**Data supplement—Computerized prescriber-order-entry assessment tool**

System Characteristics Guide

**I. General Assessment Overview**

The FDA Computerized Prescriber Order Entry Medication Safety (CPOEMS) project involves an assessment of inpatient and outpatient clinical information systems at participating sites to better understand the role of computerized prescriber-order-entry (CPOE) in preventing, and potentially introducing medication errors.

This guide sets out standardized procedures to facilitate comparative analyses across the sites. These protocols are intended as a general guide to examine the ten systems in a standardized and comparable fashion. However because investigators, test subjects, and system characteristics vary across sites, assessment processes may be altered, as necessary to maximize the learning and efficiency of the testing activities. The goal will be to document and understand how the varying CPOES displays and processes look and work, as well as examine the vulnerabilities of these systems to potential prescribing errors. We will emphasize collecting of information of interest based on the FDA 18 elements of interest, utilizing a combination of screenshot review, remote interactive sessions, and onsite review to be followed up with interviews of CPOE HIT leaders and developers at each site.

**Screenshots Review**

The centerpiece of the screenshot review exercise will be a walkthrough of selected CPOE ordering features with regular users of the system (i.e. not the developers or IT experts). Prior to this formal review, we will conduct interactive examination of screenshots with each of the local investigators to allow us to familiarize ourselves with the basic look of the site-specific system and to collect data on some of the elements that a user or even IT expert may not know about such as font size of the text, etc.

**Live Interactive Sessions**

The remote interactive sessions with regular users at each of the sites will be conducted through the use of WebEx as a webinar tool along with SnagIt and Camtasia to capture screenshots. These session tools will be hosted by local Site investigators and led and conducted by the team at Site 4. There will be 2–3 Site 4 staff involved in each walk-through to: (1) ask questions and interact with the user; (2) collect screen shots representative of medication ordering scenarios, and to ask clarifying questions; and (3) take typed notes. In addition, the sessions will be recorded.

**Onsite Visits**

Once screenshots have been reviewed and live interactive sessions held with a number of the roles at each site, an assessment will be made of the outstanding areas and questions that are important to cover in an in-person meeting with site coordinators and staff. As mentioned, this approach will allow for more in-depth exploration of critical findings during the site visits.

The overarching focus of this evaluation will be on order entry systems with clinicians as the end user. There are multiple entry points for a medication to enter a patient’s electronic health record (EHR); however, the focus of this assessment will be on the inpatient and outpatient medication order entry EHR systems. Therefore, we will be excluding medication reconciliation applications, laboratory ordering systems, and other ancillary systems that could be used for entering orders (besides medications) or those that do not have the physician as the end user (e.g. pharmacy order entry systems). CPOE system and related EMR medication displays for the inpatient and outpatient settings will be reviewed.

The following pages of this guide present general system overview questions and the specific medication ordering scenarios that users will enter into their systems to elicit the system characteristics of interest in this study.

**II. General Overview of Your CPOE System**

1. Please describe the following characteristics of your system for both outpatient and inpatient systems:
   - a. History
     - i. Length of time system has been implemented at your institution
     - ii. Is your EHR commercial-off-the shelf or created by your institution?
     - iii. Is your medication knowledge base commercial-off-the shelf or created by your institution (such as a proprietary medication dictionary)?
b. How can the system be accessed (e.g., kiosks, iPads, desktop only)?
c. Who is capable of entering orders in the system? Do the ordering capabilities and clinical decision support (CDS) features vary by role?

2. Please walk us through the components of your system to help us understand the process of entering a new prescription—completing the process of entering a medication order

(Note to interviewer: All the different screens associated with ordering a medication through the different processes will be named and recorded by the interviewer)

III. Assessment of 15 System Characteristics
1. Fonts Used (type, size, serif/sans serif): captured but does not need to be specifically evaluated during the interview
   a. Task 1: Patient Chart Summary Screen
      Enter test patient and retrieve patient chart summary screen
   b. Task 2: Medication Summary Screen
      Enter test patient and retrieve medication summary screen.
   c. Task 3: Ordering New Prescription
   d. Task 4: Reactivating Previous Prescription
      [How is this information retrieved for viewing?]
   e. Task 5: Patient Medication/Allergy List Screen
      Enter test patient and retrieve medication/allergy list screen
   f. Task 6: Medication Alert: Drug-Drug Interaction [will be multiple ones]
      [How is this information retrieved for viewing?]

