Health IT Policy Committee

Request for Comment Summary

February 6, 2013

Comment review process

- RFC posted on ONC website November 16, 2012, comment period closed January 14, 2013 at 11:59pm - 60 days

- ONC staff has been vigorously working to review and summarize comments

- February 6th HITPC
  - High level review of public comments
  - Feedback from the HITSC

- Following HITPC meeting, workgroups will conduct a deep dive of public comments and HITSC feedback

Meaningful Use

Michelle Consolazio Nelson
Meaningful Use Workgroup Lead

Comments

- 606 Comments
- Types of organizations that commented
  - Allied professional organizations
  - Consumer organizations
  - EHR consultants
  - Eligible hospitals
  - Eligible professionals
  - Federal Agencies
  - Other (e.g. REC community, individual citizens)
  - Payers
  - Provider organizations (clinician and institutional)
  - Vendors
  - Vendor trade groups

Overarching Themes from Comments

- Focus on clinical outcomes in Stage 3
  - Empower flexibility to foster innovation, limiting the scope of recommendations
- Concerns about timing
  - Experience needed from stage 2 before increasing thresholds, accelerating measures, or moving from menu to core
  - Concerns about the readiness of standards to support stage 3 goals
- Address interoperability limitations
- Meaningful Use is one component of provider responsibilities
  - Continue to invest in quality measurement alignment, infrastructure and standards
- Ensure that patient safety remains a high priority and any related requirements are synchronized with Meaningful Use
- Make use of all technology available, everything does not need to happen in the EHR

Improving quality, safety, and reducing health disparities

ID#	Summary

SGRP101	**Meds, labs, rads are recorded using CPOE**
	• Overall support for the objective
	• Varied opinions on increasing and decreasing the thresholds
	   • More leaned towards not increasing, particularly for labs and rads
	   • Concerns about the concept of external DDI checking

SGRP130	**Referrals/transition of care orders are recorded using CPOE**
	• General support
	• Great deal of confusion as to whether this proposal simply required the recording of the referrals/transition of care orders created by the EP or whether it actually required the electronic transmission of these orders.
	   • For actual electronic transmission, commenters were most concerned about the lack of interoperability and standards
	   • Need to factor differences between EP and EH

SGRP103	**Generate and transmit permissible prescriptions electronically**
	• Commenters were not in agreement with this proposal
	   • Clarifications, concerns and revisions were suggested
	   • Standards for pre-authorization and formularies were suggested

Improving quality, safety, and reducing health disparities

ID#	Summary
SGRP104	**Record demographics (retire?)** • 337 Comments • Commenters were fairly evenly split on retiring this objective, though many who support retirement do so with reservations • Many requested clarification on what 'retirement' and 'topping out' really mean • Concerns that retiring would encourage providers to no longer collect the data, leading to disparities and quality loss • Commenters suggested a number of additional data elements • Requests for additional specificity on race/ethnicity • Certification criteria: Occupation and industry codes • Commenters overwhelmingly support adding • Some would like there to be a MU use case so that practices actually capture this information • A few commenters opposed these data elements due to the cost of maintaining, updating EHR systems to capture it, and the complexity of system development • Certification criteria: Sexual orientation, gender identity • Most commenters agreed with inclusion, but want more specificity regarding data standards, definitions and how data will affect other parts of EHR systems

Improving quality, safety, and reducing health disparities

ID#	Summary
SGRP105	**Certification criteria for up-to-date problem lists** • 101 Comments • Overall, commenters were concerned that this item, as written was too vague • A number of commenters suggested integrating this requirement with CDS, indicating that it is duplicative
SGRP106	**Certification criteria for up-to-date medication lists** • 84 Comments • Many commenters expressed support for this additional functionality, while others equally expressed concern • Concerns about the vagueness of the certification criteria, potential for alert fatigue, and additional costs and complexity for providers

Improving quality, safety, and reducing health disparities

ID#	Summary

SGRP107	**Certification criteria for med allergies**
	• 66 Comments
	• Commenters generally supported recommendations
	   • Need for a clear and precise certification criteria and standards (some recommendations provided).
	   • Suggested inclusion of other allergens and the need to differentiate allergy intolerances and adverse reactions.
	   • A few commenters were concerned about alert fatigue and costs

SGRP108	**Record vitals (retire?)** • 99 comments • Commenters were evenly split on retirement of this measure.

Improving quality, safety, and reducing health disparities

ID#	Summary
SGRP109	**Record smoking status (retire?)** • 103 Comments • Many commenters expressed support for this additional functionality, while others equally expressed concern • Concerns about the vagueness of the certification criteria, potential for alert fatigue, and additional costs and complexity for providers

SGRP112	**Advance Directive**
	• 81 Comments
	• Commenters generally supported recommendations
	    • Suggested revisions to threshold
	    • Enhance by lowering age, including actual advance directive document, establish standards for transmitting

Improving quality, safety, and reducing health disparities

ID#	Summary

SGRP113	**Clinical Decision Support**
	• 157 comments
	• Approximately the same number expressed favor/opposition to increasing to 15 interventions
	   • Concerns included: alert fatigue, lack of CDS interventions relevant to specialty practice (especially ones related to the CQMs).
	   • Clarification needed regarding whether the 15 interventions are to be at the practice/group level or the provider level (which could be burdensome for larger organizations).
	• Comments were varied about the tie to CQMs and focus areas
	   • Some opposed, viewing it as too burdensome or not enough relevant CQMs available
	   • A few contended that the links and focus areas were "too arbitrary" and detracted from targeted QI
	   • A few suggested that ONC focus on outcomes and let providers pick what CDS they need to improve CQMs
	• Most opposed the DDI requirement (noted as a source of alert fatigue)
	• Many expressed concern that standards will not be available for structured SIG
	• Few commenters were in favor of tracking provider responses to CDS
	• Clarification was requested related to preference-sensitive conditions and vendors indicated concern about modularity of patient versus provider-facing CDS
	• The criterion for the ability to consume CDS interventions was generally met with support
	   • Concern about readiness of standards and the cost of content subscriptions to providers.
	• There were only a couple of comments related to food-drug interactions and were concerned about the specificity of information likely to be available in an EHR.

Improving quality, safety, and reducing health disparities

ID#	Summary

SGRP114	**Incorporating clinical lab tests**
	• 73 comments
	• Most agreed with the increase in threshold to 80%
	    • Clarify if this measure is menu /core.
	    • Evaluate experience in stage 2 prior to increasing threshold
	    • Consider exclusion criteria

Improving quality, safety, and reducing health disparities

ID#	Summary
SGRP1 15	**Generating patient lists** • 98 comments • Generate lists of patients for multiple specific conditions • Most commenters agreed with the intent of this measure, but requested specificity on the number of lists, what they should include, and when they should be used • Present near real-time (vs. retrospective reporting) patient-oriented dashboards • Commenters requested clarity, as the language was not specified well-enough to offer recommendations • Dashboards are incorporated into the EHR's clinical workflow • Commenters were divided on this measure and requested more specificity around the type of information presented and where it fits into clinical workflow • Uncertainty around how this would be measurable as proposed • Actionable and not a retrospective report • Commenters were evenly divided on whether this should be included - requested a definition of actionable
SGRP1 16	**Reminders, per patient preference** • 77 comments • Agreement on increasing the threshold, but disagreed with decreasing the time to period • Specificity requested regarding 'clinically relevant', definition of reminder and patient preference , whether core/menu.

