A National Web Conference on the Purpose and Demonstration of the Health IT Hazard Manager and Next Steps

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June 11, 2012

Moderator, Presenters, and Disclosures

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Agency for Healthcare Research and Quality

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There are no financial, personal, or professional conflicts of interest to disclose for the speakers or myself.

Agency for Healthcare Research and Quality

Advancing Excellence in Health Care www.ahrq.gov

Health IT Hazard Manager

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June 11, 2012

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GEISINGER

Abt ASSOCIATES

Hazard Control

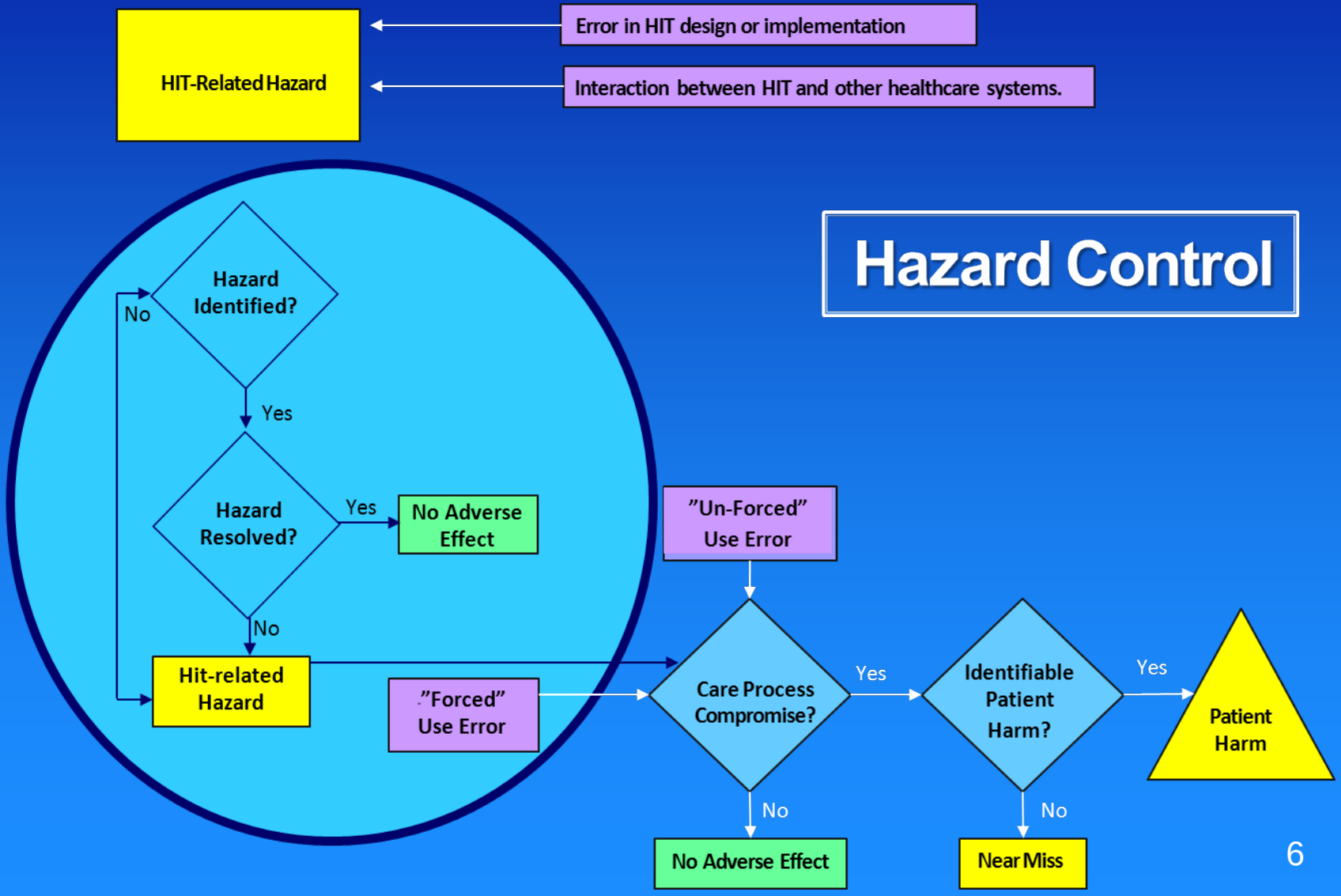
"Hazard analysis is accident analysis before the accident happens."

