MINUTES
Kidney Care Quality Alliance Steering Committee
August 18, 2008
Conference Call

ATTENDEES

ANNA	Gail Wick (Co-chair)
ASPN	Barbara Fivush
CMS	Barry Straube
DaVita	LeAnne Zumwalt/Allen Nissenson
FMC	Ray Hakim (Co-chair)
NKF	Dolph Chianchiano
NRAA	Maureen Michael
RPA	Ed Jones
KCP	Linda Keegan, Robyn Nishimi, Lisa McGonigal

SUMMARY

Dr. McGonigal opened by taking a roll call, after which minutes from the July 21 Steering Committee conference call were approved by the Steering Committee. Drs. Hakim and Nishimi then reminded the Steering Committee that an overall measure-testing plan intended to test the five KCQA measures that received time-limited endorsement from the National Quality Forum (NQF) had been approved during the previous conference call, and that this call would be used to review additional details of that plan. Dr. Nishimi led the ensuing discussion during which the Steering Committee deliberated on and finalized testing details and particulars related to data collection and recruitment.

REVIEW OF APPROVED MEASURE TESTING PLAN

Dr. Nishimi noted that on July 21, the Steering Committee had approved patient and facility-related sampling factors, geographic considerations, and a general recruitment protocol, as summarized in the following sections.

Facility-Related Sampling Factors

The Committee previously agreed to the following:

- Testing will be performed on a nationally drawn sample containing a mix of for-profit and not-for-profit dialysis organizations. Department of Veterans Affairs-affiliated and other public facilities will be excluded.
- Hospital-affiliated and freestanding facilities will be included.
- Urban, suburban, and rural settings will be included.
- Facilities with and without EMRs will be included.
- A final sample size of 60 facilities will be sought. Three facilities will be recruited from each of the 18 ESRD Networks plus an additional six sites primarily from Network 7 in Florida. Network 7 will be oversampled to take advantage of the location of the CMS contractor that developed the CROWNWeb 1.0 Data Dictionary, so as to facilitate potential consultation during travel related to data auditing.

- Sampling will approximate the current industry profile: 60% for-profit large dialysis organizations (LDOs); 15% not-for-profit LDOs; 20% for-profit non-LDOs; and 5% not-for-profit non-LDOs.

Dr. Nishimi informed the Steering Committee that, based on the above parameters, an initial recruitment list was generated and was shared with and approved by the Committee on July 21. However, she noted that as hospital-based facilities were not initially included in the staff calculations, the totals across the categories differ slightly from those initially identified. Additionally, for-profit non-LDOs are over-represented in the invitation list owing to both the focus on KCP members and geographic availability. Finally, while the original intent had been to oversample/over recruit only in Network 7, more than three facilities are likely to result for a few Networks due to the need to reflect the current industry profile, recruit chiefly from KCP members, and achieve an appropriate mix of urban/suburban/rural facilities.

***STEERING COMMITTEE ACTION*: The Steering Committee reviewed and approved both the testing parameters and updated recruitment list.**

Patient-Related Sampling Factors

Dr. Nishimi next reviewed the patient-related sampling factors that the Steering Committee had agreed to on July 21. Specifically:

- 25 patients per facility will be sampled.
- The measures' specifications require that patients be 18 years and older. Dr. Nishimi noted that while NQF endorsed the Influenza Immunization measure for the pediatric population, KCQA did not agree to adopt this specification and thus will not test this measure in the pediatric population. However, she reported that because date of birth will be a standard CROWNWeb data field, the age of patients sampled is not necessary per se in assessing the feasibility, validity, and reliability of the KCQA measure.

She then proposed the following additional testing details:

- The technical specifications also require the inclusion of home and in-facility dialysis patients, peritoneal and hemodialysis patients, and patients categorized by length on dialysis. Based on data from the 2007 USRDS Annual Data Report, Dr. Nishimi advised the Committee that this equates to 23 hemodialysis (98%) and 2 peritoneal dialysis (2%) patients per facility. For the few facilities in the recruitment list that do not provide peritoneal dialysis, all 25 patients will be hemodialysis patients. She stated that facilities that offer home hemodialysis will be asked to submit data on both home and in-facility patients.
- For the Vascular Access measures, Dr. Nishimi reminded the Committee that the technical specifications require that patients be categorized according to time on dialysis (< 90 days; 90 days to 1 year; > 1 year), equating to 6 patients, 11 patients, and 8 patients, respectively. Dr. Nishimi noted that communications with CMS have indicated that data for these measures will be collected on a point-in-time, rather than rolling, basis, and proposed that KCQA test the measure in this manner as well. She advised the Steering Committee that as patients on dialysis < 90 days are not included in the measures' denominator populations, collecting data in this manner effectively means

that for 6 of 25 patients in a facility's sample, the Vascular Access measure form will not need to be completed beyond the initial question related to time on dialysis.

