Comments on SAFER Guides

General Comments

We applaud the development of guides intended to help Hospitals, physicians and their staff implement and use their health information technology (HIT) in a way that promotes and enhances safe care of their patients. We have some suggestions to increase their effectiveness and as well as the likelihood of their widespread use.

We encourage the developers and distributers of these guides to make them living tools that are corrected, updated, and enhanced with supporting tools and materials. In the spirit of that goal, we have made specific recommendations on each of the worksheets that we encourage you to consider implementing prior to release.

We are concerned about the length of time it would take for a practice or organization to complete these worksheets and the resources that would be necessary to do so. It is our understanding that the intention is for the user to review the guides and only complete a subset of the worksheets. We suggest that you separate these guides into acute care and ambulatory worksheets to facilitate end-users identifying what might be relevant to their specific situations. Many of the examples suggest EHR/HIT functionality that is not widely available, so the introduction should clearly state that examples used may include functionality that is not currently available.

Under *Suggested Sources of Input*, it would be helpful to provide examples of what type of input these sources might provide. More specificity is needed with regard to "Health IT Support Staff" to clarify if this is vendor or organization HIT staff. It should also be clear whether hardware support or software expertise is required.

We want to caution that without formal evaluation in clinical practice, these "examples of potentially useful practices/scenarios" should not become de facto required metrics in the meaningful use incentive program, other federally-mandated programs, or in the Joint Commission's review of healthcare providers. Moreover, some of the recommendations are beyond the current capabilities of HIT, and some may adversely affect usability and even introduce risk and we have a general concern that recommendations calling for specific EHR functionality are beyond what we believe to be the intended scope of the Safer Guides. We will address these latter instances within our comments on the individual worksheets. We would also comment that many of these examples are only relevant for acute care environments and not applicable to ambulatory practices.

Detailed Comments

Computerized Provider Order Entry with Decision Support

Worksheet #1
- The EHR system permits entry of medication intolerances, distinguished from true allergies.
    - *This is not currently required functionality under ONC certification and may require development work on the part of the HIT vendor.*

Worksheet #2

- Order sets for medications, diagnostic tests, and procedures are developed on the basis of Institute for Safe Medication Practices (ISMP) guidelines.
    - *ISMP guidelines in general are only relevant to the acute care environment and not the only appropriate source for order sets, which also are not limited to medications.*
- EHR developer-provided clinical content is based on authoritative sources and is updated whenever those sources are updated.
    - *Updates to clinical content occur within the software development cycle and require regular upgrades on the part of end-users. Consider changing this to review of EHR developer content for currency on a regular basis and upgrade the EHR software regularly as updates are available. (As you have already addressed this in worksheet #6, you might remove it here.)*
- Order sets for medications include complete pre-written medication orders ("order sentences") that include dose, dose form when necessary, route of administration, frequency, and a PRN flag and indication, if appropriate.
    - *It is not always appropriate for an order for a medication to include the dose in cases where dosage should be modified based on non-weight-based patient parameters such as blood pressure, blood glucose.*
- Personalized order sets are not used. If an institution permits them, there is an annual review process, (e.g., clinical quality committee or medical director approval).
    - *Personalized order sets allow for increased usability, and much of clinical practice involves orders where there is no clear cut evidence for one recommended way of doing things. While evidence-based guideline order sets should be created at the organizational level for appropriate situations, there are many where personalized order sets should be used.*
- The CPOE list of orderable items (i.e., medication dictionary or orderable catalog) includes all formulary medications.
    - *The wording here suggests this is for the acute care environment. In the ambulatory environment, all medications available are orderable but formulary information often is not available because not all payers provide this information to Surescripts.*
- The CPOE list of orderable items includes acceptable, non-formulary medications, which are clearly marked, that users can order for out-of-formulary fulfillment.
    - *Since it is not clear what would be acceptable non-formulary medications, perhaps this example should indicate that in the acute care setting the pharmacy and therapeutics committee should identify non-formulary medications which should be able to be ordered if appropriate.*

Worksheet #3

- Users can look up all orderable items (e.g., medications, laboratory, and radiology tests) and pick terms from lists instead of entering free-text. This should support various word orders (e.g., "abdominal ultrasound" or "ultrasound, abdominal"), various names (e.g., generic, brand, or synonym), and should be able to be browsed alphabetically.
    - *This item seems to suggest a particular design and may even introduce risk since it has been shown that one can easily select the wrong item from a pick list. We believe the authors are suggesting that user-defined medications, labs, and radiological studies should not be*

allowed, and that all orders should be selected from a codified data set of possible tests or meds.

Worksheet #4
- The user can look up whether the lab has received the specimen for testing or not.
  - *This would require development of new functionality and requires that the lab sends and HL7 message verifying receipt and that the interface supports those messages. Such functionality is rare in an ambulatory environment.*
- When medication orders are canceled, information is received and acted on appropriately by the responsible pharmacy.
  - *Surescripts does not currently support "cancel orders", so this item should be noted to only apply currently to acute care environment situations where there is an internal pharmacy.*

Worksheet #5
- Ambulatory alerts for cancer screening protocols should not be presented in the inpatient setting.
  - *It might be very relevant to present these alerts, certainly at discharge, so the patient can be reminded/made aware of necessary screening that has not been done.*

Worksheet #6
- The expertise supporting CDS is demonstrated to EHR users before adoption.
  - *It is not clear what demonstrating expertise means. There is already a requirement for references for CDS in EHRs and that should suffice. We suggest rewording this to harmonize this with the meaningful use requirement to display the sources for evidence based CDS as follows: "CDS should contain references or links to the references for the evidence supporting the recommendation."*

Worksheet #7
- Clinicians are trained and tested on CPOE operations before being issued login credentials.
  - *We agree that clinicians should not be allowed to enter orders electronically without training and testing, but there are situations where it is appropriate to give a clinician access to the system for limited functionality (e.g., read-only or acknowledgement capabilities). We recommend changing the wording to reflect those distinctions.*

Worksheet #8
- Clinician overrides (i.e., decisions not to follow a computer generated suggestion) for high-priority CDS elements are logged and available for review and reporting.
  - *This may require new HIT development by some vendors, so we suggest rewording: "If the EHR audits Clinician overrides (i.e., decisions not to follow a computer generated suggestion) review of high-priority CDS element overrides should be reviewed periodically."*

Worksheet #11
- Nurses are notified via the EHR when new results or orders are entered into the system for one of their patients (e.g., when they login to the system, an alert tells them that new orders are available, or they are sent an informative page or text message).
  - *As worded, this may require new development work and is more relevant in the acute care environment. More general wording applicable to all domains would be: "Workflow should*

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be evaluated and optimized to assure that nursing and other support staff responsible for carrying out orders are alerted to the presence of new orders. Examples of alerts could be a task in box, messages on the edge of the screen, alerts at log on, text messages, or pages."

