AGA Institute Quality Measure Development and Maintenance Protocol

Purpose and role

This document was prepared to inform members of the Quality Committee (QC) of the steps involved in development of quality measures from new or existing AGA guidelines. This document also outlines the process for developing quality measures using adoplopment of other guidelines if there is no existing AGA Institute guideline covering a clinical area as well as proposing content areas with quality gaps for measure development. One role of the QC is to develop meaningful quality measures for the fields of gastroenterology and hepatology to help produce a positive impact on patient outcomes. These measures may also be used by other specialties when appropriate to increase or broaden the positive impact for patient care. The QC has adopted the following criteria developed for accountability measures by The Joint Commission (TJC):

- Research: Strong scientific evidence exists demonstrating that compliance with a given process of care improves health care outcomes (either directly or by reducing the risk of adverse outcomes).
- Proximity: The process being measured is closely connected to the outcome it impacts; there are relatively few clinical processes that occur after the one that is measured and before the improved outcome occurs.
- Accuracy: The measure accurately assesses whether the evidence-based process has actually been provided. That is, the measure should be capable of judging whether the process has been delivered with sufficient effectiveness to make improved outcomes likely. If it is not, then the measure is a poor measure of quality, likely to be subject to workarounds that induce unproductive work instead of work that directly improves quality of care.
- Adverse effects: The measure construct is designed to minimize or eliminate unintended adverse effects.

There are eight steps in the QC development and maintenance process to create quality measures that may be used in internal quality monitoring or in external accountability programs such as the Quality Payment Program (QPP).

I. & II. Quality Committee structure and process (Appendix A)
III. Use of AGA guidelines and, when applicable, adolopment of non-AGA guidelines for measure development
IV. Evidence review/prioritization brief
V. Measure alignment and harmonization process
VI. Voting phase – full QC discussion and ranking
VII. Implementation, use, and public comment
VIII. Measure maintenance

Below are the suggested procedures to follow for each step in the measure development and maintenance process. **Steps I and II are listed below in Appendix A.**

III. Use of AGA guidelines and adolopment of non-AGA guidelines for measure development

Process for measure development when an AGA Guideline exists

Each workgroup will begin their measure prioritization by reviewing new and recent AGA guidelines within their content scope. From these guideline recommendations, a list of potential measure concepts will be compiled based on strong recommendations based on high or moderate quality evidence Additional measure concepts not meeting these thresholds may be included at the discretion of the workgroup if specific justification is provided and may be used for the development of quality indicators or the process for developing quality measures from non-AGA guidelines.

Process for developing quality measures for non-AGA Guidelines and/or if no AGA Guideline Exists

If non-AGA guidelines are published and conform to the same standard of methodologic rigor in assessment of evidence and recommendations (*i.e.*, GRADE) then these guidelines may also be reviewed by the QC and considered for adolopment by the AGA's CGC when pertinent measure concepts justify development.

If the QC identifies an area of practice that is not currently covered by AGA or non-AGA guidelines but warrants measure development, this concept may be developed by the QC and reviewed with the CGC to consider evidence base review and future measure development.

There are two different approaches by which members of the QC can submit measure concepts to the CGC for evaluation and literature review.

1. Contemporaneous feedback from QC members prior to the drafting of recommendations by the CGC to allow for additional evidence to be considered to address a measure gap based on a guideline in development; and
2. A measure gap has been identified without a current AGA supported GRADE guideline and a review of the evidence is needed to support the quality measure.

Process for evidence review to address a measure gap for an established guideline or a guideline in development.

Following the initial literature review by the CGC, and prior to the drafting of the recommendations, the CGC workgroup will meet with the associated QC workgroup to discuss the results of the literature review and the likely recommendations.

The associated QC workgroup will determine if 1) the recommendations align with measure development process and 2) whether there is a measure gap (*i.e.*, substantial variability in care delivery that can impact outcomes) that needs to be addressed and is not supported by the existing literature review.

The QC workgroup will review the anticipated guideline recommendations against the criteria established in the measure prioritization SOP for: Meaningfulness, Magnitude of Effect, Quality Gap/Variation in Care, Feasibility, and Applicability to GI.

- If the initial review results in a finding that a quality measure should be developed based on the anticipated strong recommendation AND at least moderate or high quality of evidence, then the QC will follow the measure prioritization SOP. Representation from at least 1 member of the QC will be invited to the face-to-face meeting where recommendations are decided.
- If there are no quality measures that should be developed from based on the initial review of evidence, however the QC determines that a quality gap exists in the related subject matter, then the QC will submit a request in writing to the chair of the CGC outlining the rationale for the request and provide references supporting the request.
- The CGC Chair will have 30 days to review the request and determine if a preliminary review of the literature supports the request, what resources are needed, and provide the QC Chair a response in writing with an anticipated timeframe to complete the request. If the CGC Chair determines that the request is unmerited, a written rationale will be provided to the QC Chair explaining the decision to deny the request and/or provide alternative options for measure consideration.
- If there is an existing published guideline where a measure gap has been identified, however the recommendations do not support the development of a measure, then the process for an evidence review when a measure gap is identified without a supporting guideline will be followed as outlined in section C.