Improving quality, safety, and reducing health disparities

ID#	Summary
SGRP 117	**Electronic medication administration record (eMAR)** • 52 comments • Commenters agree with increasing the threshold to 30% • Commenters generally agreed with tracking mismatches, but wanted more specificity

SGRP 118	**Imaging results**
	
	• 88 comments
	• Commenters do not agree with moving this to core. Numerous barriers were detailed that included:
	    • Cost of interfaces and availability, especially to EP
	    • Type of images have been expanded beyond RIS/PACS which widens scope
	    • Evaluation needed of networking, transmission, and storage impact of large image files
	    • Lack of control over getting images from the various image systems
	    • Lack of high resolution displays may compromise adequate result viewing

Improving quality, safety, and reducing health disparities

ID#	Summary
SGRP1 19	**Family History** • 91 comments • Commenters disagreed with moving to core, increasing the threshold, and the change in wording to 'high priority' (this caused confusion) • Commenters requested clarification on certification criteria for CDS intervention to have the ability to take family history into account. Many thought this would be more appropriate in the CDS measure.
SGRP1 20	**Electronic notes** • 72 comments • 2/3 of the commenters wanted additional specificity before supporting, the remaining mostly agreed with the proposed changes.
SGRP1 21	**Structured lab results to EPs** • 59 comments • Most commenters disagreed with moving to core increasing the threshold
SGRP1 22	**Test Tracking** • 64 Comments • Commenters were equally divided regarding including this measure. Many requested clarification on terms in order to support (e.g. timing, abnormal)

Engaging Patients and Families

ID#	Summary

SGRP 204A	**View, download, transmit (VDT) and automated blue button initiative (ABBI)**
	
	• 124 comments
	
	• VDT: A few commenters were concerned about the threshold increase, while others asked for the threshold to be even higher
	
	   • A large number of commenters expressed concern about providers being accountable for patient actions
	
	   • A large number of commenters were concerned about accelerating the timing to 24 hours and 4 days for labs (a few thought the timing was too long)
	
	• ABBI: Overall commenters supported, but there were a number of areas of concern (e.g. provider liability, privacy and security risks (42 CFR Part 2 data needs to be clearly identified))
	
	• Very few comments related to the proposed future stage recommendations , those who commented were supportive
	
	• Imaging and Radiation Dosing: Most commenters were supportive of including imaging and/or radiation dosing, but had a few concerns (e.g. availability of standards, educating patients on radiation dosing, providing a link to PACS to avoid bandwidth issues).

Engaging Patients and Families

ID#	Summary

SGRP 204B	**Submitting patient generated health data**
	
	• 135 comments
	
	• The majority supported this item, but clarifications were requested:
	
	   • Definition of high priority health conditions
	
	   • Both EP and EH measure
	
	   • Concerns about providers being accountable for patient actions
	
	   • Availability of standards to differentiate between provider and patient data
	
	   • Concerns about burdening providers with too much information
	
	   • There was a wide disparity in comments related to the timing of this measure, some wanted it pushed to core, others thought menu was appropriate, and still others thought it should be pushed out to a future stage.
	
	• Most commenters were concerned that standards will not be available to include medical device data.

Engaging Patients and Families

ID#	Summary
SGRP 204D	**Requesting amendments to record** • 95 comments • The majority supported this item, but clarifications were requested - Many suggestions to define "in an obvious manner", documentation requirements, whether or not the provider must accept all amendments, and what parts of the record could have amendments submitted - Need to differentiate between patient and provider data and notify patients if amendment is not accepted - Many sought clarification on what the measure and threshold would be

Engaging Patients and Families

ID#	Summary
SGRP205	**Clinical summaries** • 88 comments • Commenters were supportive of evaluating this measure to ensure that the clinical summary is pertinent to the office visit. • Many commenters provided lists of items that should be included, one common theme was to provide information to patients that facilitates concise and clear access to information about their most recent health and care, and understand what they can/should do next. • Commenters were concerned about the current format of many vendor summaries and included: summaries being too long, not in plain language, and language limitations. • Quite a few commenters were confused and wanted clarification on what 'pertinent to the office visit actually meant

SGRP 206	**Patient education**
	
	• 101 comments
	
	• Many supported this recommendation, but suggested changing the non-English language from the top 5 national to the top 5 local. Other concerns included:
	
	   • Many non-English speaking patients may not be able to read materials or the materials may be printed at too high of a reading level
	
	   • Others also encouraged adding visual/pictorial materials and Braille

Engaging Patients and Families

ID#	Summary

SGRP 207	**Secure messaging**
	
	• 117 comments
	
	• Most commenters did not support increasing the threshold until we learn from stage 2
	
	    • Many commenters recommended including family, and caregivers in the measure
	
	    • Concerns about providers being held accountable for patient actions.

SGRP 208	**Record communication preference** • 76 comments • Most commenters support this requirement to document communication preferences and agree that it is a necessary requirement in order to ensure people receive information in a medium that engages them. • Many suggested constraint around the menu of communication types to avoid workflow challenges and suggested that certification criteria be developed to specify the menu of options for "preferences" and "purposes".

Engaging Patients and Families

ID#	Summary

SGRP 209	**Query for clinical trials**
	
	• 65 comments
	
	• Commenters see the value in the EHR being able to query clinical trials database and the intent of this criteria to improve enrollment in trials but a number of concerns were noted.
	
	   • Implementation challenges, including the complex functionality that would be required to query multiple sources
	
	   • Lack of specification about what fields to query
	
	   • Lack of standards or a defined use case; workflow challenges; a lack of broad applicability to practitioners (more relevant to specialists)

Care Coordination

ID#	Summary

SGRP 302	**Reconciliation of meds, med allergies, and problems**
	
	• 97 comments
	
	• Overall, commenters were supportive of this measure. There were concerns about the ability to measure outcomes, differences of opinion on the percentage needed to obtain the objective, and requests for clarification.
	
	  • Most comments asked for a higher threshold for the reconciliation items
	  • Many commenters asked for additional items to be reconciled (e.g. caregiver names and numbers), while others were not supportive of providing additional items
	  • Concerns regarding how this will actually be measured and readiness of standards

Care Coordination

ID#	Summary
SGRP 303	**Summary of care** • 119 comments • Strong support for the intent of this objective, however commenters expressed concern regarding the burden imposed by the objective, the lack of existing standards, and the lack of experience from Stage 2 MU.
SGRP 304	**Care plan** • 89 Comments • Generally commenters noted the objective is broad as written, suggested a focused, defined approach and the need to define terms clearly • Some concerns regarding over specification, lack of standards, lack of experience and burden on providers • Several commenters recommended combining SGRP 303 and 304 • Several commenters recommended soliciting more feedback on this objective possibly through a HITPC working group sessions or other format

Care Coordination

ID#	Summary

SGRP 305	**Referral tracking**
	
	• 97 comments
	
	• Overall, commenters were supportive of this measure. There were concerns about the ability to measure outcomes, differences of opinion on the percentage needed to obtain the objective, and requests for clarification.
	
	   • Most comments asked for a higher threshold for the reconciliation items
	   • Many commenters asked for additional items to be reconciled (e.g. caregiver names and numbers), while others were not supportive of providing additional items
	   • Concerns regarding how this will actually be measured and readiness of standards

SGRP 127	**Interdisciplinary problem lists** • 54 comments • Overall, most commenters supported this objective, pending further development and clarification and definitions of the terms versioning and interdisciplinary • Some commenters thought the measure would have limited benefit.

Care Coordination

ID#	Summary

SGRP 125	**Medication history/reconciliation and prescription drug monitoring programs (PDMP)**
	
	• 83 Comments
	
	• Majority of commenters supported the additional requirement to create the ability to accept data feeds from PBM
	
	• Some caveats included:
	
	    • Data sources must be highly accurate/up-to-date
	
	    • MU measure should have a low threshold and be a menu item
	
	    • Concerns about additional burden on providers
	
	    • Commenters suggested additional requirements that should be considered such as including feeds from external (i.e., non-PBM feeds) data sources. Commenters also listed a number of concerns for the HITPC to take into consideration.
	
	• Majority of commenters were supportive of a new certification criterion for EHR technology to support streamlined access to PDMP
	
	    • A majority of those supporters recommended accelerating the proposed certification criteria into Stage 3 to encourage provider access to and use of PDMP data

Care Coordination

ID#	Summary

SGRP 308	**Notification of health event (e.g. discharge from ED)**
	
	• 82 Comments
	
	• While there was support for this measure, there was a great deal of concern identified:
	
	    • Many felt the 10% threshold was too low
	
	    • Some commenters thought the two hour window was too short
	
	    • Many commenters were concerned with privacy implications and the patients role in consent
	
	    • Further clarification needed regarding the definition of "significant."
	
	    • Some commenters were concerned with there being inefficient technological infrastructure to support this measure

Population and Public Health

ID#	Summary
SGRP 401A	**Receive immunization history** • 93 Comments • Most commenters supported, with concern about readiness • A number of commenters sought clarification on the wording/intent • Several commenters recommended including vaccine contraction(s) and reason(s) for refusal in Stage 3, rather than a future stage, as many EHRs are already submitting this data • A few commenters proposed merging 401A and B

SGRP 401B	**Recommendations for immunization intervention**
	
	• 83 Comments
	
	• Commenters were fairly even split on their support for or against
	
	    • There were a number of concerns about readiness and the complexity to implement
	
	    • Concerns about another CDS requirement
	
	    • Clarification on the definition of 'receipt'

Population and Public Health

ID#	Summary

SGRP 402A	**Electronic lab reporting**
	
	• 56 Comments
	
	• Most commenters agreed to keeping this measure unchanged although the standards and Implementation Guide for this measure should be updated to reflect current Public Health requirements.
	
