# Appendix E – Inter-Rater Cognitive Testing Results

This appendix summarizes the hazard entries created by the seven test sites to describe the six hazard scenarios. The category headings are the beta version categories.

## 1.  Discontinue All Scenario

The order entry screen had a new 'Discontinue All' button added to the order screen, in response to users' requests. The vendor implemented it as a large horizontal button beside the much smaller button for 'signing' orders. One week after the upgrade went into production, a user entered 15 orders to transfer a complex patient out of intensive care, but instead of signing, inadvertently clicked the larger Discontinue All button. There was no configuration alert "do you want to do this?" and all 15 orders were discontinued, which the user noticed immediately. The user re-entered all but one order, which was inadvertently forgotten. The patient was not injured by the omitted order. Immediate notices went out throughout the facility to warn users to be careful with the Discontinue All button. The IT team worked with the vendor for several weeks to relocate the button, make it smaller, and add an alert before processing Discontinue All orders.

### Systems Involved

Three sites selected inpatient and the other four selected CPOE.

### Discovery

Six sites said an end user discovered the hazard and the seventh selected 'other' and wrote "unknown." All seven sites indicated that the hazard was not associated with a shift change. Six sites said the hazard was discovered during production use and the seventh site did not make a selection for stage of discovery. Six sites said the hazard was discovered by end-user report while the seventh again selected 'other' and entered "unknown". Six sites said the hazard was published by internal report; three of these also said it was sent to the HIT vendor. The seventh site selected "published report" for the method of publication.

### Causation

Items selected:

- Difficult data entry (1)
- Excessive demands on human memory (1)
- Confusing information display (5)
- Inadequate or confusing feedback to the user (2)
- Missing recommendation (1)
- Faulty vendor implementation/configuration (2)
- Faulty design (7)

- Unforced user error (1)
- Inadequate training infrastructure (2)
- Software design other: "no alert built in"
- Implementation other: "potential hazards training" and "inadequate testing"

## Impact

All seven sites selected 'has occurred here" for risk of care process compromise. Four identified the type of care process compromise as omission, one said commission, and two used 'other' to indicate that they would enter both omission and commission if given the opportunity. Three sites said the potential impact of the care process compromise was medium while the other four said it was high. All sites said the care process compromise had reached a patient but caused no harm.

## Corrective Action

No sites selected anything for the Hazard Mitigation Plan. Only four sites selected anything for activity status and they all chose "case closed: resolved". For the urgency of the initial fix one site selected "fix or remove within 24 hours", one selected "fix or remove within 6 months", one selected "no fix or removal possible", and one selected "no fix or removal required". Three sites said the initial fix was partially completed, two said it was complete, and one site said no initial fix was required.

Initial fix items selected:

- Software upgrade (vendor) (3)
- Training for local IT (1)
- Configuration change (local IT) (1)
- Custom programming (local IT) (2)
- Training for end users (6)
- Other: checked but nothing specified in the text field

One site characterized the urgency of the definitive fix as "fix or remove within 24 hours", one selected "fix or remove within 1 month", and two said within 6 months. Three sites said the definitive fix was complete while two said it was only partially complete and two did not answer.

Definitive fix items selected:

- Software upgrade (vendor) (4)
- Training for local IT (1)
- Configuration change (local IT) (1)
- Custom programming (local IT) (1)
- Care process change (1)
- Training for end users (5)

## Responsible for Vetting and Mitigation

Items selected for responsible for vetting:

- Medical records (1)
- Informatics/human factors (2)
- Quality/safety (1)
- Clinical leadership (1)
- Local IT (7)
- HIT Vendor (6)
- Legal department (1)
- Risk management (1)
- End-user (2)

Items selected for hazard mitigation:

- Medical records (1)
- Informatics/human-factors (2)
- Quality/safety (1)
- Local IT (7)
- HIT vendor (6)
- Risk management (1)
- Legal department (1)
- End-user (3)

## 2.  Intracranial Pressure Scenario

The formula for calculating intracranial pressure (ICP) was reentered by local IT staff after a scheduled upgrade, with a plus instead of a minus sign; all pressures were miscalculated beginning at midnight.  A surgeon came in the next morning and ordered a Computed Tomography (CT) scan for a patient with a high ICP reading, to rule out a new intracranial hemorrhage.  After seeing the normal test result later that morning, a nurse realized that the problem was with the ICP calculation and warned the surgeon. The patient received an unnecessary scan and radiation exposure, and was made very anxious by the concern about a new brain hemorrhage. The ICP formula was re-entered and a new policy created that all back-end changes, such as reentering a formula, must be double-checked by another local IT staff.

