EHR Association Comments on the Quality Data Model (QDM) Style Guide (June 2012)Internal Notes – The National Quality Forum (NQF) announced the release for comments of the Quality Data Model Update June 2012 and companion Style Guide on June 15, 2012 with a 30 day comment period. The QDM June 2012 Update and Style Guide is posted here, and the commenting periods will end on July 16 at 6:00pm ET.

This document comprises the comments collected through several joint meetings of the EHR Association Quality and Clinician Experience Workgroup and the Meaningful Use Workgroup on the Quality Data Model (QDM) Style Guide (June 2012). The QDM Style Guide is a companion document to the QDM Update (June 2012), and it specifically addresses the feasibility of QDM components with respect to electronic health records (EHRs) certified for the 2014 EHR Certification Program proposed by the Office of the National Coordinator for Health IT (ONC). The QDM Style Guide provides guidance as to which information can be expected in structured form in referenced EHRs, and which information may be important to measures but would likely require additional effort if certified EHRs are used as the only source of data.

Comments must be entered on the NQF site in no more than 1500 character blocks within six topic areas, so the EHR Association comments are drafted in that format. The topic areas are:

- General Comments;
- QDM Category;
- Standards;
- Feasible;
- Feasible but requires additional effort;
- and Overall Usability of the document.

Public comments are posted to the appropriate comment box for the topic area (e.g., 1. General Comments, 2. QDM category; etc.). When entering each set of comments, you must select one of four **comment type**s from a drop-down box:

- Previous Definition
- New Definition
- Rationale
- General

Public Comments are to be entered here:
http://www.qualityforum.org/commenting/publiccommentform.aspx?project=26542&form=50

(Note, there is a separate URL and place to enter comments if you are a NQF member, which the EHR Association is not.)

The EHR Association comments begin on the next page. In some cases, because of the length of comments for each topic area, we have broken this into sections to abide by the 1500 character limitation. The sections are separated by a line of asterisks
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1. **General Comments**
    a. Type: General

    The EHR Association commends the National Quality Forum on the creation of the Quality Data Model (QDM) Style Guide as a companion document to the QDM Update (June 2012) to specifically address the feasibility of QDM components in EHRs certified for the 2014 EHR Certification Program. We are encouraged by the intent of this document to provide direction to measure developers on the feasibility and availability of specific data elements within a 2014 Certified EHR.

    We also want to reiterate our comments made in response to the question raised by ONC in the proposed rule for Health Information Technology: Proposed 2014 Edition EHR Certification Criteria, as to whether EHR technology must be able to capture all of the data elements represented in the QDM, or only the data elements for those clinical quality measures (CQMs) the EHR vendor believed its EHR technology would need to support. We do not believe it is feasible for EHR technology to be required to be certified to capture all of the data elements represented in the QDM. Certification should only require those categories, states, and attributes that are deemed "feasible" in a 2014 Certified EHR, and only include those data elements for the CQMs that the EHR technology will (and should) support.

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    The EHR Association is concerned that, if measure developers use all of the states and attributes defined in column four for each category as they develop Stage 3 measures, this will require major development work on the part of most EHRs, and significant implementation, training, and workflow considerations on the part of providers. Parallel measure development and CQM standards development processes preclude a robust set of consistently computable measures that align with EHR capabilities.

    We would also like to note that there appears to be a discrepancy between the Measure Authoring Tool (MAT) 2012 Update User Guide, published May 1, 2012, and the QDM June 2012 Update and the QDM Style Guide. The MAT User Guide has a category taxonomy that is slightly different from the one presented in the QDM June 2012 Update and the QDM Style Guide. The categories are split into data types in the MAT User Guide, however data type is not described at all in the QDM June 2012 Update or the QDM Style Guide. In addition, the MAT User Guide describes a category called "Attribute" which is not presented in the QDM June 2012 Update or the QDM Style Guide.