Nancy Leveson

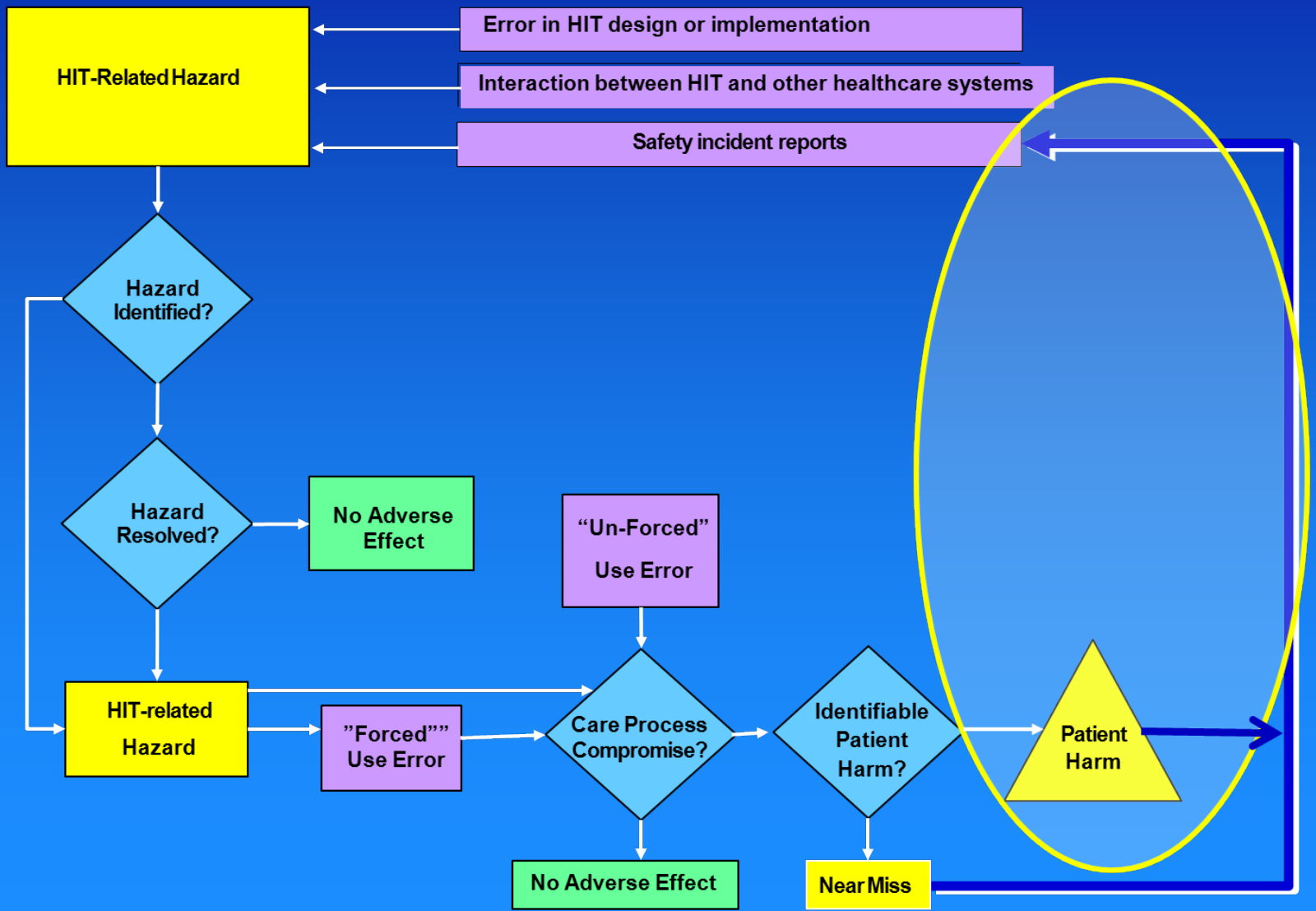
HIT Hazard Manager Beta-Test

1. Theoretical and Design Considerations
2. Hazard Manager Demo
3. Beta-Test Sites and Procedures
4. Analytic Methods, Results, and Redesign
5. Policy Implications

Hazard Control



Feeding Back Incident Reports into Hazard Control



Need For Proactive Hazard Identification and Sharing: Example

- An implementation team determined its new CPOE system could not safely interface with the existing Best-in-Class inpatient pharmacy system
- Replaced the pharmacy system with one from the CPOE vendor—a costly 9-month delay
- David Classen studied more than 62 installations and found that CPOE and pharmacy systems from different vendors can never be safely interfaced. How widely is this known?

Need for Proactive Hazard Control

"Most reporting systems concentrate on analyzing adverse events; this means that injury has already occurred before any learning takes place. More progressive systems also concentrate on analyzing close calls, which affords the opportunity to learn from an event that did not result in a tragic outcome. Systems also exist that permit proactive evaluation of vulnerabilities before close calls occur."

DeRosier JE, Stalhandske, et al. (2002). "Using Health Care Failure Mode and Effect Analysis." The Joint Commission Journal on Quality Improvement 28(5):248-269.

Hazard Ontology/ Algorithmic Search

Why is a single, consistent health IT hazard ontology important?

Example: Much of the Aviation Safety Information Analysis and Sharing (ASIAS) system budget is devoted to standardizing reports data because every airline uses different reporting language and cannot afford to change

Hazard Ontology Development and Alpha-Test: Geisinger Health System

Recognizing that care delivery organizations each identify thousands of errors and problems when installing new health IT (Bates, 2005), Geisinger informaticians developed a hazard-management tool and hazard ontology, entering several hundred potential hazards (Alpha-test)

Health IT Hazard Manager: AHRQ ACTION Task Order

Development and Alpha-Test:

Geisinger Health System

Beta-Test Website Design and Implementation:

ECRI Patient Safety Organization; Abt Associates

Beta-Test Evaluation:

Abt Associates; Geisinger Health System

Health IT Hazard Manager Benefits

1. Care Delivery Organization (CDO): manage hazard control process; prior to an upgrade, learn about hazards others have found in the product
2. Software Vendor: learn about hazards not reported directly by its customers; learn about other vendors' products that are hazardous when paired with its own
3. CDOs, Vendors, Policymakers, Researchers, Regulators: track progress in reducing health IT hazards using consistent, tested hazard ontology

Health IT Hazard Manager Design: Levels of Access (Security)

1. CDO: can enter, view, and manage its own hazards; view hazards entered by other CDOs using the same software product (deidentified as to CDO)
2. Software Vendor: can view its customers' hazards (deidentified as to CDO)
3. CDOs, Vendors, Policymakers, Researchers, Regulators: can view all hazards (deidentified as to CDO and vendor)

HEALTH IT HAZARD MANAGER VERSION 2.0 DEMONSTRATION

Hazard Manager Short Description

HIT Hazard Manager

Home | Admin | Hazards | Reports | My Account

Not all categories may be applicable. If something is not applicable, leave it blank.
When entering a Hazard, use the tabs to navigate back and forth. Do not use the back button.

1. Description | 2. Systems Involved | 3. Discovery | 4. Causation | 5. Impact | 6. Hazard Control Plan | 7. Plan Approval | 8. Notes & References

WARNING, PUBLIC INFORMATION: Do not enter any information that could identify a Patient, Clinician, Organization or Health IT Vendor!

Short Description (PUBLIC)

(Maximum characters: 550)
You have 550 characters left.