Worksheet #13
- Checking occurs when an ACE inhibitor is prescribed to ensure that a patient with a history of ACE inhibitor-induced angioedema is protected.
  - *Rather than call out one particular drug-allergy interaction, we suggest more general language: "Testing of high risk drug-allergy pair interactions should be done at implementation and with upgrades to the medication and allergy database. Specific pairs selected for testing should be those most relevant to the care setting. Examples include checking an ACE inhibitor prescription when an allergic reaction of ACE inhibitor-induced angioedema."*

Worksheet #14
- Duplicate Checking: Therapeutic duplication checking occurs before new medication orders are submitted (e.g., two orders for the same or two different beta-blockers are placed).
  - *We suggest specifically calling out the need for the site to be able to decide what orders are subject to duplicate checking as there are many situations where it is clinically indicated to prescribe duplicate therapy.*
- Duplicate checking occurs before diagnostic tests or procedures are ordered.
  - *This may require software development, particularly in the ambulatory environment or if complex parameters need to be set. For example, for a patient suffering from a GI bleed, a CBC or H/H will be ordered frequently, perhaps hourly.*

Worksheet #16
- Changes in frequency, dose, or substitutions are suggested for more age-appropriate strategies.
  - *While standard dose and frequency are common CDS from medication data vendors, recommended substitutions for anything other than formulary are not widely available and would require new development in the ambulatory domain. We recommend deleting substitution from the recommendation.*

Worksheet #17
- Renal dose adjustment suggestions along with information on the patient's renal status are clearly displayed prospectively for relevant medications.
  - *This would require new development for many HIT vendors in the ambulatory environment. This also seems to suggest a particular design. We recommend rewording so that existing functionality is leveraged: "Drug-disease interaction checking is implemented for renal insufficiency and failure and reference dosing guidelines are available either within the EHR or through info button links."*
- Patient context (age, renal function) dynamically changes the defaults prospectively.
  - *While this is widely available for age, renal function-drug interaction checking (in terms of numeric values as opposed to a diagnosis of renal insufficiency) is not widely available in the ambulatory environment and there are very complex issues related to which tests to consider (e.g., eGFR, GFR, creatinine clearance) and disparate normal values when multiple lab vendors are used.*

- Dose limits are age and body size appropriate.
  - *It is not clear what is meant by body size, so it might be clearer to indicate weight and body surface area as appropriate.*

Worksheet #18
- Alerts are modified in a dynamic fashion based on feedback from the users and monitoring of user behavior.
  - *If this includes drug-allergy alerts, this suggestion might require additional functionality because meaningful use requires that drug-drug alerts be modifiable but not drug-allergy alerts. Please be specific as to types of alerts.*

Worksheet #19
- Clinicians are required to re-enter their password or PIN to sign an order.
  - *This could be onerous in many workflows and should be driven by institutional policy. It should not apply to all orders, perhaps only high-risk or other others requiring special attention such as chemotherapy. Clinicians typically are only required to co-sign high risk orders. This requirement may also differ depending on who writes the order – i.e., attending v. resident.*

Worksheet #20
- Corollary (or consequent) orders are automatically suggested when appropriate and the orders are linked together, so that changes are reflected when the original order is rescheduled, renewed, or discontinued.
  - *This would require development work for ambulatory products. Caveats about availability of this functionality should be included.*

Worksheet #21
- Medication monographs (such as Micromedex), dosing calculators, diagnostic guides, laboratory reference materials, image atlases, anatomical diagrams, patient education materials, and disease-specific treatment guidelines are directly accessible from the order entry screen or module.
  - *We suggest that this be reworded to leverage the requirements for info buttons and similar functionality in certified EHRs. "Relevant reference materials should be accessible through info buttons or similar functionality in the order entry screen/module. Examples include medication monographs, dosing calculators, diagnostic guides, image atlases, patient education, and disease-specific treatment guidelines."*

Worksheet #22
- CPOE and CDS functionality are tested to ensure proper operation before go-live and with test patients in the production system before clinical use.
  - *We agree that this is essential. However, the example of the Leapfrog test is subject to some controversy so we suggest using a different example.*

Worksheet #24
- Clinician-reported hazards associated with CPOE and CDS due to poor usability are regularly communicated to someone in a position to make improvements. Follow-up is monitored.

- o *We suggest rewording as follows: "Clinician-reported hazards associated with CPOE and CDS due to perceived poor usability are regularly communicated to a team charged with reviewing complaints and relaying validated hazards to the creator of the CPOE or CDS for management. Regular review of validated issues and solutions should occur."*

Worksheet #25
- Pertinent clinical information (age, weight, allergies, pregnancy status, and creatinine clearance/GFR) as well as identifying patient information is displayed on or behind the ordering screen with no scrolling required to view all the pertinent clinical data.
  - o *Suggested wording to minimize concerns about prescriptive design, care setting, and end-user device variability: "Pertinent clinical information (age, weight, allergies, pregnancy status, creatinine clearance/GFR if in an acute care setting) as well as identifying patient information is easily accessible from the ordering screen, examples include in a patient header bar, on the ordering screen, from a hide/show panel. If screen resolution allows, it is preferable that the information be accessed without scrolling."*

Worksheet #26
- Clinicians are informed when non-formulary medications require additional pre-approval.
  - o This information is not always available in an ambulatory environment, suggest adding applicable domain.
- Clinicians are informed when "send out" tests require special forms or procedures.
  - o *We suggest you change "clinician" to "end-user" since often nursing or lab staff complete these orders and AOE questions.*

Worksheet #28
- Chemotherapy agents require special authorization and are displayed in a visually distinct way (e.g., different color, italics, etc.).
  - o *This functionality is not widely available in the ambulatory setting.*
- TALLman lettering is used to reduce CPOE errors from orthographically similar medication names (i.e., look-alike or sound-alike medication names; acetaZOLAMIDE and acetoHEXAMIDE).
  - o *Not all vendors have implemented this functionality, so we suggest rewording: "TALLman lettering, when available, should be implemented to reduce CPOE errors from orthographically similar medication names (i.e., look-alike or sound-alike medication names; acetaZOLAMIDE and acetoHEXAMIDE)."*

Worksheet #29
- Key CPOE and CDS safety indicators, such as the following, are monitored and reported to leadership on a periodic basis:
  - Rates of preventable ADEs.
    - o *EHRs and HIT cannot determine whether an ADE was preventable so clarification should alert the end-user that manual review would be necessary*
  - CPOE use rate
  - Frequency (volume) of orders that generate an alert.
  - Override rate (% of alerts that are overridden) in comparison to alert volume.
  - Usage of evidence-based order sets is monitored.

- - Not all of these reports are available with every EHR and the non-technical end-user may have difficulty in creating these reports.
- Median turnaround time for STAT laboratory or radiology results.
  - This is not a metric widely available in the ambulatory environment and in the acute care setting, not all vendors will have out of the box reports for this measure.
- Percent of all orders requiring modification by someone other than the ordering provider.
  - Not relevant in most ambulatory environments and not all vendors will have out of the box reports for this measure.

Patient Identification

Worksheet #1
- An enterprise-wide master patient index that includes patients' demographic information and medical record number(s) from different parts of the same organization (and, if available, from external organizations) is used to identify patients before importing data
  - Suggest that boilerplate policies and procedures for each of these items are provided.

Worksheet #2
- Clinicians can select patient records from electronically generated lists based on specific criteria (e.g., user, location, time, service).
  - This worksheet seems to be a list of proposed requirements for an EHR product rather than policies and procedures that an end-user would adopt to reduce risk. We suggest removing these items and replacing with action items such as: "Providers should be allowed access rights to print their hospital rounding schedules or office appointments and these lists should be sorted by location or chronology as appropriate" and "Hospital rounding lists should include at least two patient identifiers to correctly identify the appropriate patient."

