Summary of eCQM3 Kaizen
December 8th-12th, 2014

Background:

Kaizen, also known as continuous improvement, is a long-term approach to work that systematically seeks to achieve incremental changes in order to improve efficiency and quality. Kaizen focuses on large scoped processes to remove waste and maximize value to the customer. During this week long event, participants map out the current process, identify waste in the current process, create a future state of the process, develop success indicators, and build out a project roadmap for implementation, all with the ultimate customer in mind, the patient.

Purpose:

The Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) chose to focus on the electronic Clinical Quality Measures (eCQM) development cycle for several reasons. First, it is central to the way in which we monitor the success of our various healthcare delivery programs, such as Meaningful Use (MU) and Physician Quality Reporting System (PQRS). eCQMs are directly tied to payment, quality improvement and public reporting. Additionally, the current rate of defects in our eCQMs provides opportunities to utilize lean principles to address deficiencies. Secondly, the eCQM development process varies widely. By aligning the way in which eCQMs are developed, we decrease the likelihood of downstream defects and reworks. Lastly, eCQMs are the future of quality measurement. As the nation progress towards Health Information Technology (HIT) adoption, much of the successes will rely upon solid electronic representation of measurement and support. The week focused on education and outreach around eCQMs, value set versioning, creating a national test collaborative, annual measure update processes, standards timelines, certification, and engaging providers upstream of their provider implementation workflows.

The recent eCQM Kaizen was a follow-up to the last two years of eCQM Kaizen which yielded impressive results. For example, CMS was able to create one implementation guide for all CMS programs, aligned reporting calendars for Eligible Hospitals (EH) and Eligible Professionals (EP) electronic measures, integration of the Bonnie testing tool into the Measure Authoring Tool, which will soon integrate with HQMF R2. These are only a few of the many examples that demonstrate how the participants were able to reduce re-work, meet or exceed deadlines, increase quality, save personnel hours, and create a better product. It was a very productive week - with around 150 participants ranging from federal employees, contractors, EHR Vendors, Practices, Health Information Exchange (HIE), and many more.

Kaizen Common Themes:

- Significant variation and lack of standardization across most processes
- Need more upfront and ongoing stakeholder engagement and transparency
- Need for streamlined communications and governance
- Huge impact of not having all players at the table upfront
- Measure development is very complex and has lots of hands in the mix
- Eco-system is starting to get better around the electronic measures

The Kaizen participants were divided into sub groups according to areas of expertise/background and the need for various levels of perspectives around a particular step of the process. The following groups were identified:

- **Communication Education & Outreach (E&O)**
- **National Test Collaborative**
- **Value Set Versioning**
- **Annual Updates**
- **Future Standards & Timelines**
- **Certification**
- **Implementation Workflows**

A summary of each group is captured below including the scope for each group, key players, and critical challenges and next steps. Over the next 9-12 months, the future states discussed below will be worked on by the team members listed in each section. If you are interested in joining one of the groups please contact the project champion.

Communication E&O	
Scope Start: Communication Packet Development (Provider/Association/Vendor)	**Scope End:** Evaluation of Completed Communication Plan (Provider/Association/Vendor)
Project Champions: CMS	

Challenges/Aha's:

- Notable differences between eligible hospital (EH) and eligible professional (EP) sides, including messaging strategy, eCQMs are not just Meaningful Use – touches multiple programs
- Need complete release notes (tracked changes) of specifications and annual updates
- There is listserv and email fatigue and no single source of truth. Users are bombarded with messages.
- Experienced different terminology usages/meaning, especially for "FAQs" (i.e., system vs. document/use)
- Associations/vendors are expected to produce/turnaround info within 24-48 hours of updates or release of Rules
- Need to document/communicate changes happening to the annual updates/specs/etc. – release notes or post clean and tracked versions for comparison, or table listing revisions, etc.