	    • Most agree with keeping as core, but some felt that laboratory functions should not be part of Meaningful Use and that this requirement should be removed
	
	    • Many commenters also mention that capacity at the state level is still an issue and that states require additional resources to ensure that they can receive this data

SGRP 402B	**Case reports**
	
	• 56 Comments
	
	• Majority of commenters support the inclusion of this objective in either Stage 3 core set or the future stages of Meaningful Use
	
	    • Concerns expressed about the readiness of public health agencies to receive this data electronically and the maturity and availability of content and vocabulary standards
	
	    • Why weren't EHs included?

Population and Public Health

ID#	Summary
SGRP 403	**Submit syndromic surveillance data** • 56 Comments • Most commenters agree that this measure should remain per the recommendations unchanged, concerns that standards are still not mature, especially for EPs • Many states are not ready and need additional funding to implement

SGRP 404	**Submit ongoing reports to a jurisdictional registry**
	
	• 82 Comments
	
	• Commenters disagreed with the expansion of the scope beyond cancer registry
	
	    • Commenters did not want the scope expanded to include other registries
	
	    • Commenters wondered at the impact on the cancer registry from the expansion to include EH, many of whom already have established reporting mechanisms in place
	
	    • A uniform reporting standard needs to be adopted prior to including other registries

Population and Public Health

ID#	Summary

SGRP 405	**Submit ongoing reports to an additional registry**
	
	• 83 Comments
	
	• Commenters support the Stage 3 changes but requested specificity regarding the following:
	
	   • Will this remain menu or move to core
	   • Commenters recommended a standard format for reporting be defined
	   • Specificity requested regarding which registries qualify under this objective

SGRP 407	• **Send standardized Healthcare Associated Infection (HAI) reports** • 82 Comments • Comments in favor of this cited that this function was already in place and operating within some EHRs and noted alignment with Federal goals of decreasing HAIs • Negative comments noted the need for more Federal funding and support of implementation of this function • Determining an HAI is not a simple function for EHRs

Population and Public Health

ID#	Summary
SGRP 408	**Send adverse event reports** • 64 Comments • Comments were mixed on this measure • Comments in favor of this cited that this function was already in place and operating within some EHRs and aligns with federal goals of decreasing HAIs. • Those opposed, noted that determining an HAI by NHSN criteria was not a simple function for an EHR and that it usually involved manual review of data and a chart audit • Multiple comments also felt it was premature as the pilot of electronic transmission to NHSN is currently only conceptualized

Overarching MU Comments

ID#	Summary

MU 01	**Is there flexibility in achieving a close percentage of the MU objectives, but not quite achieving all of them? What is the downside of providing this additional flexibility? How will it impact providers who are achieving all of the MU criteria? If there is additional flexibility of this type, what are the ways this can be constructed so that it is not harmful to the goals of the program and advantageous to others?**
	
	• 75 Comments
	• Most commenters urged the HITPC to recommend more flexibility in the MU program
	    • Flexibility will be important for full year reporting
	    • recommendations that providers be considered in compliance if they meet 75 percent of the objectives

Overarching MU Comments

ID#	Summary
MU 02	**What is the best balance between ease of clinical documentation and the ease of practice management efficiency?** • 59 Comments • Most commenters favored improvements in overall usability that could be expected to make this balance more manageable. One specific form of usability improvement, natural language processing (NLP), had a small but clear following. • After improvements in usability there was an expectation that changing the Meaningful Use requirements to accommodate the growing burden of documentation is a viable answer • Another highly favored solution was a reallocation of the practice workflow to more evenly distribute the work and increase overall practice efficiency • It should be noted that there were a number of statements that the question was beyond the scope of the Meaningful Use program

Overarching MU Comments

Putting the **I** in Health**IT**
www.HealthIT.gov

ID#	Summary
MU 03	**To improve the safety of EHRs, should there be a MU requirement for providers to conduct a health IT safety risk assessment? Are there models or standards that we should look to for guidance?** • 63 comments • Overwhelming opposition to a MU requirement as premature, but support for the need for EHR users to do a safety assessment

Overarching MU Comments

ID#	Summary
MU 06	**What can be included in EHR technology to give providers evidence that a capability was in use during the EHR reporting period for measures that are not percentage based. This capability will need to support measures that occur in all stages of MU (e.g. there are yes/no measures in stage 1 that still need to be supported). Are there objectives and measures that should be prioritized to assist providers in showing that the capability was enabled during the reporting period?** • 48 Comments • Commenters (mainly providers) generally agree that EHRs should be able to track usage for yes/no measures. Many suggested that the audit log would be an appropriate functionality for tracking usage and that providers should have only "read-access" to the log. • Commenters equally noted the difficulty in tracking activities that occur in (or partially within) the EHR technology and those that occur outside the EHR technology (or partially outside the EHR technology)

Information Exchange

Kory Mertz
Information Exchange Workgroup Lead

Information Exchange Workgroup

ID#	Summary
MU05	78 comments - There were many suggestions for what can be done to foster innovation. Some of the comments had several key points listed for the measure. - Key Points that were identified in the comments were: - Implement standard interface specification to support integration for the EHRs and other systems - Differing views on CCDA and Direct and Exchange ability to communicate between EHRs and other kinds of systems. - Believe that publishing of healthcare APIs will speed the development of truly integrated systems

Information Exchange Workgroup

ID#	Summary
IEWG01	• 102 comments • Many commenters expressed support for the inclusion of this objective in Stage 3. • Quite a few commenters seemed confused about the focus and scope of this objective. Many seemed to think it was focused on requiring providers to utilize a HIO leading to concerns about the level of access to fully functional HIOs. • Quite a few commenters expressed the need to complete additional work around the privacy and security implications of this objective. • A number of commenters stated that HIE/HIOs should be able to support providers in achieving this objective. • *Measure*: The majority of those who commented on the measure suggested it should be based on a percentage. Requested additional detail on how the measure will be calculated. • *Patient matching*: A few commenters on this objective requested ONC establish explicit standards to support patient matching. A few commenters felt it was important to establish a national patient identified to support correctly matching patients for this objective.

Information Exchange Workgroup

ID#	Summary
IEWG02	• 62 comments • Most commenters agreed that there are not sufficiently mature standards in place to support this criteria at this time. • Comments were fairly evenly split on if the criterion should be kept in Stage 3.
IEWG03	• 56 comments • The majority of commenters felt this criterion was important and that further progress needed to be achieved around data portability. • Requests for a variety of data elements to be added common themes were to ensure new data elements included in Stage 3 be added to this criterion and that any historical data required to calculate Stage 3 CQMs be included as well. • A number of commenters felt this criterion was unnecessary or duplicative of other criteria. • A few commenters questioned if this criterion would add significant value as substantially more data would need to be migrated to maintain continuity.
MU05	• 78 comments

Quality Measures

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Step Back and Look Forward

For Stage 2 the QMWG contributed CQM sub-domains and concepts to the RFC and Transmittal Letter.

For Stage 3 the QMWG intended to take a broader view of HIT enabled quality measurement.

Conceptual Framework

Purpose	E-measures	CQM Pipeline	QI Platform
• What problem are we trying to solve?	• How do we achieve this with better measures?	• Which measures should we choose?	• How can we better leverage CQMs for QI?

In the RFC for Stage 3 the QMWG tested these ideas with the general public.