2. **QDM Category**
    a. Type: General

    The EHR Association provides the following comments on the QDM Categories listed in column one:

- Category: Intervention
    - In the QDM June 2012 update, the word "intervention" is used in multiple definitions of categories with different connotations. How does this category relate to other similar categories? The QDM definition is unusual in excluding "hands-on" interventions that most people understand the term "intervention" to mean. Elsewhere in the QDM update, "procedures" (definitely physical) are described as a category of "intervention" which makes the definition of "intervention" internally inconsistent within QDM. If it truly is only supposed to include non-physical interventions, it should be specifically called "non-physical intervention", or, if it primarily refers to education, we would suggest renaming it to "education". Otherwise, this category is confusing.
- Category: Response to Care
    - From the EHR vendor perspective, we do not feel this category is feasible in a 2014 Certified EHR. We acknowledge that this category may have some degree of clinical significance. However, we believe that a data element of "response to care" can be represented more explicitly with other data elements like vital signs, lab results, etc.

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The EHR Association provides the additional comments on the QDM Categories listed in column one:

- Category: System Resources
    - We have a general concern as to why the category of system resources is included and with the description of the category, as it seems to be mixing many different types of concepts such as nursing ratios, DME, etc. We are also not sure of the relevance of all of these concepts for quality measures, and think the number of use cases will be small.
        - We also note that it should not be assumed that all of this information would be feasible to be found in an EHR. For example, healthcare staffing would likely be a function of another system.
        - We recommend that this category be removed from the QDM style guide and redefined for the QDM.

3. <u>Standards:</u>

a. Type: General

The EHR Association provides the following comments on the standards listed in column two, based on the standards included in the Proposed 2014 Edition EHR Certification Criteria:

- Category: Adverse Effect, Allergy
    - For meaningful use certification, only medication allergies are required, so only medication allergies should be considered feasible. If in the future the general certification requirement is expanded beyond medication allergies to all allergies, then a consistent standard should be chosen for non-medication causative agents.

The consolidated CDA (C-CDA) proposes UNII, but this document proposes SNOMED, which is a discrepancy that confuses vendors.

- Category: Care Goal
    - There are no standards defined for care goals in the C-CDA or in the proposed certification standards. Therefore, we think that is it is feasible to expect care goals to be documented (column three) but not feasible to expect care goals to be documented using LOINC or SNOMED.
    - Documenting patient understanding of education is not part of certification and that should not be considered feasible. (Certification establishes whether education was prompted and provided, not patient understanding.)

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The EHR Association provides the additional comments for column two:

- Category: Characteristics
    - The defined vocabularies call for SNOMED-CT to be used to document appropriate responses to instruments, including patient preference. Patient preferences are only recorded in relation to communication media for meaningful use, so that latter usage is the only one that should be considered feasible. We do not believe that use of SNOMED-CT should be required for this use case.
    - "Payers" are not required to be documented for certification, and this information typically falls outside of an EHR, and should not be considered feasible.
    - Many of the defined vocabularies at the beginning of column two do not match the ONC 2014 Certification Standards listed. We have concerns regarding the following:
        - The CDC PHIN-VADS HL7 Race and Ethnicity is not an exact match to the standard defined, § 170.207(f) OMB standards
        - There is no defined standard for Administrative Gender or Appropriate Responses to Instruments in the ONC 2014 Certification Standards.
        - The use of ISO-639-2 for Patient's Preferred Language requires mapping to the certification standard of ISO-639-1. We recommend the use of the certification standard rather than requiring additional mapping capabilities.
    - Some of the codes referenced are very granular. Is the expectation that all granularities in the code set would be captured? If so, we do not think this is feasible, and recommend the use of the parent-level of these standards, not the child-level of detail.

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- Category: Communication
    - We are not clear on the reason for the reference to 170.314(d)(1) and patient preferences. There is no inclusion of patient preferences in the authentication criteria. In addition, we are not clear on how that criterion relates to communication. Is this an error?

        - Is the Authentication criteria referenced in relation to sender/receiver? Authenticating into the EHR does not necessarily mean that a granular sender/receiver is known when documents are transmitted.
    - SNOMED-CT is listed as the vocabulary, and we do not believe that SNOMED-CT is required for this use case, so therefore it is not feasible.
    - The items in the second column, although not incorrect, may be misleading. The confusion here is that most of the listed standards are NOT vocabulary standards, and are more related to "communication" standards related to health information exchange (HIE).