- (Multiple groups) Need help with JIRA process (determined to be out of our scope); SLAs needed with JIRA.
- Templates will help with CMS review and approval process: will also help project a coordinated look and feel/same voice.
- Mantra: Right message to right audience at the right time
- Need to highlight non-alignment; perhaps programs are "coordinated" but not truly "aligned"
- Different programs have different processes and help desks/support
- Everyone struggling with amount of wait time to get their answers/info and approval
- E&O development is in multiple places and not necessarily consolidated or portrayed as "one voice"
- Two agencies (CMS and ONC) are developing materials separately

Top 3 Road Blocks:

- Sharing analytics among CMS/ONC
- Review standards/roles (e.g., minor edit review (admin) vs. content/big picture)
- Create packet to help support criteria

Future State:

- Leverage workgroup to do pre-Rule publication
- Branding CQMs as own eHealth section; include impacts to programs/audiences (checkboxes, icons, etc.)
- Badge/icon to help with program branding (i.e., high efficiency (HE) icon on laundry detergent)
- As new information released, also follow-up with plain language listserv messages addressing "what's in it for me" (WIIFM) to drive to relevant source (Resource Center, PQRS site, etc.)
- Complete 90% of materials from Proposed to Final Rule timeframe, then vet with a small stakeholder group.
- Divide between EP and EH
- One stop shop for eCQMs makes sense, but providers still need their regular program info – all points of dissemination can still point back to program info on cms.gov
- Metrics/feedback should be addressed.
- Increase linkage/communication with CMS internal workgroup and related contractors - to get business owners on same page
- ONC workgroup?
- Need to build in a combined ONC/CMS workgroup

Ideal State:

- One day eCQM branding will be a life of its own
- E&O customers do not have to read the entire Final Rule (as all clearly communicated in our products)
- One-stop shop for personalized information

Open Questions/Sr. Leadership Asks:

- Resources (time, finances, and new tools): Who is tasked/contracted/funded to undertake this new work?

National Testing Collaborative (NTC)	
Scope Start: Formation of collaborative	**Scope End:** Pilots completed

Project Champion: TBD

Challenges/Aha's:

- Different measure developers may have different processes and sequences of steps during measure testing
    - Measure developers are generally working towards the same goals of illustrating feasibility, validity and reliability of the measures, However the approach, tools, data and sequencing can vary widely
    - In most cases, measure developers do not move forward if the initial feasibility assessment indicates industry readiness does not align with a concept or measure
        - For example, if the current standards or data elements are not available, the measure will not move forward
        - However, the opposite applies as well - some measure development contracts are focused on pushing future capabilities and working around constraints
- Despite process differences, there is significant duplicative effort involved in identifying and recruiting providers and getting all necessary agreements in place before testing can begin
- Creating an NTC can align the interests of measure developers, providers, and EHR vendors. Reduce time and cost for measure development while engaging providers early in the testing resulting in higher quality.

Future State:

- By creating a rolodex of providers interested in being involved in measure development, providing a common framework of legal templates to shorten the time to initial engagement, etc.). The below activities will be done in order to create this:
    - Creating national testing collaborative framework
    - Governance research
    - Funding potential/strategy
    - Awareness campaign and promotion
    - Create contracting and SOW template – poll NTC charter members and other kaizen champions to request contracting documents used by measure developers; send sow template, reps/certs
    - Create tools templates/best practices library – pull sample Data Element Table, Data Collection Form, sampling code and STN code and poll members for similar
    - Recruiting and vetting
    - Incorporate MU3 (not sure we got to discuss this in great detail at the Kaizen but we already know the Kaizen measure implementation work future state includes looking to the NTC for pilot testing participants around June 2015)

Open Questions/Senior Leadership Asks:

- Help developing contract templates by encouraging the sharing of redacted old contracts and beginning necessary conversation begins with legal teams
- Funding or manpower necessary to create and maintain National Testing Collaborative infrastructure and manage communications
- Help gathering support from other organizations, i.e. Healthcare Information and Management Systems Society (HIMSS) and College of Healthcare Information Management Executives (CHIME)

Value Set Versioning	
Scope Start: Value Sets are ready to Publish	**Scope End:** Implementation of Value Sets at Provider site
Project Champions: MD Partners	

Challenges/Aha's:

- Vendors do not work closely when measures are being developed. They "react" after or during measure development, but do not have an early engagement in measure feasibility study.
- Need a common data definition for structured data -i.e., in the structured data, there is no common understanding between what the measures define versus what the physician uses in clinical parlance.
- Some JIRA tickets never get answered in time or the answers are not pertinent. Decisions based on these answers are affected.
- Need to capture true quality or intent of the measure. UNABLE to capture the "Great quality" of clinical
- Value set definitions ARE queries into code systems.
- Authors of value sets are different than authors of measures, even though authors of measures play the role of being authors of value sets.
- Definitions:

  Binding: A value set that is tied to a measure.

