NATIONAL QUALITY FORUM
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Meeting Summary

Appeals Board Web Meeting – Appeal of the Consensus Standards Approval Committee Endorsement Decision of NQF #0500 Severe Sepsis and Septic Shock: Management Bundle

The National Quality Forum (NQF) convened the Appeals Board for a web meeting on April 29, 2022, to adjudicate the appeal received for the spring 2021 Consensus Standards Approval Committee (CSAC) endorsement decision on NQF #0500 *Severe Sepsis and Septic Shock: Management Bundle*.

Welcome, Review of Agenda and Meeting Objectives, Introductions, and Disclosures of Interest

Dr. Matt Pickering, NQF senior director, and Dr. Tricia Elliott, NQF senior managing director, welcomed the Appeals Board, the appellant, the developer, the CSAC chairs, and members of the public to the web meeting. Dr. Pickering further thanked the Appeals Board and all relevant parties for their time and preparation in advance of the web meeting.

In her opening remarks, Dr. Elliott noted that the Appeals Board plays a vital role in NQF's measure endorsement process and is responsible for adjudicating all appeals submitted regarding the CSAC's endorsement decisions. She further reminded the Appeals Board that the appeal being discussed today is for NQF #0500 *Severe Sepsis and Septic Shock: Management Bundle*, which was submitted for maintenance endorsement as part of the spring 2021 endorsement cycle.

Laurel Pickering and Larry Becker, Appeals Board co-chairs, also provided welcoming remarks. Ms. Pickering outlined the process for the meeting. She shared that both the appellant and the developer will have three representatives present on the call who will speak to the issues outlined in the appeal. Additionally, the appellant and measure developer will both have up to seven minutes to give opening statements. Then, the Appeals Board will have an opportunity to ask clarifying questions, which will be triaged accordingly to the appellant, measure developer, CSAC chairs, or NQF. Ms. Pickering reminded the Appeals Board that the first two votes will determine whether there are sufficient grounds for an appeal based on NQF's eligibility criteria. These criteria include the following: (1) procedural errors likely to affect the outcome of the original endorsement decision or (2) whether there is new evidence that was unavailable at the time of the CSAC's endorsement decision. The outcome of these first two votes will determine whether the Appeals Board will continue further consideration of the appeal.

In his opening remarks, Mr. Becker stated that the Appeals Board conducts important work and that he appreciates both the appellant and developer, the work of the CSAC, and everyone who has spent time on this measure. Mr. Becker further shared that his 10 years of service on the NQF Board of Directors and service on other NQF Committees, including as chair for some of them, provides him with sufficient knowledge of and experience with the NQF endorsement process.

Dr. Pickering proceeded to summarize the agenda for the web meeting. He stated that the purpose of today's meeting was for the Appeals Board to review, discuss, and adjudicate the appeal of the CSAC's endorsement decision on NQF #0500 *Severe Sepsis and Septic Shock: Management Bundle*. Dr. Pickering then conducted roll call and reviewed NQF's disclosures of interest policy.

The roll call confirmed that four Appeals Board members and one alternate were present for the meeting. Per the NQF Appeals Board policy, the alternate in attendance was elevated to a voting member for this meeting to replace an Appeals Board member who was unavailable to attend the call. This meant that the Appeals Board had five voting members present. The quorum (n=4) was met and maintained for the entirety of the meeting. None of the Appeals Board members or alternates present on the call disclosed any conflicts of interest. Dr. Pickering explained that the Appeals Board has two alternates who will serve if an Appeals Board member has a conflict with a measure under appeal review or is unable to attend the Appeals Board meeting. Lastly, Dr. Pickering mentioned that he and Co-Chair Pickering are not related to the best of their knowledge.

Overview of Appeals Board Meeting Process

Dr. Pickering then provided an overview of the following procedure for the Appeals Board meeting:

- The appellant gives an opening statement, followed by a response from the developer.
    - Each party may have up to three (3) representatives speak on their behalf.
    - Each party has up to seven (7) minutes for their opening statement.
- Following opening statements, the Appeals Board has an opportunity to ask the measure developer, appellant, or NQF staff qualifying questions.
- The Appeals Board moves to vote on whether the issues presented in the appeal meet one or both of NQF's eligibility criteria. The Appeals Board votes on each criterion separately.
- The outcome of the vote determines the next steps:
    - If both votes are *no*, the measure remains endorsed, public comments are not provided, and the meeting concludes.
    - If either vote is *yes*, the meeting moves forward with immediate further consideration and discussion of the appeal regarding the CSAC's endorsement decision.
- If the Appeals Board proceeds, questions may be asked of the appellant, measure developer, CSAC chair and vice chair, and/or NQF staff.
- Prior to the final vote, the Appeals Board opens the meeting for public and NQF member comment.
    - Each speaker is allowed up to two (2) minutes for their statement.
    - The Appeals Board, the appellant, measure developer/steward, or CSAC chairs do not respond to each individual public commenter.
- Lastly, the Appeals Board moves to final discussions and votes on whether to uphold or overturn the CSAC's endorsement decision on the measure. For all votes, Dr. Pickering noted that the Appeals Board has to reach a 51 percent majority. In addition, Dr. Pickering explained that there are no tie breakers and "consensus not reached" is not a voting result.

