# **National Dry Run Summary Report**

# Standardized Readmission Ratio (SRR) for Dialysis Facilities

July 7, 2014

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# **Executive Summary**

# Introduction

The Centers for Medicare & Medicaid Services (CMS), through a contract with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), recently provided dialysis facilities with confidential reports of their results on the *Standardized Readmission Ratio (SRR) for dialysis facilities* through a national dry run held March 31 – May 2, 2014. CMS conducted the dry run in accordance with the guidance provided in the Measure Management System (MMS) Blueprint. The primary aims of the dry run were:

- 1. to educate dialysis facilities and other stakeholders about the measure in advance of public reporting
- 2. to provide facilities with an opportunity to ask questions about the measure before its use in public reporting
- 3. to test the reporting process and identify potential changes that may be made to the measure as a result of the dry-run and questions received
- 4. to provide the dialysis facilities with their results on the measure using facility-specific reports
- 5. to allow dialysis facilities to request the detailed discharge-level data used to calculate the measure
- 6. to provide information to the facilities to help them understand the measure, interpret their measure results and to provide feedback on the SRR Dry Run process and reports

CMS took comments and answered questions through a question and answer (Q&A) helpdesk, through two national provider calls.. Throughout the dry run, CMS received comments and recommendations regarding measure methodology and the dry run process. This report describes the dry run, presents the results of the dry run, summarizes the questions and recommendations from stakeholders, and presents CMS's response to comments and questions.

# **Summary of Dry Run and Results**

# **Dialysis Facility Participation**

A relatively small percentage of dialysis facilities participated in the dry run. CMS provided individual reports of measure results to 5,889 dialysis facilities. Of these, 782 (13%) facilities downloaded their reports for the SRR measure, and 273 facilities requested their discharge level data files. Independent facilities and facilities that are part of small dialysis chains had the highest participation rate in the dry run, while facilities that are part of two of the large national dialysis organizations (LDOs) had a substantially lower participation rate. LDO-facility participation is discussed further in a later section of the report.

## **National Provider Calls**

Approximately 672 callers attended the two SRR dry run national provider calls. The majority of questions asked during each call were about methodological aspects of the measure. Methodological questions focused on inclusion/exclusion criteria and the outcome definition. People also asked about policy implications of the measures and clarification of plans for reporting. Table 1 summarizes the types of questions asked during each call.

|                           | 3/20/2014 | 4/17/2014 |
|---------------------------|-----------|-----------|
| Number of Callers         | 399       | 273       |
| Total number of questions | 26        | 22        |
| Methodology               | 20        | 7         |
| Policy and Reporting      | 1         | 5         |
| Website                   | 2         | 3         |
| Facility-specific results | 0         | 1         |
| General                   | 3         | 6         |

## Table 1: Summary of the dry run national provider calls' Q&A sessions

## E-mail Q&A Period

During the dry run, CMS received 6 emails (containing a total of 31 questions and comments) for the SRR measure. CMS responded to every question or comment received. These questions and comments are discussed in detail later in the report.

In addition to the questions and comments received about the measure and the reports, the SRR dry run helpdesk responded to approximately 520 questions from dialysis facilities and other stakeholders regarding the dry run process and the website. A total of 273 facilities requested and received their discharge-level data files. Table 2 summarizes the types of questions to which the helpdesk responded.

#### Table 2: Summary of helpdesk questions

| Summary of helpdesk questions                  | Ν   |
|--|-----|
| Total number of questions                      | 520 |
| Request for MAH* password (re-sent to          | 149 |
| original MAH)                                  |     |
| Request for MAH password (provided to          | 115 |
| alternate MAH)                                 |     |
| Request for password (could not be provided)   | 27  |
| General (dry run process, website instruction, | 229 |
| etc)   |     |

\*Master Account Holder

# CMS Actions in Response to the Dry Run

As a result of comments and questions received the dry run, CMS will continue to study the following issues regarding the measure:

- 1. CMS will investigate adjusting for prevalent BMI, instead of BMI at ESRD incidence.
- 2. CMS will investigate the possibility of including a covariate for recent failed kidney transplants.
- 3. CMS will further examine the list of diagnoses defining planned readmissions to confirm that they are appropriate for the ESRD population.
- 4. CMS will investigate the issue of excluding planned readmissions using only the primary diagnosis.