### System Involved

Four sites selected inpatient, one selected CPOE.  Two sites selected "other" and wrote "inpatient" and "monitoring results."

### Discovery

All seven said end user discovered it.  All seven said not associated with a shift change.  Six said it was discovered during production use, and two said it was discovered during an upgrade (one site also selected both production use and upgrade).  Six said it was discovered via end-user report, one site did not select anything (even though they said an end user discovered it).  Only five entered how it was published and they all selected internal report.

### Causation

Items selected:

- Mismatch between HIT function and clinical reality (1)
- Inadequate or confusing feedback to user (1)
- Incorrect patient information (2)
- Faulty reference information (4)
- Miscalculation of a result (3)
- Data Quality Other: keying error, Miscalculation due to human error in setup of calculation
- Faulty recommendation (2)
- CDS Other: erroneous, faulty logic
- Faulty design (1)
- Software Design Other entries: client configuration error, local IT config error, inadequate system alerts
- Inadequate software change control (6)
- Inadequate project management (1)
- Implementation Other entries: Lack of adequate usability testing (1)

- Unforced user error (2)
- Inadequate change management (2)
- Unclear policies (1)
- Loss of pre-existing safeguards (1)

## Impact

All seven sites said "it has occurred here" and all sites also selected "commission". One site selected medium potential impact of care process compromise while the other six chose high. Two sites chose "reached patient but did not cause harm" and the other five chose "harmed patient." Of the five who said it harmed a patient, four said it was "minor adverse effect likely to be temporary" and 1 said "minor adverse event likely to be chronic" because radiation exposure is cumulative. Three sites said the type of patient harm was physical and psychological, and two other sites said it was just psychological harm. One site selected physical, psychological and financial harm (the cost of the unnecessary scan).

## Corrective Action

Only one site filled out the hazard mitigation plan and they selected "do not implement affected software." That one site along with three others entered the activity status of "case closed: resolved." Two of those sites and one other site categorized the urgency of the initial fix as "fix or remove from use within 24 hours;" no other sites entered the urgency. One site that said the fix was complete also entered the corrective plan of "corrected configuration/logic."

Initial fix items selected:

- Software upgrade (vendor) (1)
- Training for local IT (1)
- Configuration change (local IT) (2)
- Policy change (1)
- Training for end users (2)

Four sites categorized the urgency of the definitive fix as "fix or remove from use within 24 hours;" one site selected "within 72 hours." One site said the definitive fix was partial and five said it was complete. Three plans were entered: "correct the calculation setting, "need software testing plan," and "software corrected with."

Definitive fix items selected:

- Software upgrade (vendor) (1)
- Training for local IT (5)
- Configuration change (local IT) (3)
- Policy change (5)
- Training for end users (1)

## Vetting and Resolution

Responsible for vetting items selected:

- Informatics/human factors (2)
- Quality/safety (3)
- Clinical leadership (2)
- Local IT (7)
- Risk management (3)
- Legal department (1)
- End-user (3)
- Other: EHR policy

Responsible for hazard mitigation items selected:

- Medical records (1)
- Informatics/human factors (2)
- Quality/safety (1)
- Local IT (7)
- HIT vendor (1)
- Risk management (1)
- End-user (1)

## 3.   **Potassium Overdose Scenario**

During a busy holiday weekend, with several physicians covering on a medical floor, a patient with low potassium was given K+ both intravenously (IV) and orally (PO), and over-dosed.  The patient suffered cardiac arrhythmia and renal dysfunction, and survived with chronic renal damage.  Local IT staff identified the problem as being completely separate screens for IV and PO orders, with no display of the total K+ dose given.  IT staff conducted a retrospective investigation that did not identify any other patients receiving inappropriate K+ doses due to this problem.  Despite many months of interactions with the vendor, the IV and PO portions of the ordering system display have not been merged – either in terms of presentation to the user or calculation of total dose; the potential for a repeated failure remains.  In the absence of a fix, training has been added to alert users to double-check both the IV and PO orders, and total dose, especially when prescribing K+.