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- Category: Device
    - We question the inclusion of 170.210(e) in this category, as this standard applies to the EHR data, audit log, and end user devices, and would not be relevant to the type of medical devices referenced by this category.
- Category: Diagnostic Study (non-laboratory)
    - We question whether the inclusion of imaging for the proposed 2014 EHR Certification means that this entire category is covered, especially since the imaging objective is a menu item for providers for Stage 2 Meaningful Use.
- Category: Encounter
    - The listed vocabulary is SNOMED-CT but most existing QDM value sets are using CPT.
- Category: Family History
    - Standards listed are not proposed for certification.
- Category: Functional Status
    - There is no certification standard or criterion for capturing Functional Status, so we would suggest that everything should move to column four.

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- Category: Health Record Component
    - There is no certification requirement that LOINC be used for naming the components and their relationships, thus you cannot assume that the health record component is captured using LOINC. If LOINC is a requirement, all of these should go into column four.
        - LOINC is used within the CDA for each section, but the fact that it exists in a CDA does not mean it is accessible to measure calculations in the EHR – it is a transmission standard rather than a data model attribute.
- Category: Procedure
    - It is not feasible to capture procedures in SNOMED-CT because SNOMED-CT is not in the Certification and Standards NPRM for procedures. More specifically, SNOMED CT is *NOT* the standard for procedures for certification. The standards listed are 170.207(b)(2) HCPCS and CPT-4; and 170.207(b)(3)ICD-10 PCS
- Category: Transfer
    - SNOMED CT for transfers should not be considered feasible. There is no certification standard currently for documenting a transition of care (transfer).

4. **Feasible:**
    a. Type: General

The EHR Association provides the following comments on the States and Attributes in column three, Feasible in an EHR meeting proposed 2014 certification requirements:

- Category: Adverse Effect, Allergy
    - We agree with the removal of "declined" and "reconciled" for the reasons presented.
- Category: Communication
    - We do not believe that the "subject" is feasible, and recommend that this attribute move to column four.
    - Not all communications sent/received will have specific sender/receivers (for example, there might be organizational senders/receivers in HIEs or other healthcare provider groups).
    - It is not clear that having a "documented" state is currently contained in certification requirements (conceptually an EHR might be certified and only track things transmitted from the EHR, not things transmitted otherwise and documented discretely within). We recommend that this state be moved to column four.
- Category: Device
    - We recommend that all of the states and attributes in the feasible category move to the column four, feasible but requires additional effort.

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- Category: Diagnostic Study (non-laboratory)
    - We have the following feedback on the states and attributes in column three. In general, the implementation of interfaces for diagnostic studies is not widespread in the ambulatory setting, and even though an imaging result may be communicated as a report, this typically lacks structured data:
        - Performed – may not be known comprehensively, since absence of a study does not mean it was not performed elsewhere.
        - Ordered – this would actually be the ordering criterion that covers it (not listed in certification).
        - Declined – would not necessarily be recorded, should not be considered feasible.
        - Result – this attribute is fine.
        - Start datetime – not necessarily documented in the EHR or communicated
        - Stop datetime – not necessarily documented in the EHR or communicated
- Category: Intervention
    - We ask for clarification between documented and performed for patient education, as we think it is difficult to distinguish between these two states.
    - Declined is not necessarily documented in an EHR, so should move to column four.
    - For the attribute "start datetime", the time of documentation may be known, but the time of the intervention may not be known.

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- Category: Encounter
    - Encounters are not always “ordered”, so we would suggest moving this to column four.
    - Capturing “declined” is not feasible. (The EHR might have record of no-shows for appointments, but not declined.)
    - Please clarify the difference between “performed” and “documented” for an encounter.
    - “Start datetime” and “stop datetime” are not necessarily feasible for outpatient visits.
    - There is no “discharge status” for outpatients, so this would not be feasible.
    - “Facility location” is not feasible and should move to column four.
    - It is not clear why “frequency” is included, and may not be feasible. The reference is to homecare, but homecare is not included in meaningful use today.
- Category: Experience
    - We agree that the capture of any states or attributes related to “experience” is not feasible.
- Category: Functional Status
    - “Declined” should be moved to column four.
    - “Start datetime” should be moved to column four.