Conceptual Framework

Purpose	E-measures	CQM Pipeline	QI Platform
• **What problem are we trying to solve?** • How de we stay patient centered? •How should we engage with a broader group of stakeholders? .	• **How do we achieve this with better measures?** **- Package Process-Outcome suites** **-Develop *de novo* instead of legacy CQMs** -Align CQMs and components with functional objectives	• **Which measures should we choose?** -Review Prioritized Domains -Identify Exemplars: Expand or Refine **-Promote innovation: "Democratize " the measure set**	• **How can we better leverage CQMs for QI?** -Support consistent novel architecture and standards to meet provider QI needs **-Encourage development of Population Management Tools**

In the RFC for Stage 3 the QMWG tested these ideas with the general public.
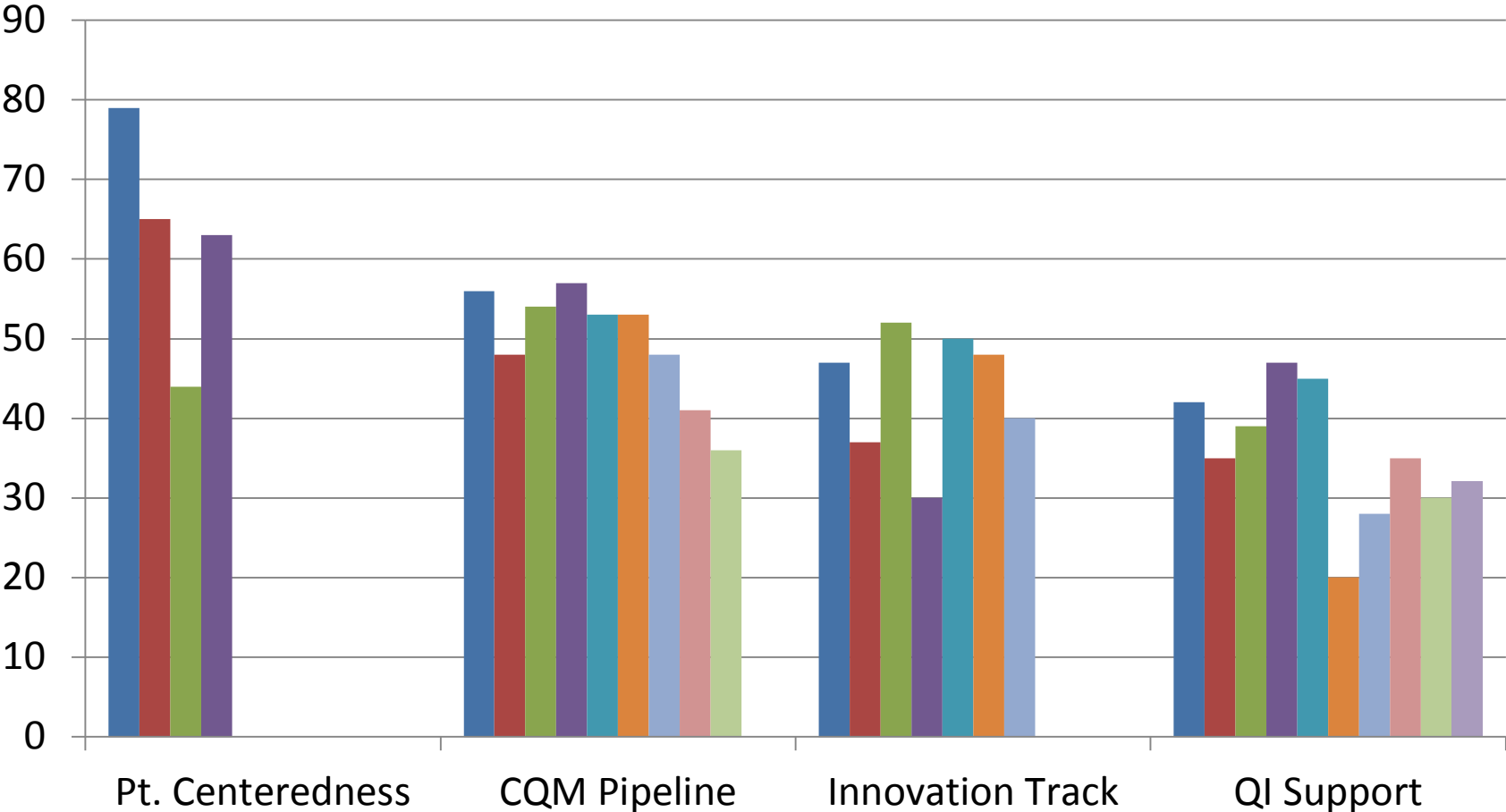
The QMWG intends to capture insights broadly from stakeholders and actively engaged as providers, purchasers and recipients of care.

- How should the HITPC and QMWG capture input from a wider variety of providers, patients, organizations and societies?

- What additional channels for input should we consider?

Stakeholder Engagement
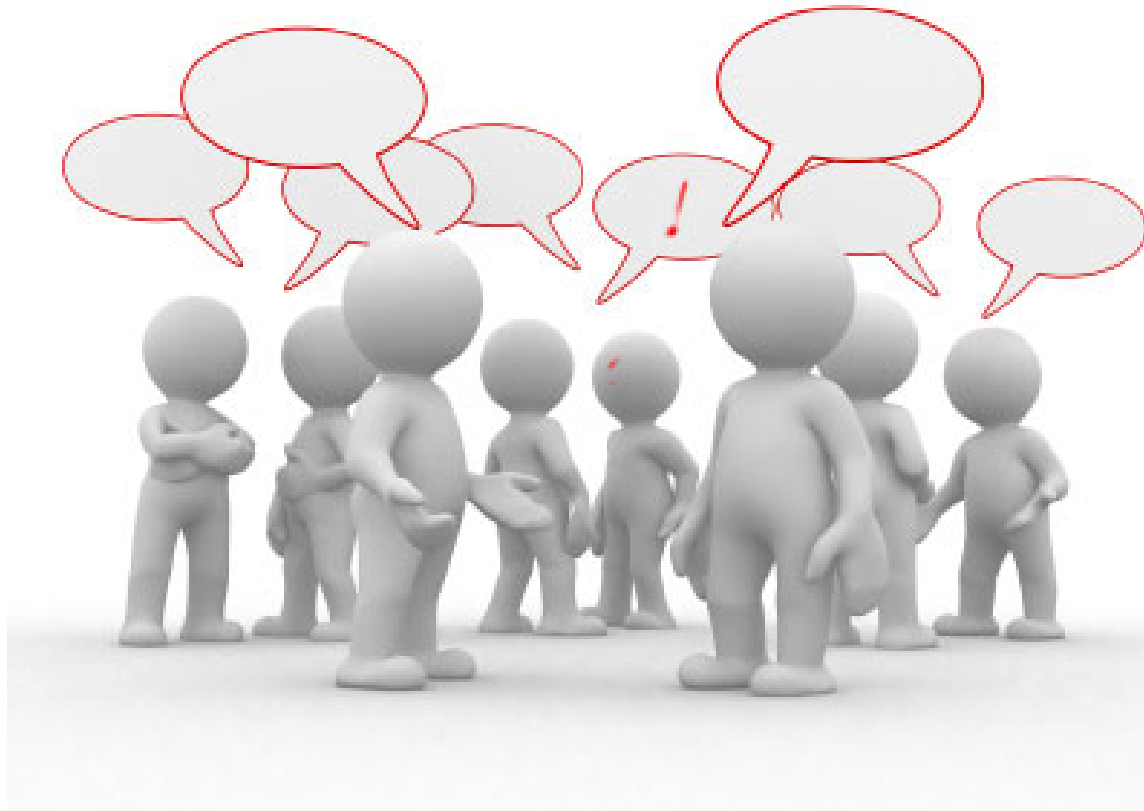
Stakeholder Engagement-Nearly all of the 56 commenters encouraged the HITPC and QMWG to actively seek input from a broad variety of stakeholders.

Purpose and Engagement

- **Active Outreach Strategies for Stakeholder Engagement** – many felt the RFC and open meetings are a "great start"
  - **Social media**
  - Webinars
  - Open forum per measure
  - **Outreach to professional societies and patient advocacy groups**
  - Establishing an "e-measure steering committee" (Federation of American Hospitals)

The majority of the responders agreed that increased patient input is necessary to improve quality measurement.

The Quality Measure Workgroup in the October 2010 "Tiger Team Summary Report" and the December 2010 Request for Comment, has previously described our intention to support HIT-sensitive, parsimonious, longitudinal, outcomes-focused CQMs.

- Should the HITPC focus its efforts on building point-of-care **process measures** or value-centered **outcome measures**?

- Should we instead consider a third approach, to promote **process-outcome measure "suites",** combinations of end outcome measures that are potentially associated with process measures?

Should the HITPC focus its efforts on building point-of-care process measures or value-centered outcome measures?