### Systems Involved

Two sites selected inpatient, two different sites selected pharmacy; the three other sites selected CPOE.

### Discovery

Four sites identified the end user as the discoverer of the hazard while two sites said it was local IT.  The remaining site selected "other" and entered "end user/local IT."  Six sites selected that the hazard was not associated with a shift change and one site did not make a selection.  All seven sites said the hazard was found during production use.  One site said the hazard was discovered by chart review, four said by end-user report, and one site selected "other" and wrote "local IT staff"; one site did not indicate how the hazard was discovered.  For the method of publishing the hazard, six sites said it was an internal report and five of those six also said it was sent to HIT vendor; one site also selected published report.

### Causation

Items selected:

- Difficult information access (3)
- Difficult data entry (1)
- Excessive demands on human memory (1)
- Confusing information display (5- includes all 3 that selected difficult information access)
- Mismatch between HIT function and clinical reality (4)
- Inadequate or confusing feedback to user (3)
- Electronics-induced credulity (2)
- Usability other: "incomplete data display"
- Incorrect patient information (1)
- Faulty recommendation (1)
- Missing recommendation (4- no overlap with faulty recommendation)

- Clinical content inadequate (1)
- Decision logic inadequate (1)
- Inappropriate level of automation (1)
- CDS other: "inadequate information display"
- Faulty vendor implementation (3)
- Inadequate clinical content (1)
- Faulty design (4)
- Non-configurable software (1)
- Software design other: "missing data display"
- Inadequate software change control (1)
- Unforced user error (3)
- Inadequate training infrastructure (2)
- Excessive workload (1)
- Inadequate change management (1)
- Compromised communication among clinicians (2)
- Loss of pre-existing safeguards (1)
- Other organizational factors other: "poor vendor client relationship"

## Impact

All sites chose commission as the type of potential care process compromise. One site chose low potential impact of care process compromise while the other six chose high impact. All sites said the hazard harmed a patient. Two sites chose major adverse effect likely to be chronic while the other five chose major adverse effect chronic. Seven sites classified the harm as physical, four also said it was psychological, and three of those thought there was financial harm to the patient as well because he was left with chronic renal failure.

## Corrective Action

Only three sites filled out the hazard mitigation plan and all three said there was no mitigation feasible. Four sites said the corrective action is still in progress and two sites selected case closed: not resolved. Four sites filled out the urgency of the initial fix and two selected fix or remove within 24 hours while the other two chose no fix or removal possible. Five sites said the initial fix was partially complete and one said there was no feasible initial fix

Initial fix items selected:

- Plan: "educate end users to double check both IV and PO orders"
- Software upgrade (vendor) (1)
- Training for local IT (1)
- Configuration change (local IT) (1)
- Custom programming (local IT) (1)
- Training for end users (6)

Three sites classified the urgency of the definitive fix as no fix or removal possible, and two of those sites said the definitive fix was partial. Two sites did not enter anything for definitive fix.

Definitive fix items selected:

- Plan: "upgrade from vendor to merge screens of IV and PO orders"
- Software upgrade from vendor (3)
- Training for local IT (1)
- Configuration change (local IT) (1)
- Custom programming (local IT) (1)
- Training for end users (4)

## Vetting and Resolution

Items selected for vetting:

- Pharmacy (5)
- Medical records (1)
- Informatics/human factors (3)
- Quality/safety (5)
- Clinical leadership (5)
- Local IT (6)
- HIT vendor (5)
- Risk management (4)
- Legal department (3)
- Laboratory (1)
- End-user (3)
- Other: EHR policy

Items selected for mitigation:

- Pharmacy (3)
- Medical records (1)
- Informatics/human factors (1)
- Quality/safety (2)
- Clinical leadership (1)
- Local IT (6)
- HIT vendor (5)
- Risk management (1)
- Legal department (1)
- End-user (4)

