

KIDNEY CARE QUALITY ALLIANCE

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The National Quality Forum

FR: Ray Hakim, MD
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RE: National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations

DA: May 7, 2008

Thank you for the opportunity to review and respond to the recommendations pertaining to the harmonization of endorsed influenza vaccination measures. We appreciate the NQF Steering Committee's recognition that because of the particular vulnerability of the end-stage renal disease population, a separate measure applying specifically to these patients is both necessary and appropriate, and we welcome this opportunity to assist NQF in its worthy quest to better align vaccination measures across populations and healthcare settings.

The NQF has recommended that the Kidney Care Quality Alliance's (KCQA) "Influenza Vaccination in the End Stage Renal Disease Population" measure, which was granted time-limited endorsement in November 2007, be modified to mirror the NQF Committee's proposed standardized influenza vaccination measure. To achieve that end, the following conditions must be met:

1. **Numerator:** The measure must contain a three-part numerator that captures the following patients:
 - Patients who receive the vaccine;
 - Patients who were counseled but refuse the vaccine; and
 - Patients who have a medical contraindication to the vaccine (i.e., hypersensitivity, a history of Guillain-Barre Syndrome within six weeks after a previous influenza vaccination, or receipt of a bone marrow transplant within the past six months).

As currently specified, the KCQA's numerator includes only those patients who receive the vaccine.

2. **Denominator:** The denominator must be expanded to include all patients over the age of 6 months. The KCQA measure currently considers only patients 18 years of age and older.
3. **Exclusions:** The measure must incorporate an exclusion for patient encounters when providers' vaccine supply has been ordered but has not yet been received. The KCQA measure does not presently contain such an exclusion.

We are aware that submission of developers' proposed modification plans is not required until NQF's immunization recommendations are finalized this summer, and that implementation of the recommended modifications is not expected until the time-limited review in two years.

Nevertheless, we believe it prudent to address this issue at present to avoid substantial modification at the conclusion of the testing period.

The KCQA is not without concern over the potential for increased administrative burden with expansion of the numerator and incorporation of the recommended exclusion, as chart review and/or software modification will likely be necessary to effectively capture these data elements, particularly for small facilities that may not have an advanced IT system. However, we agree that the recommendations to document (1) patients with medical contraindications to the vaccine and (2) patients who refuse the vaccine despite appropriate counseling are reasonable modifications that will strengthen the measure, provide a more accurate reflection of performance, and will minimize the risk of inappropriately penalizing providers adhering to accepted standards of care. We anticipate that the benefits of incorporating these modifications will ultimately outweigh the incremental burden resulting from the collection of this small amount of additional information. Furthermore, the KCQA believes that it is important that each component of the numerator be reported and analyzed separately, and thus urges NQF to recommend this level of data analysis; it is particularly important to have patient refusal reported separately in order to identify situations of high patient refusal where educational interventions could be deployed to reduce that number. In addition to the proposed modifications, the KCQA also proposes a fourth element be added: "Number of patients who were assessed and offered an influenza vaccine but who reported receiving one elsewhere." As with the other additions recommended by the NQF, such a change will provide a more accurate reflection of performance and would also capture the increasing variety of sites (e.g., grocery stores, pharmacies) where patients may elect to receive their vaccinations.

With respect to the recommended changes to the denominator, the KCQA has reservations regarding the suggested expansion. Specifically, the KCQA notes that there is both a lack of evidence-based data and considerable professional controversy regarding the use of live attenuated influenza vaccine (LAIV) in children with chronic renal disease, and believes that this and other nuances particular to this vulnerable pediatric population is sufficient grounds to justify continued exclusion of these patients from the measure at this time. We note, however, that as a patient age field is likely to be a core data element of testing, this decision would not, at face, appear to materially affect our data collection testing per se and should new information arise, collecting and reporting an expanded age range would be feasible. We will continue to monitor developments and be prepared to more completely address changes to the specifications at the time of NQF's review.

Finally, while the KCQA recognizes the controversy surrounding the exclusion of providers whose vaccine supply has been ordered but not yet received, and appreciates the NQF's concerns about fairness to small providers, it is not clear to us at this time that collecting this information is feasible, and - even if it is - whether this exclusion would strengthen the measure to a sufficient degree to justify the added burden of collecting this data element. Moreover, the KCQA is concerned that the exclusion might absolve from attribution not only those providers who are the victims of distribution variations but also, inappropriately, those who have merely failed to order their vaccine in a timely fashion.

In summary, the KCQA is at this time inclined to agree to test the following recommendations for its "Influenza Vaccination in the ESRD Population" measure:

1. Incorporation of the numerator modifications as recommended.

2. Preservation of the current denominator age range in recognition of the existing lack of clear and consistent guidelines on influenza immunization in young ESRD patients.
3. Preservation of the denominator without any exclusions, as currently specified.

A final decision by the KCQA as to whether to incorporate such changes in modified specifications would occur following pilot testing and after review by the KCP membership. However, additionally and more importantly, the KCQA must engage in further conversation with the Centers for Medicare and Medicaid Services (CMS) as to how it plans to implement its Final Rule with respect to reporting of clinical performance measures (CPMs) by ESRD facilities. Ultimately the KCQA must align its data capture with the CPM reporting requirements set forth by CMS. Should the agency mandate elements that are in conflict with or do not align with the proposed modified specifications, the KCQA would need to align its specifications with CMS requirements.

Again, thank you for this opportunity to respond to the recommendations of the Immunization Steering Committee. We look forward to continuing our important work with NQF to assess and advance the quality of care provided to the ESRD population.