- Different Question Answered 11%
- Should Not Build Measures 6%
- Process eCQMS 6%
- Outcome eCQMs 34%
- Both 43%
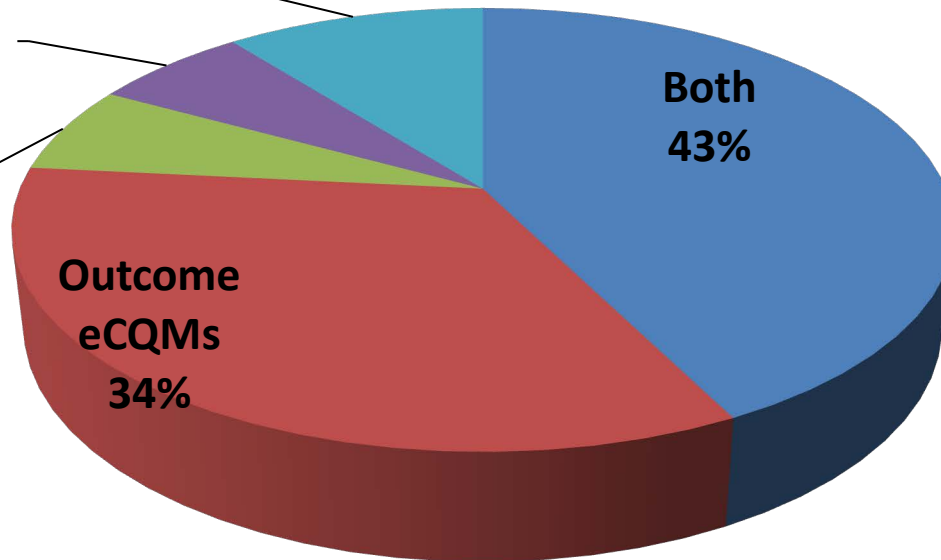
Should we promote process-outcome measure "suites", that attach outcomes to potentially associated with processes?

Process Only 4%

Outcome Only 15%

Do NOT Support Suite 4%

Support "Suites" 77%

eCQM: Process and Outcomes Insights
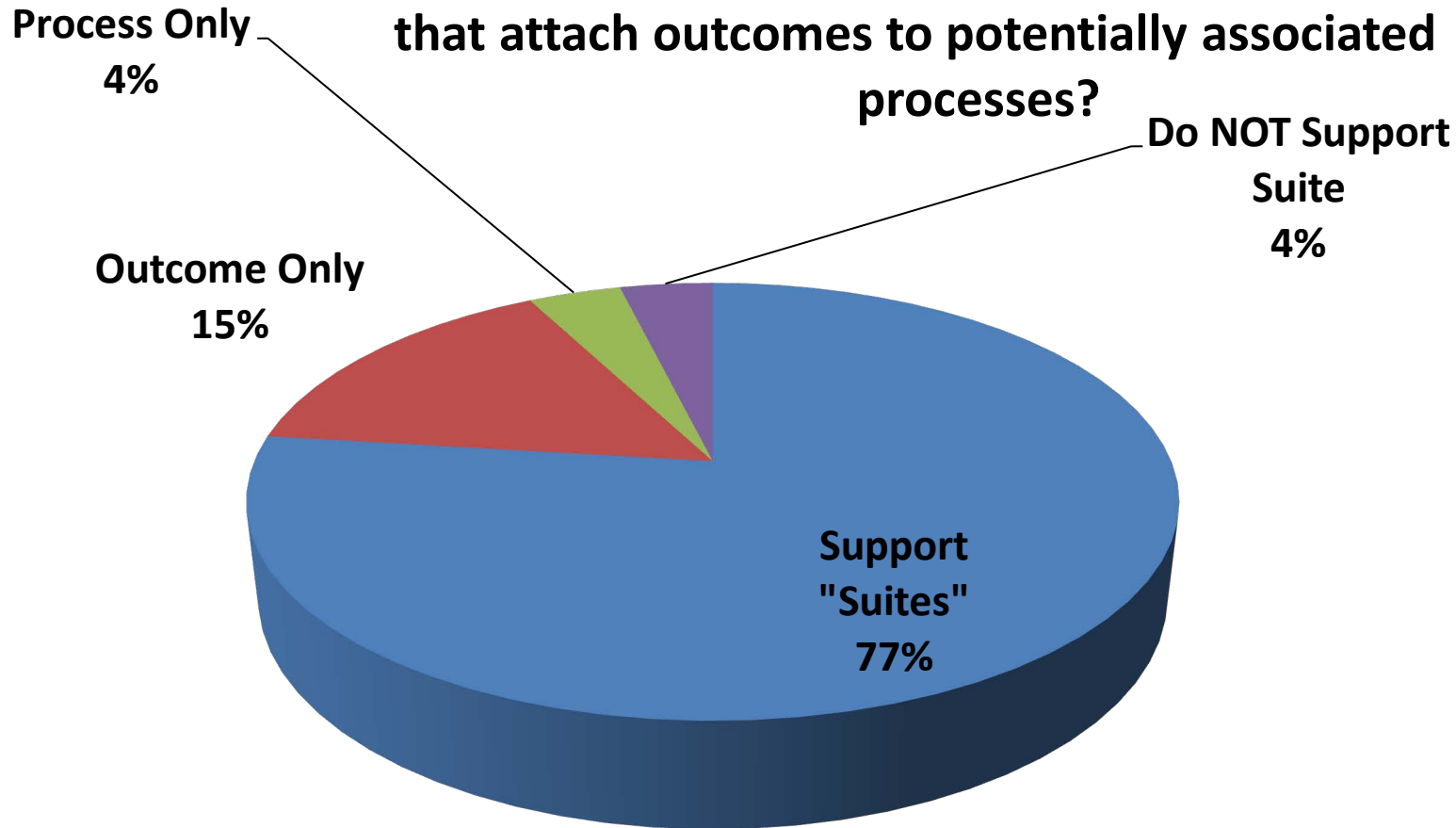
For HITPC Consideration/General Suggestions

- Outcomes should be the focus. Providers need freedom to choose processes that will allow them to achieve
- It is critically important that pediatrics be included in the development of such suites
- Include specialist expertise to ensure relevance of measures clinically and for patient perspective
- Quality improvement should shift from quality measurement to registry reporting

eCQM Suite will be Challenging

- Suites may require the same denominator for each measure.
- Complexity can hinder reporting

"Suites" are an opportunity for Research

- Use measure suites to evaluate strength of relationship to outcome. With time, refine the process measures used in the suites.
- Preventive health measure suite. To capture - screening, counseling, referral, and follow up

The QMWG will make recommendations both on the types of measures that are developed and on the process for measure development. The QMWG understands that "retooling", the process of translating legacy measures into XML code, at times does not fully preserve the original intent of measures and measure components (logic and value sets). Furthermore, retooled measures often do not take full advantage of the richness of clinical data in the EHR.

- Please comment on challenges in retooling legacy paper abstracted and claims based eCQMs.

- **Is a shift away from retooling legacy paper-based CQMs in exchange for designing eCQMs *de novo* a reasonable and desirable course of action?**

Should development continue with de novo or retooled claims/abstracted measures?

eCQM: *de novo* or Legacy Comments
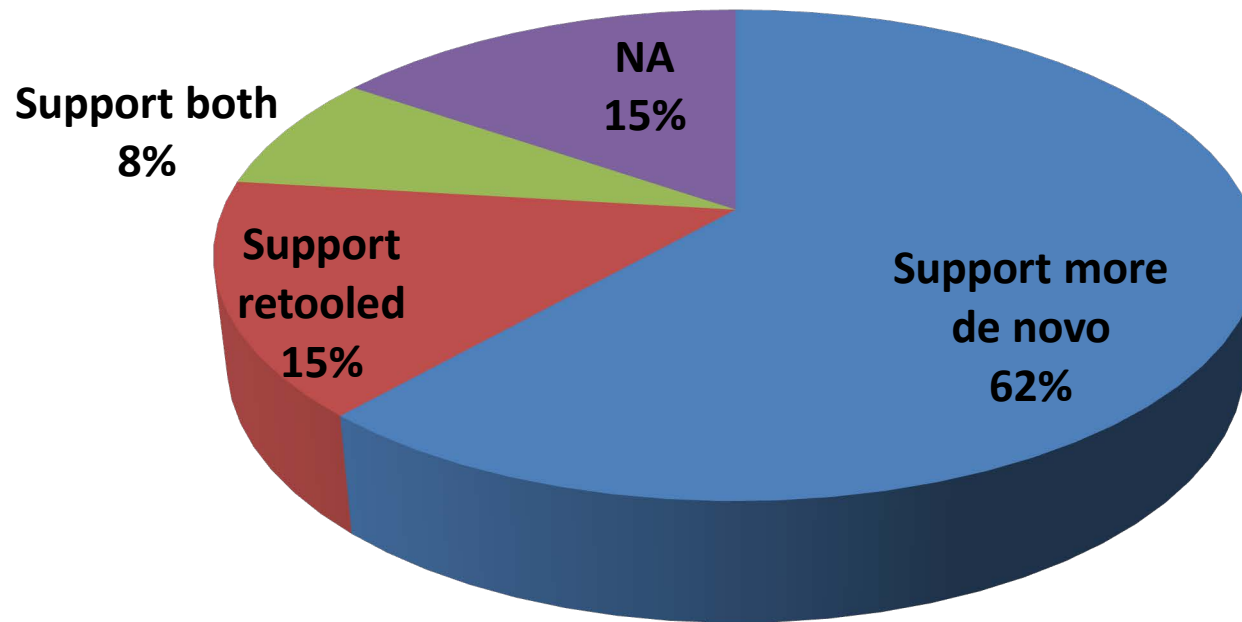
- Boston Medical Center – "In contrast to legacy paper measures we have found that the de novo measures, if well designed, are easier to complete."