# 4. Patient Named "Test" Scenario

During an upgrade, many test orders were placed, test prescriptions and labs filled, test notes entered, etc. using the word Test in place of patient name. Some of these entries were incorrectly associated with a true patient with the surname of "Test". No one on the IT or clinical teams noticed the large volume of contradictory information in Mr. Test's chart for several weeks. The patient used a PHR portal to view his lab results, noticed the errant entries, and contacted his physician. No treatment decisions were made based on the inaccurate information, and the patient was not harmed The IT staff identified three other patients with surnames beginning with "Test" and changed the names of test patients to this format: zzGHS1234. IT staff notified the vendor so that other users could be warned about the potential for this problem to occur.

## Systems Involved

One site selected inpatient, one selected outpatient, one selected ADT, one selected CPOE, and three selected Other and entered that multiple/all systems were involved.

## Discovery

Six sites said the hazard was discovered by a patient or caregiver and one site selected Other and entered "patient." Five sites indicated that the hazard was not associated with a shift change; two did not select anything for that question. One site said the hazard was discovered during go-live, one said during an upgrade, and four sites selected during production use; one of those four sites also selected testing as the stage of discovery. Six sites said the hazard was discovered by patient report and one site did not indicate the method of discovery. Five sites indicated that the hazard was published by internal report; two of those sites and one other site said the publication was sent to the HIT vendor.

## Causation

Items selected:

- Confusing information display (1)
- Incorrect patient information (5)
- Information linked to the wrong patient (5- same sites that selected "incorrect patient information")
- Faulty reference information (2)
- Miscalculation of a result (1)
- Lost data (1)
- Inaccurate natural language processing (1)
- Data quality Other: "use of patient TEST"
- Faulty design (2)
- Software design other: "organizational configuration error"
- Inadequate software change control (2)

- Inadequate project management (3)
- Implementation other: "inadequate control of configuration personnel"
- Lack of professionalism (1)
- Inadequate training infrastructure (2)
- Unclear policies (4)
- Organizational factors other: "test pts poorly defined," "poor organizational oversight"

## Impact

One site said the risk of care process compromise was 'high likelihood' while the other 6 sites said that the care process compromise 'had occurred- here'.  Five sites said the type of potential care process compromise was 'commission' while one wrote in "patient care not affected."  The seven sites unanimously entered that the potential impact of this care process compromise was high.  One site said the care process compromise did not reach a patient, while four said that it did but caused no harm.

## Corrective Action

One site entered a selection for the hazard mitigation plan and it was implement only after written acceptance.  The two sites that entered an activity status both selected case closed: resolved.  Four sites classified the urgency of the initial fix as 'fix or remove with 24 hours', one said within 72 hours, and two said within 1 month.  One site said the initial fix was partially complete and the other six said it was complete.

Initial fix items selected:

- Software upgrade (vendor) (1)
- Training for local IT (4)
- Configuration change (local IT) (1)
- Care-process change (1)
- Policy change (4)
- Training for end users (2)
- Other: "chart corrections completed," "define process for naming test pt," and "make sure no test patients are placed in live environment"

Three sites said the urgency of the definitive fix was 'fix or remove within 24 hours', one said within 72 hours, and one said within 6 months.  The completeness of the definitive fix was entered as partial by one site and complete by five sites.

Definitive fix items selected:

- Software upgrade (vendor) (2)
- Training for local IT (5)
- Configuration change (local IT) (1)
- Care-process change (1)
- Policy change (5)
- Training for end users (3)

## Vetting and Resolution

Items selected for vetting:

- Pharmacy (1)
- Medical records (3)
- Informatics/human factors (1)
- Quality/safety (1)
- Clinical leadership (1)
- Local IT (7)
- HIT vendor (2)
- Risk management (2)
- Legal department (1)
- Laboratory (1)
- End-user (1)

Items selected for mitigation:

- Medical records (2)
- Quality/safety (1)
- Clinical leadership (1)
- Local IT (7)
- HIT vendor (2)
- Risk management (1)
- Legal department (1)
- Laboratory (1)
- End-user (1)

## Notes

One user entered the following in the notes section: "When reading this scenario, I had trouble determining whether there was problem with the application linking test orders, etc. to real pts or whether the IT staff was incorrectly entering test info on real pts d/t surname being Test. I entered the event as the latter, IT incorrectly entering test data on real pts."