In addition, CMS will take the following steps regarding future dry runs:

- 1. CMS will investigate the feasibility of using a different patient identifier for future patient-level data files. A number of users expressed concern over using the CROWNWeb patient ID, as it required a number of steps in order to confirm the identity of a particular patient.
- 2. CMS will seek to work with the Division of the ESRD Program and Community Health and the ESRD Networks to ensure a more efficient and accurate method for distributing master account passwords.
- **3.** CMS will communicate effectively with representatives from LDOs prior to implementing future dry runs in order to obtain buy in and encourage participation in the dry run.

# **Dry Run Process**

# **Overview**

CMS held the dry run of the SRR measure from March 31 through May 2, 2014. CMS contracted with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to manage implementation of the dry run. CMS made available all materials and information about the dry run through the dialysisdata.org website.

The goal of the dry run was threefold:

- 1. Familiarize dialysis facilities with the measure
  - Allow facilities to review and understand the data used to calculate the measures
  - Inform facilities how to interpret their measure results
- 2. Provide an opportunity for facilities to ask questions about the measures prior to use in CMS programs
- 3. Test the reporting process
  - Ensure data and coding used in measure calculation and production are accurate

To achieve these goals, CMS and UM-KECC took the following steps:

- 1. Reached out to dialysis facilities, ESRD Networks and other stakeholders to announce and encourage engagement in the dry run.
  - CMS announced the dry run to the community in the February 27, 2014, edition of the MLN Connects Weekly Provider Newsletter.
  - CMS announced the dry run to dialysis facilities in the March 10, 2014 CROWN memo, which included a description of the process for accessing the dry run website.
  - On March 6, 2014, CMS and UM-KECC contacted the 18 ESRD Networks regarding the dry run, and requested that they pass along the announcement to the facilities in their respective network.
  - UM-KECC provided website passwords and access instructions in a personalized letter emailed to facilities on March 13, 2014.
  - Information regarding the dry run and national provider calls were also included in the March 6, March 13, March 20, March 27, April 3, April 10, and April 17 editions of the MLN Connects Weekly Provider Newsletter. A final reminder that the dry run was ending on May 2, 2014, was included in the April 24 edition.
  - CMS and UM-KECC worked with the Network Coordinating Center (NCC) to announce the dry run and national provider calls to facilities in a series of e-mail blasts (March 5 and March 12, 2014).

- UM-KECC worked with CMS Provider Communications Group to announce the dry run and national provider calls to invested stakeholders, including professional organizations (e.g., American Society of Nephrology, Renal Support Network, etc) and renal news outlets (e.g., Nephrology News and Information, Renal Web, etc).
- 2. Prepared and posted supporting information and materials on www.dialysisdata.org. UM-KECC and CMS developed the following set of materials to support the dry run. These materials were posted on the dry run website, www.dialysisdata.org.
  - Detailed technical reports describing measure rationale and methodology, and specifications
  - Frequently asked questions (FAQs)
  - A mock-up version of the facility-specific report

## 3. Provided dialysis facilities with their results.

- Confidential facility-specific reports containing their detailed measure results, overview of measure methodology and information about the dry run.
- By request, discharge-level data containing detailed information on the patients included in their measure calculation and risk factor information.

CMS provided these files confidentially to dialysis facilities via upload to the secure website pages of the www.dialysisdata.org website on March 31, 2014. CMS provided discharge-level data files to facilities by request through a secure storage site.

## 4. Held a Q&A period for the SRR measure for the dry run period.

- The dry run announcements distributed prior to and during the dry run informed dialysis facilities of the Q&A period and provided instructions on how and where to submit their questions.
- CMS directed dialysis facilities to send their comments and questions by May 2, 2014, the close of the dry run period.
- CMS responded to each email received.
- 5. Conducted national provider calls to present the measure methodology and answer facilities' and other stakeholders' questions about the dry run and the measures.
  - CMS held two national provider calls for the SRR measure; the first call was held prior to the beginning of the dry run, and the second call took place approximately midway through the dry run.
  - CMS informed dialysis facilities of the national provider calls through the MLN Connects Provider Newsletter and e-mail blasts from the ESRD Network Coordinating Center. UM-KECC posted information about the calls on www.dialysisdata.org.
  - The calls consisted of a review of the logistics of the dry run, presentation of the measure methodology and a description of the dry run report. These presentations were followed by a Q&A session. CMS posted a recording and transcript of the calls, and the call agendas and

slides, on the CMS National Provider Call page on the CMS website. This information was also linked on www.dialysisdata.org.

