Item 6, which begins on page 14 and ends on page 15, identifies how the Quality & Safety Review System (QSRS) will collect and query systems for patient safety events. This appears to be a good data collection instrument. ANA recommend the inclusion of vendor name, software version, and release number to make data collection more comprehensive.

7 MAUDE

Further, item 7 proposes monitoring of adverse event reports submitted to the Manufacturer and User Facility Device Experience (MAUDE) database. While monitoring is important, ONC does not relate any information on how the monitoring will reduce adverse events and improve care. Such information would be valuable to readers, including providers, patients, and policymakers.

8 MU

9 Cer

Item 2 on page 17 needs revision of the last sentence in the first paragraph as it is currently unclear to the reader.

10 Testing, User Tools, best practices

- Item 3 on page 18 infers many aspects of a LHS approach without directly calling it a Learning Health System. Although ONC covered the LHS approach in a previous section, reiterating the approach herein would aid the reader in understanding its pervasive nature and serve to improve the likelihood of its general adoption. For instance, a LHS could inform best practices on the integration, implementation, and optioning of new systems, as well as informing users of best methods for transitioning between systems.

ANA strongly urges the ONC to support research that will contribute to the understanding of how health IT either mitigates or potentially contributes to medical errors. The Plan recognizes that EHR adoption presents the opportunity for harm as well as to improve patient safety. ANA believes that we need to grapple with this question and be clear about what elements of EHR will mitigate medical error and promote patient safety and what elements it will not. Both the public and the private sector are investing heavily in health IT. In addition, registered nurses and other health care practitioners must have faith that these systems are truly creating efficiencies and supporting patient care. If ONC can speak to this concern then clinicians not using health IT functionality that is intended to prevent error will likely decrease.

11 Edu

- Item 4 on page 18 appropriately focuses on educating clinicians to incorporate health IT safety into their respective practices. ANA suggests rewording the item to improve inclusiveness. The reworded item would read:

4. Incorporate health IT safety into clinical education and training for all clinicians and support personnel.

The purpose of changing “medical education” to “clinical education” is to remove the inference of Medical School, which is a physician training school to include other forms of clinical education, including nursing, pharmacy, social work, and other schools, as well as to include continuing education programs. The purpose for changing “health care providers” to “clinicians and support personnel” is to include all clinical providers and their unlicensed assistive and administrative personnel whose roles often involve input to and use of information from health IT sources.

Within item 4, the second paragraph states, “ONC will work with the organizations to foster a culture of safety and the dissemination of best-in-class tools…” This is a laudable goal, but goes beyond the present scope and mission of ONC. The organizations mentioned in item 3 (i.e.: National Institute for Standards and Technology [NIST], the Administration for Health Research and Quality [AHRQ], and the National Library of Medicine [NLM]) are more likely candidates for the capture and dissemination processes. A LHS organization, such as the Kanter Family Foundation, would be a more logical choice for the role of fostering a culture of safety, which is a role that should surpass governmental control.

12 Investigate Corrective Action

• Finally, item 5 on page 19 describes information regarding the IOM suggestion of "…establishing a new federal entity, similar to the National Transportation Safety Board…" with the role of investigating adverse events. ANA strongly recommends significant dialogue about the scope of such an entity and how this will intersect with other regulatory and state licensing board activities. Implementation of such an entity would benefit from a strong intersection among government, professional and industry organizations. This model is similar to that in fields such as electrical safety, the government places considerable weight on input from IEEE (formerly the Institute of Electrical and Electronics Engineers) and the Underwriters' Laboratories (UL). Similarly, ONC and AHRQ would benefit from broad consultation on the development of a monitoring methodology that would empower clinicians while creating the "just culture" proposed as an important aspect of an effective LHS.

The *Actions* response to Recommendation 4 (page 29), provides additional information to "Health IT Patient Safety Strategies and Actions: Improve" item 5 from page 19. From ANA's perspective, this represents a significant expansion of ONC's activities and scope. As previously noted, ANA sees a strong role for professional organizations, regulatory and standard setting bodies in delineating the appropriate monitoring activity that should be undertaken by the ONC. The *Actions* response to Recommendation 7 (pages 30-32) proposes analysis, review, and mitigation of health IT-related adverse events. ONC does not indicate which entities will bear the costs or any idea of what costs would be incurred by any of these several actions. ANA recommends including a proposed budget and distribution of costs to give readers some idea of the economic impacts of these actions on providers, developers, and end-users.

13 Priority areas, Measures, Targets

The *Actions* response to Recommendation 1. a. (bottom right cell on page 24) ought to be reworded to replace the "physicians" with "eligible providers" or "clinicians" to ensure inclusion of non-physician providers in this important action

14 Publish Report on strategy and recommendations

The *Actions* response to Recommendation 9. b. (page 33) explains that the Food and Drug Administration (FDA) will collaborate with the Federal Communication Commission (FCC) to release a report "…proposing a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT which promotes safety and innovation." ANA recommends incorporation of considerable input from clinicians, developers, patients, and other interested parties in the implementation of this action to ensure that it is reasonable, practicable, and economically feasible.

15 ONC Safety Program

• ANA is concerned about the overall capacity to successfully implement this plan given the challenges associated with the current limited use of health IT less than 10% of all information exchanges use health IT_ and by the lack of interoperability among existing systems.

Comments on Health IT Patient Safety Strategies and Actions: Lead: This section of the Plan provides very useful information on the prospect of leadership in the development of necessary safety and regulatory frameworks to reduce health IT-related adverse events. ANA recommends implementation of these items with considerable input from clinicians, vendors, and patients to ensure successful implementations for users, developers, and the persons on and about whom these technologies will be used.

16 State Governments

17 Private Sector Leadership

18 Other

• Ana is concerned that the perspectives of patients, their families, or their lay caregivers as they relate to health IT and its use to improve patient safety are not reflected in this plan. This limitation extends from the failure to include these same perspectives underlying IOM report commissioned by ONC.

• ANA appreciates ONC's commitment to maintain clinician neutrality in past planning and draft documents. Strict adherence to this neutrality is important so that the documents such as this do not inadvertently disenfranchise any provider. To this end, ANA strongly recommend s that the ONC use the term "eligible provider" instead of "physician" particularly in footnote 30 on page 19 and on page 24 under recommendation 1.a.

Comments on Health IT Patient Safety Objectives

- ANA recommends that an introductory paragraph be added to this section, such as is used in each of the other sections of the document. This introduction could reinforce how the objectives relate to the goal and lean forward toward the strategies and actions. The objectives speak to the full range of stakeholders. It is essential that the ONC genuinely engage in active dialogue with these identified stakeholders. Magnifying the voice and concerns of patients and their

caregivers would be particularly meaningful in this work.

- ANA supports the focus on clinical decision supports (CDS) as a means of reducing harm to patients and in particular, to the reference to the Partnership for Patients programs related to hospital-acquired conditions and other adverse events. The document speaks to several areas where CDS have been used (venous thromboembolism, labor and delivery, falls and pressure ulcers). ANA would recommend the inclusion of references to support this section.
- ONC also presents information on the use of CDS supporting ePrescribing and prevention of adverse drug events, adverse drug reactions, and medication errors. These usages make CDS inherently valuable. ANA recommends that ONC add discussion about patient preferences and economic considerations. This would further enhance the value of CDS

ANA suggests adding to these strategies additional opportunities for direct patient family, and lay caregiver input and evaluation to ensure the goals are met to their satisfaction and needs. Further, ANA suggests incorporation of patient preferences into the strategies and actions.

Names

Stowers, Ray E., DO

Comment ID

76

Organization

American Osteopathic Association (AOA)

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	1. Reporting, 12. Investigate & Corrective Action, 16. State Gover

1 Reporting

- The AOA agrees with the ONC's recommendations that the nation could improve the safety of HIT systems by:

1. Collecting more and better data about HIT-related risks.
2. Targeting resources and corrective actions to improve HIT safety.
3. Promoting a culture of HIT safety at the federal and state levels.

2 Vendor Engagement (CoC, etc)

We also believe that just as health care professionals are being held accountable for meaningful use of HIT, vendors also should be held accountable for the safety of their products, programs, and software since many HIT-related safety issues are the result of the technology itself and not key stroke errors or other human errors

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

- The AOA agrees with the ONC's recommendations that the nation could improve the safety of HIT systems by:

1. Collecting more and better data about HIT-related risks.
2. Targeting resources and corrective actions to improve HIT safety.
3. Promoting a culture of HIT safety at the federal and state levels.

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

• The AOA agrees with the ONC's recommendations that the nation could improve the safety of HIT systems by:
1. Collecting more and better data about HIT-related risks.
2. Targeting resources and corrective actions to improve HIT safety.
3. Promoting a culture of HIT safety at the federal and state levels.

17 Private Sector Leadership

18 Other

As the ONC finalizes its HIT Patient Action and Surveillance Plan, we would like to submit for your consideration some of the challenges our members face in adopting and using cost effective and interoperable HIT. In a recent questionnaire of our membership on barriers to meaningful HIT adoption and use, osteopathic physicians identified a range of concerns when asked if their EHR contributed to any patient safety or adverse events. Acknowledging the link between EHR use and patient safety, one respondent, in particular, noted that if he "did not catch these events…some patients could have died." Provided below is a summary of the feedback we have received from our members to date:
•Medication errors: some of the computer generated prescriptions have the incorrect dose, strength, or form due to defaults in the system, pick lists, "canned directions," and limited editing ability on the part of the user; dose calculator problems; medication/lab data is often missing and non-retrievable; orders are sometimes duplicated or unrecognizable ("nurses have double dosed patients with meds when they haven't been able to access a computer to sign it off").
• Pop-ups for drug allergies and adverse reactions are distracting and displayed in an awkward manner. Too many interaction notices cause the user to ignore them, which results in critical interactions being missed.
• Templates result in incorrect/inaccurate data input. No ability to adjust orders or insert specialized information, especially related to medications, due to software limitations. Finding the right keywords to search also is frustrating and leads to incorrect and omitted testing.
• Lack of trust that the EHR will catch every important detail ("it only has to miss one important thing to cause me a lot of trouble").
• Inaccuracies in exam notes, which results in users viewing them as useless, distracting, and fatiguing ("notes of referral doctors seem to all look the same-they 'blow in' nonsense info and [document] exams I know they didn't do…to achieve a higher billing code;" "it seems we have more med errors and wrong charting than ever before").
• Slowing of direct (emergent) orders ("continuity of care with our local PCPs has been crushed, as they cannot tell what we have done for their patients in the ER").
• Takes extra time, which results in short cuts being taken where partial records pass as complete records.
• Distracts from physician-patient relationship. Staff focus is diverted from the care of the patient to addressing the computer and documentation requirements ("practice is contorted to fit reporting instead of reporting to fit how we practice," "patients are less safe because design is not for patient care, rather billing and meaningful use…clinicians have less time for patients.")
• Orders often missed or misinterpreted, which requires numerous additional phone calls to clarify an order.
• Lack of integration with lab and radiology.
• Inadequate on the job training opportunities for busy professionals.
• Diagnostic codes at the clinical encounter are changed by the software and morph into a different diagnosis.
• Lack of ability to quickly get information from the system in an emergency.

Names

Tessier, Christopher

Comment ID

78

Organization

American Urological Association

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	1. Reporting, 18. Other

1 Reporting

• Despite the fact that input from providers is necessary in order to study the issues, gather data, and eventually improve the situations causing such incidents, providers have no motivation to report such events. Most providers are overloaded with EHR - related tasks currently; so the prospect of voluntary reporting is bound to fail without some incentive. It would appropriate to “credit” providers with something such as Physician Quality Reporting System (PQRS) activity for their time, insight, and effort

AUA supports the adoption of a required [for vendor Certification Commission for Health IT (CCHIT) certification] and universally recognized application that facilitates reporting (similar perhaps to the “BlueButton” or “infobutton” standards). This would enable providers to easily recognize the reporting application among the various EHR systems that they may use in the spectrum of their work.

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

The AUA found the action and surveillance plan recently outlined by the ONC to be very thoughtful and should significantly benefit healthcare.

Names

Fickenscher, Kevin, MD;

Comment ID

86

Organization

AMIA (American Medical Informatics Association)

Org Typ1	Org type	Categories
9	9. Allied Professional Organization	1. Reporting, 10. Testing, User Tools, best practices, 12. Investigat

1 Reporting

Page 22. AHRQ has encouraged states to use the Common Formats to make it possible to aggregate and compare adverse events across federal and state programs. AMIA urges ONC to align state and federal adverse event reporting requirements to minimize undue burden and fragmentation for reporting entities.

• **Reporting Burdens**. We urge ONC to consider the potential burdens on healthcare providers and organizations to implement, administer, and manage the proposed reporting process. Furthermore, we believe that the reporting burden must be monitored to ensure that it remains as feasible as possible. We believe that any HIT-related incident reporting should work within existing healthcare quality and safety processes, state reporting requirements, and accreditation and licensure regulations.

• Finally, the ONC should acknowledge that in any complex, adaptive work system the vast majority of errors or safety events are not detectable by a single individual (and thus not reportable) due to the complex, hidden, inner workings and data transformations of these systems.6 For example, when clinicians send an order for a specific medication to the pharmacy, they have no way of knowing what the pharmacist receives. Furthermore, the pharmacist has no way of knowing that the medication order received is not what the ordering provider sent. When this order is transmitted to the automated, robotic, medication bar-coding packaging system, filled and sent to the registered nurse (RN) for administration, once again, the RN has no way of determining whether the medication received is what the doctor ordered or the pharmacist filled. Even when the RN scans the barcode on the medication and the patient, and gets a match, the wrong medication can be administered. If there is such a “systematic” error in any one of the interfaces between the order entry system, pharmacy inventory system, barcoded packaging system, or medication administration record system (all potentially made by different vendors and never tested by an external, independent party), these errors can and have continued unabated and undetected for extended periods of time. We suggest that ONC acknowledge these types of complex issues and consider asking licensing and/or accrediting bodies (such as the Joint Commission or local health departments) to include random inspections of computerized provider order entry (CPOE)/pharmacy interfaces in their routine surveillance activities.

• P. 9 of Plan: AMIA believes that it is important to differentiate the reporting of EHR related safety events from using the EHR as a “reporting tool” for safety events. However, a mechanism by EHR vendors to report HIT related patient safety events to Patient Safety Organizations (PSOs) seems reasonable. It also seems reasonable for PSOs to adopt the AHRQ Common Formats. We refer ONC to AMIA’s prior comments submitted to AHRQ7 about the Common Report Formats and we urge ONC to continue to work to enhance and improve those formats as related to HIT. We are not convinced that it will be possible to clearly distinguish instances where EHRs have not been used appropriately, as intended or as designed.

Page 11. Ensure health IT developers work with a PSO, 15 or a similar entity, to report, aggregate, and analyze health IT-related safety events. While there is agreement with this statement, we urge ONC to clarify how to assure that there will not be any unintended duplicate reporting when a provider organization may report to one PSO and the IT vendor reports to another PSO.

2 Vendor Engagement (CoC, etc)

Recommendation 2a. We are concerned that a voluntary code that carries no penalties for failure to report adverse events is unlikely to significantly improve the patient safety environment. While there is merit in avoiding penalties so severe as to discourage innovation, the current unacceptably frequent occurrence of patient safety events may indicate that a voluntary approach is inadequate.

• Recommendation 7a. ONC should engage developers and facilitate the development of a mandatory code of conduct that requires vendors to work with safety organizations to aggregate and analyze events and promote adverse event reporting among providers. AMIA believes that consideration of the developer and vendor code of conduct is critical to the successful implementation of any approach to assuring patient safety and health information technology. There is a need to reconcile potential (real and/or perceived) tensions between the organizational (developers/vendors) need to protect intellectual property and the equally compelling need to share safety issues and safety experiences. Thus, it is important to support the developer/vendor code of conduct.

Page 11. Step 2, the Plan discusses "engage Health IT developers to embrace their shared responsibility." In our view, this step does not sufficiently address concerns expressed in previous AMIA writings.8 Although ONC has cause to avoid truly Draconian penalties for failure to comply, we believe that current experience indicates that a voluntary approach may fail to ensure complete and comprehensive reporting and adverse event reduction. In addition, ONC-ACBs should be required – not simply encouraged – to review documentation of complaints and provide de-identified reports to ONC. Some of our members question the potential role of ONC-Authorized Certification Bodies (ACBs) given the potential far reach of this process into the health system enterprise, its organization, workflows and clinical practice standards that are best determined locally by health care providers. The role of the ONC-ACB to indicate whether the EHR technology is functioning in a manner consistent with certification may potentially be an overreach for a government.

3 PSO

Infrastructure Costs. AMIA believes that appropriate aggregation, investigation, and dissemination activities are likely to be resource intensive and potentially costly and we are concerned that they will not be performed. It is essential to investigate and publicly report on the findings from recent simultaneous major, widespread, multi-site, multi-state, multi-organization EHR failures affecting thousands of patients, such as those reported in the press on May 9, 2006 at Kaiser Permanente;2 on Aug 31, 2007 within the VA healthcare system;3 on April 21, 2010 at the Rhode Island Hospitals;4 and on July 23, 2012 by the Cerner Corporation.5 We are concerned that future publicity about these types of events may contribute to perceptions that such potentially catastrophic patient safety events could re-occur unabated. It is vital that the nation's increasingly HIT-enabled healthcare system study and learn from these events so they are not repeated.

We are also concerned that the proposed strategy for integrating Health IT patient safety into existing federal programs (p. 20) may not be sufficient, and we question if there is sufficient capacity within existing Federal agencies and programs to do so. Further, we are concerned that the activity will not be adequately resourced. We believe that monitoring activities should be conducted at multiple levels. For example, relatively isolated and non-life-threatening patient safety issues could be investigated and reported to the organization's leadership on a periodic basis, while more widespread and potentially harmful events could be reported to the organization's PSO and investigated with their help. Finally, larger scale or widespread events could be reported to the local PSO but also to an independent national body who could help conduct the investigation and disseminate the findings.

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

Page 17. It appears that ONC intends to continue using its standards and certification criteria and certification program rulemaking in ways that enhance health IT patient safety, focusing on human factors, safety culture, and user -centered design. AMIA agrees and urges ONC to continue to emphasize this focus.

• Recommendation 5. The public listing of health IT products should include a list of the features incorporated by vendors to promote patient safety. Listing such product features in a public place will aid health care organizations in selecting products and promote innovation by allowing vendors to track, in general terms, the state of the art in patient safety initiatives.

•

• We support embedding reporting functionality in certified EHR systems, and we suggest that such reported data should remain separate from the legal patient record so that information is confidential and undiscoverable.

• There are a number of existing and applicable standards that could be adopted and used to the fullest extent possible. One example is the National Quality Forum (NQF) Safe Practice for Computerized Provider Order Entry which includes post deployment testing of EHRs for high impact safety interventions as recommended in recommendation # 1c in the IOM

Report (Health IT and Patient Safety: Building Safer Systems for Better Care).
We are concerned that the lack of specificity makes it difficult to assess whether the proposed implementation steps are realistic. For example, the report continues to portray EHRs as self-contained, software applications developed and installed by a single vendor that users simply install and run within a healthcare organization. This is far from the actual practice. More commonly, the EHR is but a small part of a complex network of interconnected software applications from different vendors that a healthcare organization, often with help from a systems integrator, implements over time to address the myriad clinical work processes required to care for complex, acutely ill patients1. **Simply testing and certifying the individual components does not address how they will function when combined and integrated within a complex healthcare delivery system.** While HIT offers opportunities to improve reliability and to enhance safety, it also may contribute to complexity in terms of workflow and work processes that need to be considered in the development of the Plan. Thus, AMIA believes that the surveillance plan would be significantly improved by acknowledging these types of challenges and committing new resources to developing solutions for ways to oversee these complex systems.

10 Testing, User Tools, best practices

Recommendation 1.a. We support the expansion of AHRQ and NLM funding for research, training, and education of safe practices. We believe such funding should be allocated in addition to the funding of existing health IT programs, rather than as a reallocation of funds currently budgeted for health IT.

- We believe that the Plan should leverage relevant current and ongoing research that contributes to the growing body of science and evidence about what works to improve patient safety. AMIA strongly suggests more scientific grounding and evidence for the recommendations set forth in this Plan.

AMIA strongly recommends that HHS continue to fund and widely disseminate findings from HIT-related safety research and evaluation efforts including methods to:

- Automatically identify and track potential HIT-related safety issues
- Address the potential inherent limitations of self-reporting of adverse events
- Investigate, evaluate and report on HIT-related safety issues
- Test and certify highly networked and inter-connected HIT components and applications
- Test and certify highly networked and inter-connected data sources including medical devices

- **Usability.** As EHR adoption increases, HIT and EHR usability issues must be addressed along with a growing body of evidence and concerns about patient safety. We recommend that usability be considered in the context of each health care delivery setting in addition to the proposed focus on vendor/supplier organizations. Human factors and implementation science precepts are central to understanding and improving usability and patient safety. We believe that that both domains should receive greater focus in future iterations of the draft plan.

AMIA directs ONC to a new health information technology (IT) policy report that has been published in the Journal of AMIA (JAMIA) entitled, Enhancing Patient Safety and the Quality of Care by Improving the Usability of Electronic Health Records: Recommendations from AMIA. The report reflects the results of a year-long project undertaken by AMIA to help address usability issues as EHR adoption increases against a growing body of evidence and concerns about patient safety issues. The AMIA report recognizes that numerous stakeholders, organizations, and individuals play a critical role in addressing challenges with EHR usability, and AMIA makes recommendations for various stakeholders. The report is available online at http://jamia.bmj.com/content/early/recent.

11 Edu

12 Investigate Corrective Action

Page 32. Currently, the Health IT Safety Plan does not include the establishment of an independent federal entity. However, the plan incorporates many of the functions described in IOM's recommendation 8 into existing patient safety efforts across government programs and the private sector — including health care providers, technology companies, and health care safety oversight bodies. While we acknowledge ONC's current decision not to identify a separate federal entity for investigating HIT safety, we recommend that ONC leverage (and harmonize) existing processes across the multiple bodies/organizations that investigate patient safety events including HIT. We also suggest that consideration be given to the intersection of HIT safety in the context of existing state and/or national level regulatory, licensure and accreditation oversight.

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

Page 21. Congress passed the Food and Drug Administration (FDA) Safety and Innovation Safety Act of 2012. This Act tasked the FDA – in collaboration with ONC and the Federal Communications Commission (FCC) – to create a report, within 18 months, that proposes a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT that promotes safety and innovation. This report will be developed with significant public input and will incorporate what HHS learns about risk, safety, and opportunity for innovative technologies to support improved health outcomes. AMIA is concerned that a heavy-handed and tightly regulated approach by the FDA/FCC would have the potential to stifle innovation and the speed of products to market.

15 ONC Safety Program

We suggest that ONC implement a flexible approach with feedback loops so that over time ONC can update and refine the Plan and address the likely evolution of technical capabilities and new technologies. These updates should reflect lessons learned and be evidence-based.

• **Infrastructure Costs.** AMIA believes that appropriate aggregation, investigation, and dissemination activities are likely to be resource intensive and potentially costly and we are concerned that they will not be performed. It is essential to investigate and publicly report on the findings from recent simultaneous major, widespread, multi-site, multi-state, multi-organization EHR failures affecting thousands of patients, such as those reported in the press on May 9, 2006 at Kaiser Permanente;2 on Aug 31, 2007 within the VA healthcare system;3 on April 21, 2010 at the Rhode Island Hospitals;4 and on July 23, 2012 by the Cerner Corporation.5 We are concerned that future publicity about these types of events may contribute to perceptions that such potentially catastrophic patient safety events could re-occur unabated. It is vital that the nation's increasingly HIT-enabled healthcare system study and learn from these events so they are not repeated.

We are also concerned that the proposed strategy for integrating Health IT patient safety into existing federal programs (p. 20) may not be sufficient, and we question if there is sufficient capacity within existing Federal agencies and programs to do so. Further, we are concerned that the activity will not be adequately resourced. We believe that monitoring activities should be conducted at multiple levels. For example, relatively isolated and non-life-threatening patient safety issues could be investigated and reported to the organization's leadership on a periodic basis, while more widespread and potentially harmful events could be reported to the organization's PSO and investigated with their help. Finally, larger scale or widespread events could be reported to the local PSO but also to an independent national body who could help conduct the investigation and disseminate the findings.

16 State Governments

Page 22. AHRQ has encouraged states to use the Common Formats to make it possible to aggregate and compare adverse events across federal and state programs. AMIA urges ONC to align state and federal adverse event reporting requirements to minimize undue burden and fragmentation for reporting entities.

17 Private Sector Leadership

18 Other

We are concerned that the lack of specificity makes it difficult to assess whether the proposed implementation steps are realistic. For example, the report continues to portray EHRs as self-contained, software applications developed and installed by a single vendor that users simply install and run within a healthcare organization. This is far from the actual practice. More commonly, the EHR is but a small part of a complex network of interconnected software applications from different vendors that a healthcare organization, often with help from a systems integrator, implements over time to address the myriad clinical work processes required to care for complex, acutely ill patients1. Simply testing and certifying the individual components does not address how they will function when combined and integrated within a complex healthcare delivery system. While HIT offers opportunities to improve reliability and to enhance safety, it also may contribute to complexity in terms of workflow and work processes that need to be considered in the development of the Plan. Thus, AMIA believes that the surveillance plan would be significantly improved by acknowledging these types of challenges and committing new resources to developing solutions for ways to oversee these complex systems.

It is unclear if clinical decision support systems (CDSS) are included within the focus on HIT. We suggest that ONC clarify the extent to which CDSS will be considered as a central component of enterprise clinical systems.

Names

Haley, Dan

Comment ID

29

Organization

Athena Health

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 10. Testing, User Tools, best practices, 12. Investigat

1 Reporting

• Accordingly, we enthusiastically support the measures outlined in the ONC Plan that are intended to increase and support collection and analysis of patient safety information, the laudable goal of a "learning system," and the broad vision of a system that improves continuously overall, based on real data and substantive, analysis.
• We strongly agree with the need to collect and analyze data on how health IT functions, including through reports of patient safety issues, in order to continuously improve patient safety.
• We agree that to facilitate such reporting and analysis, steps must be taken to make it easier for clinicians—and developers—to collect and report such information.
• We disagree that AHRQ Common Formats, in their current form, are an adequate or appropriate means of such reporting. First and foremost, the Common Formats are not currently applicable to the ambulatory setting, a deficiency that renders them unusable for most of our clients. More broadly, as currently conceived the Common Formats reflect unrealistic assumptions about how HIT is integrated into provider workflows. HIT is a part of a larger sociotechnical system, and it therefore should be incorporated into all common formats. For example, in precisely the same fact scenario one clinician might choose to use the format for HIT to record an event, while another chooses the format for medications, leading to inconsistent reporting of factually similar events. If Common Formats are to be used as a basis for reporting and collection of safety events, they must first be overhauled and updated to reflect current technology and its role in multiple care environments.

2 Vendor Engagement (CoC, etc)

We further agree that members of the health information industry should agree to maintain, uphold and abide by a uniform set of high standards related to data portability, patient safety, freedom of choice, and meaningful, ethical use by healthcare providers of health information technology.
• To that end, shortly before publication of the ONC Plan athenahealth published and began to circulate within the industry our proposed 'Health Information Industry Code of Conduct,' which we believe fulfills the objectives of the ONC Plan and more. Its provisions are:
1. Empowering Data Portability and Provider Choice:
In the event that any client opts to change to the Electronic Health Record (EHR) of another signatory, we will, at our own expense, facilitate the intact transfer to the latter's EHR of all of the provider's clinical data.
2. Building a True Nationwide Information Backbone:
We will build, maintain, and curate reliable interfaces on behalf of any qualified healthcare provider that requests one.
3. Protecting Patients:
We commit to public reporting of adverse patient safety event
information. Within one year of signing, we will affiliate with a Patient Safety Organization (PSO), report all patient safety-related events to that PSO, and work proactively with clients to identify and resolve the causes of any such issues.
4. Preventing Fraud:
We will actively monitor, and report to clients, changes in provider billing patterns that could indicate up-coding or fraud.
5. Driving Meaningful Use
We will adjust reporting to accommodate government quality reporting programs, at no incremental cost to clients.
• We are actively seeking signatories to this Code among our peer companies and other industry stakeholders.
• We disagree, however, that it should be ONC's role to actively monitor, much less "ensure" compliance, with the above—

or any—voluntary industry Code of Conduct. We believe that the provisions above reflect principles that are essential for the continued viability and growth of the health information industry. Inasmuch as the provisions also increasingly reflect the desires of the providers who are the HIT industry's customers, the market will itself provide more than adequate enforcement of compliance.

• As indicated in provision 3 of our proposed Code, we strongly support the ONC Plan's repeated calls for developer reporting of patient safety information to Patient Safety Organizations (PSOs). However, we note that the ONC Plan only passingly mentions that HHS "would consider suggestions on how to expand PSWP [patient safety work product] protections" to "mitigate risks" of developer reporting of adverse patient safety event information to PSOs. Expansion of PWSP protections to developers (or creation of a new category of similar protections) so that developers can play their proper role in creation of a confidential, non-punitive learning health system is essential to meaningful reporting by developers to PSOs. Mindful again of the ONC Plan's repeated observation that patient safety is a shared responsibility, we argue strongly that expanded PSWP protections are necessary to empower developers to shoulder our share of that responsibility.

• We absolutely "support provider reporting of patient safety events," and agree that contractual relationships should not be leveraged to prevent such reporting.