Detailed Description (private):

Save Hazard and Exit

Narrative Hazard Description

- Short Description: Public (verified to ensure no identifiers are revealed)
- Long Description: Private (visible only to CDO entering the hazard)

Hazard Manager Ontology

- **Discovery:** when and how the hazard was discovered; stage of discovery
- **Causation:** usability, data quality, decision support, vendor factors, local implementation, other organizational factors
- **Impact:** risk and impact of care process compromise; seriousness of patient harm
- **Hazard Control:** control steps; who will approve and implement the control plan

Hazard Discovery

Ontology: Discovery

- How was the hazard discovered?
- Stage of discovery
- How long was this hazard present in the system when it was discovered?
- How was the hazard communicated?
- When was the hazard discovered?

Hazard Causation

HIT Hazard Manager

Home | Admin | Hazards | Reports | My Account

Not all categories may be applicable. If something is not applicable, leave it blank.
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1. Description | 2. Systems Involved | 3. Discovery | **4. Causation** | 5. Impact | 6. Hazard Control Plan | 7. Plan Approval | 8. Notes & References

Usability: (Check all that apply.)

- ☐ Information hard to find
- ☐ Difficult data entry
- ☐ Excessive demand on human memory
- ☐ Sub-optimal support of teamwork (situation awareness)
- ☐ Confusing information display
- ☐ Inadequate feedback to the user
- ☐ Mismatch between real workflows and HIT
- ☐ Mismatch between user expectations (mental models) and HIT
- ☐ Other (specify)

Data Quality: (Check all that apply.)

- ☐ IT design contributed to entry of data in the wrong patient's record
- ☐ Organizational policy contributed to entry of data in the wrong patient's record
- ☐ Patient information/results routed to the wrong recipient
- ☐ Discrepancy between database and displayed, printed, or exported data
- ☐ Faulty reference information
- ☐ Unpredictable elements of the patient's record available only on paper/scanned documents
- ☐ Lost data
- ☐ Inaccurate natural language processing
- ☐ Virus or other malware
- ☐ Other (specify)

Decision Support: (Check all that apply.)

- ☐ Excessive non-specific recommendations/alerts
- ☐ Faulty recommendation
- ☐ Missing recommendation or safeguard
- ☐ Inadequate clinical content
- ☐ Inappropriate level of automation
- ☐ Other (specify)

Vendor Factors: (Check all that apply.)

- ☐ Sub-optimal interfaces between applications (and devices)
- ☐ Non-configurable software
- ☐ Faulty vendor configuration recommendation
- ☐ Unusable software implementation tools
- ☐ Inadequate vendor testing
- ☐ Inadequate vendor software change control
- ☐ Inadequate control of user access
- ☐ Faulty software design (specification)
- ☐ Other (specify)

Local Implementation: (Check all that apply.)

- ☐ Faulty local configuration or programming
- ☐ Inadequate local testing
- ☐ Inadequate project management
- ☐ Inadequate software change control
- ☐ Inadequate control of user access
- ☐ Sub-optimal interface management
- ☐ Other (specify)

Other Factors: (Check all that apply.)

- ☐ Inadequate training
- ☐ Excessive workload (including cognitive)
- ☐ Inadequate organizational change management
- ☐ Inadequate management of system downtime or slowdown
- ☐ Unclear policies
- ☐ Compromised communication among clinicians (i.e., during hand-offs)
- ☐ Interactions with other (non-HIT) care systems
- ☐ Physical environment (e.g., hardware location, lighting, engineering)
- ☐ Hardware failure
- ☐ Inadequately secured data
- ☐ Use error in the absence of other factors
- ☐ Other (specify)

Save Hazard and Exit

Ontology: Causation Categories

- Usability
- Data Quality
- Decision Support
- Vendor Factors
- Local Implementation
- Other Factors

Hazard – Potential Impact if Not Corrected

Hazard – Potential Harm if Not Corrected

Hazard – Potential Number of Patients Affected, if Not Corrected

Hazard – Potential Severity of Patient Harm if Not Corrected

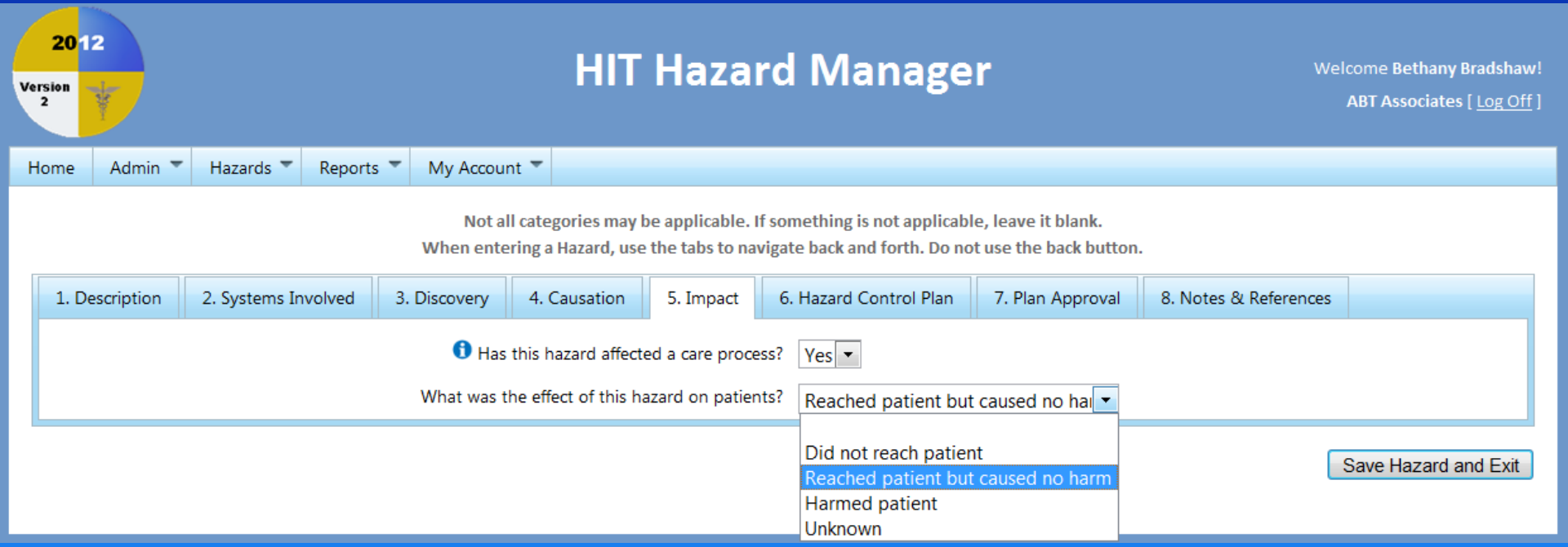
Ontology: Impact

Has this hazard affected a care process?