B. Adolopment of non-AGA generated guidelines

When the AGA QC discovers a quality gap or variations in care and there is no existing AGA guideline, however there is another guideline recommendation meeting the criteria for the development of a quality measure, the AGA QC may use the adolopment process. Guideline developers can 1) adopt existing recommendations from others, 2) adapt existing recommendations to their own context, or 3) create recommendations *de novo*.

- When the AGA QC identifies a practice area in which a measure would potentially address a quality gap, the committee may use the evidence review conducted by the external source, provided that the evidence review utilizes the GRADE review process.
- The QC will provide the guideline to the CGC Chair with the request outlined in Section I of this document.
- The CGC will determine if the evidence review meets GRADE standards and within 30 days, provide a written response to the chair of the QC outlining recommendations for use of the non-AGA publication. If a measure concept is valid for development after an assessment of the methodology by which a practice recommendation is made, then the measure will be developed according to the existing SOP.

- If a guideline does not use the GRADE process, and a measure gap is identified, the guideline will be submitted to the CGC for an evaluation of the methods and strength of evidence to determine if it meets GRADE standards.

C**. Process for evidence review when a measure gap is identified without a supporting guideline.**

When a measure gap or variation in care has been identified, however there is no current AGA guideline that supports the measure gap, then the QC Chair will submit a formal request for a literature review to the chair of the CGC. The chair of the CGC will have 30 days to review the request and respond to the chair of the QC with an action plan outlining the strategy to fulfill the request. If the chair of the CGC believes that the request is not merited, then a written response outlining the rational for the denial will be sent to the chair of the QC.

If the CGC determines that the request is appropriate, the CGC will conduct a singular review of a specific topic area outlined by the QC as a measure gap to determine if the literature exists to support a quality measure. Upon completion of the literature review, the CGC Chair will send the recommendation(s) to the QC Chair for further consideration aligned with the guidelines to measures process.

IV. **Evidence review/measure prioritization brief**

For each quality measure identified as high priority in voting phase I, the workgroup will develop a (one to two page) evidence review summary indicating measure prioritization that describes the following elements of the measure:

Meaningfulness: Whether the measure is valuable to physicians, patients and/or payors. Measures should be meaningful across multiple populations to help facilitate behavior change and improve patient outcomes. If a measure is not meaningful, the measure will not be used by providers to benchmark their practice annually, by patients to inform their selection of providers, or by payers to help determine those providers that are providing high value care to patients.

Magnitude of effect: The reach that a particular measure has across a population. If the measure reaches a minor subset of a population, the amount of time to develop a measure and resources expended will outweigh the impact of the measure. If the measure reaches a large population, it could have a significant impact.

***Practice Variability/Variations in Care*:** The gap, or variations in care, between the desired performance level and actual performance level. Measures should be evaluated for these gaps in performance. If providers have a performance rate above 90 percent, building such a measure would create a limited opportunity for improvement. The QC should look for opportunities to improve upon performance and, therefore, the quality of care.

***Feasibility*:** The ease of implementation for a particular measure using data elements available within existing infrastructure. The unfortunate reality is that data for some of the best measures cannot be collected because there are no existing data sources to collect that measure. The feasibility of implementation should be considered when developing a measure. A measure for which data cannot be collected is not a feasible measure.

Applicability: Whether a measure applies to gastroenterologists, acknowledging some measures may be "cross-cutting" and reasonably apply to primary care or other specialties such as thoracic or colorectal surgery, pathology, etc. The QC should consider whether a measure specifically applies to gastroenterologists, or other specialties. The applicability of a measure should also evaluate whether any other measures exist related to a specific condition. If other quality measures exist, then the workgroup should determine whether the intent of the measure is aligned with the existing measure or if the intent of the measure is different than the existing measure. The workgroup should follow the measure alignment and harmonization process.

Stratification: Every quality measure that is developed must be reviewed for the impact on socially disadvantaged populations and clinicians caring for them. This evaluation will include patient factors that may impact the intended outcome(s). These factors may include gender, race, ethnicity, socioeconomic, and any other factor that may influence a patient outcome utilizing the **CMS blueprint for risk adjustment.**

The QC will use the measure prioritization brief to inform voting in later stages of prioritization.