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- Category: Health Record Component
    - The following list was derived from the EHR certification criteria for capturing certain data that could be considered a “health record component.” For these, and only these, it should be feasible to say they are in the “documented” state.
        - Demographics
        - Vital Signs
        - CPOE orders (for Lab, Rad, Meds)
        - Problem List
        - Medication List
        - Allergy List
        - Smoking status
        - Lab Results
        - Immunizations
        - Clinical Summaries – We question why this is listed as a “component” but it is included in the Health Record Component definition on page 22 of the Quality Data Model June 2012 document. Nevertheless, an EHR should know and track Clinical Summaries since they are a meaningful use measure.
    - There is no requirement in certification for care plans to be reconciled so this should be moved to column four.

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- Category: Laboratory Test
    - Declined – This would not necessarily be recorded, and should not be considered feasible.
    - Performed – This would have to be inferred from the result, so would not consider it feasible.
- Category: Medication
    - We do not think that "dispensed" is feasible. This state is typically only known by the pharmacy system, not the EHR. It is not always communicated to the EHR that the medication was actually dispensed, especially in the ambulatory setting.
    - We do not think that "reconciled" is a feasible status of an individual medication; it is a status of an overall medication list, and this is how we are capturing it today.
    - We are not sure how the attribute "effective time" would be used in regard to a medication, and therefore question whether it is feasible.

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- Category: Physical exam
    - "Declined" may be difficult for an EHR to capture, and should not be feasible for Stage 2, we recommend that it move to column four.
    - In the statement in column three, "*…limited to vital signs that are captured as structured data and also data that are captured in routine inpatient assessments",* we recommend removing the phrase "*and also data that are captured in routine inpatient assessments",* as this is a vague undefined scope and, in any case, not part of the proposed 2014 certification standards.
- Category: Procedure
    - "Declined" would not necessarily be recorded, and should not be considered feasible.
- Category: Risk evaluation
    - Because the concept of "risk evaluation" is not in either meaningful use or the 2014 EHR certification criteria, and is not commonly or consistently captured in an EHR. It should not be considered feasible to be able to collect any discrete data. Therefore, we recommend that all states and attributes be moved to column four.

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- Category: Substance
    - Because the concept of "substance" is not in either meaningful use or the 2014 EHR certification criteria, and is not commonly or consistently captured in an EHR, it should not be considered feasible to be able to collect any discrete data. Therefore, we agree that all states and attributes should be in column four.

- Category: Symptoms
    - Because the concept of "symptom" is not in either meaningful use or the 2014 EHR certification criteria, and is not commonly or consistently captured in an EHR, it should not be considered feasible to be able to collect any discrete data. Therefore, we agree that no states or attributes should be considered feasible.
    - NQF asked for comment regarding the value of 'documented' if 'active,' 'inactive,' or 'resolved' are available. We think that this state would be redundant in those instances.

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- Category: Transfer
    - We need further definition and examples of what an "equipment performer" would be in the case of a transfer in order to determine whether this attribute is feasible.
    - We need further definition and examples of what makes up a "participant" in order to determine whether this attribute is feasible. Is this the patient?
    - We ask for clarification on the difference between "origin" and "source". This is not clear.
    - We also ask for clarification on the difference between "documented" and "performed".