If no:

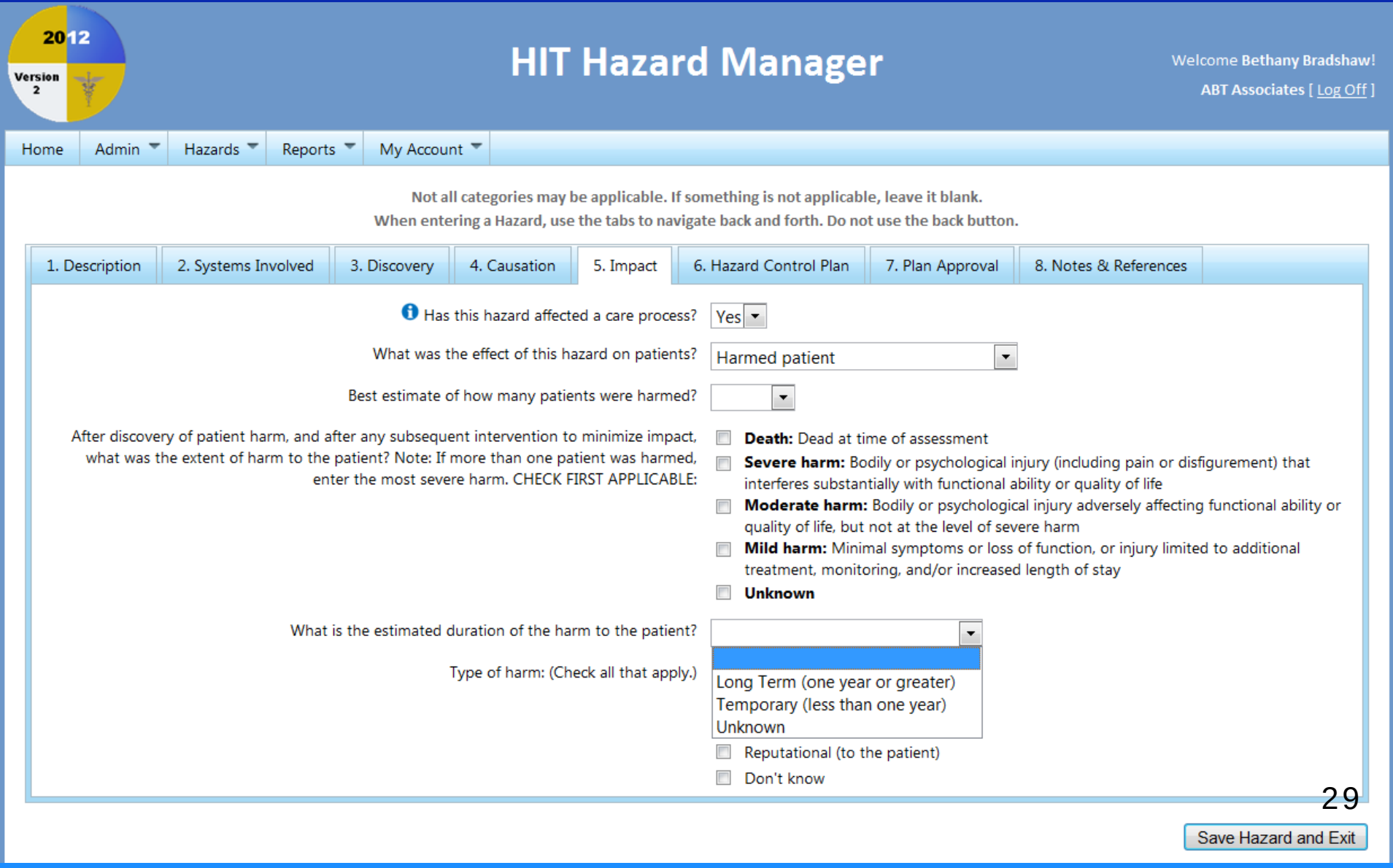
- Risk that this hazard could affect a care process if it is not controlled?
- If the hazard were to affect a care process, how likely is it that an end user would notice before a patient was harmed?
- Best estimate of how many patients could be affected if this hazard is not fixed?
- Most serious/worst harm that could happen if this hazard is not fixed?

Hazard – Effect on Patients



If the hazard affected a care process but no patients were harmed, there are no further impact questions

Hazard – Actual Impact and Patient Harm



Ontology: Impact

Has this hazard affected a care process?

If yes:

What was the effect on patients?

- Did not reach patient
- Reached patient, caused no harm
- Unknown
- Harmed patient
  - How many patients were harmed?
  - Extent of harm?
  - Duration of harm?
  - Type of harm?

Hazard Control Plan – Urgency

Hazard Control Steps

Ontology: Hazard Control

How quickly must this hazard be controlled?

- Do not control: the risks exceed the benefits
- Already controlled: no action needed
- If hazard is in production: URGENT- control within 24 hours
- If hazard is in production: control within 1 month
- If hazard is in production: control within 6 months
- If hazard is not yet in production: delay implementation until software is fixed
- Other (specify)

First control step

How complete is the control/correction of this hazard?