- HIMSS continues to call attention to the increased burden on the provider to collect data for both manually abstracted measures and eMeasures, and we continue to urge the HIT Policy Committee to reduce this burden.

- Kaiser Permanente - There are too few de novo measures designed and intended for EHR-based measurement to provide an informed comment.
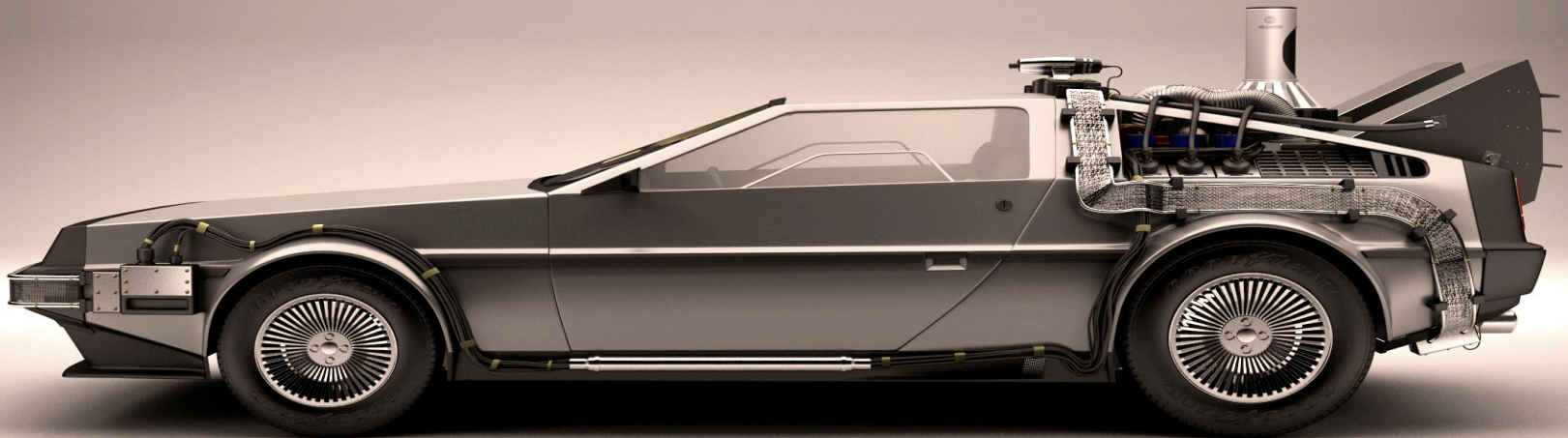
eCQM Innovation: The majority of responses either fully supported an innovation track or supported the track while describing reservations.

CQM Pipeline: Innovation Track QMWG18-24

To leverage CQM innovation from health systems and professional societies, the QMWG has discussed a proposal to allow EPs or EHs to submit a innovative or locally-developed CQM as a menu item in partial fulfillment of MU requirements. Health care organizations choosing this optional menu track would be required to use a brief submission form that describes some of the evidence that supports their measure and how the measure was used in their organization to improve care.

- We have considered two approaches to provider-initiated eCQMs.
    - A conservative approach might allow "Certified Development Organizations", to develop, release and report proprietary CQMs for MU.

    - An alternate approach might open the process to any EP/EH but constrain allowable eCQMs via measure design software(e.g., Measure Authoring Tool).

- What constraints should be in place?

Please comment on the desirability and feasibility of such an innovation track as a voluntary, optional component of the MU CQM requirement.

eCQM Innovation Track Insights
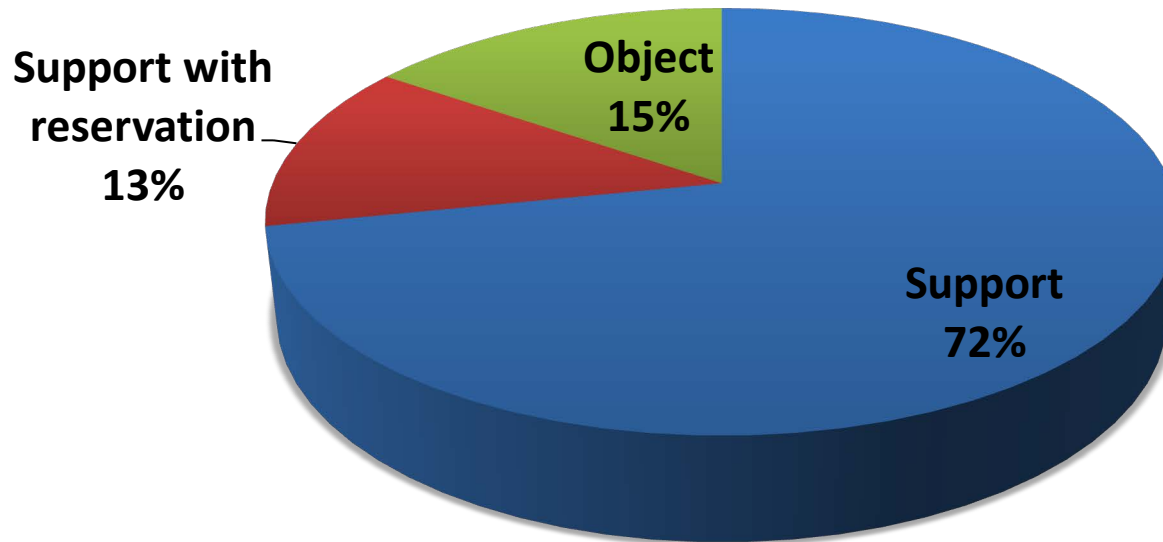
- **Support Innovation Track: 28 comments**
  - **"We fully support this concept,** as it fosters provider level innovation and rewards them for their efforts...**We have found that QI departments want to continue their work and use MU as a stepping stone**." -Boston Medical Center

- **Support...with reservations: 5 comments**
  - "We would **find this to be a very challenging way to develop CQMs**. However, we do believe organizations should be recognized for their innovative work and be paid additional dollars for that work if it is broadly applicable."-Geisinger

- **Do Not Support: 6**
  - "CHIME recommends the MU Stage 3 not engage in the development of new quality measures ..."

Should we pursue a conservative approach that limits development to professional societies and IDNs ? Or an alternative that opens the process to any EP/EH within certain constraints?
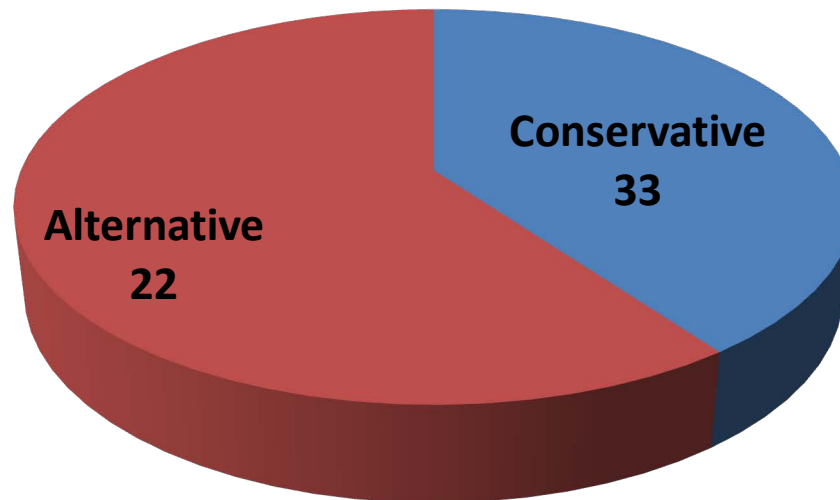
Conservative approach(22)

- **"We encourage HITPC/ONC to consider the more conservative approach,** which would **encourage adoption and use of EHRs among professionals by ensuring more relevant and feasible CQMs developed directly by professional societies** while also **ensuring a minimum level of consistency** among members of the same specialty so that the data could be analyzed over time for trends and patterns related to performance." -American Osteopathic Association

Alternative approach: (33)

- **"Flexibility needs to be given for the organization itself to determine its own high priority conditions** and report on CQMs relating to those conditions, preferably using a national measure if one exists already but if not, using its own proprietary measure. " -VA

- **"The innovation of eCQMs should be open to all stakeholders who wish to improve the quality of healthcare outcomes**. However, the design standards should include oversight to ensure the consistent creation of eMeasure specifications." -Federation of American Hospitals

Should we constrain development in the innovation track with standards for e-measures that are already in place?