Patient medication lists
Other drug summary list

2. Drug Name Types
   Drug names may be listed in CPOE databases by generic name, proprietary name, or both.

   Questions for the interviewer to consider:
   • Which med name(s) (brand/generic) appear in the search results?
   • Which med name(s) appear in the general search results under favorites?

   a. Task 1: Generic name/Proprietary Name
      Example 1
      1. Enter “lovastatin” into the medication ordering search field and complete the order – should generate drug pregnancy alert (previously entered ‘pregnancy’ in the problem list)
      Example 2
      2. Enter “plavix” into the medication ordering search field and complete the order
      Example 3
      3. Enter “warfarin” into the medication ordering search field and complete the order
      Example 4
      4. Please enter ‘amytriptiline’ and complete the drug order (example of misspelling)

3. Drug Name Presentation (Does not need to be evaluated during the interview)
   Drug names are presented in various ways in CPOE databases (e.g. capital or mixed case letters) and may differ based on generic or proprietary name and individual screen display.

   Questions for the interviewer to consider:
   • How are drug names added to the medication list in your system? By generic name, proprietary name, either, or both? [may differ based on different screen display]
   • How do the drug names appear? (e.g. in capital or mixed case lettering?)
4. **Presentation of Combination Products**

The presentation of names of combination products varies in CPOE systems.

<table>
<thead>
<tr>
<th>Questions for the interviewer to consider:</th>
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<tr>
<td>• When a drug name is searched, do the search results display all of the options that include that drug name as an ingredient or only that drug?</td>
</tr>
<tr>
<td>• In what order are the ingredients placed?</td>
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<td>• Are the strengths for the ingredients listed separately?</td>
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a. **Task 1: Drug made of combination products**

1. Enter “Bactrim” into the med ordering field and choose “Morphine sulfate and naltrexone extended-release capsules in the 60mg/2.4mg combination”
   
   i. This is an example of both a combination product and one with extended release characteristics by type of release.
   
   ii. Note how strengths of ingredients are listed.

b. **Task 2: Drug that constitutes a combination product**

1. Enter “hydrochlorothiazide” into the medication ordering search field and choose a HCTZ/Lisinopril combination such as “Prinzide or Zestoretic”.
2. Can you do an automated sig selection choosing the default dose?
3. Does this generate an alert for drug lab (potassium is too high: set at 8.0meq/L)

c. Enter Sinemet (Carbidopa/Levodopa) combination and complete the order.

5. **Drug Names with Modifiers**

How are modifiers of drug names presented in your CPOE system?

<table>
<thead>
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<tr>
<td>• Are the modifiers in all caps?</td>
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<td>• Are they ever cut off by the text box or character limit?</td>
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<td>• Where are they located in the string; ahead of the drug name, following it?</td>
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<tr>
<td>• Is there ever text spelling out the modifier or only abbreviations?</td>
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a. **Task 1: Type of Release** (extended release, sustained release, etc.)

b. **Task 2: Route of administration**

1. Enter “fentanyl” into the med ordering screen
2. Note whether system distinguishes between the transdermal patch and the sublingual spray. Should be able to see different formulations of fentanyl, e.g.,
   
   - Abstral™ (FENTANYL SUBLINGUAL TABLET)
   - Actiq™ (FENTANYL TRANSMUCOSAL LOZENGE)
   - Fentora™ (FENTANYL BUCCAL TABLET)
   - Lazanda™ (FENTANYL NASAL SPRAY)
   - Onsolis™ (FENTANYL BUCCAL SOLUBLE FILM)
   - Subsys™ (FENTANYL SUBLINGUAL SPRAY)
3. Please select Subsys, the sublingual spray, for breakthrough cancer pain, in an opioid-tolerant patient: how will you enter the following order:
   
   i. 100 mcg under the tongue; may repeat once after 30 minutes; do not use more than 2 doses per episode of breakthrough pain; repeated treatment of subsequent episode should be separated by at least 4 hours; if adequate pain relief is achieved, use this dose for subsequent episodes of breakthrough pain.

b. **Task 3: Salt name**

1. Enter “ferrous” into the medication ordering search field and generate the search results.
2. How does the system distinguish between ferrous sulfate, succinate, gluconate, lactate? May have to ask user to enter these terms separately or will be visible from search results.
3. Choose ferrous sulfate
d. Task 4: Formulation (liquid, powder, capsule, etc.)
   See above for fentanyl example

6. Automated Selection of Drugs
Describe auto-fill for drug names and sigs [need full range of how drug names AND sigs can be selected. Determine with site coordinator beforehand whether there is anywhere in the system where putting in the first 3 letters will auto-fill the med name]

Questions for the interviewer to consider:
- If a drug name appears in the favorites list does it also appear in the regular medication selection list or is it removed from regular list when it appears in favorites?
- Are the options presented in alphabetical order?

a. See 5b for Prinzide example for auto SIG.