- Complete
- Partial; additional steps needed
  - Additional hazard control steps

Plan for Hazard Control (free text: private)

Hazard Control Plan Approval

Ontology: Hazard Control Plan Approval

Who must approve the control plan? (multi-select)

Who will implement the control plan? (multi-select)

Clinical Leadership
Administrative Leadership
End User Representatives
Local IT
Software Vendor
Informatics/Human-Factors
Quality/Safety
Risk Management
Medical Records
Facilities and Engineering
Legal
Other (specify)

BETA-TEST METHODS AND RESULTS; ONTOLOGY REVISIONS

Hazard Manager Beta-Test

7 test sites: integrated delivery systems, large and small hospitals, urban and rural

- Usability (individual interviews)
- Inter-rater scenario testing (individual Web or in-person sessions)
- Ontology of hazard attributes (group conference)
- Usefulness (group conference)
- Automated reports (group conference)

4 vendors offered critiques

All-project meeting: 6 test sites, 4 vendors, AHRQ, ONC, FDA

Beta-Test Analytic Methods

- Content analysis of short descriptions
- Frequencies of hazard ontology factors: combinations often selected together; factors never selected
- Inter-rater differences in entries of mock hazard scenarios/vignettes
- Suggestions from testers to improve ontology clarity, comprehensiveness, mutual exclusivity
- Content analysis of “Other Specify” entries

Caveat Emptor

- The data presented in the following slides
  - Were used only to test the Hazard Manager, not to understand the hazards present at the test sites or elsewhere
  - Are partial and non-representative
  - Should be interpreted only as indications of limitations with the Beta version of the Hazard Manager
- Many hazards retrieved from incident reports were still salient after months or years, probably because they were high impact
- One organization's hazards were preapproved by legal department before entry