Overview of Measure Under Appeal Review

Prior to the opening statements, Dr. Pickering provided a brief overview of NQF #0500, noting that the measure is stewarded by Henry Ford Hospital and was recently evaluated for maintenance endorsement during the spring 2021 cycle. Dr. Pickering summarized that this measure focuses on the management of severe sepsis or septic shock in adults 18 years of age and older. He further stated that NQF #0500 is a composite measure consisting of the following components: measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement.

Dr. Pickering then outlined the endorsement history of NQF #0500. Since its initial endorsement in 2008, NQF #0500 has returned to NQF for maintenance endorsement in 2013, 2017, and most recently, in

2021. During its first maintenance endorsement review, NQF #0500, then an NQF-endorsed measure, received an appeal. The appeal expressed that resuscitation must be guided by a central venous catheter and that patients are identified retrospectively via International Classification of Diseases, Ninth Revision (ICD-9) codes by data abstractors. The appeal argued that this could lead to inaccurate assessments of performance, considering the discharge diagnosis and the time identified as "time zero" for patients who develop sepsis while in the emergency department or hospital may not reflect how treating physicians interrupted and treated patient symptoms in real time. Dr. Pickering explained that the then NQF Board of Directors upheld the CSAC's endorsement decision and recommended an ad-hoc review (most recently termed Early Maintenance Review) when the evidence came to light regarding these issues. An ad-hoc review was conducted in 2015 by NQF's Patient Safety Standing Committee. The Standing Committee expressed concerns about the invasive monitoring of central venous pressure and oxygen levels near the central lines. A compromise was reached with the developer of NQF #0500 to revise one of the measure's components to allow for flexibility for noninvasive approaches for monitoring of the volume status and tissue perfusion. With this change to the measure, the endorsement of NQF #0500 was upheld.

Dr. Pickering concluded the overview of NQF #0500 by noting that the measure did return for maintenance review in spring 2021. The Patient Safety Standing Committee recommended the measure for endorsement, which was unanimously upheld by the CSAC.

Appellant and Measure Developer Opening Statements

Ms. Pickering opened the floor for opening statements from the appellant, followed by the measure developer.

The representatives from the appellant were as follows:

- Michael Klompas, MD, MPH
- Aisha T. Terry, MD, MPH, FACEP
- Sara E. Cosgrove, MD, MS

The representatives from the developer were as follows:

- Sean Townsend, MD
- Robert Dickerson, RRT, MSHSA
- Emanuel Rivers, MD, MPH

Appellant Opening Statement

Dr. Michael Klompas, head of infectious disease control at Brigham and Women's Hospital and co-author of the most recent Surviving Sepsis campaign guidelines, provided the opening statement for the appellant. Dr. Klompas noted that he was speaking on behalf of the six co-signers of the appeal letter, including the American College of Emergency Physicians (ACEP), Infectious Diseases Society of America (IDSA), Pediatric Infectious Diseases Society (PIDS), Society for Healthcare Epidemiology of America (SHEA), Society of Hospital Medicine (SHM), and Society of Infectious Diseases Pharmacists (SIDP).

Dr. Klompas recognized that both the appellant and developer have the same goal of improving care and outcomes for sepsis patients. He posited that there are two issues regarding the re-endorsement of NQF #0500. First, Dr. Klompas expressed concern with the process, in which two key members of the Patient Safety Standing Committee were recused from discussions due to NQF's conflict of interest policy. These two Standing Committee members had published technical critiques of NQF #0500,

including modification suggestions. Dr. Klompas expressed that the deep interest and expertise these two Standing Committee members have with NQF #0500 are like that of the developers, and therefore, they should not have been recused from discussions. In addition, Dr. Klompas claimed the developers interrupted and contradicted NQF Standing Committee members during the measure evaluation meeting.