Minimize Constraints 20%
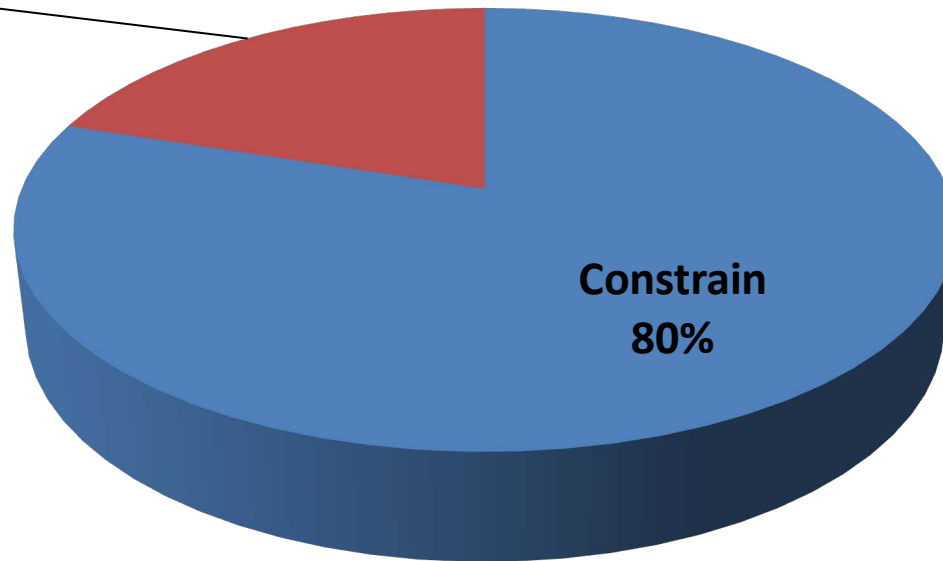
Constrain 80%

- **Constrain to existing Standards and tools for eCQM development: (20)**
  - **Children's Hospital Association**: "Some reasonable constraints, such as conforming to the Quality Data Model, would seem appropriate. Again, the balance between fostering innovation and measurement that is meaningful with allowing comparability across providers and hospitals is one that needs to be carefully thought through. It would be helpful to think through a trajectory for how locally developed measures could become more widely used and disseminated…"

  - Greenway; "If the end goal as stated is to assess innovation, the next logical goal would be to leverage any findings back into the program… **A simple HQMF** would be the minimum level of detail needed to allow for decomposition and ensure reuse in the future. We encourage the use of the **Measure Authoring Tool (MAT) to ensure consistent use of Values sets and QDM elements…**"

  - The Joint Commission: **the use of standardized quality measures, ensures, at least to some extent, comparability of the data across healthcare providers and supports measure alignment across settings**

- **Have no constraints, maximize innovation in measures that fit clinician need: (5)**
  - MN Department of Health: ""100% of the measures should not be constrained. That may stifle innovation. Instead, allow a very limited number with the understanding that the measure logic would be submitted along with the measure result. "

There is strong support for population management software to leverage ECQMs for QI.

The QMWG intends to encourage the development of HIT tools that leverage use of eCQMs for population management. The work group is especially interested in development of CQM population mapping and task-management platforms that allow users to view, track, and identify care gaps and assign tasks both for individual patients and for user-determined cohorts. The workgroup understands that this technology is desired by providers and requests comments on the potential role of the HITPC and HHS in this space.

- Please comment on the value of these tools. Is there a sufficient evidence basis for clinical population management platform use? Is there a business case?

- What are the technological challenges to widespread release and adoption? Can the HITPC encourage technology in this area without being prohibitively prescriptive?

Please comment on the value and feasibility of eCQM Population Management Platforms.

Do not Support 3%

Guidance Only 22%
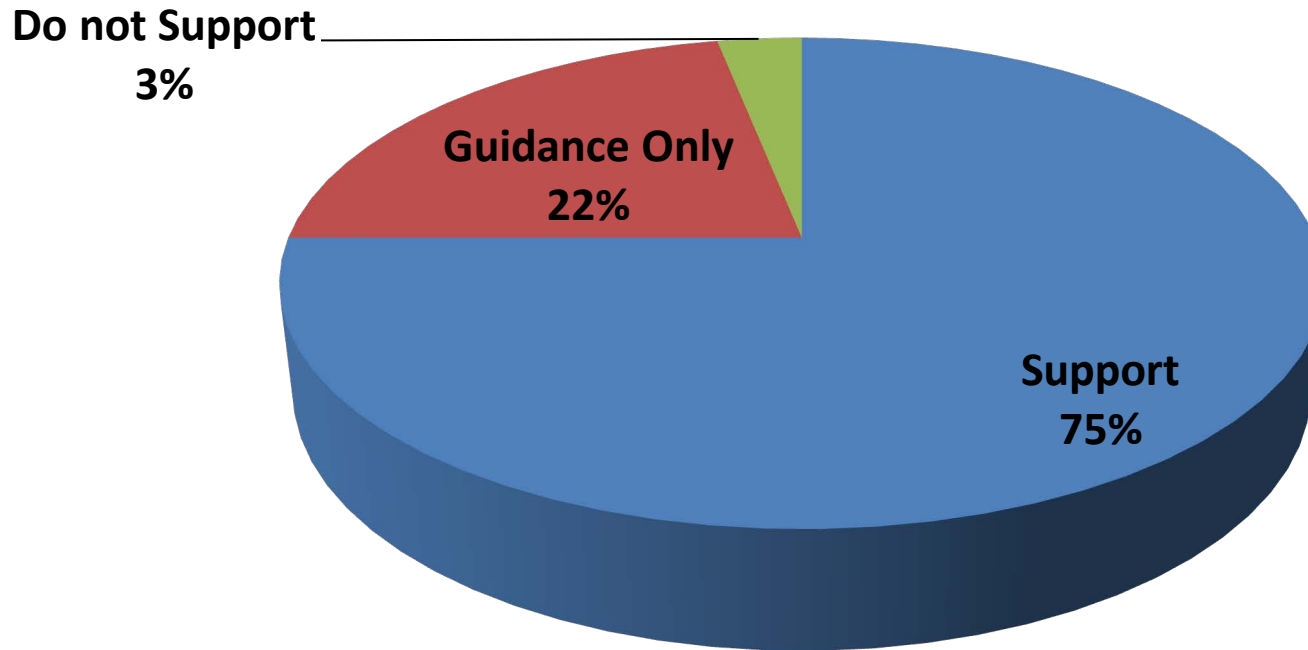
Support 75%

There is broad consensus that a business case exists for population management platforms.

- Support Population Management Software and standardization:
  - The majority of commenters (24), especially the providers, feel there is a role for increased standards and possibly certification for population health platforms or features.

  - Demonstrated evidence and value- a number of commenters provided specific evidence of value, especially in chronic disease management, managed care and public health

  - A few commenters, especially software companies and some organizations, worry that the market and standards are too immature for certification at this time.
    - They propose a combination of guidance, incentives and grants with continued work on data and interoperability standards (7) rather than certification.

- "Population management tools should be part of CEHRT. The market will likely lead to the development and implementation of these tools as ACOs and CCOs pick up steam. **However, HITPC can and should set a baseline for functionality of such a system**." Tom Yackel- OHSU

- **"We feel that there will be a role for this type information from a population management platform for ACOs.** Since this is a recommendation we suggest that HITPC takes this back to the industry to look into this issue and talk to providers to see what they are expecting." - AHIMA

- "Given the immaturity of this market, CHIME believes it is better **to let the market evolve** without further federal involvement at this time. The technology is not currently available, and there would be additional cost."