7. Short Code Capability
What is your system's short code capability? How are they developed and, if they are listed in a particular order, why was this order selected?

Questions for the interviewer to consider:
- Does this system search only from the stem?
- Search only from the beginning of the word, or inside the drug name
- Filter more selectively as you add letters?
- Present different results for different scenarios (search vs. quick order, etc)
- Present results in which the words all run together or are parsed out?
- Present drugs that appear consistently across results (gets at oddities—how is the system searching if not simply from the medication column?)
- Accept impossible drug names and allow you to enter orders from them

a. Example 1
1. Order amoxicillin 500mg by entering “amox 500” into the medication ordering search field and generate the search results. Please enter the order for amoxicillin 500mg PO, q12h.
2. You have previously entered that the patient is renally impaired and creatinine clearance ($\text{CL}_{\text{Cr}}$) is 5.0.
3. Does this generate a nephros dose adjustment alert?
4. Does it provide value of $\text{CL}_{\text{Cr}}$ or do you have to look it up? (CL$_{\text{Cr}}$ is previously set at 5.0 ml/min)
5. Does the system provide suggested new dose? (should be 250 - 875 mg PO q24h for $\text{CL}_{\text{Cr}} < 10$ ml/min)

8. Indication of Spaces
How are spaces indicated on your CPOE screen (e.g. all words run together, spaces appear as actual breaks in name, or other?)

Questions for the interviewer to consider:
- Are ‘+’ symbols ever used in lieu of spaces?
- Is there consistency across screen elements?

a. Task 1
Example 1 – Long drug name with special characters
1. Enter “Chlorhexidine mouthwash 0.12%” into the medication ordering search field and generate the search results

9. Navigation Method
How do practitioners navigate the CPOE system? Indicate all that apply. [This information could be collected prior to interview]

Questions for the interviewer to consider:
- Is more than one method possible?
- Does it differ across different CPOE elements within the system?
10. Drug Presentation Limitations
Limitations on drug name presentation include maximum character limitations, minimum characters for medication search, and limitations on the number of medications displayed. To elicit these different characteristics, please complete the following tasks.

Questions for the interviewer to consider:
- If the box in which the med name is small enough that it hides parts of the drug name, is it possible to make it larger and/or is it possible to hover over the text until the full drug name appear?
- Does the search display as a drop down list, list of meds, a favorites list, etc?

Please search for the following drug names:

a. methylprednisolone sodium succinate
   Repeat the action of searching for the med in the following screens:
   1. Patient Chart Summary Screen Medication List
   2. Task 2: Main Medication List Summary Screen
   3. Task 3: Medication List – Favorites

b. This item tests minimum # of characters needed to look for a medication concept:
   1. Enter “klo” in medication ordering search field and display list of meds
   2. Enter “clo” in medication ordering search field and display list of meds

11. Common Alerts Used
Describe any common alerts used consistently in the system (duplicate therapy alert, wrong dose/route alert). [Can site coordinators let us know how many levels of alerts are in their system prior to the interview?]

Questions for the interviewer to consider:
- What are the types of alerts that are used? Are there tiers?
- In what contexts do they appear?
- How are each type displayed on the screen?

a. Task 1: Duplicate Therapy alert
   1. Example 1 - Same Drug
      i. You have already ordered Plavix for this patient
      ii. Order “clopidogrel” into the medication ordering search field and generate the search results
      iii. Selected clopidogrel [specify exact drug selection]
      iv. What appears on the following screen?
      v. Please cancel the order for Plavix and continue with the order for clopidogrel
   2. Example 2 - Drug class
      i. You have ordered lovastatin for this patient.
      ii. Order “atorvastatin” into the medication ordering search field and generate the search results
      iii. What appears on the following screen?
      iv. Please cancel the order for atorvastatin and keep the order for lovastatin

   [The following examples were generated based on Site 4’s outpatient alert scheme]

b. Task 2: Drug-Drug Interactions alert
   1. Example 1 -Level 1: HMG Co-A reductase inhibitors-Protease Inhibitors
      i. You have already ordered lovastatin
      ii. Now order “indinavir”
iii. What appears on the following screen?
iv. Can you override the alert and order both medications?
v. What reasons can you provide?
vi. Is there a free text field to provide additional comments for overriding the alert?

