Summary of Electronic Clinical Quality Measure (eCQM) and Clinical Decision Support (CDS) Kaizen
Feb 10th-14th, 2014
Washington, DC

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 harmonization of measure elements (standards, value sets, logic, reporting requirements) and elimination of defects through test driven development and testing in production.

The recent eCQM Kaizen was a follow on to last year's eCQM Kaizen which yielded impressive results. For example, CMS was able to reduce the number of clearances from 23 down to 1 for the Measures Under Consideration (MUC) list. This is only one 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. In 2013, the focus was on the very front end of the process including, contract development, rulemaking, and the origins of eCQM development (e.g. research/TEP/feasibility,

etc.). This year we picked up where we left off starting with the harmonization of CQM logic and values sets through the data coming back to CMS for analysis and processing. With over 130 participants ranging from federal employees, contractors, EHR Vendors, Practices, Health Information Exchange (HIE), and many more it was a very productive week even with the loss of a full day due to a winter storm.

Kaizen Common Themes (listed in order of occurrences):

- Need more upfront and ongoing stakeholder engagement and transparency
- Need for streamlined communications and governance
- "One Stop Shop" for documentations (i.e., single authoritative source)
- Support for earlier and non-traditional testing methodologies
- Harmonization/alignment between programs and calendar year (CY)/fiscal year (FY)
- Timing/timelines of rules, development cycles, software development, etc.
- eCQM tool investment including JIRA, Bonnie, and National Test Bed
- Significant variation and lack of standardization across most processes
- Lack of understanding of roles

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:

- Measure Authoring Tool/Unit Testing (later renamed to MATRESS)
- Value Set Authority Center (VSAC) Harmonization (later renamed to Take the Harm out of Harmonization)
- Measure Updates
- Logic Harmonization (later renamed eHarmonization: where logic meets its match)
- Electronic Health Record Certification
- Data Processing/Re-Use
- Harmonized Implementation of Standards (H.I.S.)

A summary of each group is captured below including the scope for each group, key players, and critical challenges and next steps.

Measure Authoring Tool/Unit Testing (MATRESS)	
Scope Start: Creating a Synthetic test record	**Scope End:** Measure is handed off to the vendor
Project Champion: Telligen	

Challenges/Aha's:

- Measure Developers all had different approaches for how they did this piece of the process, including general terminology and measure testing.

Future State:

- Test driven development is a standard process for measure creation – resulting in defect free measure specifications and tests that can be re-used by many others.

- Start with the narrative specs rather than draft the HQMF spec first. Build, measure, and test cases simultaneously using the test driven development methodology.
- Combine Bonnie/Cypress with MAT in a single application.
- Develop templates to populate test cases.

Open Questions/Senior Leadership Asks:

- How many measures would be tested in 3, 6, 12 months and what do developers think of this process?
- How do they involve measure developers and educate them?
- Some concerns with timing as developers are currently in the process of updating their measures.

VSAC Harmonization (Take the Harm out of Harmonization)	
Scope Start: Need for Harmonization	**Scope End:** Harmonization complete
Project Champion: ONC	

Challenges/Aha's:

- Each development project team has different compositions, some have one member for each expertise, while others leverage multiple teams; also will need to clarify communications.
- While able to map out most of the current state they could not get as granular with future state tasks since not all of the key players were in attendance; focused on developers and users of the VSAC as well as the NLM team.
- Identified lack of funding to continue VSAC and maintenance of VS after contract ends.
- Technical roadblocks to UMLS tool/Crowdsourcing.

Future State:

- Vision – VSAC decrease duplication Value Set (VS) through high quality tool that provides automated testing and support combined with clear documentation
- Begin with clear definition of data elements, improve ability for author & value set steward to review, QA to be included in the process through external feedback

Open Questions/Senior Leadership Asks:

- Where is the governance to manage this new process? New platform/process to include all stakeholders.
- Funding for VSAC and Maintenance.
- Need external support for harmonization/intentional content.
- Need "enforcement" support from HHS agencies and standards.