• We agree in the abstract with the proposition that it could be useful to "compare user experiences across different EHR systems." There is an extraordinarily broad range of "EHR systems," however; from legacy products still using a static software platform to cloud-based services like those provided by athenahealth. Further, many EHR interfaces are configured and/or customized for the use of specific clinicians, making generic "comparison of user experiences" very difficult. To do this, the ONC or another governing body will have to create specific tasks, common data sets with representative patient information, a common test methodology, and a common set of measures. ONC must carefully evaluate whether the comparisons ultimately produced by such a necessarily prescriptive structure would be valuable enough to off-set the inevitable detrimental effects of the workflow and interface changes that would have to be made to implement the structure. Alternatively, we believe that ONC's resources would be better spent in two places to drive actual competition among vendors on usability characteristics: 1) educating clinicians and health IT purchasers to enable them to more seriously consider usability when making purchasing decisions; and 2) creating a framework for true data portability among EHRs (per provision # 1 of our Code of Conduct) so that providers can more easily change EHR vendors and systems. Fostering competition among vendors on usability characteristics will improve the usability across all HIT, without the disruption that might be created by yet another new standards framework intended to allow for comparison of current EHR user experiences.

• We have committed publicly to our clients and to our industry to affiliate with a Patient Safety Organization within one year (see online "HIT Code of Conduct" at http://www.athenahealth.com/blog/2013/01/04/athenahealth-newyear%
• E2%80%99s-resolutions-our-proposed-hit-code-of-conduct/).

3 PSO

• We support the leveraging and enhancement of the current PSO structure, which provides a very good initial framework to identify, aggregate, and analyze safety event and hazard reports. Given the complexities in the health care system, we encourage ONC to continue with an iterative approach to patient safety that learns and improves from each phase, which minimizes the risk of unintended consequences throughout the system. We also note persistent questions that must be addressed, such as whether the deidentified and aggregated information that is submitted to the NPSD and AHRQ provides sufficient detail for meaningful learning. We believe the ONC Plan describes a reasonable first step toward answering that question and others.

• Since patient safety is a shared responsibility, we suggest that there should be a place for developers in Figure 1, page 12, describing the PSO information aggregation and analysis structure.

4 ACB

• The regulatory prescriptions and proposed structure set forth in "Learn" sections 4 and 5 of the ONC Plan are inconsistent with the ONC Plan's correct observation that "[t]he proper steps to improve the safety of health IT can only be taken if there is better information regarding health IT's risks, harms, and impact on patient safety." Creation of a certification, post-market surveillance, and auditing scheme puts the regulatory horse before the information-gathering cart, and risks establishment of exactly the kind of innovation-stifling, duplicative regulatory regime that Congress intended to avoid with its three-pronged FDASIA mandate.

• if developers are to be "required to keep a record of [patient safety-related] complaints," as part of creation of a culture of safety and continuous improvement, they must be afforded appropriate PSWP protections or some equivalent thereof.

• We do not believe the Meaningful Use certification process, which is part of a wholly-voluntary financial incentives program, is either appropriate or viable in the long term as a mechanism for creating a patient safety surveillance system.

5 CMS

6 QSRS

• Subject to the concerns noted above with respect to the current limitations of the Common Formats, we agree generally with the ONC Plan's proposal to leverage the QSRS to perform retrospective surveillance of adverse events. We additionally suggest that ONC should be mindful of the administrative burdens placed on providers with each new reporting requirement. A mechanism should be established to allow providers to report each event only once, rather than to multiple repositories.

7 MAUDE

8 MU

• We agree that "meaningful use" (as a program or merely as a concept) of EHR technology has the power to improve patient safety. Indeed, we believe that improvement in patient safety is inherent in increasingly widespread and "meaningful" use of continuously-improving HIT.
• As explained previously, however, we do not agree that the Meaningful Use program itself is an appropriate or viable mechanism for establishing and enforcing certification criteria specific to patient safety, or that prescriptive certification requirements, however implemented and enforced, will improve patient safety in the long run. Continued innovation to meet the needs and desires of the medical providers will inevitably include innovations that improve patient safety in myriad ways that no prescriptive certification criteria can possibly anticipate.
• We believe the ONC Plan as drafted does not sufficiently emphasize the need to foster innovation and avoid duplicative regulation.
We do not believe the Meaningful Use certification process, which is part of a wholly-voluntary financial incentives program, is either appropriate or viable in the long term as a mechanism for creating a patient safety surveillance system.

9 Cer

• We believe the ONC Plan as drafted does not sufficiently emphasize the need to foster innovation and avoid duplicative regulation.

10 Testing, User Tools, best practices

• In addition to our comments about comparisons of user experiences and the need to improve usability, we note that current SHARP-C usability testing tools assume an installed-software model, in which the developer "sends" the EHR to be evaluated. Such an evaluation model is not applicable to dynamic, cloud-based services. Further, evaluation of a static system cannot account for the myriad individual variations in how an EHR is actually used in the context of highly-collaborative care environments involving multiple caregivers, clinical staff, etc.
We strongly agree that "[t]he accurate and efficient matching of patients to their health information is critical to ensuring [and, we would add, enhancing] patient safety." As we have noted in multiple forums, to achieve such matching on a national level true interoperation between systems is a must. As we did in our recent comments to the Meaningful Use Stage 3 draft recommendations, we urge ONC to continue and enhance its efforts to achieve actual interoperation, as opposed to theoretical "interoperability."

11 Edu

12 Investigate Corrective Action

• We strongly agree with the baseline proposition that serious adverse events and/or "unsafe conditions" created by EHRs must "trigger investigations and, when appropriate, corrective actions." This seems to us a common sense and inarguable assertion. Again, however, we must point to the ONC Plan's summary of currently available data pertaining to adverse patient safety events, which uniformly indicates that HIT is involved in less than 1 (one) percent of such events, and to the ONC Plan's correct statement that "[t]he proper steps to improve the safety of health IT can only be taken if there is better information regarding health IT's risks, harms, and impact on patient safety" (emphasis added). As the ONC Plan is only intended to remain in effect from fiscal 2013 through fiscal 2015, at which time presumably the risk-based regulatory framework mandated by Congress in the FDASIA will go into effect, we urge ONC to focus primarily on the need to gather the aforementioned "better information," and to leverage that information to help shape a permanent, risk-based regulatory framework based on a fuller understanding of the actual magnitude of risk.
• We strongly agree with ONC's decision to leverage existing Federal authorities to address serious adverse events and unsafe conditions, in lieu of a creating a new, dedicated bureaucracy as recommended by the IOM

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

• We believe the ONC Plan as drafted does not sufficiently emphasize the need to foster innovation and avoid duplicative regulation.
• We understand that the ONC Plan as conceived is intended to fill a perceived gap between the present and eventual implementation of the "risk-based framework" mandated by Congress in approximately 2015. Still, we expect that the ONC Plan as eventually implemented may well form a significant part of the foundation for a lasting framework, and we believe accordingly that a greater degree of focus should be placed on the second two prongs of the FDASIA mandate, so that the ONC of the future will remain as mindful of the crucial need to support and foster private sector innovation as is the ONC of the present.
• Continued innovation is a necessary condition for continued improvement inpatient safety. One of the two "Health IT Patient Safety Objectives" in the ONC Plan is to "[c]ontinuously improve the safety of health IT," an objective that can only be realized if the government in its understandable impulse to provide direction and leadership also affords industry the necessary room and flexibility to innovate. If fostering innovation and avoiding duplicative regulation are not explicit objectives of the ONC Plan, there is a risk that the central objective—continuous improvement of the safety of health IT—will be eventually undermined by insufficient attention to supporting the innovation required to power that continuous improvement. Congress's recognition of that danger is clearly reflected in the FDASIA. The second two prongs of the three-part mandate for a risk-based framework stand essentially as a Hippocratic Oath for would-be HIT regulators: "First, do no harm." We strongly urge that this concept should be integrated more explicitly and fully into the ONC Plan.
We believe the ONC Plan as drafted does not sufficiently emphasize the need to foster innovation and avoid duplicative regulation. We also applaud ONC's thoughtful effort, via the ONC Plan, to fill the gap between the present and eventual implementation of a risk-based regulatory framework for HIT mandated by Congress.

15 ONC Safety Program

• We believe the ONC Plan as drafted does not sufficiently emphasize the need to foster innovation and avoid duplicative regulation.
• We applaud and support efforts across the relevant agencies of government focused on improving safety in HIT. We are again mindful, however, of the need to gather information first, and to avoid both regulatory duplication (either existing or future) and measures that unnecessarily stifle innovation.
• As explained at multiple points in this letter, we believe that ONC's efforts and its leadership should appropriately be focused during that gap period on gathering the "better information" on HIT's role in patient safety required to ensure that the eventual risk-based regulatory framework takes the "proper steps to improve the safety of health IT".
• We appreciate the leadership role that ONC is assuming in the effort to craft a risk-based regulatory framework, and its stated intention to develop a report with "significant public input." We strongly urge that a broad range of industry stakeholders, including developers, be included in that effort.

16 State Governments

As ONC appropriately urges state governments to incorporate HIT into their own patient safety oversight programs, we urge ONC to exercise leadership to encourage uniformity in such programs.

17 Private Sector Leadership

• We appreciate the ONC Plan's acknowledgement of the need for private sector leadership and shared responsibility for patient safety in the use of HIT. We respectfully suggest that ample evidence of such leadership is already evident. Developers of HIT are strongly committed to patient safety, not only because we and our families are ourselves often patients, but also because our clients demand and rely upon that commitment. That private sector leadership, among a wide range of industry stakeholders, will be demonstrated in the short term by a forthcoming report to be issued by a collaboration convened under the auspices of the respected Bipartisan Policy Center.
• athenahealth agrees that responsibility for patient safety should be shared by the full range of industry stakeholders, including developers.
• In lodging that criticism we are very cognizant and appreciative of the fact that ONC and its leadership are consistently supportive of private sector innovation in HIT. Indeed, very often ONC leadership identifies empowering innovation as a core mission of the agency. Given that welcomed focus, the scant mention of innovation in the ONC Plan is all the more striking.

18 Other

While the writers correctly point out that much of the information to-date was gathered at a time when HIT adoption and use was relatively limited, the fact should not be ignored that the existing data is strongly indicative of an overall excellent record of patient safety in the use of HIT. According to the Institutes of Medicine (IOM), “a review of seven papers using large databases of reported errors found that health information systems were involved in less than 1 (one) percent of reported errors.” ONC Plan, page 5.

Names

Tim, Wareham

Comment ID

100

Organization

AtHoc, Inc.

Org Typ1	Org type	Categories
12	12.. Other	12. Investigate & Corrective Action, 18. Other

1 Reporting

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

One item I would like to register for your consideration under “Improvement” in your planning strategy is a corrective action which should be in place in policy to address EMR availability outages whether by plan during a scheduled software upgrade, or more importantly, when unexpected system failures occur within the Electronic Health Record (EHR) documentation system. There have been numerous of these outages reported in the news over the past year, and it seems across almost all IT vendors.

• A recommended corrective actions to improve Health IT safety and patient safety which would help alleviate the adverse impact on patient safety during these unforeseen events would be the recommendation in the ONC Health IT Safety plan to include a business continuity plan for system downtime. This plan should incorporate immediate notification to all staff within the potential effected clinical setting. The notification should be immediately available on a multitude of devises (pop up message on all computer screens, phone notifications to all floor phones as well as cell devices in use, overhead message and seamless transfer of the message to all devices used within the organization). This alerting component is an important patient safety consideration for the period of downtime and after the system has come back on-line. If there is not a good mechanism to ensure that all information recorded on paper during the outage is entered in the system, there is a potential for harm to be caused as a result. The notification system should not only alert, provide a plan of action to the end user, and track the users response, but also be able to identify on a simple dashboard time sent, time received and time acknowledged by the recipient in order to completely ensure the message was received and understood.

13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

After thoroughly reviewing the Health IT Safety Plan we applaud your efforts to ensure that your goals 1) Use health IT to make care safer and 2) Continuously improve the safety of health IT are addressed throughout the entire healthcare community.

Names

Saphner, Mary,RN

Comment ID

85

Organization

Aurora Healthcare

Org Typ1	Org type	Categories
1	1 Provider (institution)	8. MU

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU

I would encourage the integration of the Safety Risk Assessment as part of the projected Meaningful Use requirements. Adding the requirement of Safety Assessments brings to the forefront a common weakness of the use of EMR/HIT. Many users believe that they are not required to use their clinical training or judgment, but rely too heavily on the HIT decision made for them by the software. Often the concept of using the EMR as a tool to their training is lost. What occurs is that their training and knowledge is secondary to the decision placed for them by the software/EMR. For the EMR's to follow the IOM recommendations of safety, two components must occur: clinical judgment must go hand in hand with HIT, not one overtaking the other. Requiring safety assessments would encourage the trained clinical provider to not merely "click through the screens", but read the screens and use their trained judgment in conjunction with the EMR to result in the safest and best care possible.

9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

Names

Alessio, Julie M.

Comment ID

105

Organization

Bay Clinic, Inc

Org Typ1	Org type	Categories
12	12. Safety Organization	

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

Names

Bipartisan Policy Center

Comment ID

106

Organization

Bipartisan Policy Center (BPC)

Org Typ1	Org type	Categories
12	12.. Other	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

• Stakeholder organizations should encourage reporting of patient safety events through raising awareness of the benefits of reporting and clarifying the confidentiality protections around reporting (4.4)
• Developers should report patient safety events to PSOs with expanded protections and requirements for reporting events that cause death or serious harm (4.2)
• Reporting should be embedded in current work flows and health IT systems to reduce the administrative burden (4.3)
• Organizations representing PSOs, developers, clinicians, hospitals, and other providers should take steps to encourage reporting of patient safety events through raising awareness of the benefits of reporting and clarifying confidentiality protections (4.4)
Developers should raise awareness among their clients that reporting of patient safety events to their PSOs is permissible under existing contracts (4.5)

2 Vendor Engagement (CoC, etc)

• Health IT vendors should raise awareness among clinicians and providers on the permissibility of reporting patient safety events to PSOs under existing contracts (4.3)
• Vendors should clarify language in future contracts regarding the permissibility of patient safety events (4.3)
• PSOs should demonstrate their baseline knowledge and capabilities through a PSO-led accreditation program associated with health IT-related safety events. This should have support from developers, implementers, users, and experts (4.5)
• Developers, implementers, PSOs, and experts should collaborate with government to agree upon and promote adherence to standards and guidelines of patient safety in health IT (1.1)
• Developers, implementers, PSOs, and experts should collaborate with government to enable stakeholder participation in patient safety activities including reporting, analysis, and response (1.1)
• Software developers and implementers must have the ability to participate with PSOs and healthcare providers in patient safety activities (4.1)
• Developers should participate in the reporting of patient safety events just as providers do (4.1)
• Software developers and implementers must have the ability to participate with PSOs and healthcare providers in patient safety activities (4.1)
• Current law should be extended to provide confidentiality protections to health IT developers to permit them to report safety events, review PSO-protected information, receive and analyze event reports, create and receive quality improvement recommendations from the PSO, and work with the providers to develop strategies for improvement (4.1)
• Developers should report patient safety events to PSOs with expanded protections and requirements for reporting of events that cause death or serious harm (4.2)
• AHRQ should explore options for enabling developers to participate in patient activities with protections (this should include reporting, review and analysis of patient safety events, creation and receipt of quality improvement recommendations from PSOs and dialogue with the PSO regarding corrective actions that can be taken to mitigate further risk (4.3)
• Health IT vendors should work with healthcare providers to educate them on the permissibility of reporting patient safety events to their PSOs under existing contracts and clarify language in future contracts (4.3)
• Developers, implementers, users, patient safety and health IT experts should be involved with the development of standards, guidelines, and best practices for traditional PSO activities (4.5)
• PSOs should collaborate with developers, implementers, users, and patient safety and health IT experts on the development and launch of an accreditation program that reflects established standards, guidelines, and best practices and promotes effective implementation of patient safety activities related to health IT (4.7)
• Developers, implementers, users, PSOs, patient safety and health IT experts, and consumers should collaborate on the development of key attributes and requirements associated with the aggregation and analysis of non-identified patient safety event data to facilitate

learning (5.1)
• Developers and implementers who report patient safety events to a PSO or the NPSD should be encouraged to utilize standardized formats (AHRQ Standardized Formats should be leveraged when possible) (5.1)
Developers and software implementers that are not part of provider organizations should demonstrate adherence to recognized and agreed upon standards and guidelines by undergoing accreditation administered through independent, recognized bodies (2.3)

3 PSO

• Authorities, structures, and organizations created by the Patient Safety and Quality Improvement Act should be leveraged to support the reporting and analysis of health IT-related public safety events (4.1)
• PSOs should collaborate with developers, implementers, users, and patient safety and health IT experts on the development and launch of an accreditation program that reflects established standards, guidelines, and best practices and promotes effective implementation of patient safety activities related to health IT (4.7)
• Standardized formats should be used for reporting to improve the ability for data to be aggregated and analyzed PSOs should collaborate with developers, implementers, users, and patient safety and health IT experts on the development and launch of an accreditation program that reflects established standards, guidelines, and best practices and promotes effective implementation of patient safety activities related to health IT to support system-wide response and improvement (4.7)
• Software developers and implementers must have the ability to participate with PSOs and healthcare providers in patient safety activities (4.1)
• Developers, implementers, users, PSOs, patient safety and health IT experts, and consumers should collaborate on the development of key attributes and requirements associated with the aggregation and analysis of non-identified patient safety event data to facilitate learning (5.1)
• PSOs should explore aggregating patient safety events associated with health IT either through reporting to the NPSD or to other PSOs that are aggregating the data for learning and improvement (5.4)
• Current law should be extended to provide confidentiality protections to health IT developers to permit them to report safety events, review PSO-protected information, receive and analyze event reports, create and receive quality improvement recommendations from the PSO, and work with the providers to develop strategies for improvement (4.1)
• Developers should report patient safety events to PSOs with expanded protections and requirements for reporting of events that cause death or serious harm (4.2)
• AHRQ should explore options for enabling developers to participate in patient activities with protections (this should include reporting, review and analysis of patient safety events, creation and receipt of quality improvement recommendations from PSOs and dialogue with the PSO regarding corrective actions that can be taken to mitigate further risk (4.3)
• The development of standards, guidelines, and best practices for traditional PSO activities-such as reporting and analysis of reported events, development of corrective action plans, aggregation and analysis of large data sets, and development of strategies to mitigate future risk for health IT-related patient safety events is needed (4.5)
• PSOs should demonstrate their baseline knowledge and capabilities through a PSO-led accreditation program associated with health IT-related safety events. This should have support from developers, implementers, users, and experts (4.5)
Appropriate governance, policies, protections, and capabilities will need to be established for entities that choose to aggregate large sets of patient safety data to garner trust, assure confidentiality, provide ease of use, minimize burden, and deliver value to participants (5)

4 ACB

• Existing accreditation bodies should be evaluated for support of standards and guidelines for software implementation and use (2.4)
• Developers and software implementers that are not part of provider organizations should demonstrate adherence to recognized and agreed upon standards and guidelines by undergoing accreditation administered through independent, recognized bodies (2.3)

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

Policies, processes, and systems associated with assuring safety in health IT should be aligned with and integrated into well-established patient safety and quality programs, including accreditation, certification, and reporting (4)

10 Testing, User Tools, best practices

• Stakeholders should collaborate on the research, development, and dissemination of strategies and best practices for patient safety throughout the health IT life cycle. (3.1)
PSOs should collaborate with developers, implementers, users, and patient safety and health IT experts on the development of standards, guidelines, strategies, and best practice for collecting, analyzing, and investigating health IT-related patient safety events and taking necessary actions to mitigate future risk. (4.6)

11 Edu

• Independent, voluntary consensus bodies should engage stakeholders in developing and dissemination educational programs on agreed upon standards and guidelines (2.2)
• Awareness-building and education programs should be in place to explain and clarify the benefits of reporting and the confidentiality protections that are in place (4.3)
• Awareness-building and education programs should explain and clarify the Patient Safety Act and the benefits of reporting and the confidentiality protections that support provider reporting. (4.3)

12 Investigate Corrective Action

• PSOs, developers, implementers, users and health IT and patient safety experts should collaborate on defining corrective action and providing timely feedback and other necessary actions to mitigate future risk. (4.6)
AHRQ should explore options for enabling developers to participate in patient activities with protections (this should include reporting, review and analysis of patient safety events, creation and receipt of quality improvement recommendations from PSOs and dialogue with the PSO regarding corrective actions that can be taken to mitigate further risk (4.3)

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

Independent, voluntary consensus bodies should engage developers, implementers, users, health IT and safety experts, and consumers to gain ongoing agreement on a set of standards and guidelines for assuring patient safety in the design, development, implementation, and use of health IT (2.1)

16 State Governments

Health IT developers and their products must comply with existing federal or state consumer protection laws, privacy and security laws and regulations (4.1).

17 Private Sector Leadership

The oversight framework should enable public and private sector collaboration and leadership (1.1)

18 Other

Oversight Framework
• The oversight framework for patient safety should recognize the following principles: health IT's role in improving care and patient experience; assuring patient safety and positive outcomes are a shared responsibility among the entire healthcare system; be risk-based, flexible and innovative; leverage existing safety and quality-related processes, systems, and standards; reporting patient safety events is essential and establish a non-punitive environment to encourage reporting (1.1)
The oversight framework should call upon stakeholders to: agree upon and adhere to recognized standards and guidelines for assuring patient safety in the development, implementation, and use of health IT; support the implementation of standards and guidelines and develop and disseminate best practices through education, training, and technical assistance; enable stakeholder participation in patient safety activities; and create a learning environment, aggregate and analyze non-identified patient safety reports to identify and monitor trends, mitigate future risk, and facilitate learning and improvement. (1.1)

Names

Bell, Karen M MD MMS

Comment ID

53

Organization

CCHIT

Org Typ1	Org type	Categories
10	10. ACB	10. Testing, User Tools, best practices, 15. ONC Safety Program, 4.

1 Reporting

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

• As noted above, ONC Authorized Certification Body (ACB) surveillance of EHR technologies certified to ONC 2014 Edition certification criteria may be premature until further attention is paid to a robust set of patient safety criteria that can be tested both before and after implementation of the technology. Field surveillance and testing by ACBs for patient safety issues for thousands of physician and hospital installations after implementation of ONC certified technology will be costly and likely of small yield without more specified and substantive testing approaches. We are aware of a testing tool that has been developed by Drs. David Bates and David Clausen, and Jane B. Metzger that allows hospitals to assess the degree to which their computerized physician order entry (CPOE) systems function as intended. Such a tool would not only be a significantly more efficient approach to assessing how certified technology functions in situ, but also a more useful, actionable approach. Rather than engage ACBs in the surveillance of implementations of previously certified EHRS for patient safety issues, we recommend that

• 3. ONC should identify those HIT functions that are most likely to be associated with patient safety events and support the development and use of testing tools that can be used by the delivery system to assess the degree to which its HIT performs as expected. The results of those tests may then be sent to the technology's chosen ACB for analysis, recommendations for improvement, and oversight.

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

• 2. ONC should release and fund an RFP to develop an HIT Patient Safety Testing Program that can be used to assess the degree to which EHR technology includes a set of criteria focused on patient safety based on multi-stakeholder consensus. Such a testing program would be separate from ONC's HIT Certification Program in order to assure that it can accommodate new approaches in a timely way, engage a more diverse set of stakeholders (i.e., practicing physicians) that may require compensation for time spent on development, and allow for more creative and useful ways of presenting results of testing.

• While a number of elements in ONC's HIT Certification Program described in the Plan have been made to attend to patient safety, many opportunities to improve patient safety through HIT have not been included. First and foremost among these omissions has been integration testing. We are, therefore, pleased to see the recent release of Test Scenarios that address integration of data across a limited set of criteria, even though this testing is not a requirement for ONC certification. Without reliable interfaces among EHR modules and data integration within an EHR system, patient data may be corrupted, leading to significant patient safety problems. CCHIT has also had experience with a number of other HIT functions that would contribute to patient safety: closed loop order entry that indicates to an ordering clinician that a patient has not kept an appointment for a test or referral or not filled a prescription, drug/laboratory alerts, and usability testing to minimize

errors at the human/computer interface are a few examples of these functions. Before any type of meaningful surveillance in the field occurs, every effort should be made to assure that EHRs include functions known to mitigate patient safety risk.

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

1. ONC should establish a Patient Safety Workgroup through one of its two HIT Advisory Committees to develop a roadmap for logical and timely implementation of the final Plan. This Workgroup should take into account all aspects of preparing for efficiently run processes when considering the elements of the Plan including a focus on decreasing administrative burden on the delivery system.

16 State Governments

17 Private Sector Leadership

18 Other

Names

Marshall, Meg , JD

Comment ID

30

Organization

Cerner

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 12. Investigate & Corrective Action, 13. Priority are

1 Reporting

• Cerner agrees with the ONC that the process by which clinicians report patient safety events and risks should be augmented with data stored in the patient's electronic health record as collected by EHR technology. We also agree that reporting mechanisms should standardize the reporting process in a meaningful, intuitive way for end users and such standardization is critical to the appropriate aggregation and accurate analysis of safety event-related data. We are cautious of the role the actual EHR technology and workflow plays in the reporting process.

• The Patient Safety Organizations (PSO) regulations call for creation of source records for PSO reporting as a distinct type of records a healthcare provider maintains as the source for PSO reporting. It can include data contributed from EHRs. ONC should structure any certification criteria to affirm this contributory role, and not suggest direct submission from EHRs to some external entity that bypasses it. We are concerned that ONC's Proposed Plan introduces potential challenges for those concerned with boundaries of the legal medical record, and strongly recommend that EHR technology is not the appropriate mechanism for such reporting. Cerner's recommends the ONC conduct more study into the data requirements for EHRs to provide EHR information to reporting systems.

• We further recommend the private market development of a reporting tool that gathers appropriate event-related data from the provider, allowing for the option to capture EHR-stored data, for all patient safety events – not just those related to health IT. Health IT suppliers should augment this process by direct reporting to MedWatch, which leverages data elements best suited to IT.

• We also recommend that any contribution of data from the EHR for any such reporting be subject to the requirements of the HIPAA Security and Privacy rules that address any other disclosure of protected health information as to handling, transmission, storage or maintenance.

• Cerner suggests the ONC implements an approach that recognizes the varying level of risk associated with different types of health IT functionality. Specifically, we suggest the ONC collaborates with industry stakeholders to develop a definition of high-risk health IT functions. Patient safety events that are associated with high-risk level functions should then be required

to be reported, and those associated with less risky functions may be reported voluntarily.
• Cerner suggests that ONC collaborates with industry stakeholders to develop a materiality standard that triggers reporting of an adverse event.
• Cerner agrees that requirements for EHR certification under the Meaningful Use program should include an EHR supplier's practices to report high-risk safety events and implement an appropriate Quality Management System. Cerner urges the ONC to recognize that technologies in addition to EHRs are leveraged in patient care and to define guidance accordingly.

2 Vendor Engagement (CoC, etc)

• We caution the ONC that a regulatory-directed code of conduct for health IT suppliers may impact innovation and introduce a level of accreditation and accountability activities the ONC may not be equipped or prepared to provide. We urge ONC to defer the development and enforcement of a Code of Conduct to the industry to address as a whole.
• Cerner suggests that ONC ensures providers have access to critical information during the health IT selection process through the implementation of transparency and labeling requirements similar to those afforded through consumer protection laws. Specifically, we recommend the ONC: 1) require health IT suppliers to be transparent in regard to potentially harmful contract provisions, such as intellectual property provisions that restrict the sharing of data necessary to report patient safety events, and 2) provide educational support to providers as they evaluate health IT. In the alternative, Cerner suggests ONC encourages industry stakeholders, led by health IT suppliers, to collaborate on the identification of elements considered to define the standard of good business practices. Health IT suppliers can voluntarily self-attest their compliance and market their solutions accordingly.
• To this end, we are confident the private market will successfully force the evolution- or ultimate extinction- of non-supportive suppliers.
• Cerner suggests the ONC implements an approach that recognizes the varying level of risk associated with different types of health IT functionality. Specifically, we suggest the ONC collaborates with industry stakeholders to develop a definition of high-risk health IT functions. Patient safety events that are associated with high-risk level functions should then be required to be reported, and those associated with less risky functions may be reported voluntarily.
• Cerner suggests that ONC collaborates with industry stakeholders to develop a materiality standard that triggers reporting of an adverse event.
• Cerner strongly believes all health IT vendors should report patient safety events associated with high-risk health IT functions in this manner and encouraged to voluntarily report patient safety events associated with lesser risk.
• Cerner believes that the design and development of health IT solutions in accordance with the Quality System Regulations, the implementation of quality management systems, and the use of post-market surveillance and transparency are viable ways to mitigate potential safety risks. Cerner does not believe, however, that all health IT solutions should be defined as medical devices that require pre-market clearance or approval by the FDA. Such a broad definition would be excessive for the level of risk posed by most health IT systems.
• There is an intuitive concern that public disclosure of adverse events will generate an overreaction by the public and unfounded fears about the safety of health IT. Cerner, however, has enjoyed great success in the marketplace during the period in which it has publicly reported events that have the potential for material adverse impact on patient/donor safety. Our experience has been that end-user health care providers use this information appropriately in evaluating the risk that Cerner solutions may pose to their patients against the benefits and safety enhancements that will be derived from the use of Cerner's health IT solutions. Moreover, the relatively small number of adverse events should serve to allay public concerns about the relative benefits of health IT and the low risk health IT poses to the public. For all of these reasons, Cerner believes that public reporting of events that pose material risks to the public is, overall, a positive. However, in order to encourage transparency, ONC must address barriers for both health IT developers and providers by maintaining patient confidentiality and expanding work product protections for disclosure. Along these lines, Cerner encourages ONC to facilitate and incent, where feasible, state-level tort reform activities focused on providing the appropriate protections and safeguards that encourage transparency by both providers and vendors regarding the reporting of patient safety-related events.

3 PSO

• Based on our previous experiences with patient safety event reporting, the industry must overcome two issues to facilitate appropriate data aggregation and appropriate data analysis: 1) a "mapping" mechanism that coordinates the reporting process in regard to a single patient-safety event and all of its associated data as reported by the patient, the provider and the health IT technology supplier, 2) adequate participation of those with understanding of the health IT infrastructure capabilities in the review of a patient safety event to determine the extent, if any, to which health IT may have been involved.

