Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

AGA Institute Quality Measure Development for the Diagnosis and Management of COVID-19

This document presents the official recommendations of the American Gastroenterological Association (AGA) regarding quality measures related to the diagnosis and management of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). The current report outlines the process by which the Quality Committee (QC) evaluates guidance statements published by the AGA's Clinical Guidelines Committee (CGC) to inform measure development. The recommendations discussed in this report relate to what remains an unprecedented event in contemporary history with unique challenges for CGC guidance-related measure development. The following recommendations were developed by the QC in consultation with the CGC. Their development was fully funded by the AGA Institute, with no additional outside funding.

The novel coronavirus, SARS-CoV-2, was first described in December 2019 in patients in Wuhan, China, who developed severe pneumonia, and was named coronavirus disease-19 (COVID-19) by the World Health Organization on February 11, 2020.[1] It was classified as a pandemic on March 11, 2020,[2] and there have been 26,523,297 cases in the United States as of February 5, 2021.[3] It is readily transmitted via aerosols.[4] Since the first descriptions of the pulmonary complications, numerous extra-intestinal manifestations have been described, as well as gastrointestinal (GI) symptoms that include abdominal pain, nausea, vomiting, and diarrhea in addition to elevated transaminases. The target entry receptor for SARS-CoV-2 is thought to be the angiotensin converting enzyme II, which is expressed throughout the upper and lower GI tract as well as in the hepatobiliary parenchyma. As a result, endoscopic GI procedures in particular are considered high-risk encounters. Although progress has been made in the treatment of COVID-19 infections, and while 36,819,212 vaccine doses have been administered as of February 5, 2021, there remains no cure. Therefore, infection control and prevention remain paramount.

Measure Evaluation and Development

The AGA recently published 3 guidance documents to assist in interpreting the available evidence regarding COVID-19, with the goals of summarizing data and providing evidence-based recommendations for the (1) evaluation and management of GI and liver manifestations of COVID-19, (2) risk of COVID-19 transmission during endoscopy with recommendations for personal protective equipment (PPE), and (3) the role of implementing a SARS-CoV2 pretesting strategy before endoscopy.[5–7]

The aggregate recommendation statements from these documents, exclusive of good practice statements, were evaluated for development as potential quality measures. Best practice statements which had their certainty assessed using a Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework were also evaluated as they pertained to recommendations for the consultative management of patients with COVID-19.

A standardized process first implemented by the AGA in 2016 and outlined elsewhere[8] was used and concordant with previously used methods for measure development.[9] An optimal understanding of this measure evaluation process will be enhanced by reading applicable portions of the topic guidelines. Briefly, the AGA QC follows a "guidelines to measures" protocol that is based on best practices outlined by the American Thoracic Society.[10] This process relies on the evaluation of forthcoming guideline recommendations to be reviewed by the QC. Recommendation statements are evaluated as potential measure concepts along several axes, including the strength of the recommendation and quality of the evidence as specified using GRADE methodology. Only those statements with strong recommendations based on high or moderate quality evidence are considered for further measure development, which includes an assessment of their potential usefulness for practicing gastroenterologists. This assessment involves a QC subcommittee analysis of measure importance and, when appropriate, is followed by the formal creation of a measure prioritization brief outlining the decision rationale whereby topics are rated on their meaningfulness, potential magnitude of effect, quality gaps, feasibility, and applicability to gastroenterologists. High priority measure concepts subsequently undergo review and voting by the entire QC ahead of a 30-day public comment period before testing and formal adoption. Finally, measures that receive $\geq$60% of the full QC vote are recommended for national implementation.

Recommendations

Maintaining high-quality care is essential in a pandemic, not only to facilitate early diagnosis and detection, but also to halt its spread and optimize the use of limited resources. Developing measures to define high-quality care for use throughout the COVID-19 pandemic is challenging. Best practice recommendations are derived from a synthesis of the currently available data that, despite the abundance of interest in the topic, remains limited to date. The dynamically changing prevalence rates and resource availability assessments continue to change; therefore, the evidence regarding diagnosis and treatment is evolving, too. While working toward establishing a measurable standard for high-quality care for COVID-19, rapid dissemination of quality and peer-reviewed data such as that found in the recent guidance documents is paramount.