Number of Hazards Entered by Beta-Test Sites

May – October 2011

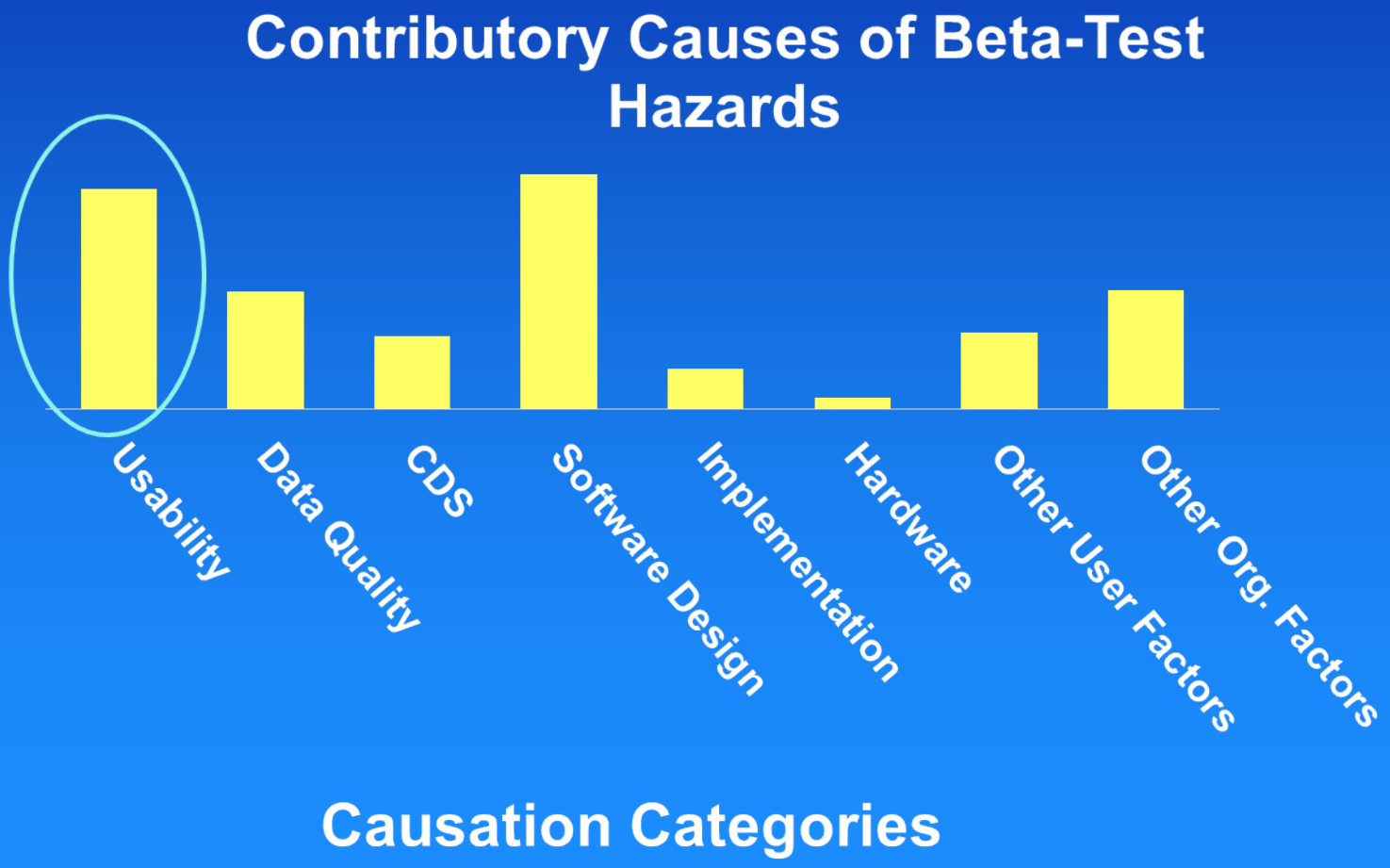
Target: 100 hazards/site

Site A	Site B	Site C	Site D	Site E	Site F	Site G
104	105	66	20	100	100	0

Total = 495 Hazards

Beta-Test Findings

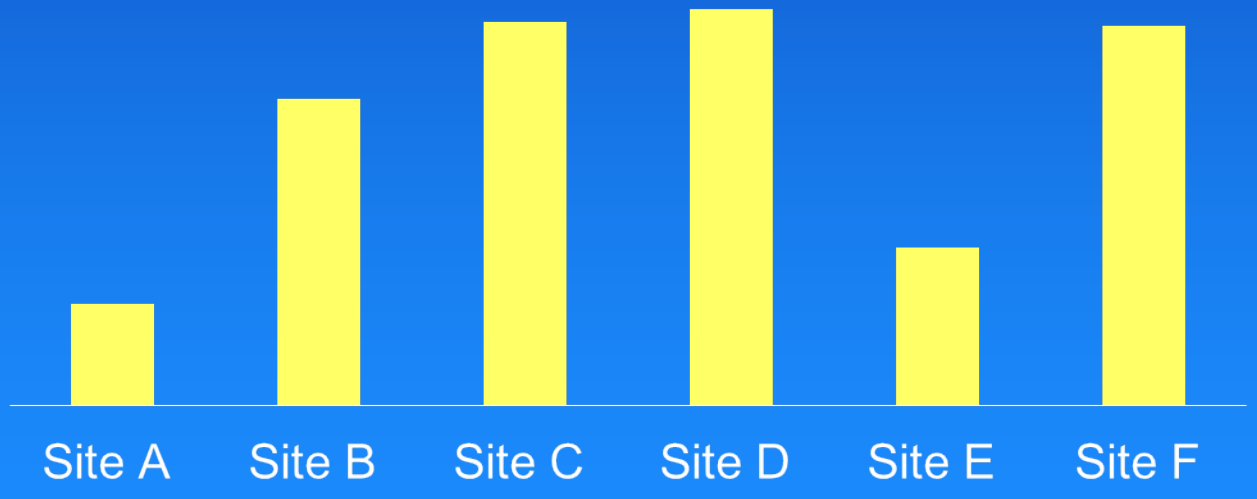
(Usability and software design—often together—were frequent contributors to health IT hazards)



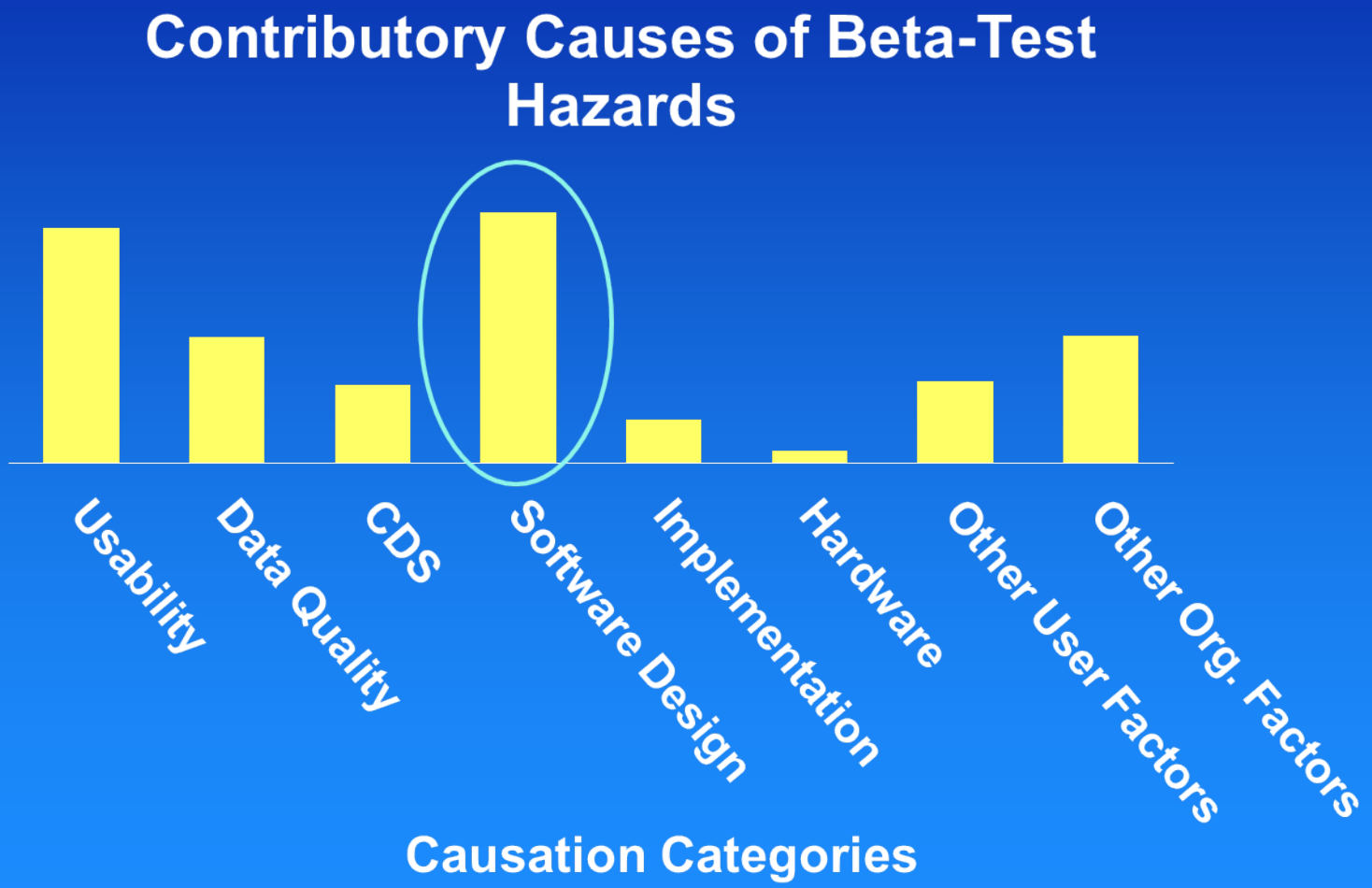
Beta-Test Findings: Usability

(Usability may be less of a contributor to hazards in CDOs that extensively customize their health IT products)

Share of Hazards Involving One or More Usability Issues, by Study Site



Beta-Test Findings: Software Design



Beta-Test Causation Category Software Design: Subsidiary Factors

- Faulty vendor implementation/configuration recommendation
- Inadequate clinical content (including third party)
- Unusable software-implementation tools
- Sub-optimal interfaces between applications
- Unnecessary/unauthorized sharing of personal health information (PHI)
- **Faulty design**
- Non-configurable software
- Other (specify)

