

## NRDS Content Working Group

Tuesday May 26, 2015

### Meeting Minutes

Action Item	Who	By When
Send out meeting minutes	Neesha Desai	5/28/15
Take back the various options for modifying the OPEN Demography CDE attributes and identifying which option works best for them: <ul style="list-style-type: none"> <li>○ Using coded values</li> <li>○ Using the existing PVs and modifying them as needed</li> <li>○ Using the user data string</li> </ul>	NRDS Content WG Members	6/1/15
Bring back the OPEN Demography elements from the Rave integrations	Dianne Reeves/Neesha Desai	6/2/15

### Agenda Topics

**Meeting Recap** – Neesha Desai welcomed the callers to the meeting and provided a brief meeting recap from the last meeting.

**Content Review Strategy** – Dianne Reeves explained that the outcomes of the meeting should focus on a formal consensus to start with OPEN Demography and discuss considerations and questions about the changes.

- Shauna: I do not recall speaking about adding the Social Security Number (SSN); will this be a mandatory field?
  - Dianne: SWOG had a need for this element but we have not discussed it being mandated yet, just how it is collected.
- Shauna: Are we just saying how we expect elements be collected? What do you mean by Content?
  - Dianne: We want to start with the first 8 elements captured in OPEN to see how they will be collected. Our current content goal is to agree on the elements that we are going to work on.

*Elements (\*\*All members on the committee agreed to move forward with these 8 elements in the OPEN Demography module)*

1. Initials Name
2. Patient's Date of Birth – **\*\*Request** to change question text to just Date of Birth
3. Ethnicity
4. Gender of a Person – **\*\*Request** to change question text to Gender
5. Country of Residence
6. Zip Code
7. Method of Payment
8. Race

- The group agreed that for the core variables ONLY, we would not accept alternates for these attributes. These include alternate questions text, definitions and value meanings. This does not apply to all the elements, only the core elements.
- Ginger: OPEN integration/OPEN to Rave; it is very difficult to make any changes to the OPEN standard form. The changes are not retrospective so people are using different versions.
  - Angela: We should try and collect any changes we want to recommend and if the technical team comes back and says that some things cannot be changed, that is ok. But we need to put the recommendations forward.
- Dianne: We have four items on here that are connected to a list of Permissible Values (PVs), do we want to keep them as text terms or change them to coded values?
  - Peter: I vote coded values, Theradex currently uses the CDUS coded values
  - Thalia: CDUS already uses coded values for this; we may want to use this coding to ensure the coding matches, even once CDUS reporting goes away.
  - Angela: It seems it would be good to use the codes as long as there is still a value meaning. We will have to do extra mapping work once we get beyond these core (8) elements.
  - Shauna: It is easier to get confused or have an issue when mapping codes (numbers) instead of text; we are adding another level of confusion/error to the output. It feels safer to use verbiage (using M/F instead of 1/2)
    - Katie: I agree that this can be confusing with mapping. And if we display the meanings alphabetically it would be 1 for Female and 2 for Male.
  - Angela: I feel there is a level of risk, but it seems this will be inevitable. As long as this is limited to the core, I think this would be acceptable. We are only going to be able to recommend one way, either allow the groups to use their own codes in Rave (and Rave would have to do the mapping) or allow CTEP to use their own codes (and the groups will have to do their own mapping).
    - Andrea: At the end of the day, there will always be a need for data mapping. The data mapping that everyone has just needs to stay current and up to date for data sharing needs.
  - Katie: Using the user data string for reporting instead of coded value was also brought up at some point.
    - Angela: This makes sense in some places, but not when taking the data out of OPEN.
  - Vanitha: I think we need to analyze all of the systems and come up with a standard way of doing this.
    - Katie: Can you have a coded value and still use a character string?
    - Vanitha: OPEN accepts the value meaning and the user string. I think if we make changes to the standard, we can make a one-time effort to update work.
    - Shauna: This will create a lot more work for ourselves
    - Katie: Yes, but it is work either way.
- Vanitha: When you say coded values, do you mean only Rave validation forms or all of the CDEs?
  - Dianne: Right now we are just referring to OPEN Demography variables, the first 8 variables we are considering as the core set to standardize.
  - Shauna: Yes, but we want to stay consistent overall. Let's say we end up with 20 core items that we mandate everyone use. That's why we want to keep the core small.
  - Dianne: Yes, whatever the core number of variables turns out to be, we want to be consistent in the changes we recommend, and apply those to the full set of core variables. Remember this is the first set, and the work will be iterative.

- The group agreed to take back the following options and discuss them with their organizations:
  - Use coded values, potentially the CDUS values although CDUS is not meant for long-terms use
  - Use existing text terms for Permissible values (PVs) that would be coded values in Rave
  - Use User Data Strings for reporting

### *Discussion*

- Shauna: Are people collecting this data twice, in OPEN and in RAVE?
  - Dianne: It is being entered into OPEN and pushed into Rave
  - Angela: We collect it through OPEN and then collect it from Rave when it is ready.
  - Wendy: Every study that has ever been studied, they keep the same patient ID.
  - Smita: Everything is populated from the center registry and pushed into Rave. The form and CDEs are used like everyone else, but the sites do not enter it. We do not collect the demography from Rave.
  - Peter: The data is entered in OPEN then goes to IWRS and gets remapped to the codes we expect and loaded into our forms. We no longer reference OPEN after the IWRS is completed.

### **Next Steps**

- The group members are taking back the various options for modifying the OPEN Demography CDE attributes and identifying which option works best for them:
  - Using coded values
  - Using the existing PVs and modifying them as needed
  - Using the user data string or human readable term
- The co-leads should bring back information on how the various integrations are accepting the 8 OPEN Demography elements.