Table 1. Summary of Recommendations and Rationale for Quality Measure Development

Statement	GRADE	Decision	Rationale
AGA Rapid Recommendations for GI procedures during the COVID-19 pandemic			
In health care workers performing upper GI procedures, regardless of COVID-19 status, the AGA recommends use of N95 (or N99, or PAPR) masks instead of surgical masks, as part of appropriate PPE.	Strong recommendation, moderate certainty of evidence[a]	No measure concept to develop	Lack of demonstrated or suspected quality gap, measurement challenges, and uncertain magnitude of effect. Variation for N95 use in this context exists; as preprocedure testing is more widely available, an important caveat for contextualizing this recommendation, there may be limited impact of this recommendation.
In health care workers performing lower GI procedures, regardless of COVID-19 status,[a] the AGA recommends the use of N95 (or N99 or PAPR) masks instead of surgical masks as part of appropriate PPE.	Strong recommendation, low certainty of evidence[a]	No measure concept to develop	Insufficient certainty of evidence and measurement challenges. Variation for N95 use in this context exists; practically, physicians performing a combination of upper and lower endoscopy likely would refrain from donning and doffing throughout the day. Also, local medical boards (eg, Texas) have stronger PPE requirements.
In health care workers performing upper GI procedures, in known or presumptive COVID-19 patients, the AGA recommends against the use of surgical masks only, as part of adequate PPE.	Strong recommendation, low certainty of evidence	No measure concept to develop	Insufficient certainty of evidence and lack of demonstrated or suspected quality gap.
In extreme resource-constrained settings involving health care workers performing any GI procedures, regardless of COVID-19 status, the AGA suggests extended use/re-use of N95 masks over surgical masks, as part of appropriate PPE.	Conditional recommendation, very low certainty evidence	No measure concept to develop	Insufficient quality of evidence and strength of recommendation.

Table 1. Continued

Statement	GRADE	Decision	Rationale
In health care workers performing any GI procedure, regardless of COVID-19 status, the AGA recommends the use of double gloves compared with single gloves as part of appropriate PPE.	Strong recommendation, moderate quality evidence	No measure concept to develop	Lack of demonstrated or suspected quality gap and measurement challenges.
In health care workers performing any GI procedure, with known or presumptive COVID-19, the AGA suggests the use of negative pressure rooms over regular endoscopy rooms, when available.	Conditional recommendation, very low certainty of evidence	No measure concept to develop	Insufficient strength of recommendation and certainty of evidence.
AGA Institute Rapid Review and Recommendations on the role of preprocedure SARS-CoV-2 testing and endoscopy[b]			
For most endoscopy centers, the AGA suggests implementing a pretesting strategy using information about prevalence and test performance (sensitivity/specificity) in combination with considerations about the benefits and downsides of the strategy. The prevalence of asymptomatic SARS-CoV2 infection for most endoscopy centers will range from <0.5% to 2.0%.	Conditional recommendation, low certainty evidence	No measure concept to develop	Insufficient strength of recommendation and certainty of evidence. Practical limitations include estimating local prevalence especially during "surges," accounting for patient mobility with contact tracing and assessing test characteristics.
For endoscopy centers where the prevalence of asymptomatic SARS-CoV-2 infection is low (<0.5%), the AGA suggests against implementing a pretesting strategy.	Conditional recommendation, low certainty evidence	No measure concept to develop	Insufficient strength of recommendation and certainty of evidence. Practical limitations include estimating local prevalence especially during "surges," accounting for patient mobility with contact tracing and assessing test characteristics.

Table 1. Continued

Statement	GRADE	Decision	Rationale
For a small number of endoscopy centers in high prevalence areas, the AGA suggests against implementing a pretesting strategy. In "hotspots," endoscopy should only be reserved for emergency or time-sensitive procedures with use of N95/N99 respirators or PAPRs for all procedures.	Conditional recommendation, low certainty evidence	No measure concept to develop	Insufficient strength of recommendation and certainty of evidence. Practical limitations include estimating local prevalence and defining a "hotspot," accounting for patient mobility with contact tracing and assessing test characteristics. Implementation challenges include some areas where testing is universal to facilitate retriage COVID-positive patients as the definition for time-sensitive procedures may vary.
For all endoscopy centers, the AGA recommends against serologic testing as part of a pretesting strategy for patients or endoscopy staff.	Strong recommendation, low certainty evidence	No measure concept to develop	Insufficient certainty of evidence. Additional data are needed to assess potential benefits and harms to such an approach.
AGA Institute Rapid Review of the GI and liver manifestations of COVID-19, meta-analysis of international data, and recommendations for the consultative management of patients with COVID-19			
In outpatients with new onset of diarrhea, (i) ascertain information about high risk contact exposure (ii) obtain a detailed history of symptoms associated with COVID-19, including fever, cough, shortness of breath, chills, muscle pain, headache, sore throat, or new loss of taste or smell (iii) obtain a thorough history for other GI symptoms, including nausea, vomiting, and abdominal pain.	No GRADE provided	No measure concept to develop	No demonstrated or suspected quality gap and uncertain magnitude of effect. Obtaining a detailed history of GI symptoms and non-GI symptoms is essential to evaluating all patients during the pandemic and expected as part of routine GI care which may limit impact of this recommendation.