• One example, although simple in its clinical context, illustrates the challenges of coordinating a complex health IT environment: A provider gathers data to submit in regard to a patient fall event. The fall may have been prevented if a critical data element regarding the patient's condition had been included in the patient's summary of care document received from a health information exchange (HIE). This may indicate a potential issue with the originating system's EHR, the HIE technology, or even with patient self-reported data through a personal health record (PHR). Ultimately, the reporting provider's EHR system did not fire an alert for potential fall risk. In order to identify root cause, a comprehensive analysis must be done with the cooperation of multiple stakeholders and those who have a good understanding of 1) what data is being collected, 2) where it comes from, and 3) where it is being used.
• Assuming stakeholders that are knowledgeable of the provider's health IT infrastructure environment are included in the safety event evaluation process and data is gathered from the appropriate IT sources, Cerner encourages the ONC to leverage existing PSO regulations for provider reporting. Any development of future certification requirements for this kind of reporting should emphasize the role of EHRs to contribute data to the record management systems used by providers for PSO reporting but not direct EHR submission to a PSO. As stated above, however, we submit that health IT suppliers should report via the MedWatch tool. This dual reporting process is crucial as it allows each stakeholder to focus on its workflow and data available, and can be reconciled through the use of a mapping mechanism (as we recommend above in "Focus on the data").

4 ACB

• Cerner has concerns about the utilization of ONC-ACBs for post-market surveillance activities of EHR technology. The scope of these organizations is limited to activities related to the integrity of the certification program; handling complaints related to certified product use; and questions of vendor compliance with certification program requirements as to use of labels, claims of certified products and abiding by the terms of their certification agreements. Activities that fall outside of this scope require expanded core competencies and potentially introduce inherent conflicts of objectives.
• Cerner believes that the design and development of health IT solutions in accordance with the Quality System Regulations, the implementation of quality management systems, and the use of post-market surveillance and transparency are viable ways to mitigate potential safety risks. Cerner does not believe, however, that all health IT solutions should be defined as medical devices that require pre-market clearance or approval by the FDA. Such a broad definition would be excessive for the level of risk posed by most health IT systems.

5 CMS

6 QSRS

7 MAUDE

• Introducing an additional process by which we report patient safety issues creates an additional burden for us, as well as potentially duplicates data we are already sending to MedWatch. Cerner recommends that the ONC considers leveraging the standards used by the FDA's MedWatch program to ensure processes and data are not duplicated. From our standpoint, there is no benefit to reporting data associated with health IT that is not already addressed through the MedWatch reporting process.
• Objective 1, Strategy 7 of the Proposed Plan, "Monitor health IT adverse event reports to the Manufacturer and User Facility Device Experience (MAUDE) database," should be extended to require the utilization of the MedWatch reporting process as a primary mechanism for health IT suppliers to report data associated with high-risk health IT-related safety events.
• assuming stakeholders that are knowledgeable of the provider's health IT infrastructure environment are included in the safety event evaluation process and data is gathered from the appropriate IT sources, Cerner encourages the ONC to leverage existing PSO regulations for provider reporting. Any development of future certification requirements for this kind of reporting should emphasize the role of EHRs to contribute data to the record management systems used by providers for PSO reporting but not direct EHR submission to a PSO. As stated above, however, we submit that health IT suppliers should report via the MedWatch tool. This dual reporting process is crucial as it allows each stakeholder to focus on its workflow and data available, and can be reconciled through the use of a mapping mechanism (as we recommend above in "Focus on the data").

8 MU

• Cerner agrees that requirements for EHR certification under the Meaningful Use program should include an EHR supplier's practices to report high-risk safety events and implement an appropriate Quality Management System. Cerner urges the ONC to recognize that technologies in addition to EHRs are leveraged in patient care and to define guidance accordingly.

• Cerner also challenges ONC to view patient safety oversight through a lens other than “Meaningful Use.” For example, ONC has a timely opportunity to influence safety of health IT through the potential extension of Stark/Anti-Kickback rules, currently scheduled to expire 2013. In addition, ONC may explore encouraging incentives to those who vested in patient safety activities: for example, medical malpractice liability insurers to provide discounts to providers that utilize health IT products deemed to follow safe practices.

9 Cer

• Cerner is completing actions to comply with ISO 14971:2007 – Application of Risk Management to Medical Devices, a standard endorsed by the FDA as an acceptable risk management approach for placement of safe and effective medical devices onto the market. Cerner urges the ONC to consider requiring compliance with this standard for manufacturers of high-risk health IT functions.
• Cerner believes that the design and development of health IT solutions in accordance with the Quality System Regulations, the implementation of quality management systems, and the use of post-market surveillance and transparency are viable ways to mitigate potential safety risks. Cerner does not believe, however, that all health IT solutions should be defined as medical devices that require pre-market clearance or approval by the FDA. Such a broad definition would be excessive for the level of risk posed by most health IT systems.
• [Jensen: Not sure if this belongs in Cert] in its work to create a risk-based framework, the ONC may benefit from a review of the European Commission’s Guidelines on the Qualification and Classification of Stand Alone Software Used In Healthcare Within the Regulatory Framework of Medical Devices, which outlines a process by which health IT suppliers understand whether any given standalone software is categorized as regulated under EU authority. As Cerner is, many health IT companies offer their products globally and subsequently are familiar with these guidelines. We strongly believe that the implementation of these processes [FDA’s Quality System Regulation, 21 CFR Part 820 Medical Devices, ISO 9001:2008 Quality Management Systems and ISO 13485:2012 Medical Devices] ensures the appropriate level of oversight without being too prescriptive and affecting the ability of health IT suppliers to develop innovative and safe products responsibly and in a manner expected by our clients and the individuals they serve.
• Assuming stakeholders that are knowledgeable of the provider’s health IT infrastructure environment are included in the safety event evaluation process and data is gathered from the appropriate IT sources, Cerner encourages the ONC to leverage existing PSO regulations for provider reporting. Any development of future certification requirements for this kind of reporting should emphasize the role of EHRs to contribute data to the record management systems used by providers for PSO reporting but not direct EHR submission to a PSO. As stated above, however, we submit that health IT suppliers should report via the MedWatch tool. This dual reporting process is crucial as it allows each stakeholder to focus on its workflow and data available, and can be reconciled through the use of a mapping mechanism (as we recommend above in “Focus on the data”).

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

• Cerner also challenges ONC to view patient safety oversight through a lens other than “Meaningful Use.” For example, ONC has a timely opportunity to influence safety of health IT through the potential extension of Stark/Anti-Kickback rules, currently scheduled to expire 2013. In addition, ONC may explore encouraging incentives to those who vested in patient safety activities: for example, medical malpractice liability insurers to provide discounts to providers that utilize health IT products deemed to follow safe practices.

13 Priority areas, Measures, Targets

• Cerner suggests the ONC implements an approach that recognizes the varying level of risk associated with different types of health IT functionality. Specifically, we suggest the ONC collaborates with industry stakeholders to develop a definition of high-risk health IT functions. Patient safety events that are associated with high-risk level functions should then be required to be reported, and those associated with less risky functions may be reported voluntarily.
• Cerner suggests that ONC collaborates with industry stakeholders to develop a materiality standard that triggers reporting of an adverse event.

14 Publish Report on strategy and recommendations

• Cerner believes that the design and development of health IT solutions in accordance with the Quality System Regulations, the implementation of quality management systems, and the use of post-market surveillance and transparency are viable ways to mitigate potential safety risks. Cerner does not believe, however, that all health IT solutions should be defined as

medical devices that require pre-market clearance or approval by the FDA. Such a broad definition would be excessive for the level of risk posed by most health IT systems.
• Cerner suggests that ONC collaborates with industry stakeholders to develop a materiality standard that triggers reporting of an adverse event.
• in its work to create a risk-based framework, the ONC may benefit from a review of the European Commission's Guidelines on the Qualification and Classification of Stand Alone Software Used In Healthcare Within the Regulatory Framework of Medical Devices, which outlines a process by which health IT suppliers understand whether any given standalone software is categorized as regulated under EU authority. As Cerner is, many health IT companies offer their products globally and subsequently are familiar with these guidelines.
• We strongly believe that the implementation of these processes [FDA's Quality System Regulation, 21 CFR Part 820 Medical Devices, ISO 9001:2008 Quality Management Systems and ISO 13485:2012 Medical Devices] ensures the appropriate level of oversight without being too prescriptive and affecting the ability of health IT suppliers to develop innovative and safe products responsibly and in a manner expected by our clients and the individuals they serve.
• Cerner has found that incorporating some of the requirements imposed on medical device manufacturers into the processes by which it designs and develops more advanced health IT solutions has helped the company reduce patient safety risks. In particular, quality system requirements can be helpful in providing quality assurance and quality control helping to reduce the potential safety risk of advanced health IT solutions. However, Cerner believes that such requirements can impede the pace of health IT innovation and delay benefits that come from health IT if they are applied in an inappropriate fashion. Regulators particularly will impede innovation if they impose burdensome standards on health IT for functions that do not represent appropriately high risks to patient care.
• As the EHR industry has matured, more healthcare processes are now automated, and the reach of automation has moved from simple administrative billing to more clinical activities, decision support and even condition-specific features and capabilities. These more complex systems and capabilities require the orchestration of software, configuration, processes and training. As such, Cerner believes oversight will need to be innovative as the information provided by EMRs becomes richer, more contextual and capable of providing clinical decision support. Many Cerner clients achieve innovations through a combination of assets (software, decision support, content, clinical evidence, workflows and training). Those innovations occur locally and are not automatically applicable to all Cerner clients. An oversight approach that does not allow for clinicians to apply new approaches in the field will slow the development of possible health IT benefits on outcomes.

15 ONC Safety Program

• Introducing an additional process by which we report patient safety issues creates an additional burden for us, as well as potentially duplicates data we are already sending to MedWatch. Cerner recommends that the ONC considers leveraging the standards used by the FDA's MedWatch program to ensure processes and data are not duplicated. From our standpoint, there is no benefit to reporting data associated with health IT that is not already addressed through the MedWatch reporting process.
• Objective 1, Strategy 7 of the Proposed Plan, "Monitor health IT adverse event reports to the Manufacturer and User Facility Device Experience (MAUDE) database," should be extended to require the utilization of the MedWatch reporting process as a primary mechanism for health IT suppliers to report data associated with high-risk health IT-related safety events.
• Cerner also challenges ONC to view patient safety oversight through a lens other than "Meaningful Use." For example, ONC has a timely opportunity to influence safety of health IT through the potential extension of Stark/Anti-Kickback rules, currently scheduled to expire 2013. In addition, ONC may explore encouraging incentives to those who vested in patient safety activities: for example, medical malpractice liability insurers to provide discounts to providers that utilize health IT products deemed to follow safe practices.

16 State Governments

• There is an intuitive concern that public disclosure of adverse events will generate an overreaction by the public and unfounded fears about the safety of health IT. Cerner, however, has enjoyed great success in the marketplace during the period in which it has publicly reported events that have the potential for material adverse impact on patient/donor safety. Our experience has been that end-user health care providers use this information appropriately in evaluating the risk that Cerner solutions may pose to their patients against the benefits and safety enhancements that will be derived from the use of Cerner's health IT solutions. Moreover, the relatively small number of adverse events should serve to allay public concerns about the relative benefits of health IT and the low risk health IT poses to the public. For all of these reasons, Cerner believes that public reporting of events that pose material risks to the public is, overall, a positive. However, in order to encourage

transparency, ONC must address barriers for both health IT developers and providers by maintaining patient confidentiality and expanding work product protections for disclosure. Along these lines, Cerner encourages ONC to facilitate and incent, where feasible, state-level tort reform activities focused on providing the appropriate protections and safeguards that encourage transparency by both providers and vendors regarding the reporting of patient safety-related events.

17 Private Sector Leadership

• Cerner strongly believes all health IT vendors should report patient safety events associated with high-risk health IT functions in this manner and encouraged to voluntarily report patient safety events associated with lesser risk.
• Cerner suggests that ONC collaborates with industry stakeholders to develop a materiality standard that triggers reporting of an adverse event.
• We further recommend the private market development of a reporting tool that gathers appropriate event-related data from the provider, allowing for the option to capture EHR-stored data, for all patient safety events – not just those related to health IT. Health IT suppliers should augment this process by direct reporting to MedWatch, which leverages data elements best suited to IT.

18 Other

• Cerner has categorized the most common EHR issues that can pose risks to patient safety. This listing is based on the types of software issues that Cerner's clients have reported and on industry research and intelligence. We offer the following categories for your consideration: [See comment]
• Recognizing that the clinician ultimately diagnoses and treats patients based on his or her assessment of the available information in accordance with the medical standard of care, the health IT industry neither intends nor desires to practice medicine: we simply create tools that help clinicians make better care decisions for patients. We are pleased to see the recognition that achieving and continuously improving the safer use of health IT is a shared responsibility that requires coordinated actions among all members of the health IT and patient safety community – public and private – including providers, health IT developers and patients.
• The design of health IT, including its customization and implementation, directly affect the level of its safety. Further, user education and training in regard to use of the system, clinical processes and quality of data also must be considered. To this end, no two health IT interactions are the same.

Names

Correll, Richard

Comment ID

57

Organization

CHIME

Org Typ1	Org type	Categories
9	9. Allied Professional Organization	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

• We strongly urge that attention be paid to how much time and resources are expected of providers to report on safety events. While we support the need for more information on patient safety events and we believe the general approach ONC is suggesting (through AHRQ Common Framework and PSOs) is reasonable, we believe there is a significant danger in developing a reporting regime that unduly burdens providers. CHIME recommends that ONC work with stakeholders to determine ways that reports can be compiled once and used many times. We believe there needs to be a scaleable approach that spans federal, state and private-sector reporting requirements. We want to make sure that health information is managed in a way that avoids duplicative reports to various entities and disparate data silos do not impede the learning health system that is needed to understand how health IT and patient safety interrelate.
• It is important for providers to avoid the construct where there is a separate process for addressing health IT safety apart from other safety issues. Creating a safety reporting silo that only focuses on health IT would be duplicative, increase unnecessary reporting burden, and also result in the failure to capture many relevant events. Patient safety events

associated with health IT are often identified after the root-cause analysis has been performed by a safety organization. There is also a need to clearly define what characterizes a true health IT patient safety event. There are numerous scenarios that could justifiably be called health IT patient safety events, but we urge ONC to recognize a lack in definition and leverage resources to investigate what is and what is not a safety event related to health IT.
CHIME generally supports the inclusion of AHRQ's Common Formats into certification criteria to ensure, where appropriate, EHR technology can facilitate reporting of safety events. This is not to endorse the practice of ad-hoc reporting, however. Best-practice institutions have well-defined processes that help identify the root-cause of patient safety events and we do not believe it should be the intention of this Step to circumvent such processes. We would urge close collaboration with not only vendors to understand the technological components, but also providers to understand implementation and workflow implications of generating such reports.

2 Vendor Engagement (CoC, etc)

CHIME believes objectives outlined in Learn Step 2 are important steps in the right direction – especially as it relates to increased reporting to PSOs; examining legal barriers to provider reporting based on contractual nondisclosure or intellectual property protections; and a commitment to make comparative user experience information publically available as part of a process to develop a code of conduct. We believe these are all appropriate areas for policymakers to examine, given the current scarcity of information on patient safety events and risks. However, there are instances where providers self-certify EHR products and where providers engage with developers to create an alpha-beta coding environment. We urge ONC to raise this and similar issues as they work with private organizations, developers, and providers.

3 PSO

• CHIME supports the decision to enable AHRQ to provide technical assistance and support for PSOs. We also support work to examine how AHRQ can help all stakeholders identify health IT-related adverse events, trends and risks.
It is important for providers to avoid the construct where there is a separate process for addressing health IT safety apart from other safety issues. Creating a safety reporting silo that only focuses on health IT would be duplicative, increase unnecessary reporting burden, and also result in the failure to capture many relevant events. Patient safety events associated with health IT are often identified after the root-cause analysis has been performed by a safety organization. There is also a need to clearly define what characterizes a true health IT patient safety event. There are numerous scenarios that could justifiably be called health IT patient safety events, but we urge ONC to recognize a lack in definition and leverage resources to investigate what is and what is not a safety event related to health IT.

4 ACB

CHIME supports the notion that ONC-ACBs will conduct surveillance to ensure that the capabilities of certified EHR technology work in operational settings to the same extent as when they were certified – we believe this is a critical surveillance and oversight component. However, we are concerned that the environment diagramed in Figure 2: ONC-ACB foresees a substantial reporting role for providers. We wish to reiterate our calls to avoid, wherever possible, reporting burdens. While we support and appreciate the need for more information on patient safety events and near-misses, we want to make sure that duplicative reports and disparate data silos are not created.

5 CMS

CHIME generally supports this approach, but we would encourage ONC to mitigate instances where a distributed state model leads to variation in interpretation and enforcement.

6 QSRS

CHIME generally supports these strategies.

7 MAUDE

CHIME generally supports these strategies.

8 MU

While we did not support Meaningful Use requirements for providers to conduct a health IT safety risk assessment for Stage 3, we do believe ONC should work with its federal advisory committees to build on ways to improve standards-based clinical documentation. We recommend that HHS continue to pursue complimentary initiatives, such as dissemination of best practices regarding HIT use, mining adverse event reports for useful information and making it easier for clinicians to report patient safety events and risks using EHR technology, incorporating safety into certification criteria for HIT products (as was done with the Stage 2 certification criteria relating to user-centered design and quality management systems), and funding relevant research and pilot projects. We believe these alternatives would be more fruitful in the near-term than the

imposition of yet another regulatory requirement.

9 Cer

• In areas where consensus can be reached inside and outside of the federal advisory committees, we support ONC's efforts to use certification criteria as a means to enhance health IT patient safety, as was done in Stage 2 final rules. We supported elements of ONC's 2014 edition certification criteria that support safety-enhanced design, including adherence to quality management principles and processes and user-centered design. As indicated in the safety plan, these elements of certification should be considered a starting place, and continue to evolve as we learn more about safe design and the interaction between usability of EHRs and patient safety. We believe it is important to know that the tools deployed in hospitals also are safe, as developed, sold and used.
CHIME agrees with the scope and content of ONC's primary objectives to (1) use health IT to make care safer and (2) continuously improve the safety of health IT. We would caution, however, that ONC continue to balance its regulatory approach with its desire to create a learning environment that will enable a continuously improving system of health IT safety. Achieving a "culture of safety," as defined by AHRQ, will not be possible if it is forced through regulation characterized by punitive actions based on reported errors or near misses. The Patient Safety Plan seems to choose a light regulatory approach to encourage reporting, learning and improvement. We urge ONC to maintain this heading.

10 Testing, User Tools, best practices

• CHIME strongly supports more resources being brought to bear on research, user tools and best practices. As stated previously, and echoed in ONC's Plan, patient data-matching is a principle concern for CHIME and its members. In a survey conducted by CHIME last year, it was found that a majority of CIOs believe their false negative and false positive error rates are at or below industry standard.2 However, a considerable percentage of CIOs believe their health records have rates that far exceed 8 percent.3
• Despite years of development, no clear strategy has emerged to accurately and consistently match patient data across organizations and geographies. The results of CHIME's survey suggest that now, more than ever, action is needed to ensure the right data is matched with the right patient.
• And what are the implications for such error rates? According to survey respondents, nearly one-fifth say they can attribute at least one adverse event to a patient mismatch within in the last year. For the purposes of this survey, "adverse event" was defined as a negative consequence of care that results in unintended injury or illness. Although more granular frequency information was not gathered, many respondents indicated that more than one event attributable to patient data-matching errors had occurred within the last year. Less important, but also worth mentioning, is the monetary cost component of reconciling records and merging disparate or duplicate information. According to survey respondents, just over three full-time equivalents (FTEs) are needed to perform such work. Although some respondents indicated that this type of "data cleansing" was a marginal component of other duties, many respondents said they had dedicated two or more personnel to this task.
We applaud the acknowledgement by ONC that "The accurate and efficient matching of patients to their health information is critical to ensuring patient safety." We could not agree more. Despite years of development, no clear strategy has emerged to accurately and consistently match patient data. The results of a 2012 CHIME survey suggest that now, more than ever, action is needed to ensure the right data is matched with the right patient. Unintended injury or illness attributable to patient data-matching error is a considerable, and growing, problem in this era of health information exchange. And with a substantial portion of CIOs involved with HIEs that use differing approaches to data matching, we can expect the inconsistency and variability inherent to healthcare IT systems to persist – and become more endemic – without national leadership and consistent standards.

11 Edu

CHIME supports ONC's call for an open culture of safety and integrating health IT patient safety into the programs and practices. In support of this component of the Plan, CHIME will explore ways that such education and training can be integrated with its Certified Healthcare CIO (CHCIO) program.

12 Investigate Corrective Action

CHIME again reiterates its support for ONC's approach to use existing authorities and programs to investigate, take corrective actions and publicly report on analyses of events.

13 Priority areas, Measures, Targets

CHIME generally supports ONC's plan to lead a public-private process to identify health IT safety priority areas within a larger context of patient safety. We would, as always, urge ONC to incorporate provider viewpoints so that policies are not developed without the proper implementation viewpoint.

14 Publish Report on strategy and recommendations

15 ONC Safety Program

- As mentioned in General Comments, CHIME feels that ONC's role in ensuring the safety of health IT may be somewhat overstated. We believe that ONC is properly suited to help convene and coordinate other agencies inside HHS in developing an oversight framework for health IT safety. We believe that any oversight framework should enable national focus and public and private sector collaboration and leadership. Rather than rely upon existing approaches for the regulation of medical devices, the oversight framework for clinical software should call upon developers, implementers, users, PSOs, and experts, working in collaboration with government, to:
    1. Agree upon and promote adherence to recognized standards and guidelines for assuring patient safety in the development, implementation and use of health IT;
    2. Provide support for the implementation of such standards and guidelines and develop and disseminate best practices, through education, training and technical assistance;
    3. Enable patient safety reporting and response; and
    4. Create a learning environment; aggregate and analyze non-identified patient safety reports to mitigate future risk and facilitate learning and improvement.
- CHIME believes that implementation of such an endeavor should rely on an independent "voluntary consensus body" as defined by OMB Circular A-119 to facilitate agreement among healthcare stakeholders on a recognized set of standards and guidelines for patient safety in health IT.
- We are concerned that ONC's role in ensuring the safety of health IT may be somewhat overstated in this Plan. We believe that ONC is properly suited to help convene and coordinate other agencies inside HHS in developing an oversight framework for health IT safety. But rather than rely upon existing approaches for regulation of health IT, or develop new regulations within various corners of HHS, CHIME believes that implementation of such an endeavor should rely on a stakeholder-driven organization, including – but divorced from – federal agencies. The National Technology Transfer Advancement Act and OMB Circular A-119 provide for the formation of such an organization, known as an independent "voluntary consensus body" to facilitate agreement among healthcare stakeholders on a recognized set of standards and guidelines for patient safety in health IT. We believe such an organization could then be buttressed by an enhanced network of patient safety organizations (PSOs) that could leverage appropriately aggregated reports to encourage continuous learning.
- In particular, we support the notion that pre-existing patient safety efforts across government programs and the private sector – including those sponsored by providers, vendors and healthcare safety oversight bodies – be used as foundational leverage to strengthen health IT and patient safety.
- While there certainly needs to be more coordination between agencies within HHS regarding health IT and patient safety, we do not believe that the creation of an entity, similar to the National Transportation Safety Board, is necessary. We believe ONC has articulated how existing mechanisms could be leveraged to increase and monitor health IT safety and that a decision to create another bureaucracy would be duplicative and wasteful.

CHIME agrees with the scope and content of ONC's primary objectives to (1) use health IT to make care safer and (2) continuously improve the safety of health IT. We would caution, however, that ONC continue to balance its regulatory approach with its desire to create a learning environment that will enable a continuously improving system of health IT safety. Achieving a "culture of safety," as defined by AHRQ, will not be possible if it is forced through regulation characterized by punitive actions based on reported errors or near misses. The Patient Safety Plan seems to choose a light regulatory approach to encourage reporting, learning and improvement. We urge ONC to maintain this heading.

16 State Governments

• CHIME believes HHS can play an important role in limiting variation among state adverse event reporting and believes it must do so. It is vitally important that HHS work with states to develop uniform reporting regimes, so that gains to be made in a "learning environment" are not lost due to uncoordinated reporting requirements.
CHIME supports HHS plans to encourage state involvement in the public-private process to refine health IT patient safety priorities, measures and targets – as well as help states integrate health IT into existing patient safety efforts.

17 Private Sector Leadership

• CHIME agrees that all stakeholders have an interest in ensuring that health IT is safe and that health IT enhances patient safety.
We are concerned that ONC's role in ensuring the safety of health IT may be somewhat overstated in this Plan. We believe that ONC is properly suited to help convene and coordinate other agencies inside HHS in developing an oversight framework for health IT safety. But rather than rely upon existing approaches for regulation of health IT, or develop new regulations within various corners of HHS, CHIME believes that implementation of such an endeavor should rely on a stakeholder-driven organization, including – but divorced from – federal agencies. The National Technology Transfer Advancement Act and OMB Circular A-119 provide for the formation of such an organization, known as an independent "voluntary consensus body" to facilitate agreement among healthcare stakeholders on a recognized set of standards and guidelines for patient safety in health IT. We believe such an organization could then be buttressed by an enhanced network of patient safety organizations (PSOs) that could leverage appropriately aggregated reports to encourage continuous learning.

18 Other

CHIME agrees with the scope and content of ONC's primary objectives to (1) use health IT to make care safer and (2) continuously improve the safety of health IT. We would caution, however, that ONC continue to balance its regulatory approach with its desire to create a learning environment that will enable a continuously improving system of health IT safety. Achieving a "culture of safety," as defined by AHRQ, will not be possible if it is forced through regulation characterized by punitive actions based on reported errors or near misses. The Patient Safety Plan seems to choose a light regulatory approach to encourage reporting, learning and improvement. We urge ONC to maintain this heading.

Names

White, Robert S., MD, FAAFP

Comment ID

91

Organization

Cleveland Clinic (CC)

Org Typ1	Org type	Categories
1	1 Provider (institution)	1. Reporting, 10. Testing, User Tools, best practices, 15. ONC Safe

1 Reporting

IOM Recommendation 1e
AHRQ Common Formats will provide valuable information to identify the contribution of HIT to safety events in healthcare. Healthcare organizations and their employees will need to become more intentional in considering the contribution of HIT to events. Funding development of reliable measures for HIT safety is critical.

IOM Recommendations 2 and 3
EHR vendors should make public any substantiated safety issues related to their build. Additionally, healthcare organizations should be allowed to report concerns to ONC without retribution. ONC should consider asking vendors to place language in their contracts to encourage the reporting of safety events. ONC might include this as a part of the certification process by the ONC-ACB. Ideally, the EHR vendor communities might facilitate HIT safety reporting groups between their client organizations for the purpose of sharing and learning.

IOM Recommendation 7
There is significant learning through the event reporting, including analysis and any mitigating efforts of participating organizations. As the reporting is all voluntary, visible learning and improvement from the shared data will be critical to success. We would ask that all aspects of the sociotechnical system be represented to include the people (end users and technical builders), the processes (described as the workflows) and the actual technology to include the hardware and the technical interconnectivity.
We support recommendation 7a, 7b and 7c. Healthcare organizations should be encouraged to incorporate HIT safety efforts in their overall safety plan.

2 Vendor Engagement (CoC, etc)

IOM Recommendations 2 and 3
EHR vendors should make public any substantiated safety issues related to their build. Additionally, healthcare organizations should be allowed to report concerns to ONC without retribution. ONC should consider asking vendors to place language in their contracts to encourage the reporting of safety events. ONC might include this as a part of the certification process by the ONC-ACB. Ideally, the EHR vendor communities might facilitate HIT safety reporting groups between their client organizations for the purpose of sharing and learning.

Recommendation 7
There is significant learning through the event reporting, including analysis and any mitigating efforts of participating organizations. As the reporting is all voluntary, visible learning and improvement from the shared data will be critical to success. We would ask that all aspects of the sociotechnical system be represented to include the people (end users and technical builders), the processes (described as the workflows) and the actual technology to include the hardware and the technical interconnectivity.
We support recommendation 7a, 7b and 7c. Healthcare organizations should be enc

IOM Recommendation 9
Vendor accountability to work with clients in optimizing safety and reliability is important.ouraged to incorporate HIT safety efforts in their overall safety plan.

3 PSO

IOM Recommendation 7
There is significant learning through the event reporting, including analysis and any mitigating efforts of participating organizations. As the reporting is all voluntary, visible learning and improvement from the shared data will be critical to success. We would ask that all aspects of the sociotechnical system be represented to include the people (end users and technical builders), the processes (described as the workflows) and the actual technology to include the hardware and the technical interconnectivity.
We support recommendation 7a, 7b and 7c. Healthcare organizations should be encouraged to incorporate HIT safety efforts in their overall safety plan.

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

IOM Recommendation 1d
Working with clinical partners, ONC and CMS should develop clarification for current national accreditation standards that consider the change in workflows and documentation patterns that are inherent in EHRs. Additionally, we support the development of potential standards to be tested during the current survey cycles to refine an effective set of measures for EHR safety. The ONC established standards and certification criteria for vendors and healthcare organizations will continue to be critical. We recommend the reporting of safety events be embedded in the workflow of end users and ask the vendor community to take on this responsibility. However, this reporting should never be traceable to the end user reporting the event by any electronic audit trail and must not be discoverable in a legal action.

IOM Recommendation 5
Cleveland Clinic supports this recommendation.