Recurring Themes

- Listen more…engage with specialty societies and patients

- Go *de novo*

- Liberate the data…and the providers

- Care coordination, patient engagement, and safety should be high priority domains for development

To members of and contributors to the QMWG:
We appreciate the your time, insight, suggestions, comments and edits.
Thank-you,
-ONC Staff

PSTT01 - How can the HITPC's recommendation be reconciled with the National Strategy for Trusted Identities in Cyberspace (NSTIC) approach to identification which strongly encourages the re-use of third party credentials?

- 41 comments received

- Many comments state that strong identity proofing and multi-factor authentication should be required for MU3 and that the NSTIC Model can be adopted in healthcare
  - Existing standards such as NIST SP 800-63, CIO Council Guidance, FEMA, and OMB, and DEA standards are suggested for consideration

- Some comments do not believe that multi-factor authentication should be required for MU3 citing that:
  - The deadline to implement is unrealistic
  - The requirement would introduce burden and increased costs, especially on small providers
  - Multi-factor authentication is not a core competency of EHRs

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PSTT02 Summary:
Certification Criteria for Testing Authentication

PSTT02 - How would ONC test the HITPC's recommendation (for two-factor authentication) in certification criteria?

- 26 comments received

- Comments suggest possible approaches including:
  - Developing a checklist to verify the system set-up, while also requiring appropriate documentation
  - Requiring vendors to attest to having an architecture that supports third-party authentication and demonstrate examples
  - Checking for use of a federation language standard
  - Developing a model audit protocol for the community to use to self-test
  - Developing an iterative and phased testing program covers the population of organizations

- Existing standards and guidance that could be the basis of test procedures include:
  - DEA Interim Final Rule (IFR)
  - NIST 800-63
  - FIPS 201
  - HSPD-12
  - NSTIC/Identity Ecosystem Accreditation Standards

- One comment suggests that the domain is not mature enough for certification

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PSTT03 Summary:
EHR Certification - Standalone or w/3rd Party

> **PSTT03 - Should ONC permit certification of an EHR as stand-alone and/or an EHR along with a third-party authentication service provider?**

- 30 comments received
- Many comments support both models
- Several comments suggest the EHR and third-party authentication service be certified independently of each other
- Logistic suggestions for the two models include:
  - Third-party dependencies could be handled the same way that database and operating system dependencies are handled in sectors such as the Payment Card Industry
  - In lieu of requiring certification ONC could implement NSTIC
  - Certification could be carried out to an ONC recognized healthcare trust framework by an NSTIC Accreditation Authority
  - Use external labs capable of and experienced in testing identity and authentication technologies in accordance with FIPS 201 for third party authentication providers

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> **PSTT04 - What, if any, security risk issues (or Health Insurance Portability and Accountability Act (HIPAA) Security Rule provisions) should be subject to Meaningful Use attestation in Stage 3?**

- 46 comments received

- Workforce security training:
  - Comments for - cite the importance of the workforce in keeping health information secure
  - Comments against - cite attestation is either burdensome or duplicative of the HIPAA Security Rule

- Safeguard and training areas to emphasize include:
  - Access controls
  - Audits
  - Data integrity
  - Encryption
  - Identity management
  - Implementation of backup and recovery plans
  - Policies and procedures related to prevention of local PHI storage
  - Malware on all workstations accessing EHRs and EHR modules
  - Social media, bring your own device (BYOD), and mobile devices
  - Local data storage security controls

- Some comments say more HIPAA Security Rule guidance and education is needed for providers

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PSTT05 Summary:
Certification Standard for Audit Logs

Putting the I in Health IT
www.HealthIT.gov

PSTT05 - Is it feasible to certify the compliance of EHRs based on the prescribed [ASTM] standard for [audit logs]?

- 30 comments received

- Majority of comments state prescribed standard is feasible

- Many comments focus on whether or not there should be a standard

  - Many comments suggest there should not be a standard yet

  - Some comments suggest MU standards premature until final Accounting of Disclosures Rule issued

  - Some comments say question implies combining audit log and accounting of disclosures requirements

    - Audit logs require more information than necessary for an accounting of disclosures

PSTT06 Summary:
Attestation for Length of Time Logs are Maintained

PSTT06 - Is it appropriate to require attestation by meaningful users that such logs are created and maintained for a specific period of time?

- 37 comments received

- Comments suggest waiting until the Accounting of Disclosures Rule requirements are finalized before addressing attestation

- Comments supporting attestation also suggest other audit log requirements

  – Be able to certify a separate audit log system

  – Rely on NIST/Federal or State regulation

  – Incorporate into risk assessment

  – Credential users

  – Base on standards that give guidance for content

  – Specify period of time

  – Identify a minimum data set

- Other comments suggest attestation to all requirements in the HIPAA Privacy and Security Rules

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PSTT06 Summary:
Attestation for Length of Time Logs are Maintained

- Majority of comments are neutral toward attestation requirements, citing a need to:
  - Wait for final Accounting of Disclosures Rule
  - Complete additional feasibility studies/research
  - Leverage audit log requirements in other industries
  - Defer to providers and hospitals for feedback
- Some comments do not support attestation requirements, citing:
  - Administrative burden
  - Need to also require demonstrating function
  - No improvement to security
  - Audit log is functionality of EHR, not a provider attestation requirement

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PSTT07 Summary:
Standard Format for Log Files

PSTT07 - Is there a requirement for a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise?

- 32 comments received

- Many comments state that there is no adequate standard format requirement

- Most comments support a need for standard format requirement

- Some comments are neutral toward standard format requirement, suggesting that:

  – Government should dictate what but not how

  – Variability on details captured presents a challenge to creating a standard

  – Use of SIEM standard

- Some comments disagree with need for standard format requirement

  – Requirement elements can be mandated and should define a minimum data set

  – Burden on health care organizations and vendors

- Some comments state there is no need for MU based standards related to Accounting of Disclosures Rule

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PSTT08 Summary:
Audit Log File Specifications

> **PSTT08 - Are there any specifications for audit log file formats that are currently in widespread use to support such applications?**

- 37 comments received
- Some comments mention specifications that could be considered for audit log purposes, such as:
  - IHE ATNA Specification
  - HL7
  - DICOM
  - ASTM E E-2147-01
  - World Wide Web Consortium (W3C)
  - SYSLOG
  - UNIX-based operating systems
- Some comments state there are no existing standards or no existing standards in widespread use
- Other comments oppose new MU requirements based on proposed rule

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MU4 Summary:
Patient Consent

> **MU4: Some federal and state health information privacy and confidentiality laws, including but not limited to 42 CFR Part 2 (for substance abuse), establish detailed requirements for obtaining patient consent for sharing certain sensitive health information, including restricting the recipient's further disclosure of such information. *Three questions were put forth.***

- 74 comments received

- *Question 1: How can EHRs and HIEs manage information that requires patient consent to disclose so that populations receiving care covered by these laws are not excluded from health information exchange?*

  - Approaches suggested include:
    - Metadata tagging
    - Data segmentation , such as…
      - Data Segmentation for Privacy Initiative
      - VA/SAMHSA
      - SATVA

  - Concerns expressed:
    - The necessary segmentation capabilities do not exist today
    - It is better to focus on identifying and punishing inappropriate use of data
    - Use PHR to give patients control of their data

- *Question 2: **How can MU help improve the capacity of EHR infrastructure to record consent, limit the disclosure of this information to those providers and organizations specified on a consent form, manage consent expiration and consent revocation, and communicate the limitations on use and restrictions on re-disclosure to receiving providers?***
  - Create and adopt standards to improve the capacity of EHR infrastructure
  - Create standardized fields for specially protected health information
  - Require all certified EHRs manage patient consent and control re-disclosure

- *Question 3: **Are there existing standards, such as those identified by the Data Segmentation for Privacy Initiative Implementation Guide, that are mature enough to facilitate the exchange of this type of consent information in today's EHRs and HIEs?***
  - Many comments call attention to segmentation-related initiatives that might be leveraged , such as:
    - S&I Framework's Data Segmentation for Privacy Initiative (DS4P WG)
    - HL7 confidentiality and sensitivity code sets
    - SAMHSA/VA pilot
    - eHI developed the "eHealth Initiative Blueprint: Building Consensus for Common Action"