The second concern was regarding emerging new evidence. Dr. Klompas focused on three different studies published respectively in *Clinical Infectious Diseases*, the *Annals of Internal Medicine*, and the *Journal of the American Medical Association (JAMA) Network Open*. Each of these studies contained real-world experience with NQF #0500 implementation. Dr. Klompas summarized that the three studies were congruent in their findings. One study showed an increase in one or more of lactate checking and broad-spectrum antibiotic utilization but no change in meaningful outcomes. Dr. Klompas continued to summarize that the studies also found no change in either hospital mortality or discharge to hospice but did find an increase in the relative mortality trend following the implementation of NQF #0500.

Dr. Klompas further noted that the evidence used by the developer came from observational studies, which he stated have a high risk of bias. One study focused on NQF #0500-compliant patients versus non-compliant patients. Dr. Klompas explained that this was a flawed analysis because the study favored patients with mild sepsis severity and non-shock sepsis cases. These cases make it easier (i.e., for the accountable entity) to pass the measure and have a lower mortality outcome. Furthermore, in the septic shock analysis, no difference was found in the mortality rates for NQF #0500-compliant patients versus non-compliant patients.

To conclude, Dr. Klompas argued that the procedural errors made by recused Standing Committee members and disruptions made by the developer, as well as the exclusion of critical new evidence from the past endorsement review, resulted in the re-endorsement of NQF #0500, which does not currently achieve the shared goal of saving lives.

Measure Developer Opening Statement

The developer's opening statement was provided by Dr. Sean Townsend. He began his remarks by restating the two NQF criteria for an appeal and stated that the three studies mentioned by the appellant in their opening remarks were not included in the appeal letter. Therefore, they are not appropriate to discuss because the topic of the appeal letter should be the focus of the Appeals Board's discussion.

Dr. Townsend then addressed the appellant's procedural concerns. With respect to the two Standing Committee members who were recused from the discussions during the measure evaluation meetings, Dr. Townsend expressed that both members had published critiques of the evidence that supports the measure. In addition, he stated that both individuals had worked previously with the measure developer, and per NQF policy, this degree of involvement would result in recusal.

Regarding the appellant's claim that the developer was disruptive during the measure evaluation meeting, Dr. Townsend stated that there are no NQF-published rules outlining NQF procedure at these meetings. Thus, all lapses in the meeting procedure may be subjective. He further stated that the NQF Consensus Development Process (CDP) was not interrupted and was successfully completed. To support his argument, Dr. Townsend drew attention to the documented and publicly available measure evaluation meeting summaries, which show that the CDP was in fact completed for this measure. Therefore, he recommended the dismissal of the appellant's argument of procedural errors to the Appeals Board.

Circling back to the appellant's argument that new evidence had emerged that was not available at the time the CSAC made its endorsement decision, Dr. Townsend explained that the appellant focused their appeal letter on the 2021 Sepsis Campaign guidelines. He noted that these guidelines were published during the first week of October 2021, thus making them available at both the time of the Patient Safety post-comment meeting on October 13, 2021, and the CSAC measure evaluation meeting on December 1, 2021. Dr. Townsend explained that the guidelines were discussed by the Patient Safety Standing Committee during the October 2021 meeting. He added that the Standing Committee considered whether these guidelines should result in a reconsideration of the measure. The Standing Committee voted on this decision, which resulted in not reopening the measure for further discussion and revote. This is reflected in the respective meeting summary and was shared during the CSAC meeting. Therefore, Dr. Townsend posited that the appeal does not meet NQF's criteria for an appeal and should be dismissed.

Dr. Townsend went on to express that he believed that if the Appeals Board voted to overturn the endorsement of the measure due to the new guidelines, it would show the Appeals Board's lack of confidence in the Patient Safety Standing Committee's expertise. Furthermore, he restated that the three articles cited in the appellant's opening statement were not mentioned in the appeal letter and noted that the three studies did not assess for compliance with NQF #0500. Dr. Townsend explained that if full compliance was assessed, there would be no need to assess performance gap. He stressed that the importance of looking at compliance was to assess whether mortality reduction is present when complying with the measure.

Dr. Townsend concluded by stating that NQF #0500 was downgraded from moderate to low quality in the 2021 Sepsis Campaign guidelines. He noted that in the three previous versions of these guidelines, the measure had been ranked as moderate. Dr. Townsend shared that this was because three major studies published after 2016 were not included in the evidence tables, and therefore, the evidence tables in the 2021 Sepsis Campaign guidelines are deficient.