2. Example 2 - Level 2: WARFARIN & LEVOFLOXACIN
   i. You have already ordered **warfarin**.
   ii. Now order **“levofloxacin”**.
   iii. What appears on the following screen?
   iv. Can you override the alert and order both medications?
   v. What reasons can you provide?
   vi. Is there a free text field to provide additional comments for overriding the alert?

3. Example 3 - Level 3: warfarin + levothyroxine
   i. You have previously ordered **warfarin** for this patient
   ii. Now order **levothyroxine**
   iii. What appears on the following screen?
   iv. Can you override the alert and order both medications?
   v. What reasons can you provide?
   vi. Is there a free text field to provide additional comments for overriding the alert?

   c. Task 3: Drug-Allergy Interactions
   1. Example 1 - Level 1 (DEFINITE allergy): single ingredient drug with single ingredient med: AMOXICILLIN with AMOXIL (or any other trade name of amoxicillin available in formulary)
      i. You have previously ordered amoxicillin for this patient
      ii. Please order Amoxil.
      iii. What appears on the following screen?
      iv. Can you override the alert and order both medications?
      v. What reasons can you provide?
      vi. Is there a free text field to provide additional comments for overriding the alert?
   2. Example 2 - Level 2 (PROBABLE Allergy): single ingredient drug with multi ingredient med
      i. You have previously ordered amoxicillin for this patient
      ii. Please order ampicillin (Omnipen, Principen)
      iii. What appears on the following screen?
      iv. Can you override the alert and order both medications?
      v. What reasons can you provide?
      vi. Is there a free text field to provide additional comments for overriding the alert?
   3. Example 3 - Level 2 (PROBABLE Allergy): single ingredient drug with multi ingredient med
      i. You have previously ordered amoxicillin for this patient
      ii. Please order augmentin (amoxicillin/clavulanic acid)
      iii. What appears on the following screen?
      iv. Can you override the alert and order both medications?
      v. What reasons can you provide?
      vi. Is there a free text field to provide additional comments for overriding the alert?
   4. Example 4 - Level 3 (possible Allergy): cross sensitivity
      i. You have previously ordered amoxicillin for this patient
      ii. Please order Keflex
      iii. What appears on the following screen?
      iv. Can you override the alert and order both medications?
      v. What reasons can you provide?
      vi. Is there a free text field to provide additional comments for overriding the alert?

d. Task 4: Drug Formulary Alert
   1. Example 1 - A drug not on the formulary
      i. E.g. “Zyprexa” into the medication ordering screen
      ii. What appears on the following screen?
2. Example 2 - A drug for which a lower priced alternative is available
   i. Enter “Cialis” into the medication ordering search screen
   ii. What appears on the following screen?

e. Task 5: Drug Inactive
   1. Example
      i. You have previously order lovastatin
      ii. Please Inactivate this order
      iii. Now order it again – does the system alert you that this drug has been inactivated and enable activating
         a previously entered instance of the drug?

f. Task 6: Drug pregnancy contraindication
   Ordering atorvastatin for this patient should generate a drug pregnancy alert

g. Task 7: Drug Dose Alert
   1. Example
      i. Change the dose of lovastatin to 800 mg (max dose is 80 mg).
      ii. What appears on the following screen?
      iii. Can you override the alert and order both medications?
      iv. What reasons can you provide?
      v. Is there a free text field to provide additional comments for overriding the alert?

12. Processing Telephonic and Verbal Orders
   a. Please describe the actual methods used for processing of telephone and verbal orders and workarounds that
      may also be used across users.
   b. Collect copy of institutional Policy and Procedures relating to processing these types of orders.

Policy Title:

Last Reviewed Date:

13. Discontinuation of meds:
   a. How do you discontinue a med?
   b. What happens when you do that? (screenshots)
   c. What is the result? (where does it appear and what do they think happens to the information)

14. Drop-down Menus
   How do drop down menus appear in your CPOE system given a particular view (e.g. single drug list or multiple drug
   list view)? Do drop down menus exist for searching a drug? For which of the following medication components do
   drop down menus exist in your system?

   - Drug Name
   - Med Attributes
   - Dose
   - Frequency
   - Pre-formulated SIGs
   - Strength and Form
   - Formulation

15. Summary Comments/Observations
   Medication summary screen
   Inactivate a medication and then reactivate it
   Can you generate a patient handout/prescription for the drugs that we ordered?
   How has the system evolved—change log
   Process for communicating the changes to vendors