Table 1. Continued

Statement	GRADE	Decision	Rationale
In outpatients with new onset GI symptoms (eg, nausea, vomiting, abdominal pain, diarrhea) monitor for symptoms associated with COVID-19 as GI symptoms may precede COVID-related symptoms by a few days. In a high COVID-19 prevalence setting, COVID-19 testing should be considered.	No GRADE provided	No measure concept to develop	No demonstrated or suspected quality gap and uncertain magnitude of effect. The reported prevalence continue to vary, with different thresholds for high rates, indicating a broad presentation, and often lack thereof, of GI symptoms.
In hospitalized patients with suspected or known COVID-19, obtain a thorough history of GI symptoms (nausea, vomiting, abdominal pain, diarrhea) including onset, characteristics, duration, and severity.	No GRADE provided	No measure concept to develop	No demonstrated or suspected quality gap and uncertain magnitude of effect. The majority of studies evaluated of GI symptoms in COVID-19 focused on hospitalized patients, in whom a direct association with COVID-19, cannot be confirmed. Further studies are warranted to determine the characteristics, including onset and duration, of GI symptoms in relation to other COVID-19 symptoms, in hospitalized and outpatient settings, in order to develop measures based on high quality evidence.
There is presently inadequate evidence to support stool testing for diagnosis or monitoring of COVID-19 as part of routine clinical practice.	No GRADE provided	No measure concept to develop	Insufficient quality of evidence

Table 1. Continued

Statement	GRADE	Decision	Rationale
In patients (outpatients or inpatients) with elevated LFTs in the context of suspected or known COVID-19, evaluate for alternative etiologies.	No GRADE provided	No measure concept to develop	No demonstrated or suspected quality gap and uncertain magnitude of effect. Referenced studies did not report whether alternative etiologies of elevated LFTs were considered and doing so is expected as part of routine GI care which may limit impact of this recommendation.
In hospitalized patients with suspected or known COVID-19, obtain baseline LFTs at the time of admission, and consider LFT monitoring throughout the hospitalization, particularly in the context of drug treatment for COVID-19.	No GRADE provided	No measure concept to develop	No demonstrated or suspected quality gap and uncertain magnitude of effect.
In hospitalized patients undergoing drug treatment for COVID-19, evaluate for treatment-related GI and hepatic adverse effects.	No GRADE provided	No measure concept to develop	No demonstrated or suspected quality gap.

AGA, American Gastroenterological Association; COVID-19, coronavirus disease; GI, gastrointestinal; LFT, liver function tests; PPE, personal protective equipment; SARS-CoV-2, severe acute respiratory syndrome coronavirus-2.
[a]These recommendations assume the absence of widespread reliable rapid testing for the diagnosis of COVID-19 infection or immunity.
[b]These recommendations assume that all patients are systematically screened for COVID-19 symptoms using the Centers for Disease Control and Prevention screening checklist and are required to wear masks while in the endoscopy unit.

Within this context, the QC does not currently recommend the development of any quality measure concepts for preprocedure testing, completing endoscopic procedures, or for the consultative management of COVID-19 patients. Each recommendation statement was evaluated independently and an assessment was made (Table 1). The most frequently identified limitation for further quality measure concept development is related to the insufficient quality of the available evidence and, relatedly, the strength of recommendations. For example, in the instance of performing lower GI procedures the use of N95 (or N99 or PAPR) masks is given a strong recommendation with low quality evidence. In other important instances, consequential data are lacking. In the instance of abnormal liver-associated enzymes, there are not enough data that evaluating for alternative etiologies is a change from the current practice paradigm. Similarly, the recommendations to avoid preprocedure testing in high prevalence areas may be in conflict with local or state-level recommendations with associated impacts on patient care.