## 5.  Too Many Open Charts Scenario

A physician-user had four patient charts open when a nursed asked for an urgent order on a fifth patient.  The user mistakenly entered the urgent order for Patient A's CT scan into Patient B's chart.  Patient A's test was delayed and his hospitalization extended by one day, but was otherwise unharmed; Patient B was scanned and received an unnecessary radiation exposure.  A Root Cause Analysis disclosed the cause as mis-entry of the order for one patient into the chart of another, likely caused by having too many charts open at once.  At the direction of the Chief of Medicine, local IT staff reprogrammed the system to prevent more than two charts from being opened concurrently by one clinician.

## Systems Involved

Two sites chose inpatient and four selected CPOE.

## Discovery

Five sites identified the end user as the discoverer of the hazard, and one site said safety personnel discovered it.  Of the six sites that indicated if the hazard was associated with a shift change, all six said that it was not.  The seven sites unanimously chose production use as the stage during which the hazard was discovered.  Four sites said the hazard was discovered by end-user report, and the other three said it was discovered by retrospective analysis.  All seven sites indicated that the hazard was published via internal report and one site also said that it was sent to the vendor.

## Causation

Items selected:

- Excessive demands on human memory (2)
- Confusing information display (3)
- Mismatch between HIT function and clinical reality (2)
- Information linked to wrong patient (2)
- CDS Other: "no re-confirmation of patient ID before ordering"
- Faulty vendor implementation/configuration recommendation (1)
- Faulty design (3)
- Software Design Other: "Local configuration error"
- Inadequate project management (1)
- Inadequate control of user access (2)
- Implementation other: "erroneous configuration"
- Unforced user error (5)
- Inadequate training infrastructure (2)
- Excessive workload (including cognitive) (2)
- Compromised communication among clinicians (1)
- Care processes poorly defined (1)

- Unclear policies (1)
- Loss of pre-existing safeguards (1)
- Other organizational factors Other: "poor oversight"

## Impact

All seven sites said the risk of care process compromise 'has occurred- here'. One site characterized the type of care process compromise as omission, three said it was commission, and the remaining three selected Other to write in that it was either a delay in care or both omission and commission. Three sites selected that the potential impact of the care process compromise was medium and four said it was high. All the sites said that the care process compromise did reach a patient, with three indicating that it reached a patient and caused no harm and the other four saying it harmed a patient. Of those four sites, two classified the patient harm as minor adverse event likely to be temporary, one as minor adverse effect resolved, and one as minor adverse effect likely to be chronic. Two of those users selected all three types of patient harm and the other two selected just physical and psychological harm.

## Corrective Action

One site entered the hazard mitigation plan and they selected implement only after written acceptance. One site classified the activity status as case closed: resolved while four other sites said it was case closed: not resolved. The urgency of the initial fix was described as fix or remove from use within 24 hours by two sites, while one other site said the urgency was within 1 month. The completeness of the initial fix was classified as partial by three sites and complete by two.

Initial fix items selected:

- Training for local IT (1)
- Configuration change (local IT) (3)
- Custom programming (local IT (2)
- Policy change (3)
- Training for end users (3)

The two sites that said the urgency of the initial fix was within 24 hours and the site that said it was within 1 month selected the same options for the definitive fix; two additional sites said the urgency was within 72 hours. Three sites said the definitive fix was partially completed and three said it was completed.