V. Measure Alignment and Harmonization process

Upon conducting and environmental scan of existing measures that are available in national reporting programs, the responsible QC workgroup will need to determine if a measure specification currently exists that is similar to the intent of the newly proposed measure or if the intent is different. In the event that a similar measure specification exists, and the intent of the measure is the same, then the workgroup should complete the prioritization brief outlining the similarities and forward to the QC for review and voting whether to progress the measure for further development. If the QC determines that the measure specification should progress to full measure development, then the workgroup must contact the measure steward and attempt to harmonize the AGA measure specification with that measure steward. One such example is the AGA/CAP measure specification for testing of Lynch Syndrome

If a measure specification is similar to an existing measure in a national reporting program, however the intent of the measure is different, then the workgroup should progress to full measure development. It is best practice to work collaboratively with other measure stewards to ensure the best interests of the fields of gastroenterology and hepatology are represented.

VI. **Voting phase – QC discussion and ranking**

Those measures identified as high priority in voting phase I and recommended for voting phase II will be ranked by the full QC utilizing a 9-point Likert Scale. Each QC member will receive and review the list of high priority

measure concepts and the measure prioritization brief prepared by the content workgroup for each potential quality measure. QC members will review the supporting information and then independently rate their agreement with the priority of the measure using the same nine-point Likert scale described above. At a regularly scheduled meeting of the QC (either by phone or in person), measure rankings will be reviewed and open for discussion. The goal is to come to consensus on an ordered list of measure concepts for further development. If the QC votes that a measure concept would not support a meaningful quality measure, the measure concept will not be further developed. Only those measures that received a super majority (≥60 percent) will advance to the next phase.

VI. **Implementation, Use and Public Comment**

Public Comment

Once approved for further development, AGA staff will assist with the initial draft of the new measure and post the measure specification for a minimum of a 30-day public comment period. Each workgroup will review and relevant public comments and amend the measure as needed. Following workgroup revision of the measure(s), the measure will be forwarded to the full QC for a final vote as approved and ready for testing.

Implementation

Following the 30-day public comment period and approval of the AGA QC as final and ready for testing, the workgroup must then complete the measure testing scorecard and data dictionary for the associated measure specification. The measure testing scorecard confirms that the measure can be collected in a variety of practice settings and a variety of data sources. The data dictionary outlines the data elements that need to be collected for the quality measure to confirm that the measure is valid and measuring what it is intended to measure. The workgroup is also required to develop a measure implementation flow chart that assists the user with implementation of the measure specification.

Use of AGA Institute Quality Measures

All AGA developed quality measures are available for public use and must be implemented by the user as specified. These quality measures are not clinical guidelines and do not establish the full standard of medical care, nor have been tested for all potential applications. Neither AGA or any of its affiliates, nor its members shall be responsible for any use of these quality indicators. The practitioner or institution using the AGA Institute quality measures must adhere to the intent of the measure and original recommendation.

VII. **Measure maintenance**

Measure Maintenance for Quality Measures in the QPP

In addition to supporting prioritization and development of new quality measures, each content area workgroup is responsible for annual maintenance of existing measures that AGA stewards in the QPP. For QPP measures, measure maintenance will occur during the measure maintenance cycle, as defined by CMS (typically in January of each calendar year). If an existing QPP measure is determined to no longer be relevant based on new evidence, or additional measures have been developed that obviate the need for an existing measure, the workgroup may recommend to the QC that a measure be retired from the MIPS program.

Decisions regarding de-implementation of measures will be made by the appropriate workgroup, with final decision approved by a QC supermajority vote. These decisions will be informed by data from publicly available information (QPP) as well as AGA Institute programs.

Measure Maintenance for AGA developed Quality Measures Not Currently in QPP

The following steps must be completed annually by the content area workgroups for the maintenance of AGA quality measures that are not included in a national reporting program (QPP):

Measure Specification	YES	NO
Is the measure still relevant?	Proceed	Make a recommendation to the QC for vote that the measure should be retired
Has there been a new AGA or other societal guidelines using GRADE methodology related to the measure?	Update the measure specification to align with updated guidance. If the measure specification is different than the original intent; then a new measure should be developed and aligned with the guidelines to measures process. Update clinical recommendation statement and evidence.	Proceed
Has there been any additions or deletions of CMS or ICD-10CM coding?	Update measure specification, data dictionary, scorecard and measure flow.	Proceed
Has there been an update in clinical recommendations or findings to suggest adjustments in quality gaps?	Update clinical recommendation statement and evidence as well as acknowledge change in quality assessment	Proceed
Has the measure been tested? Is additional testing, including for stratification, needed?	Proceed	Stop Put footnote of date measure was reviewed. Update specification on AGA website with reviewed date.
Did the testing show the measure was feasible? (Alpha Testing)	Proceed	Measure needs to be revised to address feasibility issues and re-tested.
Did the testing show that the measure was valid? (Beta Testing)	Stop	Determine the reason why the measure is not valid and modify measure specification.