Beta-Test Findings: Faulty Design

- Faulty Design was the most frequently chosen factor (189 hazards)
- Among 155 hazards with Faulty Design, something else was also chosen:

Usability	Other Org. Factors	CDS	Software Design	Implementation	Data Quality
111	*31*	*21*	*25*	*17*	***49***

* *Multiple selections possible*

Specific Usability Factors

- Difficult Information Access (37)
- Difficult Data Entry (34)
- Confusing Information Display (32)
- Mismatch Between HIT Function and Clinical Reality (32)
- Inadequate or Confusing Feedback to the User (28)

Specific Data Quality Factors

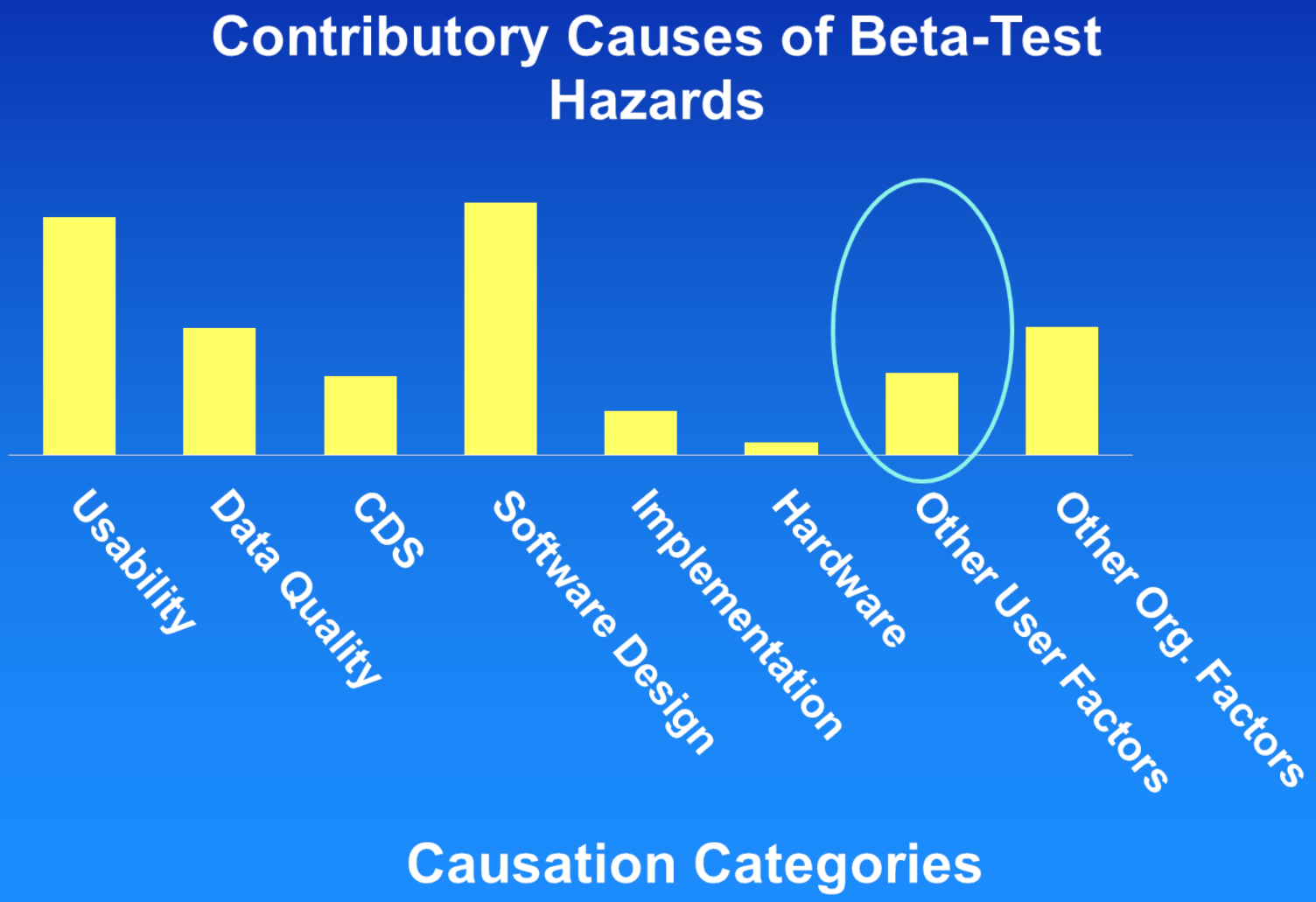
- Incorrect Patient Information (20)
- Lost Data (13)

Ontology Revisions: Software Design

Software Design category encompassed too many unrelated factors

- Eliminated Software Design category; redistributed factors to more appropriate categories of Usability, Data Quality, Vendor Factors, or Local Implementation
- New category of Vendor Factors includes redefined: “Faulty Software Design Specification”

Beta-Test Findings: Unforced User Error



Beta-Test Findings: Unforced User Error

- Unforced User Error was the second most frequently chosen factor (79 hazards)
- Among 55 hazards with Unforced User Error, something else was also chosen:

Usability	Data Quality	CDS	Software Design	Other Org. Factors
22	*9*	*12*	*9*	***33***

* *Multiple selections possible*

Specific Usability Factors

- Mismatch between HIT Function and Clinical Reality (8)
- Confusing Information Display (8)
- Excessive Demands on Human Memory (8)

Other Organizational Factors

- Other (12)
- Inadequate Training Infrastructure (11)

Inter-Rater Entry: Mock Hazard Scenario

Several patients' records are open at once; a harried physician placed an order on the wrong patient. Unforced User Error?