Worksheet #3
- Information required to accurately identify the patient is clearly displayed on all computer screens, wristbands, and printouts.
  - Some examples are overly broad. These would benefit from more detail regarding recommended policies, such as using barcodes to identify patients for med administration and lab draws.

Worksheet #4
- On all patient lists containing two or more patients with the same last name, the names in common are displayed in a visually distinct manner (e.g., bold, italics, different color).
- Use alternate line colors for adjacent patients.
  - These seem to be EHR requirements and not something the end-user can control.

Worksheet #5
- Medical record numbers incorporate a "check digit" to help prevent data entry errors.
  - How much control will HIT staff have around whether the system includes a check digit? If medical record numbers are created by the practice, rather than the software, is the expectation that the software would have functionality to check the digits of a user defined number? This functionality is not currently available and would require development.

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- Organizational policies optimize automated processes in the EHR to prevent common errors, including transposition errors, which can result in poor patient identification.
    - *This is not an example of a check digit. Instead, it's something that might be done in addition. The scope of this recommended practice is unclear.*

- The "Verhoeff algorithm" works with strings of decimal digits of any length and detects all single-digit errors and all transposition errors involving two adjacent digits.
    - *EHRs in general do not currently support the Verhoeff algorithm, this would require development. It's not clear what an organization would do with this information. Are there other check digit algorithms that might work just as well? Any recommendation of algorithms to use should go through broad stakeholder evaluation as well as standardization development if the expectation is that it would be broadly deployed.*

Worksheet #6
- Users are warned when they attempt to create a new record for a patient (or look up a patient) whose first and last name are the same as another patient.
    - *These appear to be EHR requirements rather than end-user activities. It should be reworded to focus on actions the end-user should take related to using functionality to avoid creating duplicate charts or using a four point check to make sure they are entering data/orders on the correct patient.*
    - *In a large EMPI, there will be hundreds of patients with similar names. A warning when searching for a patient chart might be appropriate. However, this should not be confused with a warning every time a chart is opened (e.g., from a patient list). That would be a large and unnecessary burden on clinical users.*

Worksheet #8
- The user interfaces of the training, test, and read-only backup versions of the EHR are clearly different from the production ("live") version to prevent inadvertent entry or review of patient information in the wrong system.
- The screen background color on the production ("live") EHR is different from all other EHR environments.
    - *The above example of screen background color would require development for many vendors. A less specific example that takes into account widely available functionality could be considered (e.g., logging into the test or training environment could give a validation warning before proceeding).*

Worksheet #9
- The organization has a process to assign a "temporary" unique patient ID (which is later merged into a permanent ID) in the event that either the patient registration system is unavailable or the patient is not able to provide the required information.
    - *The "rationale" should include those patients whose identity cannot be confirmed (e.g., unconscious).*
    - *In the examples, we recommend specifically calling out blood banks as downstream systems that likely need special processes to ensure temporary IDs and patient merges are handled*

appropriately. Blood banks are also much more relevant to patient safety than downstream billing systems.

Worksheet #10

- Patient identity is verified at key points or transitions in the care process (e.g., rooming patient, vital sign recording, order entry, medication administration, and check out).
- Clinicians are asked to "re-enter" the patient's initials before signing an order.
  - *In the examples, the list should include bar-code meds administration.*

Worksheet #11

- The EHR limits the number of patient records that can be displayed on the same computer at the same time to one, unless all subsequent patient records are opened as "Read Only" and are clearly differentiated to the user.
  - *It may not be practical in real end-user workflows to never have two patient charts open at the same time. A clinician should not be editing two charts simultaneously, but there are many scenarios in which it is necessary to open a second chart, document on it, and then return to the first chart (e.g., pharmacist verifying orders for one patient and then getting a call and re-dispensing a med for a different patient).*

- Workflow is evaluated to ensure that clinicians are able to respond to urgent situations in which they may need to look at a new record without completing review of a first patient. The practice environment should be designed to minimize the need to open and actively use more than one patient's records on the same computer.
  - *This suggests an unrealistic work environment.*

- Before allowing the user to change the current patient, the system checks that all entered data has been saved (i.e., signed) before allowing the system to display a different patient's data.
  - *This is not always the appropriate decision and oversimplifies the workflow. It may be more appropriate in some instances to save or discard information, and other times to ask the user what is appropriate. And in some of those situations, it might be important to clearly distinguish which information was not explicitly saved by the user and instead automatically saved by the system. Perhaps it would be useful to clarify that "saved" could mean to the legal chart (e.g., viewable by all clinicians with access to the chart), or in some cases saved to an "in-progress" section only viewable by the clinician who entered the partially completed documentation.*

Worksheet #12

- The system displays either a pop-up alert when opening the record or a different background color for the deceased Assessment Notes patient header in the EHR.
  - *This is suggesting specific design and better wording would be to state that the system clearly identifies when a deceased patients chart is accessed.*

Worksheet #13

- The use of test patients in the production (i.e., "live") environment is carefully monitored. When they do exist, they have unambiguously assigned "test" names (e.g., including numbers or multiple ZZ's) and are clearly identifiable as test patients (e.g., different background color for patient header).

- o *This is also mentioned in recommended practice #10 of the system configuration Guide, but is represented differently (e.g., the potentially useful practices are different). We recommend ensuring consistency across Guides for repeated suggestions.*

Worksheet #14
- The organization regularly monitors their patient database for patient identification errors.
  - o *We recommend specifying potential duplicate patient records here.*
- The order–retract–reorder algorithm can be used to estimate the rate of erroneous orders due to patient ID errors.
  - o *More details need to be provided here since readers are unlikely to follow reference links and this may not be information easily captured by all electronic health records.*
- The "inconsistent gender algorithm" can be used to estimate the number of erroneous free text notes due to patient ID errors.
  - o *More details need to be provided here since readers are unlikely to follow reference links and this may not be information easily captured by all electronic health records.*
- Industry standards for duplicate record error rates are available. The organization consistently monitors its own duplicate record error rate, and ensures that it remains at or below industry standards.
  - o *We recommend moving this example up on the list. As the "low-hanging fruit" on this list, perhaps it should be listed first and given more emphasis. It would be helpful to provide these industry standards though as practices are unlikely to know where to find them.*

System Configuration

- General Instructions
  Because the website does not include phase details, it is unclear if they are intuitive or flexible enough to accommodate most organizations' implementation strategy.

  In the second paragraph, "issues" implies software bugs, which is not the intent. Better terminology that is more consistent with standard risk management jargon might reference "potential safety hazards."

  With regard to the term "implementation level", perhaps "status" would be a better term" and consistent with the checklist.

- Introduction
  In the second paragraph, it is unclear whether "configuration team" is intended to be the same as the "multi-disciplinary team" referenced above.

  It would be useful to explain why "a configuration review and maintenance process must be developed and followed". For example, periodic improvements are necessary to maximize the potential benefits of the EHR, and those are less disruptive to business operations and more likely to be successful if implemented through coordinated change management.

  On page 4, putting this worksheet link on a separate line significantly reduces the number of practices that fit on a single sheet, as does the repetition of the "recommended practices" and

"implementation status" titles. Consider eliminating the titles and turning the number boxes into the hyperlinks. Since this is essentially a dashboard, it should be more condensed and data-rich.