## **Issues encountered**

UM-KECC and CMS encountered a number of logistical issues when preparing for the dry run. These issues contributed to the overall low participation rate from facilities in the dry run.

# **Password distribution**

The dry run was conducted on a newly developed website, www.dialysisdata.org. This site was modeled after the existing Dialysis Reports website (www.dialysisreports.org), which dialysis facilities are familiar with from accessing their Dialysis Facility Reports (DFRs), Dialysis Facility Compare (DFC) reports, and their Quality Incentive Program (QIP) reports and QIP Performance Score Certificates. The log-in process for both sites is the same. First, each facility has a designated Master Account Holder (MAH), who is provided with a password to log in to the site and set up specific user accounts for the facility; after receiving an account, users can then log in and download the reports in PDF files. For security purposes, ESRD Networks have historically been responsible for maintaining a list of MAHs for the www.dialysisreports.org website and for distributing the MAH passwords to facilities.

CMS approached the ESRD Networks in advance of the dry run, requesting that they perform the same service for the dry run website. Unfortunately, this specific task, supporting the dry run, was not specifically identified in their contract Scope of Work; therefore, the Networks SOW did not provide passwords for the dry run. Given this limitation, UM-KECC developed the following alternative system for distributing MAH passwords to facilities:

- CMS provided UM-KECC with a list of MAHs for each facility. The source of these lists was the December 2013 MAH List that the ESRD Networks provided to CMS (as a deliverable in their current contract). CMS also provided UM-KECC with a list of Facility Administrators (FAs), provided by the ESRD Network Coordinating Center (NCC).
- 2. Prior to the dry run (March 13, 2014), UM-KECC sent an e-mail to each MAH on the Network lists, providing the MAH password and log in instructions for www.dialysisdata.org. MAHs were able to log in to the website and set up user accounts prior to the start of the dry run.
- 3. The dry run helpdesk triaged calls and e-mails regarding logging in to the master account. In the event that the facility did not receive an e-mail with the MAH password and was requesting that the password be provided to them, the helpdesk took the following steps:
  - a. The helpdesk determined whether the requestor was the MAH provided by the Network. If so, the helpdesk re-sent the password to the requestor.
  - b. If the requestor was not the MAH but the MAH was still employed at that facility, the helpdesk either re-sent the password to the MAH on file or requested that the listed MAH provide verification to the helpdesk, via e-mail, that the requestor was permitted to receive it.
  - c. If the requestor was not the MAH and the MAH was no longer employed at the facility, the helpdesk referenced the FA list. If the requestor was on that list, the helpdesk

provided the password. If the requestor was not on the list but the listed FA was still employed at the facility, the helpdesk either sent the password to the FA on file or requested that the listed FA provide verification via e-mail that the requestor was permitted to receive it.

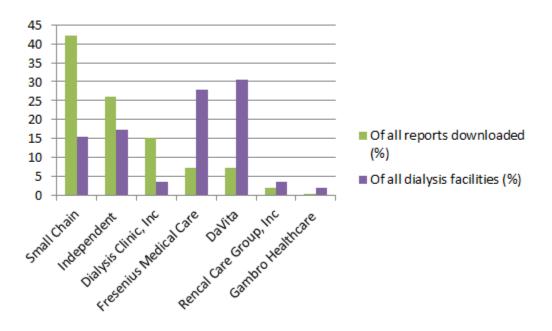
d. If the requestor was neither the MAH nor the FA, and neither of the people on those lists were employed at the facility, the helpdesk did not provide the password to anyone at the facility. These facilities were therefore unable to access their reports.

Given that CMS could not verify the accuracy of the e-mail addresses included on the original MAH list, we do not have data on how many facilities successfully received the original password e-mail on March 13, 2014. Of the 520 helpdesk questions received during the dry run, approximately 291 inquiries were about MAH passwords (via phone and e-mail). Of these, 149 were instances in which the helpdesk resent the password to the original MAH; 115 were instances in which the helpdesk provided the password to someone at the facility, either the FA or a third party who was confirmed by the FA or the original MAH. In 27 cases, the helpdesk could not provide the password.