  Dynamic: Using an OID in a measure is the way to create a dynamic binding.

  Static: Using a "static date" - "as of this date"

  Code system version + value set version ==> expansion set.

- Patient data matters: Fact- All patient data is recorded using current up-to-date code system version.
- Even though value sets are retired, those sets are still available for dynamic binding, which is a big problem.
- Need to understand the implication of versioning in patient data.
- Value set definition standard has all the DEFINITIONS of each value set.
- When change is required and being made to a value set, the vendors do not know what the change is, when it is coming. Changes are not being communicated early.
- Value set publishing: always happening without a set date for publishing.
- Nobody sees the value set until publication – usually until Apr 1st when the final rule is approved by CMS. The approval by CMS is not early to have the vendors begin to adopt the change.
- There is no change control in place for value set changes.
- The steward makes the final decision for the measure along with the value set appropriate for the measure.
- Value set publishing is done by the measure steward.

- Pre-publishing is one month before publishing.
    - pain-point: The NLM needs to review earlier.
    - pain-point : Inflexibility in the timeline if the measure steward takes issue
- The following is the sequence of events in the value set (VS) life-cycle:
    - Authoring
    - Pre-publication
    - Publishing VS definition
    - CMS releases expansion sets
    - Updates to the VSAC
    - Vendor processing
    - Provider processing
    - Patient data reported to HHS.
- Problems in VS are caused through mapping issues by multiple actors and in multiple places.
- Value set releases may need to be use-focused – think about users or value sets and how they would consume value sets.
- Some code systems might support easier updates than others.

Future State:

- We are thinking through how to add steps for social curation or a wider review of value sets before they are published and another time immediately after publication.
    - VSAC is working on a social curation or collaboration website.
    - Change VS once a year or outside the update process. VS errata and vendors/providers are in support of that timeline pending details.
    - Vendors/providers want more rapid changes for issues.
- After VS authoring, we want to add a step for people to be able to preview the value sets.
- Tag JIRA issues as value set issues.
- Suggested value set changes are posted.
    - We are considering the usage of the new VSAC collaboration tool, but that will not be ready for the 2015 annual update.
    - Resource center might be an option.
- Open a structured comment period.
- Include use cases
- Interested parties review.
- After the review period, the measure developers would have the time to take the consensus opinions to expert panels, if required.
- Make the final changes to the value sets following that.
- If an error is found, post publishing, the current thinking is:
    - From May – Oct time frame:
        - Fix any significant errors in value sets
        - Evaluate against a set of criteria
        - We would then republish the corrected value set.
    - From Oct – Apr time frame:
        - We are going to hold anything found after that into the next update cycle.
        - We are going to spend more time on fixing it.
        - These are real issues that we need more time to figure out.
        - We would like to see how our changes play out.
- In Provider mapping,
    - VS is correct, but provider does not capture it.
    - Do we want to do something in the mapping process to help providers?
    - This is an important issue, but it is out of scope for this group right now.

- We would want to stay with the VSAC stuff right now.

Open Questions/Sr. Leadership Asks:

Structured review process: Show stoppers are:

1. Errors found post publication.
2. Culture changes and clarity.
3. We need to build and pilot this for 2015 with the implementation in 2016. The big show stoppers are:
   - Infrastructure support for implementing changes
   - If we make an ***addendum*** that may require a rule change to inpatient and provider rules (IPPS and PFS).
     - Addendum to add the ability to change value sets, post-publication.
     - Assess impact/consequences on providers, vendors, tools (Bonnie, Cypress).
   - If CMS cannot update their systems to the addendum request, that would be a big show stopper.

   We need to assess the benefits of our current thinking and need to make the "ask" of CMS, clear to them.
4. (Future): Issues that are discovered after addendum, do we have an ask that would allow providers a "pass" on measures that had a serious error?