5. <u>Feasible but requires additional effort:</u>

a. Type: General

The EHR Association provides the following comments on the states and attributes in column four, feasible but require additional effort:

- Category: Adverse Effect, Allergy
    - We agree with the removal of "declined" and "reconciled" for reasons presented.
- Category: Adverse Effect, Non-Allergy
    - We agree with the removal of "declined" and "reconciled" for reasons presented.
- Category: Care Goal
    - Is "start datetime" and "stop datetime" intended to be both a state and an attribute? It is listed under both, and we think it should only be an attribute.
    - NQF asked for comments on a new attribute suggestion, "expected time", to align with needs for care planning and care coordination. We do not believe that most EHRs have the capabilities to document this attribute, or that it is commonly captured in care workflows.
- Category: Device
    - NQF asked for comment on the removal of "planned". We agree with removing it, as "planned" is not a state that is typically documented discretely as structured data. The plan for a procedure would not be tied to a specific device code and we question the value of this state for quality reporting.

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- Category: Diagnostic Study (non-laboratory)
    - NQF asked for comment on the value of "recommended". "Recommended" as a state is hard to capture. Also, we question whether a state of "recommended" of a diagnostic study is necessary. We suggest removal of this state.
- Category: Family History
    - We feel that "severity" as an attribute goes beyond what is required for documentation of family history, and we are not clear why this would be required.
    - We also question the attribute of "laterality" and why it would be relevant in quality measurement.
- Category: Functional Status
    - NQF seeks comment about the value of "reconciled" for functional status. We do not feel that "reconciled" is feasible, and we question the use of "reconciled" for a functional status. When would it be valid to compare two or more functional status results for the same concept and actually "reconcile" them? It might be valid for the clinician to "compare" results over time; however this does not mean the same thing as "reconcile".

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- Category: Laboratory Test
    - We are unsure of the definition and use of the attribute "recorder" in this context, and therefore we question whether "recorder" should be an applicable attribute.
    - We recommend that NQF consider adding the attributes of "preliminary" and "final", as they are important attributes in understanding the relevance of a laboratory result.
    - In addition, to determine the action taken, we suggest that you consider adding the attributes of "read", "recorded", and "communicated".
- Category: Medication
    - We would like clarification on the attribute "patient preference". Does this mean the preference of the patient for ePrescribing, as to whether they prefer a printed script? Or does it refer to the patient's preferred pharmacy?
    - We agree with the removal of "discontinued", along with the importance of keeping "start datetime" and "stop datetime". In this context, we also question the use of the status of "inactive". Measure reporting is usually a retrospective process. For acute disease treatments such as acute pharyngitis, the medication at the reporting time is usually "inactive". "Start datetime" and "stop datetime" are much more important in this case.

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- Category: Physical exam
    - We are not sure when “patient preference” would be used related to the physical exam. Please clarify and give examples, or consider removing.
    - We are not sure when “alerted” would be used related to the physical exam. Please clarify and give examples, or consider removing.
- Category: Procedure
    - NQF seeks comment on the value of “recommended” as a state, or context of use for procedures. We would like additional clarification on what “recommended” means and examples of the use of this state. We believe that using this state could cause workflow difficulties for providers, but we need additional clarity.
    - NQF also seeks clarification on the concept of “planned”. We would again ask for clarification and a gap analysis of when planned would be used. (versus “ordered”, “recommended” and “performed”)
- Category: Symptoms
    - NQF asks for comments on the value of “documented”. We do not think “documented” is a valid status, and that would be redundant.

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- Category: Transfer
    - Some of the attributes are feasible for some transfers (such as a patient being discharged) but not for others (such a sending a patient from a PCP to a specialist, which does not necessarily have a status). We recommend adding an attribute of “not applicable”.

6. <u>Overall usability of document:</u>

a. Type: General

The EHR Association recommends that in order to more clearly understand the intent of many of the concepts used for states and attributes, it would help to have additional examples and definitions for the intended use (over and above those found in the companion document, the QDM Update June 2012). In addition, on page two of the Style Guide, there is the following reference to an appendix: “Definitions are provided as Appendix A in this style guide for reference.” This appendix is not found in the document.

We are concerned that if we, as EHR developers, are having problems interpreting some of these categories, states and attributes, the measure developers will have an even more difficult time, which could lead to misinterpretation and potential errors in the measure specification development. In addition, our customers will also have difficultly when trying to use this document, which could be a very helpful tool for them. As revisions are made to incorporate these changes, NQF should consider the use of this document in the context of the full cycle of measure development and implementation.