Worksheet #1
- Organizational policy sets minimum standards for EHR access by clinicians (e.g., clinicians walk no more than 50 feet to access an EHR and, if there are wait times, they are minimal and ensure that urgent clinical needs can be addressed).
  - *Please clarify, "wait times" for what? Access to the EHR or EHR response times?*
- Workflows have been mapped to ensure ready and timely access to all needed EHR functionality in clinical areas.
  - *Does this refer to mapping of physical space or logical mapping of workflow tasks?*

Worksheet #2
- All data and operational systems are maintained on at least two geographically distinct hosting sites that are mirrored in real-time ("hot" or "warm" sites). This redundancy reduces the risk of a single natural or man-made disaster to disable operating capacity.
- There are at least two physically distinct network connections between the hosting sites.
  - *These may not be realistic in small ambulatory practices.*

Worksheet #3
- The organization has implemented a "single sign-on" solution that allows authorized clinicians to rapidly move between disparate clinical applications without requiring additional login information
  - *We suggest adding "whenever possible" as it is not always possible for all systems to be available via single sign-on.*

Worksheet #7
- Standard clinical and administrative reports are generated and reviewed regularly to ensure that the data on which they are based has not changed in a way that renders the report meaningless.
  - *What is meant by "standard report"? If a "standard report" means that it's in broad use, and a change renders it less useful, notification should come out quickly after the change. What would this additional process look like and where/when would it add value?*

- If data becomes corrupted, the facility has policies and processes for reverting to a backup version of the data that precedes the corruption.
  - *In this example, there should also be policies and processes for: 1) running integrity checks to ensure a successful recovery after reverting to backup; 2) temporary/unexpected downtime processes to ensure access to critical data while the system is brought back to an uncorrupted state; 3) recovering or replacing data/documentation from the period of system corruption and subsequent downtime.*

Worksheet #8
- Clinical content drives significant parts of the user experience. Failure to update, test, and maintain this content can result in significant degradations in performance.
  - *Does "performance" refer to system performance or user performance? This could be written to more clearly identify how poor clinical content can affect safety without referring*

to performance which suggests speed of actions rather than accuracy and timeliness of information.

- Clinical content is tested to ensure that items entered in one system are accurately transmitted through the system-to-system interface and received by the remote system unchanged.
  - *This example may be more appropriate in the interface section.*

Worksheet #9
- Employees who change jobs are reassigned to the appropriate roles promptly.
  - *Users should also have role-based security revoked promptly if leaving the organization entirely. This was mentioned earlier in the authentication guidance and should be repeated here in this context.*

Worksheet #10
- Both the training and test environments are as complete as possible (e.g., within the training and test environments users can enter and sign orders that will display for another user, review laboratory data, and see alerts firing appropriately).
  - *This example should explain "why": to discourage the temptation to practice or test in production because training/testing is not up-to-date.*
- The read-only backup system is password protected and clearly identifiable as read-only.
  - *All versions of the system should be password protected. Also consider recommending that generic users (used by HIT support staff and others for role-based testing) are eliminated from the live production environment or at least tightly controlled, e.g., with regular password changes or restricted admin-level rights*.
- The EHR is configured to make it difficult to confuse the live version of the EHR with other versions. For example, the screen background color or the color of the patient headers could be different.
  - *This example is on numerous worksheets and should be harmonized.*

Test Results Reporting and Follow-Up

Worksheet #1
- Abnormal test result values and interpretations are defined and stored in a standardized, coded format (e.g., high/low sodium; critical potassium; positive/negative fecal occult blood test, etc.).
  - *If a practice uses different labs, they are dependent upon each lab for supplying the results and labs all use different descriptions for the same LOINC code. HL7 defines a standard set of valid abnormal flags. These flags are just a character string and not coded either as LOINC or SNOMED. When results are received, whatever lab sends is accepted but if the flag is not HL7 compliant, the result is not interpreted that as low, high, etc. We cannot accept and store abnormal flags as coded values since HL7 does not support that.*

- There is a process to handle paper-based test results that includes, at a minimum, the entry of a coded value into the EHR to indicate whether the result was normal or abnormal along with a scanned copy of the report in the EHR.
  - *This example does not describe a functional workflow. If a test result is going to be manually entered into the system, it would be faster to enter the result than a code for normal or*

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abnormal and there is no standard code set of which we are aware for normal and abnormal results.

Worksheet #2
- Imaging results are coded as abnormal using a structured code if there is a new or unexpected abnormality that requires follow-up.
  - *Regarding the structured codes referenced in this example, it should be clear if there is a standard. There might be one in the references but we could not access those and have concerns that end-users will check the foot notes. Who defines what is new or unexpected? Could this be added to a recall list or tickler file?*

- Mammography results are stored according to BI-RADS® criteria.
  - *Are you suggesting that there be a structured field to identify the BI-RAD® category for use as a filter? This would require manual identification and entry since reports do not get sent electronically with a segment dedicated to BI-RAD® category. It may be more logical to sort by date v. BI-RAD®. We suggest collaborating with HL7 to define a segment for the BI-RAD® level before suggesting functionality that does not currently exist.*

Worksheet #3
- Efforts are made to proactively identify failure points related to EHR-enabled test results delivery.
- Specifically designed testing scripts are used to identify remediable points of vulnerability in order to build systems that are more fault-tolerant.
- Specific testing of routing logic, provider recipients, and configuration is performed to ensure accurate results delivery.
  - *All the examples are reasonable but there will need to be sample testing scenarios and examples of common failure points. This needs to be expanded to include process for updating lab compendia or data dictionaries to support new tests, mapping of same LOINC with different test names, etc.*

Worksheet #4
- Organizations identify specific types of EHR system changes that impact CPOE and diagnostic services, such as application upgrades or changes to interfaces, and carefully review data integrity at all points where data is used.
- Problems related to tables out of sync are identified with thorough testing.
  - *Please provide specific scenarios for the second example.*
- Error queues are used to monitor for proper system performance; results that cannot be automatically delivered are manually delivered.
- Order entry and result reporting interfaces are tested after every change to the laboratory or imaging ordering catalog.

Worksheet #5
- Diagnostic tests that are not orderable through CPOE for any reason are promptly added to the system.
  - *It may be useful in this example to speak to the need for a uniform data dictionary of test names mapped to LOINC, that these be reviewed and updated regularly, and every time a*

test cannot be ordered or a result does not populate a named field (other than miscellaneous).