Annual Update Timeline	
Scope Start: Measure publication from prior year	**Scope End:** Measure publication in the new year
Project Champion: NCQA and AMA	

Challenges/Aha's:

- A definition of "substantive" change is needed to enable prioritization of changes
- The R2 changes will be significant, but vendors / providers at large do not have a sense of just how substantial those changes are
- Requirements to have 508 compliance could hinder the agility of the change review process
- The annual update process is ever changing, making it difficult to plan resources and turnaround times from one year to the next
- Vendors, providers and developers need notification from NLM what the code sets will be when those are finalized in January

Future State:

- Enable release notes show how measures have changed line-by-line, so that vendors/providers no longer have to do this
- Create an agile change review process 1) quickly posts potential changes and their solutions for public comment, and 2) makes informed recommendations to developers and stewards as to which changes should be made
- Create service-level agreement (SLA) so that JIRA tickets are responded to in a timely fashion

Open Questions/Senior Leadership Asks:

- Consider sub-regulatory avenues to make clinical updates more frequently than current regulations allow. This will foster alignment across programs, and allow for real time changes in measures.
- All stakeholders, particularly measure developers, need to be represented in the development of tools that measure developers that are required to use. Including all stakeholders will help provide a sense of stability to what we all recognize as an ever changing process. The annual update group can act as a triage point to get the word out for obtaining input from measure developers, vendors, providers.
- Measure developers will coordinate a multi-stakeholder definition of what a "substantive change" to a measure is, and make the recommendation to CMS/QMHAG for their consideration.

Future Standards	
Scope Start: Updates to the Quality Data Model	**Scope End:** CMS Combined IG and Schematron Publication, Cypress Release
Project Champion: CMS, Lantana, and Batelle	

Challenges/Aha's:

- There is/was no solid current (overall) process in place for standards and tools development
- Not having a clear timeline and dependency tree leads to confusion
- Standards and tools developed in individual silos with limited collaboration and communication
- HL7 standards used in eCQM development and reporting are Draft Standards for Trial Use. They go through limited testing. We can put more effort in testing standards and schematron.
- Schematron and Sample files included with HL7 standards are informative
- CMS IG and Schematron development time has scope for waste reduction
- Standards alignment with Quality Data Model is crucial to the success of eCQM development
- Standards and Tools for eCQM Development are not dependent/can be separated from Standards and Tools needed for eCQM Reporting.
- Quality Data Model changes affect the entire standards and tools chain.
- Standards development is done using a "waterfall" methodology. We can improve this using more agile processes.

Future State:

- Split the standards and tools process into two processes: Standards and Tools for eCQM Development and Standards and Tools for eCQM Reporting.
- Freeze changes to Quality Data Model as early in the timeline as possible (6/1)
- Use Trifolia for the development of the CMS Implementation Guide and CMS Schematron.
- Employ Iterative/Test Driven Development methods for standards and tools development (MAT, Bonnie for HQMF, Cypress for QRDA). Collaboration will help find more errors and create higher quality standards.
- Conduct planning and coordination calls (e.g. standards planning and implementation calls for eCQM development and eCQM reporting)

- Continuous collaboration and Open Communication between contractors/owners of standards and tools
- Attempt to use HL7's lightweight Draft Standards for Trial Use Update process more often instead of heavyweight ballot process.

Open Questions/Senior Leadership Asks:

- Contractors' Engagement

Certification	
Scope Start: Alignment of HHS Reporting Systems	**Scope End:** Successful Submission to CMS and TJC
Project Champion: ONC	

Challenges/A'ha's:

- Don't get schematron files on time.
- Contract scope and cost
- Not having test records we need

Future State:

- **Goal: Align Workflows for QRDA Implementation Guides (base and supplemental) so all template constraints can be identified and included in a single HL7 QRDA IG prior to December 1, 2015**

Improvements Recommended for CMS Testing Tool

1. Content checks wanted. Summary from QRDA1 per measure, Denom, Num, Exclusions, Exceptions, and additional details by patient.
2. Error messages should give you enough detail that you can fix the problem yourself. Provide the line number or section where the error is located.
3. Can the validation tools be downloadable by vendor?
4. Validate if measure result section is in the file (for TJC).

Features in Cypress v2.7 for August 2015

These are "Additional Features" that vendors are asking for in support of Pre-Testing Phase of EHRs. Some of these features could be prototyped as add-on features to the Cypress Test Suite but not part of the ONC eCQM Certification Testing.