Another commonly identified factor limiting measure development is the lack of described quality gaps. Although these areas have not been broadly researched at this time, in the instance of performing any GI procedure in known or presumptively COVID-19–positive patients, it is unlikely anyone would be using surgical masks only as part of their PPE. Furthermore, reliable and specified means through which adherence can be calculated is critical for quality measures. As a result, although using 2 pairs of gloves as part of PPE is undoubtedly relevant,

reliably evaluating and calculating measure satisfaction in this area would be challenging.

Among other features particularly relevant to quality measure development is some performance stability over time, to both establish a benchmark and later against which comparisons can be made to measure practice. Necessarily, both the ongoing nature and expected impermanence of the current pandemic conditions likely limit the impact that quality measures would have, because such a process is routinely expected to require several cycles of specification, testing, validation, and final approval for inclusion in quality payment programs.

Discussion and Future Directions

Given the novelty of COVID-19 and its profound effects on individual and public health, 2020 has seen the generation and publication of enormous volumes of data to guide clinical practice. The AGA's CGC has created a comprehensive and systematic evaluation of the available data to provide much needed guidance regarding preprocedure testing and periprocedure safety as well as a context for interpreting GI signs and symptoms related to this viral illness. Although rigorously evaluated, these guidance recommendations come with several important caveats, which is primarily related to quality of available evidence and its expected evolution. Together with their time-limited nature, these recommendations do not currently satisfy criteria for further development into quality measures.

A critical initial step in evaluating guidance statements for measure concept development is assessing the quality of evidence and strength of recommendation. In the case of the COVID-19–related statements, few of the current statements achieved sufficient moderate to high quality evidence and sufficiently strong recommendations. Furthermore, the usefulness of any quality measure depends on the existence of gaps in care delivery. There are no data available to suggest any such gaps exist with respect to patient care. Finally, all practice patterns depend on the local disease prevalence and acknowledged as such in the guidelines. The nature of the evolving pandemic necessarily implies dynamic responses and adaptations will be used within that context. Together these realities limit the impact any such potential quality measure would have on practice.

However, the QC strongly believes that the best practices outlined in the CGC guidelines should be followed whenever possible and appropriate. Importantly, the lack of specified quality measures does not indicate a lack of importance to quality improvement as it pertains to COVID care. The duration in which we will be practicing in the current state is unknown; therefore, identifying opportunities for improvement is critical. Because of the increasing evidence base, establishing metrics for COVID-19 care is a first step. This work requires more data and demonstrable gaps in the quality of care.

There is also now robust evidence for disparities in outcomes between patient groups. It is highly likely care delivery gaps are also present, both among socioeconomically disadvantaged patient populations and across health systems; these gaps are probably further pronounced during periods of health care strain, such as occurs when communities experience outbreaks and "surges." Monitoring for variations in care delivery and outcomes in these situations will be important and are sources of particular interest for improvement.

In contrast, generating a quality measure, including those on which clinicians can report as part of a systematic quality program, such as the Merit-based Incentive Payment System, relies on an extensive process of specification, testing, and formal programmatic submission.[11] This goal is, therefore, more distal. There are already examples of projects that aimed to assess adherence and outcomes related to such preprocedure testing.[12] More data in this regard will be increasingly valuable the longer the pandemic lasts.

In conclusion, the current best practices, guidelines, and recommendation statements from the AGA represent an essential synthesis of the available data regarding COVID-19 regarding preprocedure testing and periprocedure safety, as well as the context for interpreting GI signs and symptoms related to this viral illness. The quality of the evidence, strength of recommendations, and lack of known quality gaps currently preclude the development of quality measures at this time. These concepts, and other, are expected to evolve with the pandemic and growing evidence base. The QC encourages practitioners to adhere to these recommendations when appropriate and feasible and track their impact through active engagement in quality improvement. With additional data, future quality concepts can be reevaluated for formal quality measure development.

DAVID A. LEIMAN
Department of Medicine
Division of Gastroenterology
Duke University School of Medicine
Durham, North Carolina

JENNIFER K. MARATT
Department of Medicine
Division of Gastroenterology
Indiana University School of Medicine
Indianapolis, Indiana

GYANPRAKASH A. KETWAROO
Department of Medicine
Division of Gastroenterology
Baylor College of Medicine
Houston, Texas
On behalf of the
Quality Committee of the American
Gastroenterological Association

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