	Put footnote of date measure was reviewed. Update specification on AGA website with reviewed date. Progress measure from “in testing” to “final”.	Re-test measure until valid.

Appendix A

Quality Committee Structure and Process

I. Identify content areas through guideline topic alignment

The AGA Institute QC reviews AGA Governing Board approved guidelines on a rolling basis and assess forthcoming guideline topics in advance to ensure that content area expertise on the Committee for the upcoming appointments. Upon receipt of appointments for the incoming class of QC members, the QC Chair will review the existing work of the QC, AGA guidelines in development, and determine if additional content areas of expertise are needed based on a review of existing and forthcoming AGA guidelines. Each guideline will be assigned to the corresponding workgroup that is responsible for evaluating potential measure concepts and developing new measures as appropriate. These workgroups currently include colorectal cancer (CRC)/general gastroenterology (which includes functional gastrointestinal disorders/irritable bowel syndrome), esophageal, gastric, and pancreatic and biliary disorders, liver disease, and inflammatory bowel disease (IBD). Workgroups may be reorganized, as needed, to align with the strategic goals of AGA.

The measure development process from AGA guidelines is as follows:

- Upon the completion of the first draft of an AGA Institute technical review (TR) resulting clinical recommendations, the TR will be sent to the chair of the AGA Institute QC. AGA staff will meet with the chair of the QC (or designee), the QC lead(s) for the assigned content area, the Chair of the CGC, the lead methodologist (or designee) and at least one content expert author from the technical review. AGA staff liaisons for the QC and CGC are also expected to participate in the meeting.
- During the joint committee meeting, the CGC content expert(s) will present to the chairs the findings of the technical review and the most likely clinical recommendations resulting from the findings. Together, the group will determine whether any likely recommendations may lend themselves to one or more AGA quality measures.
- If one or more of the recommendations from the upcoming guideline is suitable as a meaningful quality measure, the measure(s) will be developed by a sub-committee/workgroup of the QC. The CGC content expert(s) will serve as liaisons to this sub-committee and participate on calls and answer questions via email as needed. If a guideline does not meet the criteria for quality measure development as outlined below, the recommendations may be considered for Quality Indicator development utilizing the Quality Indicator process outlined in a separate document.
- Quality measures concepts will be evaluated concurrently with guideline development, though the time horizon for measure development may lead to asynchronous publication of guidelines and associated measures. The AGA QC will develop a commentary outlining the rationale for the development of a quality measure and/or not developing a quality measure and submit to *Gastroenterology* for consideration of publication.

When a past guideline is updated by the CGC, the measure data may be used to help inform any revisions to the guideline. The QC will review the list of guideline topics proposed for development by the AGA CGC for the upcoming year. When the draft technical review and guideline are prepared, but not final, the assigned content area QC workgroup will review the guideline recommendations and assess whether complementary measures are appropriate for development. The QC Chair will also review the existing workgroup structure and determine if additional content areas needed as well as evaluate the needs of the QC more broadly.

II. Assignment of QC members to content workgroups and assessment of the need for additional content experts

Based upon the potential content areas anticipated for measure development over the coming year, the chair of the QC will areas assign QC members to a content workgroup based on expertise and the needs of the QC. At least one QC member will be selected to serve as a workgroup lead for each content workgroup. Workgroups may be revised annually depending on the anticipated scope of the work to be completed over the coming year. Members of the QC may participate on as many workgroups as they wish but must participate on at least one workgroup. Upon assignment of members and the lead(s) of a workgroup, the workgroup will be expected to meet via teleconference as determined by the scope of the work. The number of meetings may increase or decrease at the discretion of the workgroup lead(s).

Each workgroup shall have, at a minimum, three content experts in a particular area. The QC chair may determine if additional content experts from outside the QC to supplement the expertise needed for the workgroup. If it is determined that additional *ad hoc* experts are needed, the workgroup lead will send a written request to the chair of the QC requesting additional content and/or methodological experts. When additional content experts are identified, AGA staff and the QC chair will meet with and onboard experts as to the measure development and maintenance protocol. All participants in the measure development and maintenance process will be required to sign a conflict-of-interest disclosure policy as well as a confidentiality notice prior to beginning work with their workgroup.

All workgroups will have the assistance of AGA staff in the measure development process.