Items selected for definitive fix:

- Training for local IT (1)
- Configuration change (local IT) (5)
- Policy change (4)
- Training for end users (4)

## Vetting and Mitigation

Items selected for vetting:

- Medical records (2)
- Informatics/human factors (2)
- Quality/safety (4)
- Clinical leadership (4)
- Local IT (5)
- HIT vendor (2)
- Risk management (4)
- Legal department (1)
- End-user (3)

Items selected for mitigation:

- Medical records (1)
- Informatics/human factors (2)
- Quality/safety (3)
- Clinical leadership (5)
- Local IT (6)
- HIT vendor (2)
- Risk management (2)
- Legal department (1)
- End-user (3)

# 6. **Note-writing Tool Scenario**

An automated tool to create a physician progress note was offered by a vendor and evaluated for use by a hospital using that vendor's electronic health record suite of products. The note writing application allows users to check various body systems and work through problem lists; it inserts text to match the selections, creating an automated note in the patient record. During the evaluation, IT staff realized that when a problem or symptom box was checked, creating an automated note in the record, a user might change his mind and try to remove the note by "unchecking" the box; when this was attempted, the text was not deleted – it remained in the note. After pointing this out to the vendor, IT staff in the health care organization decided not to implement the application, because it had too much potential for harm if clinicians were to see – and act on – information that the author thought she had deleted.

## Systems Involved

Three sites selected inpatient, one selected emergency department, two selected CPOE, and one site did not select anything.

## Discovery

All seven sites said local IT discovered the hazard. Five sites felt that the hazard was not associated with a shift change and the other two did not select anything for that field.

Stage of discovery items selected:

- Software specification (2)
- Vendor programming (1)
- Testing (5)
- Training (1)

One site said the hazard was discovered by prospective risk analysis, five sites said it was discovered because of usability testing, and one site did not make a selection.

How the hazard was published items selected:

- Internal report (not published) (3)
- Sent to HIT vendor (3)
- Received from HIT vendor (1)
- (two sites did not select anything)

## Causation

Items selected:

- Difficult data entry (2)
- Excessive demands on human memory (1)

- Confusing information display (2)
- Inconsistent information display (4)
- Mismatch between HIT function and clinical reality (3)
- Inadequate or confusing feedback to user (1)
- Electronics-induced credulity (excessive trust) (1)
- Incorrect patient information (3)
- Inappropriate level of automation (1)
- Faulty vendor implementation/configuration recommendation (6)
- Unusable in software-implementation tools (2)
- Faulty design (5)
- Inadequate software change control (5)
- User hardware not working or malfunctioning (1)
- Other: "vendor problem"

## Impact

Sites had mixed selections for the risk of care process compromise from this hazard: one site said it was ruled out definitively, three said there was a moderate likelihood of care process compromise, and three said there was a high likelihood. Two sites went on to identify commission as the type of potential care process compromise and three other sites used the "other" option to specify that both commission and omission were possible outcomes. The three sites that selected moderate likelihood said that the potential impact of the care process compromise was medium, and the three sites that selected high likelihood all said the potential impact was high. Since the hazard was identified before it was put into production, the hazard never affected care or reached patients, so none of the sites entered information about actual care process compromise.

## Corrective Action

Six of the seven sites selected "do not implement affected software" for the Hazard Mitigation Plan and the seventh site did not select anything. One site said the activity status was "in progress", four said it was "case closed: resolved", and one selected "case closed: not resolved". For the urgency of the initial fix, two sites selected "fix or remove from use within 24 hours", one selected "no removal possible" (because the note writer software was never implemented), and one said "no fix or removal required" with the same reasoning. All made identical selections for urgency of the definitive fix as for urgency of initial fix. Three sites made a selection for completeness of initial fix: two sites "none feasible" and one said "none needed".

Initial fix items selected:

- Software upgrade (vendor) (1)
- Other: "do not implement"

Definitive fix items selected:

- Software upgrade (vendor) (2)
- Other: "not implemented"

## Vetting and Mitigation

Responsible for vetting items selected:

- Medical records (1)
- Informatics/human factors (1)
- Quality/safety (1)
- Clinical leadership (1)
- Local IT (1)
- HIT vendor (4)
- Legal department (1)
- End user (1)
- Other: "vendor would need to fix the issues prior to facility testing"

Responsible for mitigation items selected:

- Medical records (1)
- Informatics/human factors (1)
- Quality/safety (2)
- Clinical leadership (2)
- Local IT (1)
- HIT vendor (4)
- Legal department (1)
- Regulatory agency (1)
- Reimbursement agency (1)
- End user (1)