Worksheet #6
- EHR can track whether or not the order was received, specimen collected, test completed, results reported, and results acknowledged.
  - *In this example, consider including in the data integrity section that labs and radiology providers do not always send back the order number or the correct order number so duplicate orders can be created for results. This needs to be discussed and a process developed for identifying these duplicate orders so they do not clutter up the incomplete order reports.*

Worksheet #7
- EHR supports assignment/transfer of responsibility for test order follow-up.
  - *Include in this example sample policies and procedures for residents rotating off service, providers out sick, and time limits for review after which it is escalated.*

Worksheet #9
- The individual changing the results is responsible for notifying appropriate clinicians of those changes. Since electronic systems do not always ensure that a critical communication will be received and reviewed promptly, for clinically important changes to results appropriate clinicians are also contacted directly.
  - *Generally speaking, results are going to be populated from an interface and would then be sent to the physicians for sign off.*

Worksheet #11
- In the outpatient setting, the ordering provider is responsible for follow-up unless he or she delegates this (e.g., to covering provider). Delegation should be documented and accepted by the delegate.
  - *It is unlikely that someone is going to document acceptance by a delegate. EHRs support delegation and most likely store that data but may not capture "acceptance".*

Worksheet #14
- Result details are reported on one screen, eliminating the need for horizontal scrolling. For example, providers should not have to use additional scrolling (e.g., on the "next page") to access critical information.
  - *In this example, this is device dependent and not all form factors will support a full display.*

Worksheet #15
- Outpatient clinicians have the option to receive results for their patients in the inpatient setting in their electronic inboxes.
  - *Not all EHRs can support this functionality.*

Worksheet #19
- The EHR incorporates automated tools and reports that enable selected lab results to be easily graphed and displayed over time to view trends.

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- - *The example does not appear to be a physician worksheet activity. It may be a design requirement for an EHR. What is expected of the practice to do here?*

Worksheet #20
- Results can be sorted according to important parameters such as date, type, urgency, patient, and location.
  - *Again, this sounds like a requirement for an EHR, not an area of action for a practice.*

Worksheet #21
- Functionality to record a follow-up action due at a future date exists in the EHR.
  - *This too sounds like a requirement for a product, not an area of action for a practice. In this case, it may be appropriate to recommend policies for how to document future tasks, handle recalls, tickler files, etc.*

Worksheet #23
- National Provider ID (NPI) is used for provider attribution of orders.
  - *This example regarding the NPI seems somewhat prescriptive in that EHRs may use other unique identifiers.*

Clinician Communication

Worksheet #1
- The organization has a policy for verbal delivery of critical information that supplements use of the EHR.
- Hospitals have policies and procedures to address timely electronic delivery of important clinical information. For example, hospital discharge summaries are delivered to clinicians responsible for follow-up within two business days.
- Messages are automatically forwarded to an alternate clinician if not responded to within a time period appropriate to the time-urgency of the message.
- The EHR allows automatic forwarding of messages to a surrogate clinician during a specific time period or circumstance, such as when the clinician is absent.
- Messages are delivered to a "pool" that several clinicians are held accountable for and the individual responsibilities for follow-up are clear.
- When a patient transitions to another setting, a clinician provides a summary of care record to the receiving hospital or clinician in a timely manner. The summary record should include, at a minimum, the Common Meaningful Use Data Set.
  - *Some of the use cases are unclear as to whether they are suggesting that the sending system or the receiving system contain the functionality. We suggest that there be clear delineation in practice review between sending /outbound messaging and receipt. So, for example, the forwarding of messages if not responded to in such a period of time assumes that the receiving EHR can send messages back to the sender that the message was received and opened. This is optional today and that type of message, even when implemented, can literally be machine-to- machine acknowledgement. The sender has no control over this and could end up resending when it is not necessary – this is likely a receiver role.*
  - *Same for auto forwarding if clinician is absent or on vacation – the receiving EHR should have forwarding capabilities. We would suggest that the use cases focus on policies for*

sending and receiving separately, not mixing the two. Not all EHRs will have these capabilities. Consideration of patient privacy should also be addressed with automatic forwarding functionality.

Worksheet #2

- The organization has a policy on secure messaging that specifies what should and should not be transmitted, and users are trained on it.
- Messages are sent only to persons who may need to act on them. "Reply all" is used only when necessary.
- Mechanisms are in place to allow communication of nonclinical information (e.g., appointment requests) in a way that does not impact communication of clinical information (e.g., abnormal laboratory results).
  - *We suggest clarifying scenarios that are patient-related v. clinician-focused. The rationale focuses on too much information and the potential to miss the really important content. Secure messaging is also reference, so it appears that this item is targeting clinician-to-patient communication. But most often the debate around the sharing of too much information is among clinicians. We suggest breaking out use cases for secure messaging protocols with patients and information exchanges of urgent and non-urgent/actionable and non-actionable information with clinicians.*

Worksheet #3

- A real-time tracking system allows referring clinicians to determine the status of all their referrals and consults transmitted and allows specialists to identify all their referrals and consults that are pending.
- Clinicians and specialists are able to print a report of all their referrals and consults including the status of each.
- Clinicians are able to identify whether their sent messages have been opened (e.g., "read receipt").
- The EHR automatically notifies the ordering clinician or team when referrals or consults are canceled or completed.
- Clinicians are notified if a message they sent has not been opened within a pre-specified number of days.
- The EHR can track whether a message was received or not.
- Outpatient practices with messaging systems that are not fully integrated into the EHR use additional tracking strategies to enable follow-up.
- The EHR includes the capability for clinicians to look up the status of their electronic communications (e.g., delivered, opened, acknowledged).
  - *These examples suggest capabilities well beyond those currently available. This assumes that EHR exchange systems have knowledge of the content of information being exchanged between providers. Today, there is a read-receipt optional Message Digest Notice but no other formal mechanisms to automate this. While closed-loop referral tracking is being contemplated for Stage 3, it may be unrealistic to think that this capability exists in most EHRs. This wording needs to be crafted in a way to build policies for closed-loop referral and consult tracking, and not necessarily assume that the EHR can manage it.*

Worksheet #4

- The EHR message interface prominently shows the date, time, and sender

o *We suggest adding a section about sender information such as sender addresses and aliases. Some direct addresses and patient addresses without aliases can be confusing. It is important to be sure that addresses/aliases reflect the appropriate sender. There should be more specificity as to whether this refers to internal or external messaging.*

Worksheet #5
- Templates are used to facilitate completion of electronic referrals and consults to meet the specialists' requirements.
- Clinicians are prompted when certain key fields, such as the "reason for referral" or "specialty" field, are left blank.
- Referral requests should include, at a minimum, the Common MU Data Set.
   o *It is not self-evident that the Common MU Data Set is needed for all or even most referral requests. We suggest establishing a practice policy or guideline that identifies the ideal content and base-level content to be provided for a given transition, and verify that workflow and system flow insure compliance. There should be organizational procedures to define required information and this should be coordinated with specialists they might refer to. Policies and procedures should be in place to collect and transmit the required information whether it is through the EHR or paper. There will be cases where there will be a mix for external referrals and this worksheet needs to address both.*

Worksheet #7
- The EHR system is updated at least monthly with a contact list of all practicing clinicians, and, for hospitals, includes clinician coverage schedules.
- The EHR automatically addresses internal messages between clinicians, so that email address or fax numbers need not be typed.
   o *We suggest establishing a policy and process for maintaining current contact information for the EHR provider directory. It is important to ensure that there is agreement to share that provider information upon request. If the EHR is using a HISP to facilitate exchange or an HIE, they might share their provider directory management practices. We also recommend establishing a best practice to maintain patient care team information within the EHR. There should be no need for an e-mail or fax number for internal messaging so the second example should be clarified.*

Worksheet #8
- The EHR has functionality to allow clinicians to flag referrals or consults as urgent when needed.
- Specialists are given immediate access to all referral and consult requests, and can triage patients and schedule appointments based on urgency.
- Messages that are administrative in nature are clearly differentiated from clinical alerts.
   o *There should be a policy that addresses an escalation process for critical alerts that are not responded to within the specified time period, including an alternate communication method. The third example should be deleted as unnecessary.*

Worksheet #9
- Written clinician-to-clinician communication is documented into or scanned into the EHR.