- Lastly, Dr. Nishimi acknowledged that data collection for patients with a functional autogenous AV fistula is considerably easier than for patients without (i.e., two versus five questions). Because the presence of a functional AV fistula appears to vary widely, she proposed that facilities be instructed to select patients with and without a functional AV fistula on an approximately 50/50 basis—i.e., up to 12 patients with and 13 (or the balance of) patients without a functional AV fistula. She noted that this sampling approach would provide sufficient statistical power to examine the primary target population for the measure—those without a functional AV fistula—while also minimizing the burden of data collection on the facilities. While, alternatively, individual sampling strategies could be identified for each facility based on its current percentage of patients with a functional AV fistula, she opined that this approach is unduly complex and does not meaningfully improve the testing protocol, which is not designed to gather results, but rather to test the specifications/data elements.

Steering Committee Discussion: While Dr. Hakim acknowledged that the NQF-endorsed specifications for the measures do not require that data be collected on patients on dialysis < 90 days, he nonetheless proposed that this data be collected during the KCQA pilot tests to provide a better understanding as to how this crucially important population is managed. Dr. Nishimi responded that while she does not object to this proposal, it would require that more data be collected than is necessary to calculate the measures' results and would increase facility burden. Ultimately the Steering Committee decided to minimize burden and not include these patients, since inclusion would not assist in testing the measure per se.

Dr. Hakim then raised the question of whether it is appropriate for clinician-level data to be collected through the facility; Ms. Michael concurred. Drs. Jones and Nissenson noted that RPA feels that clinician-level measures should be collected by the physicians. Dr. Nishimi remarked that she does not disagree per se, but noted that the proposed testing protocol reflects how CMS intends to collect this data through CROWNWeb. Dr. Hakim acknowledged that CMS does intend to make this a facility function for CROWNWeb 1.0, but noted that the organization has expressed a willingness to make some modifications with the release of version 2.0. However, Dr. Nishimi advised that while CMS has indicated its willingness to consider KCQA's recommendations, she believes that this will be more feasible with the Patient Education than with the Vascular Access measures, as the data elements for the latter are already incorporated into CROWNWeb 1.0. She further noted that with respect to the Vascular Access measures, changes to the specific data elements might be considered, but she believed CMS would not alter the overall approach of gathering the data.

Dr. Straub agreed that CMS should remain flexible with implementation of the CPMs and noted that for the time being, the focus of physician-level measure reporting is the Physician-Quality-Reporting Initiative (PQRI). He acknowledged that facilities are opposed to bearing responsibility for aspects of care primarily within the physician's realm of control. However, he remarked that facilities have leverage similar to hospitals that has not, to date, been utilized, and that there are things that facilities could influence but have chosen not to. He stated he felt it was appropriate for CMS to collect physician-level information associated with the Vascular Access measures through CROWNWeb—that such data could provide an important

verification of information that potentially would be collected through PQRI. He further noted that PQRI was voluntary, whereas data collection from facilities was a mandatory program.

Dr. Hakim responded he felt that dialysis facilities have less influence over physician behaviors than do hospitals, and that requiring facilities to report this data places the facilities in a difficult position. Ms. Michael added that as it is easier to lock into facilities than individual clinicians, and that facilities often feel that they are taken advantage of by CMS to collect data. Dr. Hakim remarked that appropriate expectations regarding who should be responsible for reporting data should be defined. Dr. Straube acknowledged the Committee's concerns and reiterated that CMS remains flexible for the moment, but noted that payment systems might evolve in a different direction. Dr. Nishimi concluded that the Steering Committee will need to continue to grapple with this issue. However, while the two vascular access measures are at the clinician-level of analysis, data will nonetheless be collected by the facilities for CROWNWeb 1.0 and she felt should be similarly collected during field-testing.

Ms. Michael next informed Dr. Straube and the Steering Committee that her facility recently conducted a trial-run on the CPMs to determine the time and cost of data collection. She noted that it averaged between 20 and 45 minutes per patient, depending on the experience level of the staff assigned to the task. She noted that even at the lower end of this range, this translated to 130 hours for the facility's 390 patients. She remarked that this time commitment would require dedicating an employee exclusively to CPM data collection for more than three weeks, at a financial cost of approximately $2,000. Dr. Straube voiced appreciation for this information and remarked that such data are invaluable to CMS. He requested that any such information be forwarded to CMS and concluded that it will be important to work together to determine the most appropriate and effective means of approaching data collection.

***STEERING COMMITTEE ACTION*: The Steering Committee approved the proposed patient sampling profile.**

<u>Data Collection</u>

Dr. Nishimi then reviewed the patient-related sampling factors previously agreed upon by the Steering Committee:

- All five measures will be tested at all facilities in the sample.
- Either electronic or paper data could be submitted at the facility's discretion.
- Finally, Dr. Nishimi noted that while a target initiation date of September 1, 2008, had been identified, it is more likely that the date will be September 15-30, 2008. She advised that this delay will compress the time to write the report, but will not delay delivering a report to NQF on the results of the pilot.