IOM Recommendation 6
We support this recommendation. In 2014, when standards are developed and then implemented by the vendors, the healthcare organizations will need to evaluate any potential impact of existing and future workflows. There should be an opportunity to report these concerns either through the vendor or through a separate body.

10 Testing, User Tools, best practices

IOM Recommendation 1a
We recognize the efforts needed around the initial sociotechnical and cultural evaluations. Cleveland Clinic supports the development and use of standardized tools for the safety assessment of design, development, and implementation of HIT. Most healthcare organizations have one opportunity to safely implement HIT as the cost generally prohibits more than one effort. Therefore, it is unlikely that there is previous experience on which to draw for large scale deployment of HIT. Utilizing tools such as those noted in recommendation 1a to complete a HIT safety risk assessment should be required. This evaluation could and maybe should be delivered by the HIT software vendor. It would be unrealistic to assume many healthcare organizations could complete these risk evaluations without some guidance and direction.

IOM Recommendation 1b and 1c
We support these recommendations.

IOM Recommendation 10
As an organization which has had a long history of clinical innovation, we welcome and support this recommendation.

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

IOM Recommendation 8
We recognize the potential value in developing an independent entity for investigating serious safety events. We do support the existing plan. If the Secretary of HHS were to consider developing this entity, we would welcome the opportunity to participate in its development.

IOM Recommendation 4
Cleveland Clinic as a national leader and contributor would welcome the opportunity to participate.

16 State Governments

17 Private Sector Leadership

18 Other

Names

Cullen, Theresa

Comment ID

82

Organization

Department of Veterans Affairs (VA)

Org Typ1	Org type	Categories
3	3. Provider Organization (Institutional)	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

- Reporting systems should be designed to allow anonymous reporting.
- Reporting systems should protect data per 38 U.S.C. 5705 regulations where applicable.
- Reporting systems should be voluntary.

Incorporating the use of 'common formats' in Health Information Technology (HIT) should not be limited to just HIT related events. Here is where using HIT can help improve overall reporting with a 'one stop' approach. It shouldn't be a separate process from other initial safety reports.

2 Vendor Engagement (CoC, etc)

- In addition to the proposed code of conduct, Office of the National Coordinator for Health IT (ONC) should consider working with the Food and Drug Administration (FDA) to draft regulatory actions regarding patient safety reporting for developers similar to the regulations in place for medical device and pharmaceutical manufacturers.

Confusion with the use of the term "developer". Looking into the footnote, the reference is to Healthcare Information and Management Systems Society (HIMSS) Electronic Health Record (EHR) Association (a trade association of EHR companies) – which is a group of manufacturers of HIT Software. There is a difference between developers and manufacturers. The culture of safety resides within the entire entity of the manufacturer and its processes.

3 PSO

- The non-identified data should not include patient, provider, or hospital data but it SHOULD include the name of the EHR product in use so trends with specific products can be identified.
- It is more important to have the safety risk itself identified than the name of the product. If there is a type of pro

It is not clear how ONC-Authorized Certification Bodies (ONC-ACBs), AHRQ Quality & Safety Review System (QSRS) and entities such as FDA Manufacturer and User Facility Device Experience (MAUDE) will share information among themselves.duct or a common feature, that level of granularity should be specified.

4 ACB

- There is potential for confusion about the difference between post-market surveillance and event reporting. Recommend clarifying. For example, if a provider identifies a patient safety issue with an EHR, are they supposed to submit a patient safety report to Agency for Healthcare Research and Quality (AHRQ) and a complaint to the developer?

It is not clear how ONC-Authorized Certification Bodies (ONC-ACBs), AHRQ Quality & Safety Review System (QSRS) and entities such as FDA Manufacturer and User Facility Device Experience (MAUDE) will share information among themselves.

5 CMS

- ONC and Centers for Medicare & Medicaid Services (CMS) should partner with The Joint Commission and other agencies to assure that surveyors are applying the same criteria when reviewing HIT.

It is not clear how ONC-Authorized Certification Bodies (ONC-ACBs), AHRQ Quality & Safety Review System (QSRS) and entities such as FDA Manufacturer and User Facility Device Experience (MAUDE) will share information among themselves.

6 QSRS

• Data in QSRS should be made available for public research.
It is not clear how ONC-Authorized Certification Bodies (ONC-ACBs), AHRQ Quality & Safety Review System (QSRS) and entities such as FDA Manufacturer and User Facility Device Experience (MAUDE) will share information among themselves.

7 MAUDE

• There is potential for confusion regarding the use of MAUDE. Recommend clarifying if MAUDE is intended to be in addition to reports to AHRQ and QSRS, or will MAUDE users be redirected/encouraged to enter reports to health IT specific databases.
• It would seem the plan would be for how ONC is bringing together the QSRS and MAUDE, and sharing that information outward.
It is not clear how ONC-Authorized Certification Bodies (ONC-ACBs), AHRQ Quality & Safety Review System (QSRS) and entities such as FDA Manufacturer and User Facility Device Experience (MAUDE) will share information among themselves.

8 MU

ONC should consider ways to incentivize PATIENTS to use EHR technologies (rebates, insurance discounts, etc.) in addition to the incentives already in place for providers.

9 Cer

ONC should REQUIRE the adoption of recognized industry standards for usability rather than just “encouraging” their adoption.

10 Testing, User Tools, best practices

• In addition to supporting research, ONC should actively reach out to EHR pioneers and leaders such as The Veterans Health Administration, Kaiser Permanente, and others, to learn from their 10 plus years of widespread integrated EHR use.
While it is good the tools are being developed, are the tools being used and how effective are the tools? Please elaborate.

11 Edu

• In addition to healthcare providers, ONC should support training of health care support personnel such as biomedical/clinical engineers, network support staff, and administrative staff.
Here is a role for the informatics community. ONC has sponsored incentives for developing the informatics community, the opportunity is within this pool of resources to be knowledgeable and advocating on behalf of providers for safer HIT products.

12 Investigate Corrective Action

If there will not be separate entity, ONC should have a team with specialized skills that are available to assist in investigations when needed, similar to a Centers for Disease Control and Prevention (CDC) response team.

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

It is not clear how ONC-Authorized Certification Bodies (ONC-ACBs), AHRQ Quality & Safety Review System (QSRS) and entities such as FDA Manufacturer and User Facility Device Experience (MAUDE) will share information among themselves.

16 State Governments

17 Private Sector Leadership

18 Other

Names

Evans, Clara

Comment ID

66

Organization

Dignity Health

Org Typ1	Org type	Categories
3	3. Provider Organization (Institutional)	10. Testing, User Tools, best practices, 15. ONC Safety Program, 18

1 Reporting

2 Vendor Engagement (CoC, etc)

• From Dignity Health's perspective, while providers are clear in our role and are held accountable for maintaining a safe patient environment, vendors are still reluctant to actively participate in remediation activities and continue to seek protection from liability. Dignity Health encourages the ONC to move forward with setting specific steps for vendors of electronic health records (EHRs) to take responsibility for the safe design, implementation and use of their products, including good quality management principles, user-centered design and human factors assessment. This code of conduct should make clear that vendors are responsible for safe design and will support safe use of their products. It should also discourage vendors from including in their contracts indemnity clauses or nondisclosure language that limits the ability of users to identify and raise safety concerns.

3 PSO

• The plan appropriately recognizes the Agency for Healthcare Quality and Research's (AHRQ) unique role in promoting patient safety. Dignity Health hopes this will lead toward creating a non-punitive data-driven environment that will support thorough and broad studies, including root-cause analyses, used to inform remediation of specific problems, including technology or clinical processes issues.

4 ACB

5 CMS

• changes in the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation must be supported by clear evidence of what is essentially a safe practice and go through the rule-making process. As these policies emerge, the ONC should build-in corresponding safety standards into certification requirements for EHR vendors. This creates balance, clearly establishes expectations and builds trust.

6 QSRS

7 MAUDE

8 MU

• changes in the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation must be supported by clear evidence of what is essentially a safe practice and go through the rule-making process. As these policies emerge, the ONC should build-in corresponding safety standards into certification requirements for EHR vendors. This creates balance, clearly establishes expectations and builds trust.

9 Cer

• Dignity Health encourages the ONC to develop standards [Jensen: Not sure if they are referring to Cert standards or just a set of standards] to support patient safety in HIE, and create a unique patient identifier to address patient matching.

10 Testing, User Tools, best practices

• Dignity Health encourages the ONC to develop standards to support patient safety in HIE, and create a unique patient identifier to address patient matching.

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

• Dignity Health encourages the ONC to assume a coordinating role in developing such an environment and cautions against developing an approach to duplicate efforts.

16 State Governments

17 Private Sector Leadership

18 Other

• the plan fails to appropriately address two central pieces of the health IT environment: 1) The central role of health information exchange to support the safety benefits of EHRs; and 2) the critical need to advance accurate and efficient patient matching.
• Dignity Health wholeheartedly supports the ONC's goal to improve both patient and provider confidence in the safety of the healthcare system, including the health IT infrastructure, and agrees the rapid integration of IT systems in care delivery has outpaced the ability to collect evidence to support confidence and build trust. In addition to the lack of evidence, the rapid shift from a people/paper process to a people/electronic system has challenged the health care ecosystem to adjust to a fundamental shift
• Dignity Health appreciates the ONC developing a patient safety action plan that recognizes the shared responsibility of health IT vendors, clinicians, health care organizations and federal agencies in ensuring health IT systems are designed, implemented and used to mitigate harm and promote safety.
• Further, Dignity Health agrees with the plan's approach to build upon existing patient safety efforts across government programs and the private sector. in the care delivery model.

Names

Lerner, Jeffrey

Comment ID

54

Organization

ECRI

Org Typ1	Org type	Categories
13	13.. Safety Organization	1. Reporting, 12. Investigate & Corrective Action, 13. Priority are

1 Reporting

• Ensure that organizations collecting HIT safety data **earn the trust** of individuals submitting reports and those relying on the analysis.
• **Protect confidentiality** for those who report HIT hazards, but **avoid creating a black hole** that produces no actionable information.
• Consider **data through multiple venues** to get the most balanced picture of HIT hazards.

• We support an approach that leverages existing patient safety infrastructure rather than creation of an HIT silo or another federal agency. The causes of HIT-related adverse events, like those that are not IT-related, are multifactorial and require multi-disciplinary analysis using methods that are well diffused in the patient safety community. HIT-related events should be investigated and analyzed in this broader healthcare context; otherwise, opportunities for capturing data and understanding the causes will be missed. Our research shows that many patient safety problems with an IT dimension get characterized by providers in other ways: as medication errors, patient identification errors, erroneous lab or radiology results, documentation errors, communication errors, and many others. Often, the PSO or organization collecting the data detects the role played by HIT. Also, many problems we observe with the EHR are analogous to those involving paper medical records. Existing mechanisms for collecting these kinds of events already contain a wealth of information on HIT and should be leveraged. Focusing on HIT solely from a computer science perspective would be too narrow a frame for this challenge.

Importantly, operating a successful safety program means earning the trust of stakeholders – those who share safety reports, those who rely on the analysis, the patients served, and others noted in the Plan. Having trust in the process and in entities collecting reports is essential to overcoming the cultural barriers that currently exist that prevent more widespread sharing of adverse events. Several characteristics help earn trust: independence, objectivity, transparency, research capacity, technical expertise, a focus on learning and improving the culture of safety, and meaningful dissemination. At the end of the day, research must be translated in actionable strategies that promote patient safety. The creation of such meaningful deliverables will reinforce participation and ensure continued relevance.

2 Vendor Engagement (CoC, etc)

• Ensure that organizations collecting HIT safety data **earn the trust** of individuals submitting reports and those relying on the analysis.
• **Protect confidentiality** for those who report HIT hazards, but **avoid creating a black hole** that produces no actionable information.
• Consider **data through multiple venues** to get the most balanced picture of HIT hazards.
• We support an approach that leverages existing patient safety infrastructure rather than creation of an HIT silo or another federal agency. The causes of HIT-related adverse events, like those that are not IT-related, are multifactorial and require multi-disciplinary analysis using methods that are well diffused in the patient safety community. HIT-related events should be investigated and analyzed in this broader healthcare context; otherwise, opportunities for capturing data and understanding the causes will be missed. Our research shows that many patient safety problems with an IT dimension get characterized by providers in other ways: as medication errors, patient identification errors, erroneous lab or radiology results, documentation errors, communication errors, and many others. Often, the PSO or organization collecting the data detects the role played by HIT. Also, many problems we observe with the EHR are analogous to those involving paper medical records. Existing mechanisms for collecting these kinds of events already contain a wealth of information on HIT and should be leveraged. Focusing on HIT solely from a computer science perspective would be too narrow a frame for this challenge.

Importantly, operating a successful safety program means earning the trust of stakeholders – those who share safety reports, those who rely on the analysis, the patients served, and others noted in the Plan. Having trust in the process and in entities collecting reports is essential to overcoming the cultural barriers that currently exist that prevent more widespread sharing of adverse events. Several characteristics help earn trust: independence, objectivity, transparency, research capacity, technical expertise, a focus on learning and improving the culture of safety, and meaningful dissemination. At the end of the day, research must be translated in actionable strategies that promote patient safety. The creation of such meaningful deliverables will reinforce participation and ensure continued relevance.

3 PSO

• Consider **data through multiple venues** to get the most balanced picture of HIT hazards.
• Address the need to **broadly disseminate** information about HIT risks and hazards, ideally in ways that facilitate and capture recipients' actions so that improvement can be documented.
Importantly, operating a successful safety program means earning the trust of stakeholders – those who share safety reports, those who rely on the analysis, the patients served, and others noted in the Plan. Having trust in the process and in entities collecting reports is essential to overcoming the cultural barriers that currently exist that prevent more widespread sharing of adverse events. Several characteristics help earn trust: independence, objectivity, transparency, research capacity, technical expertise, a focus on learning and improving the culture of safety, and meaningful dissemination. At the end of the day, research must be translated in actionable strategies that promote patient safety. The creation of such meaningful

deliverables will reinforce participation and ensure continued relevance.

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

• We support an approach that leverages existing patient safety infrastructure rather than creation of an HIT silo or another federal agency. The causes of HIT-related adverse events, like those that are not IT-related, are multifactorial and require multi-disciplinary analysis using methods that are well diffused in the patient safety community. HIT-related events should be investigated and analyzed in this broader healthcare context; otherwise, opportunities for capturing data and understanding the causes will be missed. Our research shows that many patient safety problems with an IT dimension get characterized by providers in other ways: as medication errors, patient identification errors, erroneous lab or radiology results, documentation errors, communication errors, and many others. Often, the PSO or organization collecting the data detects the role played by HIT. Also, many problems we observe with the EHR are analogous to those involving paper medical records. Existing mechanisms for collecting these kinds of events already contain a wealth of information on HIT and should be leveraged. Focusing on HIT solely from a computer science perspective would be too narrow a frame for this challenge.
• Leverage healthcare's **existing patient safety infrastructure** rather than create a silo for HIT.
The investigation of serious HIT-related events requires technical expertise as well as an understanding of workflow and operations. While computer science, systems integration, and experience with EHRs are obvious skill sets required for such investigations, others include traditional patient safety and risk management expertise, human factors, cognitive engineering, medical informatics, systems engineering, and others. Because many HIT errors involve failures of communication, data transmission, and interoperability, investigations also require expertise in the systems and devices that link to the EHR.

13 Priority areas, Measures, Targets

We recommend that ONC's plan incorporate proactive approaches to HIT safety. Proactive tactics, such as conducting failure mode and event analysis in conjunction with the introduction of new HIT, help to identify and mitigate potential safety issues before they have the opportunity to reach the patient. This presents ways to prevent the proverbial fire, not just put it out after the fact. Proactive approaches should be a shared responsibility among vendors, providers and safety experts. ONC should establish aligned incentives that help reduce the burdens associated with such proactive approaches.

14 Publish Report on strategy and recommendations

Address the need to **broadly disseminate** information about HIT risks and hazards, ideally in ways that facilitate and capture recipients' actions so that improvement can be documented.

15 ONC Safety Program

- Consider **data through multiple venues** to get the most balanced picture of HIT hazards.
- Address the need to **broadly disseminate** information about HIT risks and hazards, ideally in ways that facilitate and capture recipients' actions so that improvement can be documented.

16 State Governments

17 Private Sector Leadership

18 Other

• We suggest that ONC define the types of technologies included within the scope of the Plan. Health IT is clearly a broader term than simply the electronic health record, but what ancillary technologies does ONC mean to include or exclude? For example, the Plan does not address the EHR's integration with ancillary services such as laboratories, diagnostic imaging services, and pharmacies. The lack of information transfer has resulted in misdiagnoses and delays in diagnoses.
• Address the need to **broadly disseminate** information about HIT risks and hazards, ideally in ways that facilitate and

capture recipients' actions so that improvement can be documented.

Names

Bordenick, Jennifer Covich

Comment ID

37

Organization

eHealth Initiative

Org Typ1	Org type	Categories
12	12.. Other	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

• eHI supports ONC's commitment to fostering a culture of patient safety and confidential and/or non-punitive reporting. Collaborating with and leveraging the current patient safety program infrastructure developed by the Agency for Healthcare Research and Quality (AHRQ) will provide invaluable resources as ONC navigates the Meaningful Use program through health IT patient safety initiatives. Through collaboration with AHRQ and other public/private organizations, this will enable the development of a consistent approach toward reporting at the national level, as well as the local level.
• eHI applauds AHRQ for taking steps to promote increased reporting of adverse events and integrating health IT safety events into the latest version of the Patient Safety Organization (PSO) Common Formats. We encourage the Department of Health and Human Services (HHS) and its agencies such as the AHRQ and ONC to conduct further study and analysis to seek broad stakeholder input on how to improve the Common Formats for improved usability. We also recommend ONC commit to coordinating a balanced approach toward addressing health IT and patient safety, including its focus on the positive health IT contributions to patient safety that avoids a siloed approach. This is a complex issue and requires a broader perspective that can be supported through the engagement of all stakeholders to address multiple areas of potential concern such as interoperability (technical and data), workflow and processes, implementation and training, accurate and timely capture of patient information, etc.

2 Vendor Engagement (CoC, etc)

• eHI supports the need to engage health IT stakeholders and foster a culture of shared responsibility for patient safety. Industry-based codes of conduct that consider the issues highlighted in the Plan could be one useful tool as we address this complex issue. At the same time, we emphasize that codes of conduct should be developed by the applicable industry stakeholder and their organizations, with appropriate broader input and that ONC should avoid applying a regulatory, enforcement approach to such voluntary codes. As mentioned previously, it is critical to ensure ONC's efforts take a balanced approach to ensuring safety, where all stakeholders take responsibility for the aspects of health IT design, production, implementation and use that they control.

3 PSO

• eHI supports AHRQ's commitment to collecting data regarding health IT patient safety events, including the aggregation of data for widespread learning. More routine reporting of patient safety events to the National Patient Safety Database (NPSD) could serve as an important foundation from which common data elements have been selected to enable the collection, aggregation, and analysis to assist in determining the root cause of events. We believe this approach will serve ONC well by leveraging an existing program and collaborating with AHRQ to continue integrating health IT adverse events.

4 ACB

• We agree with ONC's consideration of post-market surveillance but believe that such surveillance can best be accomplished through a learning system and we also question the proposed role of ONC-Authorized Certification Bodies (ONC-ACB) in this process. Such a new role, if that is what is envisioned, extends beyond the core competency of the ACBs and could compromise their core mission. We request further clarity on the proposed role of ONC-ACBs in this process and whether ONC will be creating an additional functional area or current ONC-ACBs will assume these new responsibilities.

5 CMS

• eHI supports ONC's intent to work with the Centers for Medicare and Medicaid Services (CMS) to align the health and safety standards for providers and suppliers as they relate to health IT safety. We note that all changes to the Medicare Conditions of Participation must go through rulemaking, and surveyors must be adequately trained and supervised, especially when expanding into new areas.

6 QSRS

• eHI supports the collection of data on health IT safety events and the improvement of the AHRQ Common Formats to support comparability of data across health care organizations and ongoing surveillance. The move toward use of consistent data elements must be balanced against the need for narrative to support root cause analysis, and the challenges of collapsing complex analyses into structured data formats. We are also pleased to note AHRQ's intent to support patient safety research as it relates to health IT while the QSRS is being developed with the expected completion in 2014.

7 MAUDE

• eHI supports ONC's intent to monitor the Manufacturer and User Facility Device Experience (MAUDE) database; however, since most health IT is not currently regulated by the FDA and thus does not require reporting, we are concerned this recommendation could imply the need for duplicative patient safety event reporting and processes. Therefore we urge ONC to provide clarification regarding MAUDE reports for health IT in its final plan.

8 MU

• eHI supports ONC's conclusion that health IT products have inherent safety advantages over paper records in that the patient record is rarely physically lost, is legible, has the ability to be available in multiple locations, and can provide clinical decision support. In this regard, we agree with ONC's continued focus on prioritizing capabilities for meaningful use that have a documented positive relationship to patient safety. We also support ONC's plan to collaborate with its federal advisory committees on health IT-related documentation issues. We believe a critical component needs to be added to the e statement referenced, "to determine ways to improve clinical documentation, thereby, reducing the risk that records will be inaccessible or their accuracy or completeness compromised." Improving clinical documentation has been a long time struggle and continues to be a complex challenge. Improving clinical documentation and leveraging health IT applications must be addressed in tandem through sufficient training and education to enable modification of workflows and processes to maximize health IT utilization.

• We support ONC's effort of integrating important steps in the developing safety structure for health IT as demonstrated by the examples listed in the plan. We believe the addition of a safety risk assessment is premature, given that industry stakeholders have just begun Meaningful Use Stage 1.

9 Cer

• We applaud ONC for the careful approach with which it integrated patient safety issues into the 2014 Edition Standards and Certification Criteria and recommend additional research and analysis to better inform how ONC can successfully develop and integrate a balanced approach toward patient safety initiatives. As ONC begins advancing the health IT patient safety program, we encourage emphasis on the fact that health IT as just one element of the overall patient safety effort.

• eHI commends ONC's general approach towards addressing health IT safety in Stage 2 of the Meaningful Use program as described in the draft Plan. At the same time, we believe plans for incorporating patient safety standards and certification criteria and program rulemaking is premature and that, in general, these issues should remain separate from the ONC certification program. As ONC continues developing plans for addressing health IT patient safety related events we urge the review and consideration of how workflow and processes impact patient care while enabling the use of health IT. We believe there continues to be opportunity for a learning environment that informs the appropriate and accurate use of health IT in reducing patient safety events.

10 Testing, User Tools, best practices

• eHI supports ONC's intent to collaborate with the National Institute of Standards and Technology (NIST), AHRQ, and National Library of Medicine (NLM) to address and improve health IT usability to improve patient safety. Collaborating with AHRQ and helping to build upon the portfolio of excellent work to address potential safety issues will enable conducting further analysis to determine areas of vulnerability, and address those gap areas through the implementation of best practices or by the development of different interventions and tools aimed at improving patient safety.

• eHI strongly supports ONC's intent to further improve patient matching with their health information, as this is a critical patient safety issue and is a complex and challenging issue to resolve once a patient has been mismatched. As the growth of health information exchange continues to accelerate nationwide, this will become more challenging to address as more

providers and health care organizations contribute to a patient's record. We believe addressing workflow and process issues, data quality, functional and technical requirements, data standards and policy to support these efforts will further enhance the ability to accurately match patients with their health information. We look forward to learning more about this initiative and the opportunity to provide input during the development of this process.
eHI supports ONC's effort to work with organizations, as identified within the Plan, to foster a culture of safety and the dissemination of best – in -class tools and strategies to effectively reduce health IT related adverse events. We believe an emphasis on workflow and processes in using health IT for patient care is critical to a better understanding of how this is an enabler to support the capture, use, and dissemination of patients' health information.

11 Edu

• *Incorporate health IT safety into medical education and training for all health care providers.* eHI supports ONC's effort to work with organizations, as identified within the Plan, to foster a culture of safety and the dissemination of best – in -class tools and strategies to effectively reduce health IT related adverse events. We believe an emphasis on workflow and processes in using health IT for patient care is critical to a better understanding of how this is an enabler to support the capture, use, and dissemination of patients' health information.
• Improving clinical documentation and leveraging health IT applications must be addressed in tandem through sufficient training and education to enable modification of workflows and processes to maximize health IT utilization.

12 Investigate Corrective Action

• eHI supports ONC's intent to investigate and take corrective actions. We strongly encourage the development and use of formal protocols and processes that support this effort that have been developed through an open, transparent and consistent approach. We applaud HHS' approach to leverage existing Federal authorities and programs in conducting these actions.

13 Priority areas, Measures, Targets

• eHI supports ONC's intent to identify health IT safety priorities through the implementation of a public – private process. We encourage the evaluation of vulnerable areas for patient safety and the development of measures through a harmonization process that will assist in reducing health IT related adverse events.

14 Publish Report on strategy and recommendations

• eHI supports the development of a patient safety plan and we encourage the timely and appropriate integration of current activities, such as the findings from the 18-month study as required by the Food and Drug Administration (FDA) Safety and Innovation Act of 2012.
• eHI supports this step as a requirement of the FDA Safety and Innovation Act of 2012. We believe ONC's active engagement in this effort will enable the inclusion of stakeholder and expert input in developing a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications that promote innovation, protects patient safety, and avoids regulatory duplication.

15 ONC Safety Program

• eHI supports this plan and encourage the timely and appropriate integration of the findings from the 18-month study as required by the FDA Safety and Innovation Act of 2012. We applaud ONC's alignment with other agencies in the development of the ONC Safety Program.

16 State Governments

• eHI supports the approach of encouraging states to leverage and integrate into existing patient safety efforts to reduce duplication and overlap, and encourage consistency in patient safety data for comparability.

17 Private Sector Leadership

• eHI applauds ONC for acknowledging the need for all stakeholders to have a shared interest in leadership and responsibility for health IT patient safety. We agree with ONC's effort to collaborate with federal agencies and build upon the work and resources that have been developed to address patient safety issues. We strongly believe this approach will help in reducing duplication and administrative burden.

18 Other

• As ONC continues developing the final Plan, we strongly recommend addressing the critical role health information exchange plays in the successful implementation and use of health IT. As the adoption of health information exchange accelerates, it is critical to ensure a robust exchange infrastructure exists to support accurate patient matching, timely access and exchange of information for patient care.

Names

Rawling, Gillian

Comment ID

77

Organization

EHRA

Org Typ1	Org type	Categories
7	7.Vendor Trade Group	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

• We agree that it would be useful to explore how EHR technologies can be used to enhance reporting of safety events and risks in general. At the same time, we caution that it is essential to consider appropriate EHR and reporting workflows for provider communities.
• We also caution against a focus on a "magic button" that could be used by providers to report on safety issues and also suggest consideration of the electronic data entry methods used by PSOs already. In the context of potential new requirements to certification, as proposed, we assume that consideration of such new certification criteria would be for Stage 3 and urge full consultation with software developers and providers. We urge ONC to avoid dictating a single approach to use of EHRs to facilitate internal and external reporting, particularly in the ambulatory environment where patient safety documentation and reporting is less mature.
• The EHR Association supports the use of the AHRQ Common Formats for event and risk reporting. The AHRQ Common Formats need to be enhanced and updated beyond version 1.2, however, to include a health IT component such as the data set proposed by our Association which focuses on data that is useful for analytics. The AHRQ Common Formats also need to be expanded beyond hospital-based reporting into ambulatory reporting as well. We support the reporting and aggregation of reports via the AHRQ Patient Safety Organization framework. Again, it will be essential to avoid burdening and disrupting providers' EHR workflow and performance. It will also be important to consider liability implications of adding additional patient safety relevant information into the legal medical record as opposed to the protected environment that PSOs provide. Finally, we also urge that ONC, in the final Plan, recognize the critical importance of direct provider reporting to and consulting with their EHR developer when conducting root cause investigations.

2 Vendor Engagement (CoC, etc)

• To that point, we believe that the ONC Plan should build on what is known, while refraining from regulatory construction of solutions to problems that have yet to be studied and well defined. Similarly, future action by the ONC should aim to achieve the Office's objectives without jeopardizing the healthcare industry's collective ability to innovate toward better safety and usability solutions.
• In general, we disagree with these components of the Plan and do not support: ONC potentially dictating both the elements and enforcement of an industry code of conduct that would diminish the value and operation of such a code, which should operate in a truly voluntary and effective manner by virtue of being organizationally grounded in the industry and its organizations
• We believe that industry "codes of conduct" (which may ultimately bear another title) can be useful, and we are aware of several within the healthcare technology industry. The Association is actively engaged in consideration of such a document for EHR developers. At the same time, we believe strongly that such "codes" must be developed and maintained by the affected industries and their organizations. They should also be voluntary and not dictated by the federal government. In this regard, although it could be helpful for ONC to identify potential topics for consideration, we do not agree that ONC should specify the minimum content of such a "code" or to assume responsibility for enforcement of compliance. We certainly do not believe that adherence to such a code should be the subject of the certification process.
• The EHR Association appreciates ONC's thoughtful input to this industry initiative for a set of agreed upon guidelines for certain activities. We agree that safe design policies and practices should be in place for every vendor. We also agree in concept with the Plan's third and fourth bullets ("… provider reporting of safety events." and "… compare user experience across different systems …."), but note that these concepts must be executed so as to attain their objectives without violating the U.S. legal and commercial system principles that protect intellectual property rights and product reputation. We believe such a balance can be achieved and appreciates the ONC's acknowledgment of these principles in its Plan. We reiterate the point the ONC makes in the Plan's third bullet — health IT patient safety

reporting should fit seamlessly into all patient safety reporting. We agree that it would be useful for health IT developers to work with PSOs on a voluntary basis, and we agree with ONC that PSOs could play a very positive role in the health IT safety arena. At the same time, we also underscore the points made by ONC that there are likely to be necessary clarifications and regulatory changes to mitigate various risks for PSOs, providers and developers and to make such vendor engagement with PSOs feasible and effective. Furthermore, we believe that voluntary provider reporting to PSOs on safety issues should be the primary focus for reporting to PSOs, given that safety events generally happen in a provider context, and that health IT is likely to only be one element of any safety event. We also believe that aggregate data on safety reports should not identify specific developers or product brands but rather focus on patterns and types of health IT functionality involved since many reports are unlikely to undergo full root cause analysis, especially with reporting expected to extend beyond instances of death and serious injury. More generally, we agree with the ONC that provider reporting of safety events is essential and should be encouraged. The ONC draft Plan references "contractual non-disclosure clauses" as barriers to safety reporting. To date, we have not seen convincing evidence that vendor-provider contracts, including essential provisions to protect intellectual property, pose barriers to the kind of patient safety reporting systems envisioned. The ONC Plan's reference to emerging tools for comparing user experience across different EHR systems is well taken, but such tools should be one of many market-driven choices available to providers for comparing products. Such new tools, when available, should not be mandated by regulation.