Measure Updates	
Scope Start: Identify potential change to a measure	**Scope End:** Change Complete
Project Champion: Siemens and CMS	

Challenges/Aha's:

- New tools are still immature and they are still evolving such as Bonnie and VSAC/MAT.
- Process is new for everyone and there are a lot of communication issues.
- Contracts are due to expire soon and may lose institutional knowledge.

Future State:

- Publication – streamline and consolidate process.
- Single portal to consume artifacts & measures.
- Update Eligible Provider (EP) & Eligible Hospital (EH) measures at the same time.

Open Questions/Senior Leadership Asks:

- Align EP and EH measures or re-examine the timing for updates.
- Coordinate and align new tools and create a hard stop for adding new tools.

Logic Harmonization (eHarmonization where logic meets its match)	
Scope Start: Need for harmonization	**Scope End:** Harmonization Complete
Project Champion: CMS	

Challenges/Aha's:

- Often takes a long time to make any progress and show change – many rounds of review; may involve policy; often times the response is that it will be addressed in the annual updates (many months later)
- 95 steps were eliminated from the current state using waste identification leaving 1 step with ideal state.
- Use case of harmonization – 18 months until it can be resolved once it was identified.
- Challenge will be to see what can be changed in the next 6-12 months.

Future State:

- High quality reusable logic statements that will be used in multiple measures that express the same content.
- Create single point of entry for process = JIRA.
- Close loop for issue through eMeasures Issues Group (eMIG).
- Utilize eMIG subgroup to harmonize.
- Develop and catalog harmonization through future development.

Open Questions/Senior Leadership Asks:

- Need one system to identify and coordinate process – keep using JIRA issues but need resource (FTE) from CMS/ONC to appropriate categorize an issue.
- Policy defined for handling in-limbo measure (e.g. inactive stewardship)
- How will governance be handled when consensus is not reached?

Electronic Health Record Certification	
Scope Start: Change needed to Certification	**Scope End:** Change Complete
Project Champion: MITRE and Practice Fusion	

Challenges/Aha's:

- It is a long process, but there are important parts that cannot be changed or are difficult to change (length of final rule release); need to identify where changes can be made without changing effectiveness
- Ideal state looks different to different stakeholders; many people are served by downstream results of certification and need to further discuss this.
- From vendor perspective, there is a lot of review and analysis that goes into a change. This may be good, but not all of the necessary partners are brought in early enough in the process. Vendors and test labs uniformly feel that eCQM is working and providing value.
- Vendors feel changes to certification test procedures and Cypress are too unpredictable

Future State:

- A robust testing lifecycle exists for many types of testing with a rich set of tests, test case and test harnesses to be used by many parts of the quality system
- Certification use tests after they have matured and been proven valuable in the open testing processes
- Create a certification lifecycle that allows for more predictability in changes for vendors and other stakeholders with scheduled releases of test procedures;
- Certification change control board – CMS, ONC, Health Resources and Services Administration (HRSA), States, Others. The board would serve as the single point of input for changes to certification. They would be responsible for reviewing and approving changes.
- Engage stakeholders upfront to reduce downstream waste.
- Standardize how feedback is delivered to ONC on certification and change to predictable release schedule (propose quarterly).
- Crowd sharing – ideally robust library of synthetic test records, tests and testing tools are shared, used and widely available for a variety of purposes, including assuring accuracy of testing engines, transmission conformance testing, load testing etc. Vendors, states, standards developing organizations (SDOs), Feds and others agreed to share

Open Questions/Senior Leadership Asks:

- Need help with resourcing for reconciling, creating, and testing test records. Need help also with cataloging, creating and maintaining repository.
- Need location for housing test library

Data Processing/Re-Use	
Scope Start: QRDA ready to submit	**Scope End:** Data Publicly Reported
Project Champion: CMS and McKesson	

Challenges/Aha's:

- Seeing rework that takes place. Issue identification: there are a number of different ways that vendors attempt to identify where the issue may be in the specification or the EHRs.
- Identified 3 different implementation guides by which vendors have to comply.
- Feasibility of data elements: get to the end of the process and then realize that one of the data elements cannot be feasibly collected in EHRs; then cannot use the measure because of inability to collect that data element. The only way to know if successful is to submit data and not get an error report.
- A big difference between EP and EH; EH does not have a tool to enable checking.