- The EHR includes a secure messaging module with external access (i.e., to facilitate electronic communication with patients or providers who are not users of the EHR) that does not require separate, external software.
- If clinical messaging systems external to the EHR are used, a copy of every message is stored in the EHR.
    - *Not all clinician-to-clinician communication needs to be saved. This item should be changed to reflect the need for creation of organizational policies about what information must be saved. Example #2 needs to be secure messaging and not all external providers or patients will have access to secure messaging. The prohibition on user separate software should be removed as there may in fact be a need for this.*

Worksheet #10
- Messages with critical or urgent information are made visually distinct (e.g., visually highlighted).
- The EHR allows sorting of clinician-to-clinician messages by urgency.
- When sending notes/documentation to other clinicians (such as for co-signing), the EHR allows the sender to add recipient-specific explanatory messages, highlighting, or markup.
    - *This recommendation seems very prescriptive for an EHR and is forward looking as far as meaningful use certification criteria for the embedding of comments into the electronic notes. It may be better to consider a process to identify what is urgent and how it will be represented and communicated.*

Worksheet #11
- Message screens display a "responsible clinician" indicator.
- The system supports forwarding and accepting responsibility for follow-up.
- The EHR is able to capture and display when responsibility for follow-up action is accepted by a clinician.
- A comprehensive policy exists outlining responsibility for follow-up action for certain situations (e.g., no-shows).
    - *Again, this seems very prescriptive regarding EHR functionality. We suggest rephrasing this to indicate the EHR supports the ability to assign and track actions and responsible parties to inbound messages. It should be clear that the EHR does not determine who is responsible but should only support documentation or sending to whomever the user determines to be the responsible party.*

Worksheet #12
- Referring clinicians, specialists, and/or leadership are electronically notified when no action is taken on a referral or consult request or a clinician-to-clinician message within 14 days.
- Referrals and consult response times are tracked by organization leadership.
- Messaging is periodically monitored to understand and improve quality of communication.
- Policies and procedures are in place to prevent messages "lost" in the system, such as messages sent to clinicians no longer employed by the organization.
    - *We recommend establishing policies for tracking acknowledgements, and the implementation of workflows necessary to insure compliance. Again, it seems logical to reference assign and tracking functionality here.*

Contingency Planning

Worksheet #1
- The organization has a remotely located (i.e., > 50 miles away and > 20 miles from the coastline) "warm-site" (i.e., a site with current patient data that can be activated in less than 8 hours) backup facility that can run the entire EHR.
- The warm-site is tested at least quarterly.
- The organization maintains a redundant path to the Internet consisting of two different cables, in different trenches (a microwave or other form of wireless connection is also acceptable), provided by two different Internet providers.
  - *This is not relevant to most ambulatory practices who could not afford a hot, warm, or even cold back-up site.*

Worksheet #2
- Organizations evaluate the consequences to patient safety and to business operations due to loss of power that shuts down the EHR, and implement concrete plans to keep the EHR running to the extent needed to avoid unacceptable consequences.
- In the event of a power failure, there is an uninterruptible power supply (UPS), either batteries or a "flywheel," capable of providing instantaneous power to maintain the EHR for at least 10 minutes.
- The UPS is tested regularly (optimally on at least a monthly basis).
- The on-site, backup electrical generator is able to maintain EHR functions critical to the organization's operation (e.g., results review, order entry, clinical documentation).
- The organization maintains 2 days of fuel for the generator on-site.
- The generator is tested regularly (optimally at least on a monthly basis).
- The UPS and the generator are kept in secure locations that are not likely to flood.
  - *Again, this is not relevant to many ambulatory practices except the need for a UPS on key pieces of hardware.*

Worksheet #3
- The organization maintains enough paper forms to care for patients on the unit for at least 8 hours. Paper forms could include those required to enter orders and document the administration of medications, labs, and radiology on each unit.
- There is a process in place to ensure that the information recorded on paper during the downtime gets entered and reconciled into the EHR following its reactivation (e.g., this could be entering information as coded data or scanning of paper documents).
  - *The first example should be more generic to apply to all domains rather than referring to a time limit that might not apply to the situation. In an ambulatory environment, they might shut down if they lose power so they might only need enough for an hour where a hospital might need enough for days.*

Worksheet #4
- The organization has a daily, off-site, complete, encrypted backup of patient data.
- The off-site backup is tested regularly (optimally on at least a monthly basis, i.e., complete restore).
- The content required to configure the system is backed up on a regular basis (optimally on a monthly basis and before every system upgrade).

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- The organization maintains multiple backups, created at different times.
- Backup media are physically secured.
- Backup media are rendered unreadable (i.e., use software to scramble media contents or physically destroy/shred media) before disposal.
- The organization has a "read-only" backup EHR system that is updated frequently (optimally at least hourly).
- The read-only EHR system is tested regularly (optimally at least weekly).
- Users can print from the read-only EHR system.
- If there is a "unit-level" read-only backup EHR system, it is connected to a local UPS or "red plug."
    - *We suggest that in the example referencing the daily offsite back up, it should be noted that cloud-based alternatives for practices where daily offsite backups of physical media are financially impossible.*
    - *In the last example, we suggest not referring to "red plug", but rather specify it is plugged into a generator backed up electrical outlet.*

Worksheet #9
- Access to the "read-only" backup EHR is disabled (e.g., icons on the computer screens are "grayed out" or not available) during periods of normal EHR operations.
- The user interface of the read-only backup EHR system is visibly different than the fully operational system (e.g., there is a different background color for screens, a watermark across screens, or data entry fields are grayed out).
- Clinicians are trained on appropriate use of the read-only backup EHR.
    - *In the second example, please make this consistent with other examples of this in different Guides. Also, it should be less prescriptive in terms of how it clearly identifies that it is not the production version of the application. This could be an alert or message on log in and not just a different physical appearance.*

Worksheet #10
- The organization regularly monitors and reports on system downtime events.
- The organization regularly monitors and reports on system response time (optimally under 2 seconds).
- The organization has a written policy describing the different hardware, software, process, and people-related testing procedures.
- The organization maintains a log of all testing activities.
- Unplanned downtimes and the effectiveness of follow-up to prevent them from recurring are monitored by the top leadership.
    - *There need to be different response time thresholds for different tasks. Some require faster response times than others, so it should be qualified to make that clear.*

Organizational Responsibilities

- General Comments
  The SAFER Guides assume that practices have a baseline level of knowledge regarding the assessment items and related EHR content. Although larger organizations have dedicated professionals who possess this knowledge and skill set, it may prove challenging to smaller

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organizations including independent physician practices. A glossary and educational materials which defines various terms and/or presents relevant examples would be of benefit. As an example, the word "protocols" has varying meanings across different health organizations and software vendors. Other examples where educational materials may be needed include the need for formal decision-making structures, conducting a workflow analysis, etc. Although numerous references are included it is often a challenge for clinicians to devote time or resources to accessing them rather than taking advantage of educational materials which could be integrated with the worksheets.