3 PSO

• The EHR Association supports leveraging of the PSO system for aggregation and high level analysis of safety reports. We appreciate the ONC Plan's recognition of the complex issues around the legal protection framework of the PSO system in the Patient Safety Act and the general sensitivity of all parties to legal ramifications around patient privacy, legal medical records and court processes for discovery of electronic documents. We note the belief by some stakeholders that incorporation of developers into the PSO process can be effected in the context of the Patient Safety Act's protections of providers and PSOs. Certainly, we would prefer a guidance or regulatory approach to enabling software developer participation in the PSO process. Should legislative action be found necessary or advisable, the ONC Plan should include support for needed legislative changes and industry stakeholder engagement in that process.
Finally, as stated above, to fully realize a non-punitive learning environment and to increase the accuracy of safety signal detection, it is essential to address the potential negative impact of the collection of incomplete or misleading data. Aggregated reports should be de-identified by provider, developer, and specific product (as opposed to product type) and focus on trends and patterns to encourage robust, widespread, and consistent reporting.

4 ACB

In general, we disagree with these components of the Plan and do not support:
• Using the ONC and CMS meaningful use regulations and certification to embed intrusive requirements into EHR design that are not the product of the learning system as envisioned by the Plan.,
• Expanding the ONC Authorized Certification Bodies' (ACBs') role into patient safety evaluation and enforcement, which is not within their core competencies

Although the Association does not oppose the concept of a well-structured post-market surveillance process, we do not believe that the ONC ACBs are appropriate entities to implement such a system, and suggest that the role for ONC ACBs proposed in the draft Plan is inappropriate and duplicative. The ACBs have neither the financial structure nor the requisite expertise for either safety-related surveillance or "taking appropriate action with respect to complaints" in patient safety and hazard matters. We suggest that the ONC Plan rely on the outcome of the aforementioned 18-month FDA study of risk-based regulatory approaches. If ONC chooses to include ONC-ACBs in its safety strategy, the ONC guidance discussed in the Plan is critical. ONC must ensure ONC-ACBs' competency and qualifications to perform such roles. We also believe that ONC should focus on uniform approaches by ONC-ACBs, and to the greatest extent possible, both ONC and ONC-ACBs should focus on the question of whether certified EHRs are operating consistent with their certifications and not introduce additional considerations in their surveillance or review.

5 CMS

The EHR Association supports ONC efforts to align safety monitoring with CMS via the Medicare Conditions of Participation and other means. We caution, however, that the ONC Plan should squarely address the educational and harmonization efforts necessary to incorporate the CMS initiative. Furthermore, CMS should qualify (or certify) the surveyors for competency and qualifications to perform such roles. We note recent CMS Medicare Program Integrity Transmittal (438), in which CMS audit processes around electronic notes seemed to be at odds with meaningful use efforts to simplify provider workflows and enhance EHR usability. Should such conflicting guidance across regulators occur, the adverse consequences could be much more severe and could certainly lead to serious risk to patient safety and achievement of Plan goals.

6 QSRS

We welcome the opportunity to work with AHRQ, providers, and all other stakeholders to create an effective and efficient system. The EHR Association cautions that the Medicare Patient Safety Monitoring System (MPSMS) and the QSRS must be able to identify duplicate reports in order for the information to be accurate and not misleading to the public. Furthermore, as long as PSO reporting remains voluntary for healthcare facilities and providers, it is difficult to determine the true frequency of events that are reported using the

Common Formats due to lack of denominator data.

7 MAUDE

Although we have no concerns with ONC monitoring MAUDE reports, we point out that much health IT, which is not regulated by the FDA, would not be reported in MAUDE, and we urge ONC not to create any expectation that it would be. In addition, it is essential that ONC and other HHS units avoid any duplicative reporting requirements or processes.

8 MU

In general, we disagree with these components of the Plan and do not support:
• Using the ONC and CMS meaningful use regulations and certification to embed intrusive requirements into EHR design that are not the product of the learning system as envisioned by the Plan.,
• Expanding the ONC Authorized Certification Bodies' (ACBs') role into patient safety evaluation and enforcement, which is not within their core competencies

We concur with the ONC draft Plan that health IT is a very significant enabler of patient safety, and the existence of the meaningful use program underscores the federal policy commitment to that end. Our comments to the HIT Policy Committee calling for a more focused approach to Stage 3 notwithstanding, we support the approach used to-date by CMS and ONC of prioritizing for meaningful use those capabilities for which patient safety improvement is a central feature, such as CPOE and medication and allergy list functionality.
Any meaningful use requirements should be minimally prescriptive, with the overarching meaningful use patient safety coming more out of the quality management system requirements and the aforementioned FDA 18-month study. In particular, we note that, by Stage 3, most eligible hospitals (EHs) and eligible providers (EPs) will have collected all their incentive payments and will no longer be receiving any incentive payments. Providers will have much on their plates, including meaningful use, ICD-10, nascent accountable care organizations (ACOs), and the advent of the impacts of the Patient Protection and Affordable Care Act. The Association suggests the Stage 3 requirements be less intrusive than the Stage 1 and Stage 2 requirements, and begin to reflect more maintenance and truly meaningful use of the implemented standards than new functionalities. Similarly, we believe that any Stage 3 requirements around patient safety must not be prescriptive, but should remain very high level and be well integrated into work flows and responsibilities that are already incumbent on providers and developers, rather than creating new demands to ensure high adoption and compliance. In our comments to the Policy Committee, we did suggest that it is premature to add a safety risk assessment to providers' meaningful use requirements.

9 Cer

In general, we disagree with these components of the Plan and do not support:
• Using the ONC and CMS meaningful use regulations and certification to embed intrusive requirements into EHR design that are not the product of the learning system as envisioned by the Plan.,
• Expanding the ONC Authorized Certification Bodies' (ACBs') role into patient safety evaluation and enforcement, which is not within their core competencies
• ONC potentially dictating both the elements and enforcement of an industry code of conduct that would diminish the value and operation of such a code, which should operate in a truly voluntary and effective manner by virtue of being organizationally grounded in the industry and its organizations
• Equating usability with patient safety. While some usability issues can contribute to safety, in general we do not agree that comparing users' experiences can determine safety among EHRs. We suggest that it is more appropriate to implement usability evaluation processes such as reporting, analyzing and learning to determine the impacts of health IT on patient safety, before devising a regulatory framework.

Overall, ONC took a generally measured approach to including safety concerns in Stage 2 meaningful use certification criteria. We applaud the care that was taken. We urge similar care for Stage 3 to avoid approaches to process areas, such as usability and quality management systems, that are overly prescriptive, impede technical innovation, and would not be well suited for certification by ONC-ACBs, which are more product-oriented rather than process-focused. In particular, we do not believe that it is desirable for ONC to use the certification process to mandate usability or quality management processes. *We do, however, believe that alignment of the health IT industry with existing and new* 8
international standards that address quality management systems (QMS) which include risk-based approaches focused on patient safety and quality is appropriate.

10 Testing, User Tools, best practices

The EHR Association supports the development of knowledge and tools, such as SHARP-C, by ONC, AHRQ, CMS, the National Library of Medicine (NLM) and others. However, we caution that such tools must be well tested and mature before they are ready for general industry adoption. We believe good tools will be quickly and voluntarily adopted by industry and that ONC should exercise caution before considering requirements to force premature adoption. We commend ONC for recognizing the critical importance of patient matching in the new world of interoperable patient records and health information exchanges.

11 Edu

As referenced earlier, the Association agrees that patient safety is a shared responsibility. We support ONC efforts toward education of all stakeholders in the healthcare system, including patient engagement.

12 Investigate Corrective Action

- Overall, goals must be clear. Interventions should be should be made only after thorough understanding of the issues, thorough testing and demonstrated replicability of the solution and empirical experience that ensures no unintended adverse consequences of the intervention. Confidence and trust will be a matter of growth, not an overnight accomplishment of a regulatory plan. Health IT-focused interventions and solutions must also be evaluated for how they fit or do not fit with the overall patient safety systems, including both health IT and non-health IT aspects.
- We recognize the importance of potential government action in the face of serious adverse events or unsafe conditions involving EHR technology that are not addressed through other mechanisms, including timely and appropriate provider or developer action. We also agree with ONC that a National Transportation Safety Board (NTSB)-like agency, as recommended in the IOM report, would not be the most effective means to achieve the patient safety goals. We agree that a national learning system that is non-punitive and which leverages the strengths of the AHRQ PSO system is the best approach. Such a system best fulfills the national learning system objective yet it does not thwart holding stakeholders accountable for patient safety. Medical education and training should be developed by a multi-stakeholder team and published for review. We do have some concerns about ONC's stated intention to work with developers toward voluntary corrective actions and to publish notices of "serious adverse events or unsafe conditions involving EHR technology". We certainly support ONC working with developers and providers, as applicable, and believe that voluntary corrective action plans and even notices could be appropriate, but strongly urge ONC to approach such efforts through development of a detailed formal plan, and formal processes and procedures, each of which has gone through a public notification and comment process. We also urge ONC to be selective in the areas where it seeks to engage in such a manner, focusing on high and immediate risk areas, and to avoid processes that may be duplicative or have a dilutive impact on other federal efforts. The EHR Association is especially concerned with the vagueness of the paragraph that mentions the Department of Health and Human Services (HHS) publishing public notices of "serious adverse events or unsafe conditions." Although we understand the impetus to quickly alert providers to major safety risks, we do not understand how ONC would be equipped to perform an analysis and be able to determine whether the safety risk is intrinsic to the product across all users or a fault introduced by a site-specific configuration affecting one and only one customer installation of the product. In all likelihood, HHS-level alerts will be too late and too generic to be meaningful or effective. In the best case, it would accomplish little more than alert fatigue. In the worst case, it could deter many unaffected providers from using their EHR systems, dropping out of the meaningful use program, and reverting to paper in whole or in part. We agree that safety awareness and accountability should be leveraged across CMS, state, and private accreditors within their scope. But as we pointed out above, the ONC Plan must ensure ongoing harmonization across those surveillance and accrediting entities, and duplication of reporting and duplication within the aggregated data. Without robust harmonization, conflicting directives will result in increased rather than diminished risk.

13 Priority areas, Measures, Targets

Develop health IT safety priority areas, measures, and targets.

We again call out that the ONC Plan should bridge the gap until the FDA 18-month study produces a longer term set of solutions for risk-based approaches to patient safety. We strongly support ONC's stated intention for the FDA 18-month study to include extensive stakeholder input. We also want to emphasize the critical need for a risk-based approach, one that enhances the innovation that is so essential for our healthcare system, and one that recognizes that traditional regulatory approaches are not well suited to EHRs.

14 Publish Report on strategy and recommendations

We again call out that the ONC Plan should bridge the gap until the FDA 18-month study produces a longer term set of solutions for risk-based approaches to patient safety. We strongly support ONC's stated intention for the FDA 18-month study to include extensive stakeholder input. We also want to emphasize the critical need for a risk-based approach, one that enhances the innovation that is so essential for our healthcare system, and one that recognizes that traditional regulatory approaches are not well suited to EHRs.

15 ONC Safety Program

- The Association supports the two stated objectives and the necessity of mobilizing a broad spectrum of stakeholders in a mode of "shared responsibility". We also agree with the ONC Plan that "safer care" and "safer health IT products" are two distinct yet very interrelated concepts.
- We support the concept of "continuously improve the safety of health IT." But we point out that the role of government here is still evolving. Insufficient studies exist to determine which paths would impact market forces positively and which might result in adverse outcomes that diminish rather than advance patient safety. Federal agencies and regulators should be partners among the engaged stakeholders. Narrow or over-reaching mandates should be avoided. We repeat our belief that the current role of the ONC should be

helping to build a framework and initial plan, while deferring to the insight of the 18-month FDA study to identify the longer term role of the federal government.
The EHR Association believes that an ONC Safety Program is an appropriate component of the Office of the National Coordinator, with a recognition that this program could need to shift in approach following the completion of the more comprehensive study referenced above.

16 State Governments

As previously stated, the Association agrees that many stakeholders must be involved. That includes state government. But, as we have also already stated, coordination of vision across the fifty states, the District of Columbia, and the territories is a herculean challenge. Collisions among state program activities, meaningful use, PSO, JCAHO, and other federal initiatives are almost inevitable. To enable the state oversight in harmonized fashion, we suggest establishment of a national framework of formats and standards so as to minimize potential for local/national conflicts.

17 Private Sector Leadership

18 Other

In general, the Association agrees with and supports the following components of the Plan:
• Instilling awareness that patient safety is everyone's responsibility
• Ensuring that health IT-related patient safety is approached as a seamless component within the overall patient safety ecosystem, rather than a stand-alone system
• Developing the concept and then building a nationwide, non-punitive safety data reporting, analysis, and learning system
• Leveraging the Patient Safety Act and the Patient Safety Organizations created under that Act
• Leveraging enhanced versions of the AHRQ Common Formats that will incorporate health IT-related data sets into existing reporting processes, and aggregation and analysis processes for both inpatient and ambulatory settings
• Conducting and publishing research
• Providing coordination of patient safety monitoring programs across diverse industry programs, e.g., the Center for Medicaid and Medicare Services (CMS) Conditions of Participation, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and others
• Providing for participation of patient safety stakeholders (certainly including EHR developers) in the dialogue for development of the 18-month study on a risk-based regulatory framework as authorized by the FDA Safety and Innovation Act of 2012 (FDASIA)

In general, we disagree with these components of the Plan and do not support:
• Using the ONC and CMS meaningful use regulations and certification to embed intrusive requirements into EHR design that are not the product of the learning system as envisioned by the Plan.,
• Expanding the ONC Authorized Certification Bodies' (ACBs') role into patient safety evaluation and enforcement, which is not within their core competencies
• ONC potentially dictating both the elements and enforcement of an industry code of conduct that would diminish the value and operation of such a code, which should operate in a truly voluntary and effective manner by virtue of being organizationally grounded in the industry and its organizations
• Equating usability with patient safety. While some usability issues can contribute to safety, in general we do not agree that comparing users' experiences can determine safety among EHRs. We suggest that it is more appropriate to implement usability evaluation processes such as reporting, analyzing and learning to determine the impacts of health IT on patient safety, before devising a regulatory framework.

Finally, the EHR Association would like to point out several important concepts that are missing from the draft Plan:
• Irrespective of the patient safety reporting and analysis system that is eventually put into place, it is absolutely critical to patient safety that such a system not distance providers from their EHR
10

developers. When a patient safety event occurs, it is imperative that the affected provider be able to report the issue directly and immediately to their vendor allowing the developer to address the event, investigate it, inform any other affected clients if necessary and resolve it. Any national reporting or analysis system should work in parallel with the vendor-client relationship, not in lieu of that relationship. To do otherwise would delay and confuse the response to the safety event.

• For most analytical purposes, no patient, provider, nor developer/brand should be identified in the national learning system.
• Within the national learning system, developers need to be able to access data anywhere in the system that involves their own product.
• We believe there is a significant gap in the maturity of patient safety analysis and reporting processes between large, integrated organizations and small ambulatory practices. We suggest that the ONC final Plan address education programs to remediate that gap.
• Without adequate lead time to develop, test, and implement new functionality required by the meaningful use incentive program, there is the potential to create usability issues as well as risks to patient safety. As was stressed by vendor CEOs during our meeting with ONC in November 2012, it is important to consider the pace of new development requirements to ensure the success of the program. The EHR Association would like to reiterate our request for 18 months between Stages 2 and 3 in order to avoid potential issues for developers, providers, and patients that might not only introduce risk, but also undermine the objectives of the program and compromise the benefits that EHRs can deliver.

In the ONC's review of comments received by the EHR Association, our members, and other stakeholders, we also urge that you give careful attention to the forthcoming report by the Bipartisan Policy Center on "Assuring Safety, Quality and Innovation in Health IT."

Names

Katzen, Jay

Comment ID

59

Organization

Elsevier Clinical Solution

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

• Strongly supports ONC's desire to make it easier for clinicians to report patient safety incidents and risk through CEHRT utilizing AHRQ's CF
• We urge ONC to endorse best practices for standardization to enable better and faster alignment to AHRQ's Common Formats.
• Potential problems can be avoided by assuring that evidence-based practice is supported in every healthcare setting and that health IT functionality continually incorporates this evidence-based practice to ensure patient information discovered during treatment that could create patient safety issues is immediately and properly highlighted for providers through HIT
• Elsevier has collaborated with PSOs to mitigate risk and facilitate reporting
• Although AHRQ's CF for pt safety reporting v1.2 provide a greater level of clinician documentation, Elsevier also encourages, and is currently investigating, the development of methods to allow for natural language processing of patient complaints, which could be captured as part of clinical narratives and used to populate CF documentation

2 Vendor Engagement (CoC, etc)

• Elsevier supports this objective as we agree that pt safety should be the highest priority for developers. Apart from its potential to improve quality of patient care while reducing costs, when HIT is used propeorly it can quickly recognize and mitigate risk in any care setting.
• Elsevier's experience has shown that greater pt safety can be achieved by successfully leveraging data analystics and computer assisted diagnosis. Our Pinpoint Review solutions, for example, uses real0time med record data at the point-of-care to report risk predictions based on predictive modeling. The use of real-time data ultimately produces more actionalble clinical information.

3 PSO

4 ACB

• Elsevier has collaborated with PSOs to mitigate risk and facilitate reporting

5 CMS

6 QSRS

7 MAUDE

8 MU

• Supports ONC's proposal to utilize EHR tech adopted and used as part of the MU incentive program to improve pt safety.

9 Cer

• WE support

10 Testing, User Tools, best practices

• Agrees with and supports this objective. Any pt safety plan should demand that the most current and best practices are used to keep patients safee. Our experience has shown that improvements to pt safety can be best achievged when EHRs and content used in conjunction with EHRs incorporate analytics, best-available evidence, best-practice workflows, ongoing clinician training, and other tools to ensure that patients are both educated and empowered.

11 Edu

• Incorporating HTI into med and interporfessional edu and training, including training on how to use tech safety and effectively, is strongly encouraged

12 Investigate Corrective Action

• Elsevier has methods to investigate reporting by leveraging protocols HL7

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

• Elsevier supports a properly designed risk-based regulatory framework for health IT; however, we encourage ONC and other regulators to recognize the clear difference between innovative clinical content, which is designed to enable greater pt safety and quality of care, and med devices. We urge ONC to work with other regulators to ensure that any additional regulation of clinical content is done deliberately and consistently with existing regulatory structures.

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

• Elsevier agrees that all health IT stakeholders have a role to play in providing the safest possible environment for patients

18 Other

• Supports ONC's overall patient safety objectives
• Agree that patient care can be made safer through heatlh IT and that the safety of HIT itself can be continuously improved

Names

Segal, Mark J., PhD

Comment ID

93

Organization

GE Healthcare (GEHC)

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

We agree with Using enhanced versions of the AHRQ Common Formats that will incorporate HIT related data sets

- We agree with Focusing on a non-punitive and voluntary learning system approach to patient safety, emphasizing data reporting, analysis and learning
- We agree with ONC's focus on reporting and establishing baseline information and focusing on using existing government and industry processes associated with patient safety in addressing HIT and patient safety.
- It is important to create an environment conducive to detecting HIT-related safety signals; adding complexity and noise by layering additional reporting requirements and regulatory oversight will not achieve this goal.
- We agree that it would be useful to explore how EHRs can be used to facilitate reporting of safety events and risks (in general and not HIT-specific). At the same time, we caution that it is essential to consider appropriate EHR and general patient safety reporting workflow and to also look to ways in which EHR data could provide insights into patient safety via the use of safety-relevant clinical quality measures. Given that most patient safety reporting will not be done by a single EHR user, and will occur after intra-organizational workflows and review processes, it is more appropriate to consider how EHRs can help collect the data needed by health care organizations as they review safety issues internally and potentially report externally, We also caution against a focus on a "magic button" that could be used by providers to report on safety issues and also suggest consideration of the electronic data entry methods used by PSOs already. In the context of adding new requirements to certification, as proposed, we assume that this type of new criterion would be for Stage 3 and urge full consultation with software developers and providers and consideration of the points made above and below. We urge ONC to avoid dictating a single approach to use of EHRs to facilitate internal and external reporting given the need to allow for innovation and to accommodate varying EHR and provider workflows. We agree that it would be valuable to utilize the AHRQ Common Formats used for PSO reporting and we support research on the how these formats can be enhanced and best used. Again, it will be essential to avoid burdening and disrupting EHR workflow and performance. It will also be important to consider the liability implications of adding additional patient safety relevant information into the legal medical record as opposed to the protected environment that PSOs afford to health care professionals and organizations. Finally, we also urge that ONC, in the final Plan,

recognize the critical importance of direct provider reporting to their HIT vendor as well as consulting with their HIT vendor when conducting root cause investigations in order to assure the most direct and rapid resolution of product-specific issues.

2 Vendor Engagement (CoC, etc)

We disagree with ONC potentially dictating both the elements and enforcement of an industry code of conduct that would diminish the value and operation of such a code, which should operate in a truly voluntary and effective manner organically grounded in the effective industry and its organizations

We agree with ONC's stated desire to engage IT developers to embrace our shared responsibility. As a company, GE Healthcare has certainly fully accepted our responsibilities with respect to patient safety. We are also active participants with industry organizations working on this and related issues, including the EHR Association, the Bipartisan Policy Center, MITA, and relevant standards organizations. We believe that industry codes of conduct can be useful, are aware of several within the healthcare technology industry and have engaged with the EHR Association in its consideration of such a code for EHR vendors. At the same time, we believe strongly that such codes must be organic to and developed and maintained by the affected industries and their organization. They should also be voluntary in application, and not dictated by the federal

government. This approach ensures open rules of competition on a level playing field for vendors and efficiently leverages customer-driven market forces to drive compliance. In this regard, although it could be helpful for ONC to identify potential topics for consideration, we do not agree with ONC's seeming attempt to dictate the minimum content of such a "code" or to assume for itself the responsibility for enforcement of compliance. We also do not believe such a code should be in any way part of the certification process, consistent with our rationale for Item #4 below. In terms of the specific topics identified by ONC, these are generally reasonable, at least in the context of issues that have been raised by various industry stakeholders. Certainly, we agree that safe design and policies/practices should be in place. We also agree that it would be useful for HIT developers to work with PSOs on a voluntary basis, and we agree with ONC that PSOs could play a very positive role in the HIT safety area. At the same time, we also underscore the points made by ONC that there are likely to be needed clarifications and regulatory changes to mitigate various risks for PSOs, providers and developers and to make such vendor engagement with PSOs feasible and effective. Also, we do believe that voluntary provider reporting to PSOs on safety issues should be the primary focus for reporting to PSOs, given that safety events generally happen in a provider context and that HIT is likely to only be one element of any safety event. We also believe that, as we look to cast a broader net for potential safety events to be reported to PSOs, with many reports unlikely to undergo full root cause analysis, aggregate data on safety reports should not identify specific vendors or product brands but rather focus on patterns and types of HIT functionality involved. More generally, we agree with ONC that provider reporting of safety events is essential and should be encouraged. We do not believe that vendor-provider contracts, including essential provisions to protect intellectual property, do or should present a bar to such reporting to appropriate bodies or for sharing among product users. With respect to comparative user experience, we believe that the market should operate here and that ONC should not seek to dictate particular approaches, whether directly or through its influence on development or application of codes of conduct. Finally, and to reiterate, we do not believe it appropriate for ONC to seek or assume an enforcement role, whether direct or indirectly, for industry codes of conduct.

3 PSO

We agree with Using the Patient Safety Act and the Patient Safety Organizations (PSOs) created under that Act
We agree with ONC's plan for support for by ONC and AHRQ for PSO efforts in this area, including data aggregation and analysis. As stated above, it is essential as part of a non-punitive learning environment, and to increase the accuracy of safety signal detection by addressing the potential negative impact of the collection of incomplete or misleading data, that aggregated reports should be de-identified by provider, developer, and specific product (as opposed to product type) and focus on trends and patterns. We would be eager to consider the results of such analyses in our own design and implementation work.

4 ACB

We disagree with The proposed expansion of the ONC-Authorized Certification Body (ACB) role into patient safety evaluation and enforcement, a role that is not within their core competencies, could divert from their substantial and as yet untested duties in the "2014" certification process, and could also create duplicative processes for surveillance and corrective action
We have substantial concerns with expanding the role of the ONC-ACBs into HIT patient safety, including post-market surveillance. We do not believe that patient safety surveillance is within ONC-ACB core competencies, could divert from their substantial and as yet untested duties in the "2014" certification process, and could also create duplicative processes for surveillance and corrective action. The creation of duplicative processes may, moreover, dilute the effectiveness of existing processes and introduce additional risk to patient safety. If ONC chooses to include ONC-ACBs in its safety strategy, we emphasize that the ONC guidance discussed in the plan is critical. ONC should focus on uniform approaches by ONC-ACBs, and to the greatest extent possible, ONC and ONC-ACBs should focus on the question of whether certified EHRs are operating consistent with their certifications and not introduce other considerations in their surveillance or review.

5 CMS

Comment: We are generally in agreement with this section of the Plan, which is consistent with ONC's very positive focus on leveraging existing safety relevant processes and organizations, but emphasize the need for CMS training of surveyors on safety issues as well as the role of PSOs in the process.

6 QSRS

Comment: The plan regarding the QSRS and AHRQ's interim work seems appropriate.

7 MAUDE

Comment: Although we have no concerns with ONC monitoring MAUDE reports, we point out that much HIT, which is not regulated by the FDA, would not be reported in MAUDE and we urge ONC not to create any expectation that it would be. In addition, it is essential that ONC and other HHS units avoid any duplicative reporting requirements or processes.

8 MU

We disagree with the Use of the ONC and CMS Meaningful Use regulations and certification processes to embed intrusive requirements into EHR design and implementation that are not the product of the learning system as envisioned by the Plan
Comment: We support the approach used to-date by CMS and ONC of prioritizing for meaningful use those capabilities for which patient safety improvement is a central feature, such as CPOE and medication and allergy lists. Patient safety should be a continuing criterion for inclusion in meaningful use, notwithstanding our comments to the HIT Policy Committee calling for a more focused approach to Stage 3 of meaningful use. In those comments, we did, however, suggest that it is premature to add a safety risk assessment to providers' meaningful use requirements. Finally, in the anticipated work of ONC on clinical documentation with its advisory committees, we urge ONC to recognize that the needs for and drivers of clinical documentation include but exist in a broader context than EHRs and other HIT, to not take on a task that lies beyond ONC's charge, and to consult closely with clinicians on any such work.

9 Cer

Comment: As a company, we have implemented robust quality processes around safety related issues, including quality management systems and usability. We believe that other HIT companies should also implement such approaches if they have not. At the same time, do not believe that is desirable for ONC to use the certification process to mandate such processes. Overall, ONC took a generally measured approach to including safety concerns in Stage 2 meaningful use certification criteria. We applaud the care that was taken. We urge similar care for Stage 3 to avoid approaches to process areas like usability and quality management systems that are overly prescriptive, impede technical innovation and not well-suited for implementation by ONC-ACBs, which are more product-oriented rather than process focused.

10 Testing, User Tools, best practices

We agree with Conducting and publishing research on HIT and safety
Comment: We support the general approach outlined in this section, including the focus on accurate patient matching. We do, however, disagree, as discussed for the previous item, with regard to increased focus on safety issues in product certification.

11 Edu

Comment: We strongly support this aspect of the plan.

12 Investigate Corrective Action

Comment: We recognize the importance of potential government action in the face of serious adverse events or unsafe conditions involving EHR technology that are not addressed through other mechanisms, including timely and appropriate provider or developer action. We also applaud ONC rejecting the proposal made by the IOM to establish new federal organizations to address HIT patient safety. We do have some concerns about potential aspects of ONC's stated intention to work with vendors toward voluntary corrective actions and to publish notices of "serious adverse events or unsafe conditions involving EHR technology". We certainly support ONC working with developers and providers, as applicable, and believe that voluntary corrective action plans and even notices could be appropriate, but at the same time, we strongly urge ONC to approach such efforts through development of a detailed formal plan and adoption of formal processes and procedures that have been vetted through notice and comment. We also urge ONC to be selective in the areas where it seeks to engage in such a manner, focusing on high and immediate risk areas, and to avoid processes that may be duplicative or have a dilutive impact on other federal efforts.

13 Priority areas, Measures, Targets

Comment: We support this part of the plan

14 Publish Report on strategy and recommendations

• We agree with ONC's active participation in development of the 18-month study on a risk-based regulatory framework for HIT required by the FDA Safety and Innovation Act of 2012, with this plan acting as a bridge and contributor, after study, toward that more comprehensive, risk-based approach

• FDA Safety and Innovation Act of 2012. We support ONC's active participation in development of the 18-month study on a risk-based regulatory framework for HIT as required by this Act, and see this Plan as a bridge and contributor, after study, toward that more comprehensive, risk-based approach. We strongly support ONC's stated intention for the 18-month study to include extensive stakeholder input. We also want to emphasize the critical need for a risk based approach, one that enhances the innovation that is so essential for our health care system, and one that recognizes that traditional regulatory approaches are not well suited to EHRs and other HIT.