Future State:

- One stop eCQM shop – only one site rather than the 6 or more we have now which would include education, specifications/requirements, webinars, etc.
- Overall submission process has upfront edits and validation that occur but there may be some quality measures that are missing from PQRS and this needs to be moved upstream
- Feedback dashboard reports/measure reports there is a fairly rigorous testing process, but R&A testing is missing; would like this to be aligned to drive efficiencies.
- Create a way for shorter feedback loops (near real-time) for the EPs similar to the way EHs function today.
- Create a central repository for data sharing via IDR for EPs/EHs to eliminate ICDs and add flexibility to our CMS customers.
- Develop an open architecture (best of breed) repository for similar code.
- Create a single testing tool and standards for EPs/EHs.
- Unified pre-integration tool that integrates with Cypress.
- Unified implementation guide for Quality Reporting Data Architecture (QRDA) 1 & 3.

Open Questions/Senior Leadership Asks:

- Barriers that need to be resolved quickly : Office of E-health Standards and Services (OESS) buy-in on the one web site; Office of General Counsel (OGC) to align Fiscal Year to Calendar Year and resource issues for combining guides and developing web site
- Is there feedback to Standard Development Organization (SDOs) on Implementation Guides (IGs)?

Harmonized Implementation of Standards (H.I.S.)	
Scope Start: Change of Standard	**Scope End:** Implementation of Standard
Project Champion: CMS and NQF	

Challenges/Aha's:

- By the time it gets to the Final Rule, a standard may have gone through more updates and cannot be used. We need to know when a standard is solid/consistent.
- After the final rule is published, vendors and others implement standards (e.g., MAT, eCQM developers, CMS systems, etc.). Providers are missing from this current implementation.
- HL7 implementation guides were published after balloted. Then CMS released IGs with conflicting requirements
- No clear strategy on standards

Future State:

- Create a more systematic process to incorporate feedback on standards; including who needs to be involved and when.
- Single place to go for identifying standards to implement.
- Being able to have governance to influence what goes into program guidance; use JIRA to capture issues with implementation against the different guides, but need to build on this in terms of how these issues are addressed and what will be done before these changes are implemented.
- Consolidate two CMS guides (within 6 months) – publish on one authoritative website alongside other measure issues.

Open Questions/Senior Leadership Asks:

- Resources; not a lot of bandwidth
- Lot of weigh in role of case manager-need support from leadership to empower.
- Currently there is only one voter at HL7 for CMS: often contractor for CMS attends, but those at CMS who can make backend changes at CMS do not attend HL7.

Overall Reflections

- Richer group this year; increased vendor representatives and more than one practice represented.
- Would like to have these events more often.
- Missing – health information exchange participants.
- Primarily focused on quality management and need to start incorporating clinical decision support (CDS) to reduce the amount of rework later on.
- Patient perspective helped.
- Perspective on whether the 6-12 month timeframe still seems overwhelming
- HHS is very receptive. Some of the groups realized that they need an empowered charter and HHS can help with that.
- Vendors appreciated being invited. The collaborative environment helped to focus on a better end product to all parties, especially patients.
- More advanced notice for subsequent Kaizens. One attendee indicated the technical folks who participated in the Kaizen are missing prime development time; this would also help with budgeting.

Final Leadership Remarks

<u>Dr. Kate Goodrich (Quality Measures Health Assessment Group Director – CMS)</u>
There are similar themes as last year's Kaizen. One thing that happened during this Kaizen was discovering a given stakeholder group is only human. This week has been good for resetting relationships. Kate hopes we can reset and work collaboratively in the future. This will start with the data processing group next week. It was good to hear the specificity of asks; it makes it clear what is needed and helps with prioritization and getting to the Future State. Over the last year Wes Perich and Patrick Conway have been instrumental in moving the needle on asks from last year.

<u>Dr. Karen DeSalvo (National Coordinator – ONC)</u>
Working together with CMS, ONC will make the processes better and more streamlined; it is important to have more frequent conversations (rapid cycle).
ONC focus post adoption, importance of certification & real world testing. Hope to do more Lean in the future. ONC will be looking at 'leaning up' in post HITECH environment.