- Overview
  The Organizational Responsibilities Self Assessment is intended to review activities, processes, and tasks intended to optimize the safety and safe use of EHRs. In contrast to the other guides, it is not organized under the same Phases and Principles rather than around principles that apply to individuals who hold responsibility for patient safety. This may prove challenging to organizations who have become adept with the other format.

Worksheet #1
- Highest-level decision makers ensure that adequate staffing and resources exist so that safety issues associated with adoption and use of EHRs can be addressed.
  - *We suggest adding "in a timely fashion."*
- Highest-level decision makers identify EHR-related patient safety goals, assess whether those goals are being reached, and address any shortcomings.
  - *We suggest adding language for decision makers to ensure staff members are identified to provide structured feedback to the software vendor regarding any perceived shortcomings as these are often addressable through training and educational interventions.*

Worksheet #3
- Developers routinely review and update decision support content they provide.
  - *We suggest adding language that user organizations should also routinely review CDS and communicate with the vendor regarding local standards of care of potential changes to CDS content.*

Worksheet #4
- Clinicians are involved in decision making about all proposed changes to the EHR.
  - *We suggest adding language to give examples of specific changes to the EHR which require clinical input as there are some changes (such as changes to database table structure, changes to field formatting, etc.) for which clinical input would provide minimal utility. Clinicians must remain focused on those changes within EHR that require their specific expertise.*

Worksheet #5
- Clear clinician oversight is maintained when clinicians delegate aspects of order entry, medication reconciliation, or documentation tasks.
  - *We suggest adding a bullet point specifically addressing the need to have a written policy and procedure in place regarding delegation.*
  - *We suggest adding a bullet point specifically addressing the need to ensure competency of delegates with regular evaluation and written documentation.*

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Worksheet #10
- Support is available on-site at least during the first week after EHR go-live.
  - *Suggest language to indicate that on-site support should be provided at appropriate levels based on the training and competency of end-users. Additional clarification on what constitutes "support" is also needed – does this refer to vendors, consultants, trainers, or super users? In the ambulatory setting the super user model is often employed to reduce the need for vendor or consultant trainers to be present. Additionally, organizations with robust programs for training, practice, and demonstration of competency may require very little on-site support and using one week as a metric is somewhat arbitrary.*
- A protocol exists so that all users know how to get technical, software, and connectivity support.
  - *Modify to include language that a written policy and procedure should be in place rather than the word protocol which can be confusing.*

Worksheet #11
- Since training and support are ongoing and expensive, continuous improvement is important.
  - *The word "expensive" can have a negative connotation. We suggest rewording: "Training and support are ongoing and consume resources within an organization. To achieve value, continuous improvement is important."*

Worksheet #12
- An effective change management approach guides any needed workflow changes based on the workflow analysis.
  - *A definition of change management or citation of relevant sources for information would be of benefit.*

Worksheet #14
- The mechanism for reporting EHR-related safety hazards internally is clear to all users.
  - *Add language supporting "no-fault" and anonymous reporting mechanisms.*

Worksheet #16
- Staff members are assigned responsibility for the maintenance of the EHR-related software, CDS, and network/ISP performance.
  - *Suggest a bullet point that high-level decision makers ensure that maintenance activities are supported through full funding and oversight.*

Worksheet #17
- Assessments are conducted regularly to assure adequate maintenance.
  - *Suggest clarification to specifically identify the benefit of checklists as a mechanism to ensure regular maintenance cycles.*
  - *Suggest a bullet point that responsible staff members should have access to recommended maintenance procedures and timelines from relevant vendors.*

Worksheet #19
- Communication mechanisms ensure that EHR users learn of EHR changes promptly and users are able to give feedback on related safety concerns.

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- o *Suggest adding language that users should be informed of scheduled changes before they are implemented with an adequate mechanism for them to report potential safety issues before the changes are deployed rather than after issues are found.*

High Priority Practices

Worksheet #3

- RxNorm is used for coding medications and NDF-RT for medication classes.
  - o *This is an EHR requirement and not a practice that a user can influence. This should be reworded as a recommendation that all medications are entered using drugs from the codified data dictionary provided by the EHR rather than using free text entries.*
- SNOMED-CT is used for coding allergens, reactions, and severity.
  - o *This is an EHR requirement and not a practice that a user can influence. This should be reworded as a recommendation that all allergies are entered using drug names from the codified data dictionary provided by the EHR rather than using free text entries.*
- SNOMED-CT, ICD-10, or ICD-9 is used for coding clinical problems and diagnoses.
  - o *This is an EHR requirement and not a practice that a user can influence. This should be reworded as a recommendation that all problems are entered using diagnoses from the codified data dictionary provided by the EHR rather than using free text entries.*
- LOINC and SNOMED-CT are used for coding clinical laboratory results.
  - o *This is an EHR and lab requirement and not a practice that a user can influence. This should be reworded as a recommendation that all labs are entered in structured fields using a codified data dictionary and standardized lab names rather than using free text entries.*
- Abnormal laboratory results are coded as such.
  - o *This is a requirement for the lab that sends the results (if using an interface) or setting up default normal ranges for all labs in the compendium if entering manually. This should be rephrased to indicate practices under control of the organization or end-user.*

Worksheet #4

- Order sets exist for the 10 most common clinical conditions (e.g., management of chest pain), procedures (e.g., insulin administration and monitoring), and clinical services (e.g., admission to labor and delivery).
  - o *Examples focus on inpatient environment. There are no examples for evaluating most common diagnoses and making sure there are templates and order sets for those diagnoses/problems/situations.*

Worksheet #5

- Each practice identifies a minimum number of highly specific CDS features and functions and monitors their availability and use.
  - o *Why specify a "minimum number"? It would make more sense to say "high priority CDS".*
- Drug-food interaction support.
  - o *Not useful in the ambulatory environment where it is unrealistic to expect that a patient diet would be entered into the EHR.*
- Drug dosing support for maximum (dose, daily, and lifetime), minimum, renal, 32 weight-based, and age-appropriateness.

- o *While this is widely available for age, renal function-drug interaction checking (in terms of numeric values as opposed to a diagnosis of renal insufficiency) is not widely available in the ambulatory environment and there are very complex issues related to which tests to consider (e.g., eGFR, GFR, creatinine clearance) and disparate normal values when multiple lab vendors are used. Lifetime drug doses are problematic in that they require calculation of drug amounts that might not be available within the EHR, so it would be important to clearly state that drug lifetime amounts have been exceeded based on data available within the system. It would be dangerous to suggest to a user that the data was complete when in fact it might not be, and they might be less likely to inquire/investigate outside dosing if this were a field presented within the EHR.*

Worksheet #6
- Interfaces (e.g., HL-7) capable of sending, receiving, acknowledging, and cancelling orders and results exist and are tested between ADT-Laboratory, -Pharmacy, and -Radiology; and CPOE-Pharmacy, -Laboratory, and -Radiology.
  - o *These examples are not all relevant to the ambulatory environment.*