• We [] strongly believe that the federal government should not pursue new regulatory-focused approaches to potential HIT patient safety risks that have not been established, defined, or evaluated. Moreover, future federal actions, while attentive to both benefits and risks associated with HIT, should avoid jeopardizing our ability to innovate and develop new and even safer HIT solutions. We also agree with ONC that EHR developers and users must remain focused to assure that development and implementation of EHRs and other clinical HIT do not introduce unacceptable patient safety risks.

15 ONC Safety Program

We agree that ONC's focus on using existing patient safety entities and processes and not pursuing the IOM's call for new regulatory agencies and structures

• We agree with Enhancing coordination of patient safety monitoring programs across multiple federal and private sector programs

Comment: We understand ONC's intention to create a program to implement this plan but also urge that this program recognize the interim nature of ONC plan relative to the complete strategy to be developed by the Department of Health and Human Services based on the 18-month study. We urge that this new program coordinate with other federal efforts as anticipated and seek to avoid and eliminate any duplicative processes or requirements.

16 State Governments

Comment: We support this element of the plan and urge ONC to seek maximum feasible consistency across states in application of standards and methodologies, to reduce burdens for providers and software developers.

17 Private Sector Leadership

In assessing potential policy actions and industry responses, it is important to ground public and private sector efforts in the nature and magnitude of the risks and the benefits associated with HIT.

Comment: We agree with this element of the plan and as a leader in the health IT industry and more generally in the health care and patient safety domains, we pledge to meet our responsibilities to advance the safety of our products, our industry's products, and the ability of HIT to further patient safety.

18 Other

• We also strongly support the conclusions in the Plan that patient safety is a "shared responsibility." GE Healthcare is committed to working with our customers, ONC, AHRQ, FDA and industry stakeholders to enhance patient safety throughout the health care system as part of a learning health care system reflecting a "culture of safety".

Agree with Ensuring that HIT patient safety is approached within the overall patient safety ecosystem, and not in a siloed manner

Names

White, Joel

Comment ID

12

Organization

Health IT Now Coalition

Org Typ1	Org type	Categories
12	12.. Other	1. Reporting, 10. Testing, User Tools, best practices, 14. Publish R

1 Reporting

• HITN supports the objectives laid out in the HIT Safety Plan, namely, to use health IT to make care interventions safer and to continuously improve the safety of health IT. We agree that all stakeholders should be a part of the objective of a safe health system and that health IT creates an infrastructure for identifying and monitoring patient safety events. We note that this is only possible if health IT systems are interoperable, reporting processes are transparent, and if patient safety information is shared freely across systems.
• AHRQ Common Formats. ONC indicates it will use the certification criteria to ensure that EHR technology can facilitate reporting of safety events in AHRQ's Common Formats. We believe this is an important step in ensuring we know better the types and frequency of adverse events. EHR functionality can automate the reporting process, but it is important that reporting, as the IOM indicates, is confidential and non-punitive. We believe health IT developers need to avail themselves of the same protections under the Patient Safety and Quality Improvement Act that are afforded to healthcare providers. We note this would require a legislative expansion of the law, and encourage ONC to support such a change.

2 Vendor Engagement (CoC, etc)

• Provider Reporting of Safety Events. As ONC indicates, IOM has identified legal and other factors that inhibit the free flow of information as barriers to patient safety and transparency. We agree with IOM and encourage ONC to view information blocking as a critical inhibitor to better patient safety.
• HITN supports the objectives laid out in the HIT Safety Plan, namely, to use health IT to make care interventions safer and to continuously improve the safety of health IT. We agree that all stakeholders should be a part of the objective of a safe health system and that health IT creates an infrastructure for identifying and monitoring patient safety events. We note that this is only possible if health IT systems are interoperable, reporting processes are transparent, and if patient safety information is shared freely across systems.
• We appreciate ONC's commitment to build on structures that work well, including leveraging the work already done by Patient Safety Organizations (PSOs) and in realigning the certification process to recommit to stronger patient safety safeguards. We believe the role of PSOs should be expanded to include health IT developers and that the certification process should be revisited to classify products by risk and appropriate regulator. Doing so will expand the knowledge base of what works and what does not, while streamlining the regulatory process. Our comments on the specific strategies and actions are outlined below with a focus on addressing deficiencies in interoperability, which raise serious patient safety concerns.

3 PSO

• We appreciate ONC's commitment to build on structures that work well, including leveraging the work already done by Patient Safety Organizations (PSOs) and in realigning the certification process to recommit to stronger patient safety safeguards. We believe the role of PSOs should be expanded to include health IT developers and that the certification process should be revisited to classify products by risk and appropriate regulator. Doing so will expand the knowledge base of what works and what does not, while streamlining the regulatory process. Our comments on the specific strategies and actions are outlined below with a focus on addressing deficiencies in interoperability, which raise serious patient safety concerns.

4 ACB

• HITN supports using ONC-ACBs to ensure EHR capabilities work in operational settings to the standards for which they have been certified. As we indicated in our Meaningful Use Stage 2 comment letter, we believe ONC-ACBs should decertify EHR vendor products on a case-by-case basis if the product cannot perform the function as certified due to policies or other efforts to block information exchange made by the vendor. We suggested requiring EHR developers to certify that their products do not block information exchange under EHR certification standards in 2014. We believe that EHR vendors who pursue blocking strategies through one or more products should likewise be decertified. When an exchange failure is reported to an ONC-ACB and it has been determined that it was not due to a technology issue, but rather a provider practice, those healthcare professionals or organizations should be made ineligible for the program.

5 CMS

• Align CMS Health and Safety Standards With the Safety of Health IT. ONC specifically raises the prospect that CMS might leverage current Hospital Conditions of Participation (CoPs) to better track adverse events related to health IT. We support using the CoPs in this respect and encourage ONC and CMS to explore using CoPs to discourage unsafe hospital environments when a hospital engages in a business practice of blocking information. Additionally, CMS might use its survey and certification tools to identify unsafe practices related to information blocking

6 QSRS

7 MAUDE

8 MU

• To the extend standards for Meaningful Use do not require interoperability and the business practice of blocking information between providers persists, the ability of health information technology to prevent medical errors and improve safety will be limited.
• Put simply, interoperability is a patient safety issue. We encourage ONC to consider technical and imposed barriers to interoperability, such as information blocking, as legitimate safety concerns, and to address these persistent issues in its broader patient safety plan.
• We appreciate ONC's commitment to build on structures that work well, including leveraging the work already done by Patient Safety Organizations (PSOs) and in realigning the certification process to recommit to stronger patient safety safeguards. We believe the role of PSOs should be expanded to include health IT developers and that the certification process should be revisited to classify products by risk and appropriate regulator. Doing so will expand the knowledge base of what works and what does not, while streamlining the regulatory process. Our comments on the specific strategies and actions are outlined below with a focus on addressing deficiencies in interoperability, which raise serious patient safety concerns.

9 Cer

• The certification process should focus on a system's ability to function as-certified and adhere to required program standards.

10 Testing, User Tools, best practices

• We suggest ONC explore a risk-based framework that calculates risk proportionally to the amount of potential variability in whether or not a technology will function as designed.

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

• We are pleased ONC has indicated it will publish a report on a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT in compliance with the FDA Safety and Innovation Act (FDASIA).
• We are disappointed the Secretary has indicated the Department will not convene an expert external panel to provide input into this process. Collaborative efforts between the Department and external experts should be fostered to bring the collective experience and expertise to bear on the serious issues that impact the safety of health care. We encourage ONC to urge the Department to rethink its approach and to convene the external panel.
• HITN agrees with IOM's assessment in their report Health IT and Patient Safety: Building Safer Systems for Better Care that, "…investigating patient safety incidents does not match the internal expertise of any existing entity, as the needed functions are under the jurisdiction of multiple federal agencies and efforts are generally uncoordinated and not comprehensive."

Clearly a new and coordinated effort to address the ascendant safety issues that correlate with more robust health IT use is warranted.
• HITN suggests building on the efforts outlined in the HIT Patient Safety Plan to promote clarity in the regulatory process, reduce duplication in regulations, streamline the regulatory process and reduce costs, promote innovation and improve patient safety. Manufacturers and end-users alike need clarity about the rules and requirements of the regulatory process. Regulators and end users (consumers and healthcare providers) need guarantees that a product will function as designed. We believe the approach must be scientific and based on testable consensus-based standards.
• Further, we suggest ONC explore a risk-based framework that calculates risk proportionally to the amount of potential variability in whether or not a technology will function as designed. An alternative regulatory process for health technologies and software is needed for those that function exclusively as information management systems. Systems that exclusively manage health information should not be required to go through the existing 510(k) or Pre-Market Approval (PMA) processes but rather should be evaluated based on risk by independent experts, such as through existing certification bodies in the Meaningful Use program. The certification process should focus on a system's ability to function as-certified and adhere to required program standards. We believe the benefits of this approach include:
• Certainty and reduced duplication.
• Lower costs (through streamlined approval and through competition).
• Harmonized standards across the market.
• De-politicization of the current approval process.

The goal of this approach is to develop a scalable methodology that can keep pace with market demand as well as infuse certainty into the process for all stakeholders.
• Using a standards base approach to stratify risk requires regulators that pursue standards testing and development but also have the necessary regulatory expertise on hand to keep pace with the technology marketplace. Without an adaptable and scalable strategy for evaluating health information systems, any regulator will run into the same problem that FDA has: burden and backlog. We believe these problems can and should be mitigated.
• As ONC indicates, adoption of innovative health technologies is itself a strategy to improve safety. To the extent the regulatory framework inhibits innovation, safety is threatened

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

• Goal: We believe HHS should modify the goal to include all stakeholders that will benefit from an increased focus on safety—such as payers, family caregivers and others whose services support the traditional provider-patient relationship.
• ACO Contracts. HITN encourages ONC and CMS to explore using the current contracting process for Accountable Care Organizations to ensure information blocking practices do not create unsafe environments.
• Business practices that preclude information sharing could be made per se illegal under revised rules [relating to Stark and anti-kickback laws]because they may create captive referral arrangements that threaten patient safety.
• HITN suggests building on the efforts outlined in the HIT Patient Safety Plan to promote clarity in the regulatory process, reduce duplication in regulations, streamline the regulatory process and reduce costs, promote innovation and improve patient safety.
• HITN is encouraged by the approach that ONC has outlined in the Health IT Safety Plan, and we hope that many of the proposals contained in the draft recommendations will be retained in the final product. We urge ONC to work with all interested stakeholders to improve on the excellent work outlined in the draft approach.

Names

Chao, Sam, MPH

Comment ID

31

Organization

IOM/Pew

Org Typ1	Org type	Categories
12	12.. Other	1. Reporting, 13. Priority areas, Measures, & Targets, 15. ONC Saf

1 Reporting

• **Reporting**. Reporting is a critical part of improving safety, as has been shown in countless articles and reports across industries.

The plan needs to focus more explicitly on reporting and investigating adverse events *and* unsafe conditions .1

I strongly urge mandatory reporting of adverse events by vendors to ONC-ACBs. ONC-ACBs should be required to submit reported events to a central organization. ONC, AHRQ, or any of the ONC-ACBs could serve as a central organization .2

This plan heavily relies on AHRQ's Common Formats, which have not yet proven successful; ONC will need to actively work with AHRQ to encourage provider adoption and use of the Common Formats .3

It is a lot to ask providers to submit safety complaints about vendors or a specific product to ONC-ACBs. ONC should serve as a point of coordination between ONC-ACBs and other recipients of adverse event reports (e.g, the Joint Commission). ONC also ought to encourage organizations such as the Joint Commission to request voluntary corrective action when providers become aware of a potential adverse event or unsafe condition .4

2 Vendor Engagement (CoC, etc)

• **Using certification to ensure safety.** It is unclear how ONC plans to ensure compliance of vendors. For example, the voluntary code of conduct for developers merely asks vendors to adopt business practices for safe reporting and to submit complaints to ONC-ACBs. A step ONC should take to actually ensure compliance is to tie development of these business practices to the certification of health IT products for meaningful use. ONC could also publicly list vendors and health IT products that meet expectations set in the code of conduct. This could be added to the information currently posted on ONC's website about health IT products certified for meaningful use.

• I strongly urge mandatory reporting of adverse events by vendors to ONC-ACBs. ONC-ACBs should be required to submit reported events to a central organization. ONC, AHRQ, or any of the ONC-ACBs could serve as a central organization.

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

• **Using certification to ensure safety.** It is unclear how ONC plans to ensure compliance of vendors. For example, the voluntary code of conduct for developers merely asks vendors to adopt business practices for safe reporting and to submit complaints to ONC-ACBs. A step ONC should take to actually ensure compliance is to tie development of these business practices to the certification of health IT products for meaningful use. ONC could also publicly list vendors and health IT products that meet expectations set in the code of conduct. This could be added to the information currently posted on ONC's website about health IT products certified for meaningful use.

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

- **Develop criteria to assess and monitor safe use of health IT**. The actions listed on page 29 delineate various parts of ONC's plan. However, it does not respond to the IOM's described need to develop criteria as part of a national strategy for evaluating and monitoring health IT safety. For example, in the development of safety measures, priority areas (e.g., usability, interoperability) need to be set. ONC should work with organizations such as the National Quality Forum to establish priority areas.
- **Measurable targets for safety**. It is disappointing that the table comparing this plan to the IOM's recommendations states that the plan serves as HHS's report on the progress of health IT safety for 2012. A report on the progress of health IT should have measurable targets, allowing for evaluation at later dates. ONC should establish and report on measures for assessing the state of health IT safety and reliability now. As it stands, this plan does not offer any insight as to whether the nation is safely using health IT. Without measurable targets for safety, HHS does not have a way to show the public it is protecting patients and should ask FDA to play a larger role.

14 Publish Report on strategy and recommendations

15 ONC Safety Program

- **Broaden membership on steering committee**. The proposed ad hoc steering committee to address major safety issues should pull from other agencies outside of HHS as appropriate (e.g., NTSB).

16 State Governments

- **Role of states**. The role of state governments was briefly mentioned. ONC should also leverage the state-based health insurance exchanges to the extent possible to promote safety and reporting.

17 Private Sector Leadership

18 Other

The plan is a useful first step; however it remains just a first step. The plan should be updated continually. ONC should consider the following points in its revision to take a few more steps toward ensuring safety.

1. **Using certification to ensure safety**
2. **Reporting**
3. **Develop criteria to assess and monitor safe use of health IT**.
4. **Broaden membership on steering committee**
5. **Role of states**

Measurable targets for safety

Names

Weissberg, Jed, MD

Comment ID

55

Organization

Kaiser Permanente

Org Typ1	Org type	Categories
3	3. Provider Organization (Institutional)	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 15.

1 Reporting

The action plan and future regulations should support creating an environment that encourages reporting of patient safety events

• We strongly support creating an environment that encourages comprehensive reporting of safety issues and hazards within organizations. The plan should focus on corrective action, such as improving policies and procedures, rather than on penalizing deficiencies. However, it is also important to recognize that, like the concept of trigger tools, there are intrinsic limitations and reliability issues associated with any system that relies on people (whether providers, patients, or others) to report.

The action plan should consider requiring adoption and use of a Common Format

We generally support the idea of adopting and using a common format for collecting and reporting data on safety of health IT among users and developers to Patients Safety Organizations (PSOs). However, most organizations are unlikely to migrate to such a format unless it is required.

2 Vendor Engagement (CoC, etc)

The action plan should establish implementation of a voluntary code of conduct for EHR vendors

We support the adoption and implementation of a more comprehensive voluntary code of conduct for EHR vendors (beyond the basic elements included in the Meaningful Use Stage 2 program) with specific commitments to ensuring and promoting safety in the design, development and deployment of EHR systems and applications. This should be extended to developers of other health IT systems, tools and applications and include good quality management principles, user-centered design and human factors analysis. The code of conduct also should address other areas, such as transparency in contracting and pricing, as well as adherence to existing coding conventions for systems that support billing.

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

The action plan should consider requiring adoption and use of a Common Format

We generally support the idea of adopting and using a common format for collecting and reporting data on safety of health IT among users and developers to Patients Safety Organizations (PSOs). However, most organizations are unlikely to migrate to such a format unless it is required.

9 Cer

The action plan should consider requiring adoption and use of a Common Format

We generally support the idea of adopting and using a common format for collecting and reporting data on safety of health IT among users and developers to Patients Safety Organizations (PSOs). However, most organizations are unlikely to migrate to such a format unless it is required.

10 Testing, User Tools, best practices

• **The action plan should recognize the importance of accurate and efficient matching of patients to their health information**

We strongly agree with the statement in the action plan that accurate and efficient matching of patients to their health information is critical. Therefore, the action plan should explicitly call for the development and deployment of a national standardized approach for matching patients to their health information. The ongoing inability to reliably and accurately match patients with their information represents a major safety concern and a substantial barrier to improving patient safety through care coordination. **The action plan should acknowledge the importance of health IT population management tools and registries**

• Kaiser Permanente is a pioneer in the use of population management tools to identify population-level health issues and develop health management, prevention and improvement programs tailored to specific populations. These population management tools and registries are among the most effective systems to support a health IT patient safety program. We encourage ONC to consider including these tools as part of the surveillance plan.

The action plan should address the development and dissemination of best practices in the safe deployment and use of EHRs and other health IT tools, systems, applications and resources

• The action plan should identify and disseminate best practices for the safe deployment and use of EHRs. We recommend that the activities outlined as being undertaken by AHRQ and ONC be expanded to include development of guidance on safety practices.

11 Edu

The action plan should establish a need to incorporate health IT safety into medical education and training

We support the need to develop a formal strategy and implementation plan to incorporate health IT safety training into medical education programs. Comprehensive provider training can help to reinforce the safe use of health IT in care delivery.

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

We strongly recommend that ONC work closely with stakeholders within the health care industry to ensure that regulations strike the proper balance between protecting patients from harm and promoting technological innovations that advance care delivery.

14 Publish Report on strategy and recommendations

15 ONC Safety Program

• Because the plan is in an early stage of development, further research and analysis will be needed to define the issues, and there is a lack of industry standards in this area, we strongly caution against adopting program policies or regulations at this time. We believe the role of regulation should be to prevent harm and stimulate innovation towards metrics of quality and safety outcomes. This is an immature discipline that is evolving rapidly through very disparate methods of innovation. To prescribe at this point anything about *how* the safety and quality initiatives are achieved would unintentionally stifle real innovation. We recommend the alternative of providing metrics, setting goals using those metrics, and letting the industry and the technology market innovate freely to achieve those targets and metrics.

We also agree with ONC's call for further research and analysis to better understand the role, opportunities, best practices and possible issues related to the way health IT helps improve patient safety, as well as the risks that may arise from the deployment of health IT systems. ONC, along with other federal agencies such as the Agency for Healthcare Quality and Research ("AHRQ") and industry partners, can assume a critical coordinating role to help avoid duplication of research and analysis of patient safety improvement.

16 State Governments

17 Private Sector Leadership

The action plan should consider the roles played by other organizations in the marketplace

The action plan should engage and involve other perspectives, like those of purchasers, employers and health plans. We also recommend including information related to workers safety events as part of the action plan.

18 Other

• Overall, we congratulate ONC for developing a sound and well-balanced patient safety and health IT action plan that recognizes both the role health IT in improving patient safety and the responsibility to ensure safe use of health IT to support patient care.

• **The action plan should involve patient and consumer representatives** It will be critical to include the perspectives of patients and consumers in the implementation of an action plan. Patient and consumer education regarding the identification and reporting of safety issues should also be an integral component of the plan

• Because the plan is in an early stage of development, further research and analysis will be needed to define the issues, and there is a lack of industry standards in this area, we strongly caution against adopting program policies or regulations at this time. We believe the role of regulation should be to prevent harm and stimulate innovation towards metrics of quality and safety outcomes. This is an immature discipline that is evolving rapidly through very disparate methods of innovation. To prescribe at this point anything about *how* the safety and quality initiatives are achieved would unintentionally stifle real innovation. We recommend the alternative of providing metrics, setting goals using those metrics, and letting the industry and the technology market innovate freely to achieve those targets and metrics.
We appreciate your willingness to consider our comments. Please feel free to contact me at 510-271-6432 (email: jed.weissberg@kp.org) with any questions or concerns.

Names

Berkey, Ann Richardson

Comment ID

60

Organization

McKesson Corporation

Org Typ1	Org type	Categories
6	6. Vendor (individual)	2. Vendor Engagement (CoC, etc)

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

Names

Sinksky, Thomas

Comment ID

6

Organization

Medical Associates Clinic and Health Plans

Org Typ1	Org type	Categories
2	2. Provider (professional), 4. Clinician Pr	2. Vendor Engagement (CoC, etc), 4. ACB

1 Reporting

2 Vendor Engagement (CoC, etc)

• How can vendors be monitored for quick and effective changes to address safety hazards? It would be helpful to develop metrics for “time elapsed from report of safety hazard to response to reporters ” and “time elapsed from report of hazard to definitive correction of the problem”.
• The capacity for rapid improvement should be publicly reported. How nimble is the system in responding to hazards or necessary modifications as the environment changes? For example how much time is required to install a registry? How easy is it to incorporate data from other systems (e.g. integrating data from EPIC into a Cerner system)?

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

• How can vendors be monitored for quick and effective changes to address safety hazards? It would be helpful to develop metrics for “time elapsed from report of safety hazard to response to reporters ” and “time elapsed from report of hazard to definitive correction of the problem”.
• The capacity for rapid improvement should be publicly reported. How nimble is the system in responding to hazards or necessary modifications as the environment changes? For example how much time is required to install a registry? How easy is it to incorporate data from other systems (e.g. integrating data from EPIC into a Cerner system)?

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

Names

Sinski, Christine

Comment ID

5

Organization

Medical Associates Clinic and Health Plans

Org Typ1	Org type	Categories
2	2. Provider (professional)	1. Reporting, 10. Testing, User Tools, best practices

1 Reporting

• Would the EHR hazards I encounter daily (see ppt) be uncovered by the steps in this plan? Without robust usability testing and reporting I • The Plan seems highly dependent on adverse event reporting, which misses the overwhelming majority of safety hazards. The most frequent, and most important hazards with HIT relate to user distraction. The information is poorly displayed or the navigational pathway to accomplish a task is unnecessarily time-consuming and complex, so the clinician misses doing something else important. None such hazard would make it into a Common Format report.
• How will the action plan lead to EHR vendors changing their medication displays to be simple, uncluttered, organized and clear? How will it cause vendors to create order entry pathways that can be accomplished on one screen with a minimum of clicks, rather than requiring two minutes, 3 screens and 4 drop down boxes to complete a single order?
• I fear unintended consequences—greater burdens placed on the end user. More security gates to pass through, more hurdles to overcome to do a simple task. For an analogous situation, where well intended end user monitoring and responsibility had an unanticipated negative effect, consider the impact of regulation on falls (see http://jama.jamanetwork.com/article.aspx?articleid=1487508#qundefined .)

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

• Would the EHR hazards I encounter daily (see ppt) be uncovered by the steps in this plan? Without robust usability testing and reporting I don't think these hazards would be uncovered and addressed. Please help me understand if I am wrong. If McKesson HAC and Cerner have already passed existing usability testing, then such testing is not sufficient to detect these problems.

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

Names

Eaton, Richard

Comment ID

50

Organization

Medical Imaging & Technology Alliance (MITA)

Org Typ1	Org type	Categories
9	9. Allied Professional Organization	1. Reporting, 12. Investigate & Corrective Action, 17. Private Sect

1 Reporting

• The federal government should not engraft new processes and requirements for reporting HIT patient safety risks. (2)
• MITA does not support the expansion of ONC regulations and certification processes to include automated safety reporting requirements in the design and implementation of EHR systems. (2)
• The ONC plan should increase its emphasis on the sociotechnical nature of health IT systems, and the need to collect data on all parts of the sociotechnical system when identifying and reporting health-IT associated events. (4)
• MITA recognizes the need for standardized reporting and supports the consideration of the use of HER technology to facilitate reporting of safety events in AHRQ's Common Formats, but only after careful analysis of appropriate workflows at the clinician and healthcare organizational level. (5)
• ONC should explore how HER or other health IT technology can be used to facilitate reporting of safety events and risks. (5)
Maintain adverse event reporting in the context of existing state and provider programs and ensure they are further harmonized as part of the regulatory framework being established across the various federal agencies. (5)

2 Vendor Engagement (CoC, etc)

• The *HIT Safety Plan* should specify multi-stakeholder reviews and comment periods for all guidance documents created which are related to Health IT. (3)
• MITA supports ONC's desire to engage IT developers in patient safety. (6)
• MITA believes voluntary codes should be developed and maintained by industry stakeholders that ensure open competition and leverage market-driven forces to ensure compliance. (6)
• Specific areas identified by ONC should be implemented, such as having in place organizational policies and practices for safe design. (6)
• Software developers should utilize appropriate usability standards and processes. (7)
• Developer reporting of events to PSOs should be voluntary and contingent on regulatory or legislative protections equivalent to those available to providers. (7)
• ONC should recognize the critical importance of direct provider reporting to their HIT vendor as well as consulting with their HIT vendor when conducting root cause investigations (7).
ONC should actively solicit health IT developer involvement in health IT safety guides, Safety Assurance Factors for EHR Resilience (SAFER) Guides development process prior to their publication.(12)

3 PSO

• MITA supports establishing a baseline data for use in policy making and system improvement, and for reporting, data aggregation and analysis. (5)
• Health IT-related reports should be aggregated by a central existing organization to avoid duplication of event reports. (5)
• Clarify the basis for HHS' belief that the risks of reporting to PSOs without legal protections can be mitigated. (7)
• MITA agrees that it would be useful for HIT developers to voluntarily with PSOs and agree that PSOs could play a positive role in the HIT safety area. The voluntary provider reporting to PSOs on safety issues should be the primary focus for reporting to PSOs. (7)
• We agree with ONC's plan for support by ONC and AHRQ for PSO efforts in this area, including data aggregation and analysis. IT is essential as part of the non-punitive learning environment to increase the accuracy of safety data, and to increase the accuracy of safety data, by addressing the potential negative impact of the collection of incomplete or

misleading data, that aggregated reports should be de-identified by provider, developer, and specific product, and focus on trends and patterns. (7)

- MITA encourages voluntary industry accreditation of PSOs regarding health IT events. (7)

ONC should develop and make publically available a plan to ensure that PSOs possess the required skills, knowledge, and ability to analyze health IT-related events. (12)

4 ACB

- MITA does not support the proposed expansion of the ACB role into patient safety evaluation and enforcement and the creation of duplicative federal agency processes for surveillance and corrective action. (2)

5 CMS

- Reflect the text in Figure 3: CMS with the text of the *HIT Safety Plan,* specify the importance of developers working with providers when a CMS plan of correction is related to health IT product deficiency. (8)

The AHRQ Common Format for "Device including Health IT" should be expanded to capture relevant information needed for its intended role in this plan, including data on ambulatory HIT uses. (9)

6 QSRS

7 MAUDE

While MITA does not have concerns with ONC monitoring the MAUDE database, MITA opposes ONC creating any expectation that non-FDA regulated products should be reported in the MAUDE database. MITA also strongly opposes HHS creating duplicative reporting requirements and processes. Reporting requirements should be harmonized as part of the regulatory framework which will be established across various federal agencies. (9)

8 MU

MITA supports the approach used by CMS and ONC to prioritize for meaningful use capabilities for which patient safety improvement is a critical feature, such as CPOE and medication and allergy lists. MITA, however, believes that it is premature to add a safety risk assessment to Stage 3 Meaningful Use requirements. (9)

9 Cer

- MITA does not support the expansion of ONC regulations and certification processes to include automated safety reporting requirements in the design and implementation of EHR systems. (2)
- MITA strongly opposes the establishment of codes of conduct dictated by federal agencies and opposes such codes being subject to the HER certification process. (2)
- MITA strongly opposes the increase in regulatory burden from ONC by expanding certification criteria from general capability to highly granular functional requirements. MITA members have robust quality processes around safety-related issues, including quality management systems and usability. MITA believe other HIT companies should also implement such approaches if they have not already done so. At the same time, MITA does not believe that ONC should use the certification process to mandate such processes. MITA believes that while QMS should be applied across the full lifecycle of HIT products (design, development, implementation, post-implementation, customization, operation, and maintenance). MITA believes being overly prescriptive in process area such as usability and quality management systems could impede technical innovation. MITA recommends usage of IEC 62366, *Application of Usability Engineering to Medical Devices,* during product design and development of medical devices.
    - Specifically, MITA makes the following recommendations
        - MITA supports research and development of testing, user tools, and best practices to health IT safety and its safe use.
        - MITA supports the focus on accurate patient matching. MITA does not support, as discussed in the previous point, the increased focus on safety issues in product certification.
        - MITA supports conducting investigations and taking corrective action, when necessary, to address serious adverse events or unsafe conditions involving EHR technology, but only under formally adopted and transparent processes adopted through notice and comment after broad stakeholder input.
        - MITA recognizes the importance of and supports potential government action related to serious adverse events or unsafe conditions involving EHR technology.