Initial Appeals Board Discussion and Vote

Following the opening remarks, Ms. Pickering called upon each Appeals Board member to ask any clarifying questions based on the opening statements from the appellant and the measure developer. Several Appeals Board members asked for additional details regarding the three published studies mentioned by Dr. Klompas during his opening statement:

1. Can the appellant confirm that the three articles discussed in the opening statement were not cited in the appeal letter, even though they were available?
2. Are all three studies before-and-after studies (i.e., implementation of the sepsis measure)? Is it correct that they do not address whether compliance with the measure is associated with better outcomes?
3. What are the publication dates for each of the three studies? Were any of them published and available before the CSAC meeting date?

Ms. Pickering then asked the appellant to respond. Dr. Klompas began to answer the questions by naming the three studies mentioned in the opening remarks, which included a University of Pittsburgh Medical Center (UPMC) study led by Dr. Ian Barbash published in the *Annals of Internal Medicine* in April 2021, a Duke University study led by Dr. Deverick Anderson published in *Clinical Infectious Diseases* on November 5, 2021, and a study led by Dr. Chanu Rhee and published in *JAMA Network Open* on December 20, 2021. NQF staff confirmed that the CSAC meeting was held on both November 30 and December 1, 2021. Dr. Klompas stated that the letter did mention the UPMC study and concluded that

the Barbash and Anderson studies were available, while the Rhee study was not available at the time of the CSAC meeting.

An Appeals Board member asked NQF staff to clarify the definition of evidence being available at the time of the CSAC meeting. Specifically, the Appeals Board member asked whether there is a distinction between information being available because it was published and publicly available, or whether the information had to be available and brought to the attention of the people who were considering the measure's endorsement at that time. Dr. Pickering stated that if the article was available but not considered by the endorsement decision body, then it would be considered unavailable.

Dr. Klompas then continued to answer the earlier question regarding whether the UPMC study reviewed compliance with NQF #0500. He stated that the UPMC looked at the use of lactate checking over time, use of antibiotics utilization, and use of fluids. The findings reported a substantial increase in both lactate checking and antibiotic utilization but no change in hospital deaths.

An Appeals Board member asked the measure developer to comment on the content and impact of the UPMC study. In response, Dr. Townsend explained that while the UPMC study is of interest, the appeal letter does not include the three studies mentioned: It only notes the 2021 Surviving Sepsis Campaign guidelines as new evidence. However, Dr. Townsend addressed the UPMC study by stating that it was available at the time of the CSAC meeting and discussed by the Patient Safety Standing Committee. He summarized that the study found a mortality rate of 4.7 percent for septic patients, which is extraordinarily low since the mortality rate for severe sepsis is 20 percent. He suggested that there was something unusual about the way patients were chosen for the study, considering the study did not include all severe sepsis and septic shock patients. Therefore, the study did not assess compliance with NQF #0500. Instead, the study assessed what had happened before and after NQF #0500 was implemented. The article does not provide information on how patients who received care, in compliance with NQF #0500, faired. The findings from the UPMC study only show that if compliance with NQF #0500 was low, then you cannot detect a change on the national scale from the period before NQF #0500 was implemented.

Following Dr. Townsend's response, Dr. Pickering reminded the Appeals Board members that they should focus only on what is in the appeal letter and that any new information not discussed in the appeal should not be considered. Co-Chair Pickering asked whether there were any additional questions for the appellant or developer. Ms. Pickering confirmed that there were no additional clarifying questions and called for the vote. NQF Analyst Gabby Kyle-Lion administered voting on the following two questions:

- Vote 1: Based on the appeal, are there procedural errors reasonably likely to affect the outcome of the original endorsement decision?
    - Yes = 0 and No = 5 (n=5)

1. Vote 2: Based on the appeal, is there new information or evidence, which was unavailable at the time the CSAC made its endorsement decision, that is reasonably likely to affect the outcome of the original endorsement decision?

    - Yes = 0 and No = 5 (n=5)

Dr. Pickering stated that due to the unanimous decision on both votes, the Appeals Board has determined that the appeal does not meet either NQF criteria. Therefore, the appeal was dismissed, public comments were not provided, and the CSAC's endorsement decision was upheld.

Next Steps

Dr. Pickering summarized the next steps, in which NQF will post the voting results to the Appeals Board webpage on May 4, 2022. In addition, NQF will post a recording of the Appeals Board meeting on the website in mid-May. The deliberations and results of the Appeals Board meeting will be reflected in the Patient Safety Spring 2021 Technical Report, which will be posted on the Patient Safety project page on June 28, 2022. Lastly, NQF will post a detailed meeting summary on the Appeals Board webpage on June 30, 2022. Any questions can be forwarded to the NQF Appeals inbox: appeals@qualityforum.org.