1. **Complete Schematron: CMS + TJC + HL7**
   This is addressed with the optional QRDA validation utility that Cypress is bundling into the UI for Cypress v2.7. A drop-down menu allows the vendors to choose the additional test that want to apply to the QRDA file.
2. **Measure Output Per File**
   Currently Measure Output is provided on a per measure basis. The vendors would like to see the output organized by patient.
3. **File Import for QRDAs – Test my own data!**

Vendors would like the ability to send Cypress a QRDA Category 1 and get the CQM calculation results reported back. Detailed requirements to be worked out.

4. **Robust Test Cases – Expand test capacity beyond certification test deck.**
   How do we expand the test cases that we make available to vendors? Can we leverage the test cases that MiHIN created? Can we leverage the test patients that measure developers create for their measures? Is there a way to "glue together" the features of Cypress, Bonnie, and popHealth to create a test suite that vendors can use to create, test, and analyze test cases for their EHR products?
5. **Export of QRDA that provides consistent and stable Test Deck (no randomization) within a Cypress Release and between Releases.**
   A random set of patients makes sense at the time of certification, but the vendors need a stable patient deck to test and retest against during their pre-testing cycle.

Other Ideas Discussed

1. Need a tool like Bonnie that helps you create a good (well-formed) QRDA.
2. Kyle Meadows Insights from an ATL Perspective – Here's some suggested improvements to help vendors with pre-testing phase:
   a. Test deck is one-time instance. No way to transfer it between Cypress versions. Cannot use same stable test deck over and over again within a Cypress version or across versions. Right now vendors have to re-enter patients and start from scratch every time.
   b. Help the smaller vendors succeed. They just don't have the resources that the larger vendors have.
   c. Need to really increase test patients and test coverage for CQMs. Issues they see are almost always with the calculations.
3. Why are all EHR vendors building a measure engine? The measure engine is not really value-add for the vendors and their products. One measure engine should exist (cloud-based and downloadable) for vendors to use as a shared service. Certification should consist of producing Category 1 files from your EHR that Cypress can validate.
4. eCQM should be testing for core competencies of the EHR, not measure by measure certification which is more onerous. Test core components of certification.
5. Submission systems for EH (HQR, Joint Commission) and EP also include a measure engine that calculates the CQMs. No testing or comparison against Cypress was done. Joint Commission system also revalidates the CQM calculation from QRDA Category I documents submitted by Certified EHRs
6. Stay in touch with state SMAs to see what additional (supplemental) constraints they define above and beyond the HL7 QRDA base standard for submission.

Implementation Workflows	
Scope Start: Measure concept proposed	**Scope End:** Measure data submitted/reported
Project Champion: ONC	

Challenges/Aha's:

- The eCQMs that are released are not optimally designed to allow for quick and efficient implementation. Furthermore, the short timeframe between posting final measure specifications and the start of reporting—as well as delays in getting answers to questions about eCQM specifications—require provides and vendors to institute workarounds that introduce defects in order to have something to report by the deadline.

- Successful implementation depends not only on the quality of EHR templates and code, but also on communication with providers about the purpose of eCQMs as well as the necessary changes in documentation practice. Such communication should begin before the new or revised EHR code is released by the vendor.
- The biggest opportunity for reducing waste involves upstream involvement of providers and vendors earlier in the measure development process to ensure that eCQMs have the right level of specificity (enough to give clear guidance on implementation but not so specific as to remove flexibility for providers) and are clearly defined at the time of the final rule. If those goals become reality, many of the implementation workflow steps can be minimized or removed.
- Although similar, the implementation workflows for new measures are different than that of updated measures. Updates to existing measures must account for the workflow changes that have already been implemented in order to report the measure. The selection and development of new measure concepts, on the other hand, should take implementation considerations into account well before the final measure specifications are posted.

Future State:

- Providers and vendors are included in the measure development and update process earlier and in more meaningful ways to ensure that measures that are proposed for programs are aligned with real-world implementation needs
- Create and disseminate resources to support the development and implementation of eCQMs, including a data element catalog, information about direct observation, and guidance about implementation testing

Open Questions/Senior Leadership Asks:

- Reboot the development of a data catalog and develop a governance structure that will ensure that measures under development use existing data elements whenever possible
- Provide better opportunities for providers and vendors to provide feedback on measures under development earlier in the development process and ensure that all measures included in programs are based on input from providers and vendors
- Support the sharing of best practices in implementation workflow processes