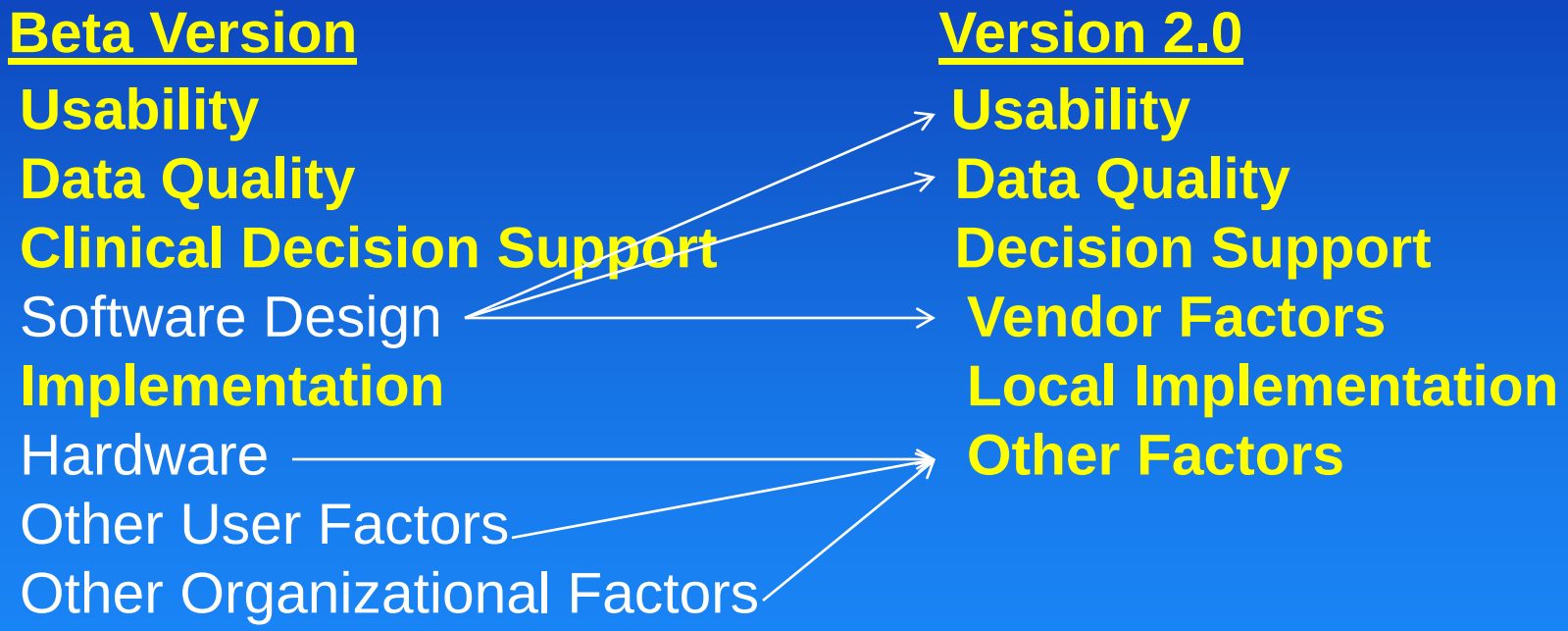
- 5 of 7 testers checked Unforced User Error
- The other 2 testers felt that that sophisticated CDS would contain safeguards to confirm patient identity and prevent this error
- 3 testers felt the software design was faulty for omitting identity confirmation
- 3 testers felt this error was also caused by confusing information display

Ontology Revisions: User Error

User Error was often due to the absence of protections or safeguards to prevent errors

- Added a new factor to the Decision Support category: “Missing Recommendation or Safeguard”
- Redefined “Unforced User Error” as “Use Error in the Absence of Other Factors”

Causation Category Revisions



Beta-Test Findings: Short Hazard Descriptions

Content analysis of short descriptions revealed two frequent patterns:

1. Medication-related hazards (dosing algorithms, formulary issues, etc.): all can be captured with the revised ontology

2. Information associated with the wrong patient (orders entered on wrong patient, results routed to wrong clinician, data stored in system correctly but displayed for wrong patient): new hazard factors added to the ontology to reflect these important distinctions

No other obvious patterns

Beta-Test Findings: Hazard Entry

An individual's role influences what hazards they become aware of:

- IT Implementation teams learn about potential hazards during testing
- IT Production teams learn about hazards that may compromise care processes
- Patient Safety teams learn about care process compromises that reach patients (with or without harm)

POLICY IMPLICATIONS: HAZARD MANAGER BENEFITS AND USE CASES

Hazard Manager: Value for CDOs

- Prior to an upgrade, learn about hazards others have reported with the new product (tester identified)
- Improve patient safety by supporting proactive hazard control
- Identify hazards that occur at the interface of two vendors' products
- Improve ability to estimate seriousness of risk and prioritize hazard control efforts
- Inform user-group interactions with vendors
- Designed for confidentiality

Hazard Manager: Value for Vendors

- Learn about the 90% of hazards that their customers do not currently raise, especially hazards experienced by multiple customers (vendor identified)
- Learn which other vendors' products frequently contribute to hazards when paired with their own
- Identify which hazards are unique to one customer, or shared by many, to prioritize software revisions
- Identify new hazards immediately following release of an upgrade
- Designed for confidentiality

Hazard Manager: Value for Policy Makers

- Identify and categorize common hazards that occur at the interface of different vendors' products (e.g., pharmacy and order entry)
- Systematically drive hazard identification earlier in the IT lifecycle (ideally prior to production use); monitor the success of such programs
- Track progress in reducing health IT hazards and their impact on patients

Hazard Manger: Future Deployment Considerations

1. Provide “as is”
2. Central Ontology Management (e.g., as part of Common Formats) to ensure version control
3. Central Hazard Aggregation
4. Central Hazard Analysis (depends on 2 and 3)
5. Central Administration Services
6. Confidentiality/Security (to promote use)
7. Information Access: database searchable by all stakeholders (depends on 2–6)
8. Securely Brokered Information Requests (depends on 2–6)

Next phase of the Health IT Hazard Manager is under discussion and not yet available for public release

Beta-Test Final Report Available on AHRQ Website

For more information:
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Q & A

Please submit your questions by using the Q&A panel to the lower right of the screen

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