Worksheet #8
- Information required to facilitate positive patient ID is visible on all screens and printouts and includes: Last name, first name, date of birth (with calculated age in age-appropriate units), gender, medical record number, in-patient location (or home address), recent photograph (recommended), and responsible physician (optional).
  - o *Not all of these data elements need to be present on every print out.*
- The master patient index employs a probabilistic matching algorithm that uses patient's first and last names, date of birth, gender, and zip code or telephone number or social security number.
  - o *This may not be under control of the practice. A better example would be that they understand what the matching algorithms are and the likelihood of a false match based on the strength of the algorithm used.*
- System generates a pop-up alert when a user attempts to create a record for a new patient or looks up an existing patient with the same first and last name as an existing patient.
  - o *See previous comments about recommending a particular alerting process such as a pop-up. These appear to be EHR requirements rather than end-user activities. It should be reworded to focus on actions the end-user should take related to using functionality to avoid creating duplicate charts or using a four point check to make sure they are entering data/orders on the correct patient.*
  - o *In a large EMPI, there will be hundreds of patients with similar names. A warning when searching for a patient chart might be appropriate. However, this should not be confused with a warning every time a chart is opened (e.g., from a patient list). That would be a large and unnecessary burden on clinical users.*
- Before allowing the user to change the current patient (and display data for another patient), the system checks that all entered data have been saved (i.e., signed).
  - o *This is not always the appropriate decision and oversimplifies things. It may be more appropriate in some instances to save or discard information, and other times to ask the user what is appropriate. And in some of those situations, it might be important to clearly distinguish which information was not explicitly saved by the user and instead automatically saved by the system. Perhaps it would be useful to clarify that "saved" could mean to the*

legal chart (e.g., viewable by all clinicians with access to the chart), or in some cases saved to an "in-progress" section only viewable by the clinician who entered the partially completed documentation.

- Information required for patient ID includes: Last name, First name, Date of birth (with calculated age), Gender, Medical record number, In-patient location (or home address), Recent photograph (optional), Responsible physician, (e.g., attending, PCP, or admitting).
    - *These appear to be EHR requirements rather than end-user activities. It should be reworded to focus on actions the end-user should take related to using functionality to assure that all important information is available on the record.*

Worksheet #10
- The human-computer interface is easy to use and designed to ensure that required information is visible, readable, and understandable.
    - *All the examples seem to be EHR requirements. Consideration should be given to either creating a separate guide to selection of EHRs where important functionality is listed or else rewording this so it makes it clear that it applies to any development under the control of the user/organization.*

Worksheet #11
- Users are notified of key actions (or inactions) relating to their orders, such as when ordered medications get discontinued (manually or automatically), antibiotic renewals are not processed, and when orders placed at later times of the day will not be acted upon till the next day.
    - *This should be reworded to clearly state that there will be procedures in place to assure that users are notified.*
- There is clear distinction (e.g., different font or color) between newly entered and copied data.
    - *This is not currently widely available functionality and, as an EHR function, it is not under the control of the end-user. Perhaps wording this to state that there should be policies in place to identify the situations where copying forward information is an acceptable option and if available, functionality should be enabled to identify information copied forward.*

Worksheet #17
- The organization has a relationship with a patient safety organization experienced in investigating and addressing EHR-related patient safety incidents.
    - *There are very few PSOs right now with this expertise. Perhaps, to reflect this reality, the example should be that the organization has a relationship with a PSO and endeavors to assure that appropriate HIT expertise is available when evaluating an event that might be related to the use of HIT.*

Worksheet #18
- Representatives from the following groups are involved in decision making about EHR safety: clinicians, administrators, patients, IT/informatics, board of directors and CEO, and quality and legal staff.
    - *Include when appropriate since many of these stakeholders will not be relevant to a small ambulatory practice.*

System Interfaces

Worksheet #1
- At a minimum, the EHR satisfies ONCs' certification requirements related to electronic exchange of information.
  - *This is an EHR requirement and out of control of the organization. It could be added to a separate pre-selection of an EHR guide.*
- The EHR is capable of sending and receiving clinical and administrative data using HL7 version 2.x messages where the sending and receiving systems use the same version.
  - *This is an EHR requirement and out of control of the organization. It could be added to a separate pre-selection of an EHR guide.*
- The EHR has 2-way, HL7 v 2.x-compatible interfaces to mission critical ancillary systems (at a minimum: pharmacy, laboratory, blood bank, and radiology).
  - *This should be reworded to make appropriate to all domains. The organization should implement all available HL7 interfaces to critical relevant partner data systems such as labs, pharmacies, registries, radiology.*
- The EHR is capable of generating, exporting, importing, and decoding clinical patient summary documents encoded in the Continuity of Care Document (CCD) standard. This includes procedures such as placing the correctly decoded clinical data into the proper location in the EHR, rather than just adding a human-readable version of the document to the patient's list of free text reports.
  - *This is an EHR requirement and out of control of the organization. It could be added to a separate pre-selection of an EHR guide.*
- If the organization has an "interface engine," the hardware running this application is duplicated (i.e., operational backup hardware is installed).
  - *This should be reworded to reflect the differing priorities/needs/resources of practice settings. If the organization has an interface engine, there are procedures and processes in place (e.g., redundant servers or downtime processes) to minimize impact in cases of technical failure of the primary hardware.*
- The EHR has links to external clinical information reference resources using the HL7 InfoButton standard.
  - *Most vendors provide the functionality; it is up to the organization to set up the external site. We suggest rewording to state that the organization has configured available InfoButton functionality to link to the most relevant reference sources for the end-user population.*

Worksheet #3
- The interface supports and encourages use of clinical vocabularies from ONC's certification requirements, for example: RxNorm for medication names, 10 SNOMED-CT for clinical problems, and LOINC for laboratory tests.
  - *Interfaces do not encourage use of any specific functionality. We suggest changing this to require that there are policies in place to encourage users to enter data in structured, codified fields. Interfaced business partners are encouraged to support and transmit data using current meaningful use specified standards.*

Worksheet #4
- Free text data fields accessible to clinical end-users of one system are transferred intact (i.e., no changes or truncation of characters) to the other system.

January 16, 2014

o *We suggest limiting this example to free text fields supported by an interface that are transferred without truncation or corruption.*

Worksheet #11
- Help desk operator manuals for quick reference are developed, readily available, and up-to-date.
  - o *This is not relevant to smaller practices. The example might be more generically useful by removing the specific reference to "help desk", and simply requiring operator manuals that are available and up-to-date.*

Worksheet #15
- The interface can transmit the units for measurements along with the measurements, and the units are stored in structured data fields (e.g., 175 *lbs.* or 500 *mg*).
- The interface can transmit information associated with a particular measure (e.g., fraction of inspired oxygen accompanies the arterial blood gas results to allow clinicians to interpret the blood gas values in the proper context).
  - o *These items belong in Worksheet #12 during documentation of specifications.*

Worksheet #16
- The sending system identifies and restricts messages that are not transmittable (e.g., incorrect data type).
  - o *This is worded as a requirement for the sending system. We suggest changing to testing includes situations where the sending system would be expected to identify and restrict a message that is not transmittable.*
- The user is notified if what they are typing exceeds the maximum size for either the storage location or the system-to-system interface.
  - o *This should be more generically worded to account for systems that prevent data entry beyond the field size by other mechanisms than notifications.*

Worksheet #17
- The system-to-system interface error log is automatically monitored and all failed transactions are brought to the attention of the appropriate staff member, investigated, and fixed within one week.
  - o *This is overly proscriptive. Consider wording that procedures should be in place for continuous monitoring of the interface and that escalation policies exist for any failure of the interface so that it can be remedied in a timely fashion.*