In addition to the above factors, Dr. Nishimi proposed the following parameters related to data collection and analysis:

- Data collection will occur based on standardized data sheets created by Drs. Nishimi and McGonigal, which were distributed to the Steering Committee for review and approval. The data collection form for each measure has been developed to capture only those data elements necessary to meet the measure's specifications. Likewise, only a minimum amount of demographic information is requested for the pilot test.

- Facilities will be assigned a unique facility identifier and 25 patient codes known only to Drs. Nishimi and McGonigal. Facilities will identify patients for each of the 25 patient codes, and only facilities will know the link between the code and patient. Only de-identified information will be transmitted, and facilities will be instructed to destroy the sheet linking the code to a specific patient once the pilot has been fully completed.
- Data will be collected monthly (due five business days following the end of the month) for the first quarter, after which collection will be quarterly (due five business days following the end of the quarter).
- Only aggregate data will be reported. No individuals will have access to the de-identified, patient-level or facility-level data except Drs. Nishimi and McGonigal.
- Data integrity will be verified via onsite audits of 10 to 20% of facilities.

Steering Committee Discussion: While the Steering Committee had no suggested *content* modifications for the Influenza Vaccination or Patient Education Awareness data collection forms, Dr. Hakim suggested that it would be useful for Committee members to review the forms in detail after the call and send any *wording* suggestions to Drs. Nishimi and McGonigal.

Conversely, Dr. Jones suggested—and the Steering Committee agreed—that the Vascular Access form as designed will inappropriately place the onus of data collection on the facilities. Dr. Nishimi reiterated her concern that the testing approach reflect, at minimum, how CMS would be using the measures, but she also noted that, given the Steering Committee's concerns, she and Dr. McGonigal would explore a separate or combination form, with part to be completed by the nephrologist—although she also stated that she felt this second collection approach was duplicative and that she had concerns it would make the instrument and instructions confusing and/or overly complicated. She proposed recirculating the new Vascular Access form to the Committee for its consideration via email. The Steering Committee concurred with Dr. Nishimi's proposed approach.

Drs. Jones and Fivush then questioned the degree of overlap between the CPMs and PQRI measures. Dr. Nishimi noted that it was reported by CMS at the last KCP Board meeting that there had not yet been any contact between the CROWNWeb and PQRI personnel. Dr. Straube remarked that he could not recall the exact degree of overlap between measure areas in the two initiatives. He noted, however, that as participation in PQRI is voluntary, there might be a resulting paucity of reported data. Conversely, he also noted that Congress mandates reporting via CROWNWeb and thus views the initiative as a means of ascertaining sufficient data collection.

STEERING COMMITTEE ACTION: **The Steering Committee approved the data collection protocol and the Patient Education and Influenza Vaccination data collection forms. Drs. Nishimi and McGonigal will revise the Vascular Access form as discussed and will distribute for Steering Committee review and approval.**

Recruitment

Dr. Nishimi reminded the Steering Committee that it had previously approved a strategy of recruiting approximately 20% more facilities than necessary (i.e., approximately 72 facilities) in order to achieve the final sample size of 60 facilities. The Committee also agreed that

invitational letters would be sent from the KCQA and, where appropriate, from the KCP member contact/Board member. She stated they will place follow-up phone calls to facilities that do not respond, and facilitation by Steering Committee and KCP members will be requested as necessary. A draft letter of invitation was distributed to the Steering Committee for review and approval.

Steering Committee Discussion: Dr. Nissenson queried how facilities that are not members of KCP will be recruited. Dr. Nishimi acknowledged that recruiting hospital-affiliated centers in particular could prove difficult, as these facilities might not belong to any KCP member organizations. However, she advised that there will be a targeted outreach to these and other non-KCP facilities. Ms. Michael also noted that the NRAA has member facilities that are hospital-based for which she could assist in recruitment.

Dr. Hakim next suggested that the letter of invitation be modified to further emphasize that field-testing will impose minimal burden on participating facilities and requested that Steering Committee members likewise review the letter and submit suggested revisions. In response to a query Dr. Nishimi advised that she hoped the invitational mailing would take place at the end of August, but the data collection form issue needed to be resolved. Dr. Nishimi then asked whether the Steering Committee had any objections to the letter going out under each Committee member's name and representing organization. No member voiced an objection.

Finally, Ms. Michael questioned when field-testing would commence. Dr. Hakim advised that testing would be launched in September. Conversely, he noted that data collection for CMS' CPMs will begin in February 2009.

STEERING COMMITTEE ACTION: **The recruitment approach and letter were reviewed and approved by the Steering Committee. Steering Committee suggestions for additional edits to the letter will be submitted to Drs. Nishimi and McGonigal by Thursday, August 21.**

NEXT STEPS

Dr. Nishimi advised the Steering Committee that after consultation with Ms. Kathy Lester, it was determined that the audit component of field-testing might require that Drs. Nishimi and McGonigal have access to identifiable data, should the facility opt not to redact the appropriate records. As such, approval of a Privacy Board will be sought once the data collection protocol was resolved—after which recruitment will begin.