Where standards are needed, ONC should use consensus-based standards as required in the National Technology Transfer and Advancement Act to increase agencies' reliance upon and participation in voluntary consensus standards and conformity

assessment systems. (10)

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

• MITA supports ONC's plan to lead a public-private process to identify health IT safety priorities and believes this process will be a useful tool in reducing health IT-related adverse events. (10)
• MITA supports ONC's plan to publish a report on a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT. MITA believes it is a critical interim implementation step for the FDA Safety and Innovation Act of 2012. MITA supports ONC's active participation with the FDA and FCC in the development of the 18 month study of a risk-based regulatory framework. MITA is pleased that this study will include stakeholder input. (11)
• MITA strongly urges ONC to recognize that it's ONC Safety Program is an interim plan relative to the complete strategy to be developed by HHS based on the 18 month study required by the FDA Safety and Innovation Act. MITA suggests that federal efforts should avoid any duplicative processes or requirements. (11)

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

MITA supports ONC's plan to lead a public-private process to identify health IT safety priorities and believes this process will be a useful tool in reducing health IT-related adverse events. (10)

18 Other

Introduction

• The ONC plan has an inconsistent use of terminology and should clarify and define terms (e.g. health IT, EHR, health information exchange, adverse event, unsafe condition). (4)
• We recommend ONC take into account:
    • Recognize that "health IT' includes many components of IT systems (LIS< RIS, EHR, HIE, etc). (4)
    • Health IT can facilitate improvements in healthcare quality but cannot ensure improvements without support from key stakeholders. (4)
    • Note that (CDS) and Computerized Physician Order Entry (CPOE) are example of capabilities that can be incorporated into electronic health records and are available in other IT solutions. (4)
• Safety will improve if it is Ensured that use of EHRs to provide insights into patient safety consider intra-organizational workflows and reporting processes from multiple EHR. (5)
• MITA opposes ONC dictating a single approach to the use of EHRS to facilitate internal and external reporting without consider alternative HIT reporting environments. (5)
• Text changes should align with the Institute of Medicine and the basis of health IT as follows:
    • Change from "By using health IT to promote effective reporting and follow-up, health IT can make patient care safer overall, as well as identify and improve patient safety issues related to health IT itself" TO "By using health IT to promote effective reporting and follow-up, health IT can contribute to safer patient care overall, as well as potentially identify and improve patient safety issues related to health IT itself."
    • Change from: "Insomuch as health IT may be one cause of medication error, the hospital's incident reporting system should be able to identify the error and its potential causes." TO "Insomuch as health IT may be one contributing factor to a medication error, the hospital's incident reporting system should be able to identify the error and its potential contributing factors." (8)

Names

Bechtel, Christine

Comment ID

69

Organization

National Partnership for Women & Families

Org Typ1	Org type	Categories
12	12.. Other	1. Reporting, 11. Edu, 12. Investigate & Corrective Action, 15. O

1 Reporting

- We strongly support national reporting systems to facilitate data collection regarding safety issues related to the technical functioning of electronic products on the market, and support aligning the Action Plan with existing reporting structures whenever appropriate and feasible.

Meaningful use of health IT to improve the care and safety of all patients must ensure methods are in place to rapidly report and address any technical issues.

2 Vendor Engagement (CoC, etc)

3 PSO

RECOMMENDATION: ONC should work with AHRQ to develop and add a question(s) to the Consumer Reporting System for Patient Safety Events regarding errors or harm caused by malfunctioning health IT products.

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

Meaningful use of health IT to improve the care and safety of all patients must ensure methods are in place to rapidly report and address any technical issues.

9 Cer

10 Testing, User Tools, best practices

11 Edu

RECOMMENDATION: ONC should compile best practices and develop educational resources to help patients and families to better identify safe and unsafe practices related to health IT.

12 Investigate Corrective Action

- We also support an approach that includes corrective action for serious adverse events.

Meaningful use of health IT to improve the care and safety of all patients must ensure methods are in place to rapidly report and address any technical issues.

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

RECOMMENDATION: ONC should create a position for patient and family representation on the ad hoc steering committee that will oversee the ONC Safety Program, to provide the consumer perspective on how best to identify and address health IT safety issues.

16 State Governments

17 Private Sector Leadership

18 Other

- While we are largely supportive of ONC's recommendations, specific action steps that **leverage the critical role of patients and their families** in developing and sustaining a culture of safety are conspicuously absent. Efforts to learn about the impact of health IT on safety must incorporate information from the patient and caregiver perspective. Consumers have vital information to contribute, both in terms of how to use health IT to improve safety, and in the effort to identify and report safety issues arising from the use of health IT. We encourage you to refine the Action Plan to recognize patients and families as sources of valuable information and powerful forces for change in identifying and preventing errors, as recommended by the IOM.

Involving consumers in the design of patient-facing technologies would likely enhance safety from a usability perspective, and could also identify design flaws that may ultimately lead to safety problems. Given the vantage point of patients and their family caregivers as the only constants in the care continuum, they are in a unique position to identify breakdowns in care that may contribute to adverse events.

Names

Sengstack, Patty DNP, RN-BC, CPHIMS

Comment ID

28

Organization

NIH

Org Typ1	Org type	Categories
1	1 Provider (institution)	1. Reporting, 10. Testing, User Tools, best practices, 13. Priority a

1 Reporting

- Page 5 - Just a comment. The second paragraph mentions the fact that the vast majority of reported EHR related events involved medication errors. I'm sure you probably know this is the tip of the iceberg (as they say). Voluntarily reported events or errors poorly represent reality. This will be a challenge – 1) the discovery of events that are HIT related, and 2) getting someone to take the time to report it.
- FYI – At the NIH Clinical Center, we have embedded what we call a Suggestion Box into our EHR. There is an icon at the top of the main toolbar in our system that users can click on and then enter their suggestion for system improvement. We give them categories to choose from such as "orders, order sets, clinical documentation, results, etc) but it's essentially a free text box and very simple to use. Because it's available 24/7, and right at their fingertips, we receive a significant number of ideas. The suggestions that are patient safety related are invaluable to us and we are currently conducting a study to look at this as a tool for reporting patient safety issues on a more formal basis. If anyone would like to see it or give us any advice for our research, just give me a call.
- Page 9 – Make it easier for clinicians to report patient safety events. I really do think that all vendor systems should have an easy to use feedback button or suggestion box to enter potential safety errors or ideas for system improvement. One of the first suggestions we received was the fact that we had configured systolic and diastolic blood pressures backwards in our trend view –oops! Thanks to an alert user and our suggestion box, we fixed it asap! I'd like to investigate enhancing our suggestion box mentioned earlier with some of the standard error reporting nomenclature being developed by AHRQ.

2 Vendor Engagement (CoC, etc)

1. Page 11 – Engage health IT developers to embrace their shared responsibilities. I'm assuming you mean the EHR vendors? It was a little confusing when reading this at first since in our IT department at NIH we have several "developers" who are responsible for the configuration of our system. I guess it's just semantics, but don't most people refer to the "developers" that work at the vendor agency as just the "vendor"?
2. Page 11 – First paragraph refers to the Electronic Health Record Association's (EHRA) Statement of Commitment to Patient Safety and Learning Healthcare System - and states it is a first step in ensuring that developers embrace a share responsibility. Could you add another sentence to clarify what this statement is and its overall purpose?
3. Page 12 – Would you consider adding the American Nursing Informatics Association (ANIA) as one of the professional forums to participate in HIT safety interest groups? There are now several doctorally prepared nurses serving on the board of directors (PhD and DNP) who are interested in advancing ANIA's research mission and improve patient safety.

3 PSO

4 ACB

5 CMS

1. Page 13 – Objective 5, Align CMS health and safety standards with the safety of health IT, and train surveyors. These surveyors are going to need tools to assess organizational systems for safety features. I realize that tools are being developed, but please allow me to add a couple of checklists that may be helpful. These are part of my doctoral work at Vanderbilt University and include:
    1. Recommendations for CPOE design to reduce errors (attached – from JHIM 2010)
    2. The Picklist Checklist (in press JHIM winter 2013)

6 QSRS

7 MAUDE

8 MU

9 Cer

1. Page 17 – Objective #2. Incorporate safety into certification criteria for health IT products. Could you clarify the "eight" certification criteria. This objective seems a bit too high level. It mentions adding criteria such as CPOE with medication and allergy lists. While CDS components would be included also, such as drug-drug, allergy, duplicate drug ordering - none of these work well unless they are configured well. While "configured well" is still somewhat elusive, there are some guidelines that need to be included. (Refer to article on CPOE design recommendations☺).

10 Testing, User Tools, best practices

1. Page 13 – Objective 5, Align CMS health and safety standards with the safety of health IT, and train surveyors. These surveyors are going to need tools to assess organizational systems for safety features. I realize that tools are being developed, but please allow me to add a couple of checklists that may be helpful. These are part of my doctoral work at Vanderbilt University and include:
    1. Recommendations for CPOE design to reduce errors (attached – from JHIM 2010)
    2. The Picklist Checklist (in press JHIM winter 2013)

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

1. Recommendation 10 – FYI – at the NIH Clinical Center we have just finished the data collection and analysis for a 6 month study looking at the potential for errors resulting from the use of the EHR's copy forward feature. We looked at over 6,000 patient assessments documented over a 6 month time frame that were 100% duplicates, assuming use of the copy forward feature. The 6,000 duplicates represented 1,500 unique instances of notes. We randomly selected 450 of these cases and reviewed each one for its potential to cause patient harm. We used a scale from a previous study with a few modifications and we hope to publish our findings soon. Feel free to contact me if you would like more information about this.

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

1. Page 3 – Introduction. Consider adding a bullet point to the three already listed that captures the importance of having a patient's medical record that is legible. Errors made due to illegible handwriting are a thing of the past with an EHR. An accurate quantification of the lives saved and errors prevented by eliminating illegible handwriting would be staggering – in a good way! Something like:
    1. Prescription errors due to illegible penmanship are eliminated. Patient's clinical progress notes that are typed into an electronic record cannot be misread or misinterpreted due to poor handwriting.

2. Page 7 – The two main objectives. These are great! I like that they differentiate between 1) releasing the power of technology to improve patient care and reduce errors and 2) Ensuring that the systems we implement are not the cause of patient care errors. I do think however that the distinction between the two could be a bit clearer, especially for those not as intimately involved in working with these systems. When reading them for the first time, I wasn't exactly clear of the difference between the two.
3. Page 8 – Might want to add another example of a CDS alert other than the typical allergy, drug-drug interactions. When inaccurate data is entered into an EHR, the downstream impact can lead to many of those unintended adverse consequences. For example, the entry of inaccurate heights and weights in the system can result in an incorrect medication dose calculation. The Healthcare Information Technology and Safety Corner of the 4th Quarter ANIA Newsletter contains an example of how this alert can help (attached).
4. Overall – very impressive and a great job at addressing the IOM report! I do wonder if your timeline is a bit too aggressive. The long list of "to do's" for 2013 seems quite daunting and I wonder if there is any chance you may want to consider a bit longer timeline. I also didn't see any mention of resources to conduct this important work. Do you have them?

Names

Walmsley, Bethany A., CPHQ, CPPS

Comment ID

42

Organization

Oregon Patient Safety Commission

Org Typ1	Org type	Categories
13	13.. Safety Organization	1. Reporting

1 Reporting

• The Oregon Patient Safety Commission is strongly committed to HIT implementation. Setting goals for HIT with regard to patient safety is necessary and prudent. Even before this report was issued, the Commission has worked hard to invest in Oregon's Patient Safety Reporting Program. When possible, we've aligned with AHRQ common formats with the hope of future standardization across the nation for patient safety measures. To date, we too have experienced the challenges associated with clearly determining the causal relationship of HIT to the adverse event reported. As mentioned on page 5 of the plan, patient harm attributed to HIT, could be attributed to the lack of use and capturing the data necessary for understanding this further has been problematic. We also know from personal experience the challenges associated with incorporating the actual clinical workflows into the HIT system in a responsible way and how essential that is to a successful HIT program to best support patient safety and reliability.

• Due to the investments we've made in Oregon's Patient Safety Reporting Program, we are quite certain that our progress here in Oregon will be viewed as progressive and already very much in alignment with the goals outlined in the plan. With Pennsylvania as perhaps the only true exception, very few states have the robustness of our program. We have the only pharmacy reporting program that I am aware of for reporting adverse events. Please note that on page 22, Oregon is also the only voluntary reporting program of this kind, yet our reporting volumes compare commendably with other mandatory reporting programs. When you consider all of this is achieved with a fee based structure that puts limitations on our funding support for the program, we are proud that our program is still one of the few across the nation that begins to capture this information in multiple healthcare settings. (Pharmacy, ASC, Nursing Homes, Hospitals)

In closing, we applaud the efforts outlines in the plan and we fully endorse the direction outlined by the goals, objectives, and strategies suggested.

2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

Names

Goldman, Julian M.

Comment ID

11

Organization

Partners HealthCare Biomedical Engineering, Massachusetts General Hospital Medical Director

Org Typ1	Org type	Categories
1	1 Provider (institution)	7. MAUDE

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE

• With regard to the statement in the Fact Sheet "Manufacturer and User Facility Device Experience: ONC will monitor health IT adverse event reports to the FDA's MAUDE database": Given that HIT systems are not being treated as medical devices it seems unlikely that the MAUDE database will adequately reflect adverse events related to HIT product performance. Furthermore, the Plan documents potential contractual barriers to the free exchange of pertinent safety information. Inability to responsibly share information can undermine the development of a culture of safety.

8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

Names

Doering, Michael

Comment ID

94

Organization

Pennsylvania Patient Safety Authority (PSA)

Org Typ1	Org type	Categories
13	13.. Safety Organization	1. Reporting, 15. ONC Safety Program, 2. Vendor Engagement (C

1 Reporting

We would point out only that it isn't necessary for reporting to be voluntary for it to be confidential and non-punitive. Our reporting program is mandatory, and we receive over 220,000 reports a year. The vast majority of these are near misses-events that for the most part are not reflected in the medical record and may not even be observable by anyone other than the healthcare workers involved. Thus, most of our reporting cannot be compelled or policed.

- What is important is that reporting program earn the trust of those submitting data. This trust is earned by making it confidential and non-punitive, and also by producing actionable information from the analysis of reports. Clinicians will report if they find it useful to do so.

If ONC plans to establish formal partnerships with organizations like ours which are collecting data on safety of HIT, we would be placed to discuss how we could help "move the needle" in this important area.

2 Vendor Engagement (CoC, etc)

The expectations for how vendors interact with reporting programs is not explicit. IT will also be important to address the flow of information from clinicians through their institute. Reporting will be of limited usefulness if they reflect only the clinician's understanding of the event. One would also want to benefit from the perspective of local experts in patient safety and risk management, IT, informatics, and clinician workflow.

3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program

Support ONC's intent to rely on existing organizations working in patient safety rather than creating a silo ofr pt safety concerns about HIT.

16 State Governments
17 Private Sector Leadership
18 Other

Names

Rising, Josh

Comment ID

56

Organization

Pew Charitable Trusts, American College of Cardiology, Consumers Union, the National Women's Healt

Org Typ1	Org type	Categories
12	12.. Other	1. Reporting, 18. Other, 7. MAUDE

1 Reporting

When the UDI system is implemented by manufacturers and fully taken up by the healthcare system, it has the potential to improve safety in a number of ways:
2) Improved adverse event reporting. Adverse event reports are an important way to bring devices with potential safety problems to the FDA's attention. Unfortunately, it can be difficult for the FDA to utilize these reports because they often lack specificity about which device was associated with the adverse event. The presence of the UDI on medical devices and their labels will go far in addressing this problem.

2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE

When the UDI system is implemented by manufacturers and fully taken up by the healthcare system, it has the potential to improve safety in a number of ways:
3) *Identification of medical devices with safety problems through active surveillance*. The presence of a UDI in electronic

health records and other forms of electronic data, such as medical claims, will facilitate robust postmarketing surveillance efforts, such as registries and FDA's Sentinel system. The FDA, clinicians, patients and manufacturers can use the information generated in postmarketing surveillance initiatives to identify devices with safety problems and take appropriate action.

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

When the UDI system is implemented by manufacturers and fully taken up by the healthcare system, it has the potential to improve safety in a number of ways:
1) *Facilitation of recalls of medical devices*. Currently, it can be difficult for manufacturers and healthcare facilities to identify patients with an implanted medical device that has been recalled or to locate unused recalled devices. Incorporation of the UDI into the electronic health record and electronic inventory management systems will result in more rapid and precise identification of recalled products, resulting in safety improvements. In addition, the UDI would allow the FDA to include more specificity in public safety alerts about the particular device that is the subject to the recall.

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

We appreciate the importance of the two patient safety objectives laid out in the document: 1) Use Health IT to make care safer, and 2) Continuously improve the safety of Health IT. Unfortunately, the plan does not outline specific strategies and actions that the government intends to take for the first of these objectives. **We urge the Office of the National Coordinator for Health Information Technology (ONC) to expand the next version of the plan to include strategies and actions to use Health IT to make care safer**.

- **In particular, we believe that the ONC should address the potential for the unique device identification (UDI) system for medical devices to improve the safety of medical care**. The FDA has issued a proposed rule that would require manufacturers of medical devices, with certain exceptions, to place a unique identifier on the label of medical devices. Some medical devices would also need to be directly marked with the unique identifier.

When the UDI system is implemented by manufacturers and fully taken up by the healthcare system, it has the potential to improve safety in a number of ways:
1) *Facilitation of recalls of medical devices*. Currently, it can be difficult for manufacturers and healthcare facilities to identify patients with an implanted medical device that has been recalled or to locate unused recalled devices. Incorporation of the UDI into the electronic health record and electronic inventory management systems will result in more rapid and precise identification of recalled products, resulting in safety improvements. In addition, the UDI would allow the FDA to include more specificity in public safety alerts about the particular device that is the subject to the recall.

2) Improved adverse event reporting. Adverse event reports are an important way to bring devices with potential safety problems to the FDA's attention. Unfortunately, it can be difficult for the FDA to utilize these reports because they often lack specificity about which device was associated with the adverse event. The presence of the UDI on medical devices and their labels will go far in addressing this problem.

3) *Identification of medical devices with safety problems through active surveillance*. The presence of a UDI in electronic health records and other forms of electronic data, such as medical claims, will facilitate robust postmarketing surveillance efforts, such as registries and FDA's Sentinel system. The FDA, clinicians, patients and manufacturers can use the information generated in postmarketing surveillance initiatives to identify devices with safety problems and take appropriate action.

We encourage the Department to facilitate adoption of the UDI throughout the healthcare system by: 1) including a UDI field as a certification standard for electronic health records, and 2) establishing a new Stage 3 meaningful use core objective to incorporate the UDI into electronic health records for patients whose care involves an implanted medical device.

Names

Spiro, Shelly

Comment ID

74

Organization

Pharmacy e-Health Information Technology Collaborative

Org Typ1	Org type	Categories
9	9. Allied Professional Organization	12. Investigate & Corrective Action, 18. Other, 2. Vendor Engage

1 Reporting

2 Vendor Engagement (CoC, etc)

We recommend ONC work with the Pharmacy e-HIT Collaborative as one of the organizations listed to make more HIT – related safety information available. The Collaborative was formed in September 2010 by nine pharmacy professional associations, representing over 250,000 members, to ensure that pharmacist-provided patient care services are integrated into the National HIT interoperable framework. The Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's associate members represent e-prescribing networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors, and other organizations that support pharmacists' services.

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

We recommend that the Collaborative be included in discussions concerning ways to improve documentation and to ensure consistency in standards that may be used for the completeness, accuracy, accessibility, security, and safe usage of these records.

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

As noted throughout our comments, the Pharmacy e-HIT Collaborative is an excellent resource and can help HHS in this regard. Again, we strongly encourage ONC to include the Collaborative in discussions with regard to investigative, corrective actions, and reporting on analyses of adverse events involving EHR technology.

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

• The Pharmacy e-HIT Collaborative is supportive of the safety and surveillance plan and the plans' goals to improve the safety of health information technology (HIT) through safely designed and implemented systems.
Including pharmacists in CMS' program would remove a barrier to ensuring a fully, integrated health care team approach with the incentive program and increase a more standardized adoption of EHR technology.

Names

Fifield, Lauren

Comment ID

22

Organization

Practice Fusion, Inc.

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 14. Publish Report on strategy and recommendation

1 Reporting

• Practice Fusion supports reporting to Patient Safety Organizations (PSOs), but encourages the ONC to consider additional survey methods facilitated by health IT that may, at least in the short-term, encourage ambulatory provider participation and not require significant infrastructure.
• Supports Developing the concept and then building a nationwide, non-punitive safety data reporting, analysis, and learning system
• Leveraging enhanced versions of the AHRQ Common Formats that will incorporate health IT-related data sets into existing reporting processes, and aggregation and analysis processes for both inpatient and ambulatory setting

2 Vendor Engagement (CoC, etc)

• Disagrees w/ ONC potentially dictating both the elements and enforcement of an industry code of conduct that would diminish the value and operation of such a code, which should operate in a truly voluntary and effective manner by virtue of being organizationally grounded in the industry and its organizations

3 PSO

• Supports Leveraging the Patient Safety Act and the Patient Safety Organizations created under that Act
• Supports Leveraging enhanced versions of the AHRQ Common Formats that will incorporate health IT-related data sets into existing reporting processes, and aggregation and analysis processes for both inpatient and ambulatory settings

4 ACB

•• Disagrees with Expanding the ONC Authorized Certification Bodies' (ACBs') role into patient safety evaluation and enforcement, which is not within their core competencies

5 CMS

• Supports Providing coordination of patient safety monitoring programs across diverse industry programs, e.g., the Center for Medicaid and Medicare Services (CMS) Conditions of Participation, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and others
• Disagrees with "Using the ONC and CMS meaningful use regulations and certification to embed intrusive requirements into EHR design that are not the product of the learning system as envisioned by the Plan.,

6 QSRS

7 MAUDE

8 MU

• While we endeavor to support our providers in their achievement of patient safety compliance, reporting, and improvement, the adoption of patient safety practices and the expansion of patient safety culture in the outpatient setting are necessary before burdensome and highly technical requirements are imposed on the provider community. Technology, of course, can play a key role in making this transition easier.

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

Supports Providing for participation of patient safety stakeholders (certainly including EHR developers) in the dialogue for development of the 18-month study on a risk-based regulatory framework as authorized by the FDA Safety and Innovation Act of 2012 (FDASIA)"

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

• The role of government in the domain of health IT and healthcare is rapidly evolving. In order to foster innovation in health IT and allow market forces to self-select for products that confer better patient safety, the government should avoid narrow or over-reaching mandates. The government can play a pivotal role in convening a broad set of stakeholders; conducting research and facilitating a learning health system; and raising awareness in the healthcare community that leads to selection of quality technology that improves patient safety.
• Supports "Instilling awareness that patient safety is everyone's responsibility

18 Other

• Supports In this comment-making, we (1) provide tangible evidence of the potential of health IT
• Supports Ensuring that health IT-related patient safety is approached as a seamless component within the overall patient safety ecosystem, rather than a stand-alone system
• Disagrees w/ Equating usability with patient safety. While some usability issues can contribute to safety, in general we do not agree that comparing users' experiences can determine safety among EHRs. We suggest that it is more appropriate to implement usability evaluation processes such as reporting, analyzing and learning to determine the impacts of health IT on

patient safety, before devising a regulatory framework".
• With the widespread adoption and use of web-based technology in healthcare, it is important that this type of technology is well-understood and that differences between the various models of technology are considered. For example, Practice Fusion provides one instance of its EHR technology to all its users through a web-based platform. If future plans from the ONC or other government entities prescribe or recommend best practices oriented around local servers settings, highly customized implementations, or versioning control it may be difficult for the provider and patient communities to trust web-based technology or understand how to utilize it.

Names

Livaudais, Gerard

Comment ID

13

Organization

Quantros

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 14. Publish Report on strategy and recommendation

1 Reporting

• I further have concerns that the common format may be missing opportunities to capture useful detail about Health IT related safety events (there are only 2 levels of process detail included in this event type: 1.2.1.1 Device defect or failure, including HIT; 1.2.1.2 Use error; 1.2.1.3 Combination or interaction of device defect or failure and use error-
• The movement toward automated surveillance for unsafe conditions (or hazards) should include acknowledging the need for analytics to triage harm potential. The volume of near miss, unsafe conditions poses huge challenges (e.g. in deciding what kind of response is possible/merited, what level of risk is exposed and even created as a result of new awareness, how to ensure this volume/level of awareness doesn't adversely impact a culture of safety).

2 Vendor Engagement (CoC, etc)

• I fully endorse the use of PSO/PSWP to encourage proactive surveillance, analysis and investigation of worrisome trends but don't believe this protection should extend to flawed design that puts patients at risk.
• Strongly support intervention to protect the complainant against IP or gag clause. The last statement in this bullet point should be amplified with specific protections of the provider surfacing an HIT patient safety issue.
• While I agree with the concept of a "shared responsibility" for patient safety as related to Health IT, I believe EHR vendors have a specific accountability for safe design. I fully endorse the use of PSO/PSWP to encourage proactive surveillance, analysis and investigation of worrisome trends but don't believe this protection should extend to flawed design that puts patients at risk. By analogy, providers remain accountable for the direct care they provide; this is their "core process". The EHR vendor's core process is the design and construction of EHR software, and like providers, they should be accountable for a safe design, one that doesn't introduce new safety risks into the care delivery process. Perhaps EHR vendors should be required to maintain publically visible/accountable service level agreements for safety (X days to correct a P1 safety risk). This dovetails with the CoP surveyors' work and ONC-ACB surveillance.

3 PSO

4 ACB

5 CMS

• Strongly support the idea of a Health IT risk assessment as a Condition of Participation. I would expect this to be a specific standard along with those requiring maintaining an safety incident reporting and remediation, and complaint management systems. However, this further emphasizes the provider's accountability to use the EHR properly and investigate mistakes – but does not enforce the EHR vendor's accountability.
• Related to [the above bullet], I appreciate the certification requirements but so much is changed in configuration and implementation that I'd also like to see ongoing accountability on the part of the EHR vendor after certification. This might be included in the CoP surveyor's review but accountability would remain with the EHR vendor.

6 QSRS

7 MAUDE

The connection with MAUDE and MEDSUN should be explored and described more fully.

8 MU

9 Cer

• I appreciate the certification requirements but so much is changed in configuration and implementation that I'd also like to see ongoing accountability on the part of the EHR vendor after certification. This might be included in the CoP surveyor's review but accountability would remain with the EHR vendor.

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

• Happy to see ONC remain the central player in this area instead of FDA.
• Although I am advocating for some specific regulatory oversight of EHR vendors, I see it as evening up the accountability with providers for Health IT safety. I fear FDA oversight might result in over-regulated environment; I hope we can avoid stifling creativity and entrepreneurship. Hence I agree with extending PSO/PSWP for surveillance, analysis and investigation, but gross design flaws or failure in timely response to "P1" or serious safety risks should not be protected.

15 ONC Safety Program

• Wonderful to see the alignment emerge starting in this section between PSO/PSWP, Common Format/Reporting, CoP Survey work, ONC certification and Meaningful Use criteria.

16 State Governments

• Agree with suggesting those states with mandatory reporting include an HIT safety event type (~NQF SRE with severe harm or death).

17 Private Sector Leadership

18 Other

• Goal: Appreciate the ambition in seeking to "Inspire confidence and trust in Health IT" but would accept "Improve confidence".
• Goal: Disappointed that the report incidence of HIT related events wasn't controlled for facilities that had a fully implemented EHR. Going a bit farther with this, there are many interesting variables to consider such as rate of reported errors in implementation and early use (e.g. during 1st 6 months), versus in more established use (during 2nd year of use). (others: open/completed chart notes by staff discipline, age; time/chart; copy paste prevalence; % completion of structured data elements, etcetera.
• Goal I think the 3rd paragraph on the difficulties of attributing specific errors to HIT is accurate but may not emphasize the critical and inherent role of HIT as a contributory factor. Conversely stated, EHRs can have a rather profound negative impact creating "information chaos"1.
• Objective: I think the two objectives are well placed but would think it appropriate to also specify accountability of EHR vendors for safe design as an objective.
• Objective: Consider modifying the statement about "Health IT creating infrastructure for identifying and monitoring patient safety events" to reflect the dependency on standards (e.g. SNOMED CT, LOINC, Rx Norm, et al to enable surveillance) and interoperability (e.g. to enable
• Objective: Enjoyed the examples of CDS and agree with its critical importance to realizing the potential safety benefit of Health IT. It would be nice to have an example of how CDS would involve the patient (beyond health maintenance reminders!).
• Objective: Great and important inclusion of "clinical workflow efficiency" – failure to attend to this has predictable contribution to work-arounds and unsafe conditions. Furthermore, wouldn't it be good to suggest that EHRs should be pointing out more efficient, safer and novel workflows as a result of new perspectives and insights (e.g., workflows that only become apparent at a population level)? This would be in contrast to detrimental workarounds born out of frustration with inefficiencies.surveillance/monitoring across care transitions, and at a population level).
• Please consider calling for a national Master Patient Index – anonymized would be fine (!).

• I definitely have a bias that a deep hierarchical taxonomy may have more utility in identifying trends and important details than a multidimensional hierarchy.

Names

Aller, Kathleen C.

Comment ID

71

Organization

Recommind, lnc.

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 15. ONC Safety Program, 18. Other, 2. Vendor Enga

1 Reporting

The adoption of the common AHRQ formats is positive. We do believe that the length of the forms and the number of entries required will limit usage by many caregivers, potentially leading to under-reporting. We also reviewed the entries to the Patient Safety Reporting Challenge intended to facilitate reporting using the common formats. All seem to envision internal approval structures within provider organizations to ensure appropriate reporting. Yet as pointed out in the IOM report, vested interests within provider organizations may discourage approval of reports, and hence contribute to underreporting.

2 Vendor Engagement (CoC, etc)

• We are disappointed by the relative lack of attention paid to the issue of vendor tiabitity. Recommind participated in one of the ONC listening sessions on this subject, and had been encouraged by the discussion at that event. Yet the text within the Plan states only an intention to: Ensure health IT developers work with a PSO,or a similar entity, to report, aggfegate, and analyze health IT-related safety events. Developers should collaborate and provide safety information related to their product for the purposes of impioving patient safety. Currently, the patient safety work product IPSWP) protectionsdo not Jxtend to developers reporting events to PSOs. However, HHS believes there may be ways developers can mitigate risks of reporting. HHS will monitor this and would consider suggestions on how to expand PSWP protections. (p' t1) Implementing the plan without first addressing the liability issues for IT developers will inhibit innovation and new entrants to the fieId. We believe it will also create a disincentive to whole-hearted participation by existing develoPers.

We encourage ONC to explicitly address the challenging issue of health IT safety issues created by flawed customer implementation decisions. Just as providers may be hampered from commenting on product design issues due to explicit or implicit contract provisions with 1T Developers, Developers have similar limitations around their customers. Confidentiality agreements often prohibit disclosing what is known about a customer implementation, and it is hardly politic to disclose that a given customer made poor implementation decisions against the advice of the Developer.

3 PSO

In general, the idea of using the existing PSO mechanism to address health IT safety issues is attractive, be we question whether sufficient health IT expertise exists within PSOs to support their proposed role, and whether such expertise will be adequately developed within the proposed framework.

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

We appreciate the commitment to addressing patient safety issues through existing agencies and processes. We do, however, have reservations about the number of different participants, mechanisms, and processes encompassed in the proposed plan. Not only does the result seem overly complex, but we believe it will be confusing to both the public and to the IT Developer community.

16 State Governments

17 Private Sector Leadership

18 Other

We encourage ONC to explicitly address the challenging issue of health IT safety issues created by flawed customer implementation decisions. Just as providers may be hampered from commenting on product design issues due to explicit or implicit contract provisions with 1T Developers, Developers have similar limitations around their customers. Confidentiality agreements often prohibit disclosing what is known about a customer implementation, and it is hardly politic to disclose that a given customer made poor implementation decisions against the advice of the Developer.

Names

Donia, Valerie

Comment ID

97

Organization

Siemens Healthcare

Org Typ1	Org type	Categories
6	6. Vendor (individual)	1. Reporting, 10. Testing, User Tools, best practices, 11. Edu, 12. I

1 Reporting

Maintain adverse event reporting in the context of state and provider programs as part of Health IT Regulatory Framework established across multiple federal agencies (p 8)

- Health IT related reports should be aggregated by a central existing organization to avoid duplicative reporting (p 8)

Maintain a separate adverse event reporting capability that may, among other inputs, use information from HIT to manage the adverse event reporting process (p 14)

2 Vendor Engagement (CoC, etc)

Opposed to the Code of Conduct described in the *HIT Safety Plan* (p 8)

- Do not agree that developer reporting to a PSO is possible in the current environment (p 8-9)
- A centralized PSO for health IT developers with appropriate legal protections would help establish a voluntary, confidential and non-punitive learning environment (p 9)
- Extend legal protection to developers who report to a centralized PSO (p 10)
- ONC should include software developers and other stakeholders in the future development of guidance documents to ensure a comprehensive and interdisciplinary approach (p 18)
- ONC should actively solicit health IT developer involvement in the SAFER Guides development process prior to publication (p 18)
- Request clarification on ONC's intent to work with developers to request voluntary correction action when HHS becomes aware of a potential serious safety risk. This duplicated work being done by developers to correct project deficiencies (p 19)
- Certified developers should make safety complaints available to the ONC-ACBs (independent third parties) (p 12)

Developers should submit health IT related safety events to a centralized health IT PSO once legal protections are granted under PSQIA (p 12)

3 PSO

Create one centralized PSO for all health IT related events, so developers can access their own product data and aggregated health IT data (p 10)

- Ensure that all PSOs meet certification requirements before de-identification and submission to NPSD (p 11)
- Extend legal protection to developers who report to a centralized PSO (p 10)
- Make all de-identified collected data and any interpretive methodology used in data analysis publically available (p 15)

Health-IT related reports should be aggregated by a central existing organization to avoid duplication of event reports, which could lead to incorrect data interpretation (p 8)

4 ACB

Use independent third parties for post market surveillance including complaint review rather than ONC-ACBs to reduce duplication across program and improve program efficiency (p 12)

- ONC should provide any specific validation criteria that would be used against a sample of EHR complaints for public comment (p 12)
- Clarify Figure 2: ONC-ACB, specifically related to reporting requirements of providers (p 12)
- Certified developers should make safety complaints available to the ONC-ACBs (independent third parties) (p 12)

Developers should submit health IT related safety events to a centralized health IT PSO once legal protections are granted under PSQIA (p 12)

5 CMS

Change text to align with IOM on the basis of health IT (p 14)

- Change FROM "By using health IT to promote effective reporting and follow-up, health IT can make patient care safer overall, as well as identify and improve patient safety issues related to health IT itself"

  TO: "By using health IT to promote effective reporting and follow-up, health IT can contribute to safer patient care overall, as well as potentially identify and improve patient safety issues related to health IT itself."
- Change from "Insomuch as health IT may be one cause of medication error, the hospital's incident reporting system should be able to identify the error and its potential causes."

  TO:

  "Insomuch as health IT may be one contributing factor to a medication error, the hospital's incident reporting system should be able to identify the error and its potential contributing factors.

- In Figure 3: CMS , note that developers will work with providers when a CMS plan of correction is related to a health IT product deficiency, and allow for stakeholder review and comment (p 14)
- CMS should provide guidance to state surveyors and accreditation organization with CMS-approved programs, so these entities can recognize and investigate health-IT related adverse events; however, these events must be analyzed in the context of the environments in which they occur (p18)

6 QSRS

Collect data on health IT safety events through the Quality & Safety Review System (QSRS)

We support AHRQ's aim to perform retrospective surveillance for adverse events, and to provide national estimates of adverse events using the Common Formats. We also support AHRQ's desire to explore the role of health IT in adverse events. However, the Medicare Patient Safety Monitoring System (MPSMS), as well as the Quality & Safety Review System (QSRS) under development, must be able to identify duplicate reports (i.e., a report submitted from the developer and healthcare facility and/or provider about the same event); failure to do so will lead to releasing inaccurate and misleading data to the public. Furthermore, as long as PSO reporting remains voluntary for healthcare facilities and providers, it is difficult to determine the true frequency of events that are reported using the Common Formats due to lack of denominator data. To minimize the risk of inaccurate data due to duplicate reports, a centralized health IT PSO should be created to collect all health IT reports. This centralized health IT PSO should provide appropriate legal protection for developers, in order to establish a confidential, non-punitive learning environment. Finally, it is important to acknowledge that when a focus is placed on reporting requirements, event reporting increases. Furthermore, if health IT facilitates event reporting as outlined in the *HIT Safety Plan*, the number of reports in systems that use health IT will be higher than those using paper records. Any interpretation of this data must take into account these well-known principles.

Recommendations:

- A centralized PSO should be created to reduce duplicative health IT reporting of adverse events (p 15)
- Amend PSQIA to extend appropriate legal protection to developers that report to a centralized health IT PSO (p 15)

ONC should make publically available all de-identified collected data as well as any interpretative methodology used in its data analysis (p 15)

7 MAUDE

Monitor health IT adverse event reports to the Manufacturer and User Facility Device Experience (MAUDE) database.

Certainly ONC may monitor the MAUDE database. However, health IT products which are not regulated currently by the FDA should not be reported to the MAUDE database. This would encourage duplicative reporting and is in conflict with the stated goal to eliminate or significantly reduce inefficiencies across programs (pg 21).

Recommendation:

- Reporting requirements should be harmonized as part of the Health IT Regulatory Framework being established across the various federal agencies.

8 MU

Instead of introducing new MU requirements, there should be an assessment, modification (if needed), and integration of current standards and requirements that promote safe, efficient, and effective care (p 16)

- ONC should utilize international standards as required in the National Technology Transfer and Advancement Act (1996), which requires federal agencies to increase their reliance on and participation in voluntary consensus standards and assessment systems (p 16)
- ONC should move away from the granular functionality requirements under Meaningful Use, and toward the adoption of known industry standards related to health IT (p 15)

ONC should analyze the information from developers under Meaningful Use Stage 2 to determine if gaps in investigations or corrective actions currently exist before developing duplicative requirements and/or systems under the *HIT Safety Plan* (p 19)

9 Cer

Strongly oppose increasing the regulatory burden from ONC by expanding certification criteria from general capability to granular functional requirements (p 16)

Strongly urge ONC to consider the benefits of operating under a third party certified QMS (p 2)

- A certified QMS be required across the full lifecycle of HIT products rather than market access requirements through granular product certification (p 17)
- Independent third parties provide post market surveillance, including complaint review, rather than using ONC-ACBs to reduce duplication across programs and improve efficiency and effectiveness (p 17)

There should be an independent third party certification criterion for a QMS which requires usability design and evaluation. Adhere to standard IEC 62366 for usability engineering (p 17)

10 Testing, User Tools, best practices

• ONC should include software developers and other stakeholders in the future development of guidance documents to ensure a comprehensive and interdisciplinary approach (p 18)
• ONC should facilitate the distribution of information related to research on usability as a supplement to a certified QMS, as opposed to prescriptive usability testing (p 18)
ONC should actively solicit health IT developer involvement in the SAFER Guides development process prior to publication (p 18)

11 Edu

We support creating a learning environment on the safe use of health IT and incorporating that into medical education. We also look forward to information which can guide the safe development, implementation and use of health IT.

12 Investigate Corrective Action

ONC should analyze the information from developers under Meaningful Use Stage 2 to determine if gaps in investigations or corrective actions exist before developing duplicative requirements and/or systems under the *HIT Safety Plan.* There should not be duplicative systems (p 19)
• ONC should clarify its intent to "work with private sector organizations that would have the ability to investigate, take corrective action, and publically report on their analysis of events" (p 19)
• HHS should develop and make publically available a plan to ensure that private sector organizations possess the required skills, knowledge, and ability to competently analyze health IT related events (p 19)
• ONC should clarify its intent to work with developers to request voluntary corrective action when HHS becomes aware of a potential serious safety risk through the programs described in the *HIT Safety Plan.* This duplicated work being done by developers to correct product deficiencies (p 19)
• If a serious safety risk is identified by HHS through a reliable source, HHS should contact the developer for information related to resolution of any product deficiency (p 19)
• HHS should develop policies and procedures related to the publication of public notices related to serious adverse events, including when sufficient information is known and verified by all appropriate stakeholders (p 19)
The *HIT Safety Plan* should specify a multi-stakeholder review and comment period for all guidance documents created which are related to health IT (p 20)

13 Priority areas, Measures, Targets

Develop health IT safety priority areas, measures, and targets.
We look forward to information related to the safe development and use of health IT.
Guidelines developed under this plan should not duplicate existing international standards; if overlap is unavoidable, they should align with the existing standards or guidance.
Recommendation:
· The *HIT Safety Plan* should specify a multi-stakeholder review and comment period for all guidance documents created which are related to health IT.

14 Publish Report on strategy and recommendations

Make all de-identified collected data and any interpretive methodology used in data analysis publically available (p 15)
• ONC should defer the implementation of the *HIT Safety Plan* until the Health IT Regulatory Framework report, due to Congress, is released, to avoid duplicative or conflicting requirements (p 21)
ONC should ensure that the work defined under the *HIT Safety Plan* aligns with, but does not duplicate, the pending risk-based Health IT Regulatory Framework report due to Congress (p 21)

15 ONC Safety Program

This program should be considered for incorporation into the Health IT Regulatory Framework currently under development, and therefore should not stand alone (p 21)

16 State Governments

We agree that state governments should incorporate health IT into their patient safety oversight programs (p 21)
Maintain adverse event reporting in the context of state and provider programs as part of Health IT Regulatory Framework established across multiple federal agencies (p 8)

17 Private Sector Leadership

ONC should clarify its intent to "work with private sector organizations that would have the ability to investigate, take corrective action, and publically report on their analysis of events" (p 19)

- HHS should develop and make publically available a plan to ensure that private sector organizations possess the required skills, knowledge, and ability to competently analyze health IT related events (p 19)

We agree with a multi-stakeholder approach and shared responsibility for health IT patient safety (p 21)

18 Other

General

- Complexity and duplication of reporting in the *HIT Safety Plan*
- Vast number of topics addressed in *HIT Safety Plan*
- Timeline challenges for stakeholders to implement the *HIT Safety Plan*
- Timeline for public comment was too short (and over holidays), so ONC should reopen for comment prior to finalizing plan and financial assessment from OMB
- Add definition section to clarify terminology (recognize that "health IT" is a general term that includes many components of IT system, and define terms related to patient safety and reporting (specifically: adverse events, unsafe conditions, safety issues, near misses, safety events)
- Strongly oppose the code of conduct in this plan because it appears to be the start of a QMS, possibly tied to certification
- Concerned about duplication of reporting of adverse events
- A Code of Conduct should not be a component of the *HIT Safety Plan*

Comments on Introduction

- Inconsistent use of technology which could lead to inconsistent interpretation and action by stakeholders
- Emphasize that medical errors can only be reduced when health IT is appropriately designed, implemented, tested, validated, and used; improvements cannot be ensured without support from key stakeholders
- CDS and CPOE are examples of how health IT coupled with clinical workflow and provider decisions support safer care
- ONC should gather any reference(s) to studies that identify the root causes of HIT related patient safety issues and present these for multi-stakeholder review and comment
- The *HIT Safety Plan* should emphasize the sociotechnical nature of health IT systems and need to collect data on all parts of the system regarding adverse events
- Change the first objective from "use health IT to make care safer" to "use health IT to support continuous improvement in patient care and outcomes"
- Emphasize that health IT should be one component of an enterprise-level healthcare risk assessment

Common Format

The AHRQ Common Format for "Device including Health IT" should be expanded to capture relevant information (p 14)

Names

Schneider, Joseph

Comment ID

58

Organization

Texas Medical Association

Org Typ1	Org type	Categories
4	4. Provider Organization (Clinician)	2. Vendor Engagement (CoC, etc)

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

Names

Villagrana, Marco

Comment ID

107

Organization

The Joint Commission (TJC)

Org Typ1	Org type	Categories
13	13.. Safety Organization	1. Reporting, 12. Investigate & Corrective Action, 17. Private Sect

1 Reporting

- The Joint Commission strongly supports a surveillance system that relies on the expertise of government and private sector patient safety and performance improvement entities, and builds upon an event reporting and mitigation process that encourages reporting in a non-punitive, protected environment, and is solution-focused.

Increase the quantity and quality of data and knowledge about health IT safety

• The Joint Commission strongly supports standardized data format reporting of events. The Joint Commission has been a leader in event reporting, receiving such reports from accredited health care organizations since 1997. The voluntary event reports made to The Joint Commission represent only a small proportion of actual events, and therefore do not constitute an epidemiologic data set. Nonetheless, they do represent a slice of patient safety issues that our accredited organizations face and are illustrative of the scope and relative frequency of types of events. These reports are sometimes the basis for Joint Commission's Sentinel Event Alerts that provide guidance to health care organizations on emergent patient safety issues, and are used to inform our accreditation standards and requirements.

• When any event is reported as a safety failure or adverse event, it is difficult to identify immediately whether there were any IT related causal factors until all of the contributing causes are identified and appropriate process "threads" are pulled. For example, an error initially classified as a medication error may end up being a result of an IT problem. Such an underlying factor is not always immediately obvious, therefore it is critical that health care organizations have the systems in place to identify, report, analyze, and implement solutions to mitigate future occurrences. This includes conducting root cause analysis and implementing cause-specific solutions. Such a process can contribute to improving the quality and quantity of knowledge about events

• Consistent with the ONC Plan's recommendations, in addition to encouraging reporting and analysis of individual events, it is imperative that de-identified and protected aggregate data about events be disseminated to foster learning across health care organizations.

Promote a culture of safety related to health IT

A Safety Culture is promoted and strengthened through three imperatives trust, report, and improve. Reporting and improvement, two of the three Safety Culture imperatives, were addressed in the aforementioned comments; however, they cannot happen without first establishing trust. An event surveillance system that adheres to Safety Culture is one in which there is trust that information is shared in a protected, non-punitive environment that fosters open, honest dialog that leads to solutions. Safety culture is an essential building block for achieving high reliability, which is the hallmark of complex, high risk industries such as aviation.

2 Vendor Engagement (CoC, etc)

3 PSO

The Joint Commission strongly supports a surveillance system that relies on the expertise of government and private sector patient safety and performance improvement entities, and builds upon an event reporting and mitigation process that encourages reporting in a non-punitive, protected environment, and is solution-focused.

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

Target resources and corrective actions to improve health IT safety and patient safety

• Though the Plan rightfully seeks to leverage activities of the private sector, it is important to recognize that despite private sector expertise, no one organization has all of the resources to address adverse events; therefore, it is imperative that private sector organizations have the necessary resources to guide health care organizations to identify, report, and implement solutions to mitigate adverse events risks.

• The Joint Commission has considerable expertise in event analysis and continues to help health care organizations address patient safety events. While Joint Commission may learn about sentinel events at an accredited organization from multiple sources, including patients or their families, or media reports, health care organizations are required to monitor events and encouraged to self-report events to The Joint Commission. Joint Commission uses a non-punitive approach that gives self-reporting organizations the opportunity to consult with Joint Commission experts during the development of the root cause

analysis and action plan. Though Joint Commission's event reporting process is conducted in a non-punitive manner, there is a clear expectation that health care organizations conduct a timely, thorough, and credible root cause analysis; develop an action plan designed to implement improvements to reduce risk; implement the improvements; and monitor the effectiveness of those improvements.
Although external event reporting is important, The Joint Commission's standards also expect that health care organizations put a premium on internal self-reporting to ensure that staff are comfortable with reporting and value the reports and the outcomes that flow from reporting risks. This approach recognizes that internal reporting, analysis, and solution implementation is as important as external reporting.

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

Target resources and corrective actions to improve health IT safety and patient safety

• Though the Plan rightfully seeks to leverage activities of the private sector, it is important to recognize that despite private sector expertise, no one organization has all of the resources to address adverse events; therefore, it is imperative that private sector organizations have the necessary resources to guide health care organizations to identify, report, and implement solutions to mitigate adverse events risks.

• The Joint Commission has considerable expertise in event analysis and continues to help health care organizations address patient safety events. While Joint Commission may learn about sentinel events at an accredited organization from multiple sources, including patients or their families, or media reports, health care organizations are required to monitor events and encouraged to self-report events to The Joint Commission. Joint Commission uses a non-punitive approach that gives self-reporting organizations the opportunity to consult with Joint Commission experts during the development of the root cause analysis and action plan. Though Joint Commission's event reporting process is conducted in a non-punitive manner, there is a clear expectation that health care organizations conduct a timely, thorough, and credible root cause analysis; develop an action plan designed to implement improvements to reduce risk; implement the improvements; and monitor the effectiveness of those improvements.
Although external event reporting is important, The Joint Commission's standards also expect that health care organizations put a premium on internal self-reporting to ensure that staff are comfortable with reporting and value the reports and the outcomes that flow from reporting risks. This approach recognizes that internal reporting, analysis, and solution implementation is as important as external reporting.

18 Other

The Joint Commission strongly supports a surveillance system that relies on the expertise of government and private sector patient safety and performance improvement entities, and builds upon an event reporting and mitigation process that encourages reporting in a non-punitive, protected environment, and is solution-focused.

Names

Ramshaw, Bruce, MD

Comment ID

68

Organization

Transformative Care Institute

Org Typ1	Org type	Categories
9	9. Allied Professional Organization	1. Reporting

1 Reporting

• …Getting actors (patients, physicians, etc.) to report more data will have little or no effect in the outcomes of a complex system unless the system structure is changed.
The current HIT tools have been designed and implemented to support the current system structure for care delivery, an ever more fragmented and inefficient design. The solution for improved patient safety is not more data, but a better understanding that the problem is inherent in and a result of the current system structure for care delivery. We should make that our effort and primary focus until we get sustainable system structures for care delivery implemented.

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

17 Private Sector Leadership

18 Other

Names

Wears, Robert L

Comment ID

4

Organization

University of Florida, University of Florida

Org Typ1	Org type	Categories
1	1 Provider (institution)	1. Reporting, 10. Testing, User Tools, best practices, 18. Other

1 Reporting

• The plan depends almost entirely on reporting to reveal hazards. This is a major deficiency for several reasons. First, it exposes patients to risks as a means of discovering risks. Second, it is much more difficult to mitigate or eliminate hazards after a system has been deployed. Third, we know that under-reporting is common, for multiple reasons. Fourth, it is often difficult for a clinician to know whether they have discovered a fault or not. For example, in problems related to delayed updating of cached information, a clinician might see a previous patient's laboratory results on the next patient they view. Their response to this confusion would often be to close the patient and reload it, which might force a refresh; the clinician is then left wondering "Did I see what I thought I saw?" and the evidence of the hazard has been removed. The extent of this sort of problem is manifested by the common notation in closing out help tickets that analysts were unable to recreate the users' problem. Thus hazards may persist for long periods of time before finally being captured in a reporting system. Finally, the emphasis in the plan is all on reporting, but there is very little emphasis placed on analysis and understanding what those reports signify.

• While it is true that the final safety assessment can only be made in the context of use, that should not be used as an excuse to avoid safety assessment at each stage of the system life cycle.

• The plan inverts the proper placement of the 'burden of proof' for safety critical systems. In effect, it presumes health IT is safe and asks users and care delivery organizations to provide evidence that it is not. In this inversion, it ignores long-standing safety engineering practices and a strong recommendation from the National Research Council specifically aimed at software systems that:

• "...the burden of proof falls on the developer to convince the certifier or regulator that the software is dependable. This approach is not novel and is becoming standard in the world of system safety, in which an explicit safety case (and not merely adherence to good practice) is usually required. Similarly, a software system should be regarded as dependable only if it has a credible dependability case..." (Jackson, Thomas, & Millett, 2007, p. 2).

It is important to note here that no other safety critical industry deploys information technology in this way – *ie*, without a prior, independent safety assessment.

2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
11 Edu
12 Investigate Corrective Action
13 Priority areas, Measures, Targets
14 Publish Report on strategy and recommendations
15 ONC Safety Program
16 State Governments
17 Private Sector Leadership
18 Other

- The proposed plan is disappointing and seriously deficient in several respects. While it gives the appearance of action, it will likely not achieve any substantive result with respect to ensuring that health IT will be developed safely, systematically assessed for hazards, implemented safely, or maintained and operated safely. Its primary value is that it at least raises the issue of the safety of these systems, a problem that should have been addressed long before billions were invested in widespread deployment. My objections are organized in 4 broad areas.
- **Lack of prospective risk assessment**
    - The report makes no provision for any sort of prospective assessment of HIT safety prior to deployment or major upgrades. It makes no mention of two ISO draft standards that specifically address this issue: one aimed at developers (International Standards Organization, 2008a), and the other at implementing (*ie*, care delivery) organisations (International Standards Organization, 2008b).
    - Taken together, these two standards require the development of a 'safety case' (Reason, 1997, p. 178): an ongoing, structured argument, updated at regular intervals and at each major step in the system's life cycle, that the risks posed by the system are as low as reasonably practicable, and that the residual risks (those that cannot be removed or mitigated) are justifiable given the benefits to be expected.
    - A great deal of experience has been gained with the safety case approach in other hazardous industries (Leveson, 1995; Storey, 1996). Safety case documentation is begun by the developer(s) in the requirements elicitation and specification of systems; at deployment, the developer delivers their safety case to the implementing organization, which continues to maintain it throughout the life of the system, including through its final decommissioning. While they are not panaceas, they are useful in identifying hazards early in the life cycle, before they become deeply embedded and difficult to remove.
    - In addition, a safety case approach does not stifle innovation, since it does not prescribe a particular process to be followed, but rather requires that, whatever their process may be followed, that developers and implementers rigorously assess and document the risks of their systems.
- **Misreading the IOM Health IT report**

In its use of the IOM's report on IT safety (IOM Committee on Patient Safety and Health Information Technology, 2011), the plan ignores an extraordinary event, the inclusion of a dissent within the body of the report (Cook, 2011). I do not believe that any other report from the IOM or NAS has contained a dissent before; since anomalous events in non-trivial systems should not go unremarked (Perrow, 1984), the failure to address substantively the arguments raised in this dissent gives the plan a sort of 'head in the sand' feel, wishful thinking that all will work out alright in the end. (One could view this dissent as making exactly that criticism of the main report; the idea that Congress would, in the present fiscal climate, fund a new Federal agency to oversee the safety of health IT after already committing billions to promote it seems a fantasy).

Names

Shneiderman, Ben

Comment ID

64

Organization

University of Maryland

Org Typ1	Org type	Categories
1	1 Provider (institution)	1. Reporting, 10. Testing, User Tools, best practices, 14. Publish R

1 Reporting

• While the focus on patient safety event reporting is appropriate, ONC should consider approaches that might enable system users to report design problems and make suggestions for improvements in software and interface designs, even before they produce a patient adverse event. These improvements could lead to improved designs that promote complete accurate data collection, speed clinician usage, and reduce wrong patient errors.
Instrumented user interfaces that capture user interactions have been effectively used to diagnose usability problems and inform redesign. Problem-reporting tools that are widely used in software development (so-called "bug-tracking tools") offer effective means for rapid and continuous system improvement. Experience with these well-studied tools might be adapted to EHR systems. Specifically, form-based tools that might require laborious data entry might be replaced with "one-click" reporting interfaces that would report problems without distracting from clinical care.

2 Vendor Engagement (CoC, etc)

While a voluntary industry-oriented approach is an admirable aspiration, I am concerned that this self-regulation may not prove effective, particularly given documented tendency to dismiss the possibility of design flaws and to treat difficulties as "user error". Stronger enforcement should be kept as a viable alternative.

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

9 Cer

10 Testing, User Tools, best practices

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11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

14 Publish Report on strategy and recommendations

1) I encourage a more speedy approach to address the serious risks to patients. The current Recommendation is: "The Secretary of Health and Human Services (HHS) should publish an action and surveillance plan within 12 months that includes a schedule for working with the private sector to assess the impact of health IT on patient safety and minimizing the risk of its implementation and use."

I recommend that the plan be developed in less than 12 months and that the schedule for working with the private sector is specified more clearly, such as "implementation of an initial public reporting system within 6 months and a revised system within 12 months." While a voluntary industry-oriented approach is an admirable aspiration, I am concerned that this self-regulation may not prove effective, particularly given documented tendency to dismiss the possibility of design flaws and to treat difficulties as "user error". Stronger enforcement should be kept as a viable alternative.

15 ONC Safety Program

• I hope ONC will continue its admirable efforts through AHRQ, NIST, and other sources to develop advanced evaluation methods appropriate for the unique needs of Electronic Health Records systems. The expertise of the usability community could be tapped to provide guidance on improved software designs, usability testing methods when there is local customization, and continuous improvement processes for user interfaces.

16 State Governments

17 Private Sector Leadership

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18 Other

Names	Endorses Dr. Ben

Hochheiser, Harry

Comment ID

63

Organization

University of Pittsburgh, Dept. of Biomed informatic

Org Typ1	Org type	Categories
1	1 Provider (institution)	10. Testing, User Tools, best practices, 17. Private Sector Leadershi

1 Reporting

2 Vendor Engagement (CoC, etc)

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10 Testing, User Tools, best practices

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11 Edu

12 Investigate Corrective Action

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16 State Governments

17 Private Sector Leadership

18 Other

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Names	Agrees with BPC Framework

Lehmann, Christoph U

Comment ID

48

Organization

Vanderbilt University

Org Typ1	Org type	Categories
1	1 Provider (institution)	18. Other

1 Reporting
2 Vendor Engagement (CoC, etc)
3 PSO
4 ACB
5 CMS
6 QSRS
7 MAUDE
8 MU
9 Cer
10 Testing, User Tools, best practices
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18 Other

I would like to bring to your attention the work of the Bipartisan Policy Center as outlined in the report entitled "An Oversight Framework for Assuring Patient Safety in Health Information Technology" and its relevance to pediatrics. This report will be shortly released by the Bipartisan Policy Center in Washington, DC. The American Academy of Pediatrics has worked with the Bipartisan Policy Center to create this report. I personally believe it presents an important framework that may be of great interest to the ONC.

Names

Benson, Sean

Comment ID

79

Organization

Wolters Kluwer Health-Clinical Solutions

Org Typ1	Org type	Categories
6	6. Vendor (individual)	10. Testing, User Tools, best practices, 13. Priority areas, Measures

1 Reporting

2 Vendor Engagement (CoC, etc)

3 PSO

4 ACB

5 CMS

6 QSRS

7 MAUDE

8 MU

In conclusion, we agree with the development of tools and processes to support the goals of the HIT safety Plan. That said, we are recommending the ONC be more aggressive and specific in the Plan by articulating a defined set of patient safety goals and metrics to be achieved through the weidespread adoption and use of Health IT. We recognize the plan itself has no enforcement mechanism but can leverage existing programs such as the HITECH to drive achievement of specific goals. For example, the Stage 3 Meaningful Use criterion for clinical decision support could include the reduction of hospital-acquired conditions by 10% as a performance metric.

9 Cer

10 Testing, User Tools, best practices

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11 Edu

12 Investigate Corrective Action

13 Priority areas, Measures, Targets

• Our only concern with the overall Plan is its lack of specific goals and metrics. Perhaps the ONC envisions the Plan as a set of high level concepts and recommendations, with specific goals and performance metrics filled in at a later date.

14 Publish Report on strategy and recommendations

15 ONC Safety Program

16 State Governments

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Cutting-edge clinical decision support solutions aimed at significantly reducing HACs [hospital-acquired infections] are already being tested and deployed by HIT vendors. At Wolters Kluwer Health, we have developed a hospital-based mobile software module that provides early detection and drives best practices in treating patients at risk for becoming septic.

18 Other

• Our only concern with the overall Plan is its lack of specific goals and metrics. Perhaps the ONC envisions the Plan as a set of high level concepts and recommendations, with specific goals and performance metrics filled in at a later date.
In our view, limiting the proposed Plan to high level concepts and recommendations wastes an opportunity to define the power and potential of HIT to reduce costs and improve quality. As such, the ONC would be well-served by including more specific patient safety goals and performance metrics in the proposed Plan.