## Large Dialysis Organization (LDO) Participation

For the QIP, DFR and DFC reports, facilities owned by two of the large dialysis organizations (Fresenius Medical Care [FMC], DaVita) typically receive download instructions from their corporate office each year prior to those respective preview periods. Prior to the SRR dry run, FMC and DaVita requested data files containing the SRR measure results, as well as the discharge level data files, for all of their facilities. They also requested corporate access to the dry run website to download all of their facility reports.

CMS informed these two LDOs that the combined data files and website access would not be available for the dry run but will be considered for future dry runs. FMC and DaVita did not require their facilities to download their dry run reports individually which reduced the overall participation rate in the dry run, as the LDOs combined (DaVita, DCI, FMC, Renal Care Group) account for 69.5% of all U.S. dialysis facilities. However, the participation rate was strong for facilities in smaller dialysis chains and for independent facilities. CMS reported measure results to 5,889 dialysis facilities. Of these, 782 (13%) of facilities downloaded their reports for the SRR measure, and 273 facilities requested discharge level data files. Figure 1 provides a distribution of the types of facilities that participated in the dry run (by ownership).



#### Figure 1: Dialysis facility participation in the dry run, by ownership

# **Lessons Learned**

To increase the participation rate in the future, CMS is working to include password distribution in a contract modification to ESRD Network statement of work. Given each Network's relationship with its facilities, they are the most appropriate entities to provide these passwords to the appropriate facility employees.

CMS will also reach out to LDOs earlier in the process to ensure their participation in the dry run. These efforts will focus on more effective communication with the LDOs to describe the benefits of participating in the dry run, which are primarily focused on providing feedback on a measure that is under development, ahead of possible public reporting. CMS will also work with the LDOs to make the dry run reporting process as effective as possible.. As part of this effort, CMS plans to add a downloadable data file option for future dry runs; this file would have all of the report data for facilities that a given user has been granted access to. Therefore, the LDOs would be able to download data for their facilities that have granted access to a corporate user account.

# Summaries of Questions/Comments Received About the SRR Measure

This section summarizes the questions and comments received for the SRR measure during the dry run email Q&A period, including a summary of CMS's responses, by topic. Overall, CMS received 31 questions and comments from 6 individuals for the SRR measure (Table 3).

## Table 3: Distribution of SRR measure questions by category

| Question Category                      | Ν  |
|--|----|
| Measure methodology question           | 3  |
| Measure methodology comment            | 15 |
| Facility-specific results (reports and | 10 |
| data)                                  |    |
| Implementation and public              | 3  |
| reporting                              |    |

In addition to these questions and comments about the measure, the SRR dry run helpdesk handled approximately 520 questions about the dry run process and website. A total of 273 facilities also requested and received their discharge-level data files.

Below are the comments and questions received during the dry run, along with the responses from CMS.

# SRR Dry Run Comment Log

# Comment #1-3

\*note: this comment was submitted three times for three separate facilities

I have reviewed this facility's report and find it to be satisfactory. I have a comment about the SRR in general. It appears to me that the SRR is duplicating data that they already collect through QIP. Much of the data collected through QIP is also an indicator of patient morbidity and quality of life. So why do we need another report to tell us what has already been said?

It also appears that the report is asking the dialysis centers to be responsible for co-morbidities which they have little to no control over.

Shouldn't the co-morbidity responsibility be evenly spread across the entire medical field from PCP's to cardiologist to pulmonologist, etc., rather than placing all co-morbidity blame on dialysis and ESRD?

#### **Response:**

As currently implemented, the QIP does not include a standardized readmission measure; therefore, the SRR does not duplicate information used by the QIP, except in the sense that the SRR is another measure of the quality of care delivered to dialysis patients. The SRR measures a different aspect of patient outcomes than those currently implemented in the QIP or those evaluated with other existing measures in that it reflects a facility's ability to coordinate the patient's care after hospital discharge. The QIP for Payment Year 2015 includes measures related to vascular access, anemia, and dialysis dose.

In this model, co-morbidities are **only** used as adjustors when calculating the SRR in order to avoid holding dialysis facilities responsible for determinant factors beyond their control. The SRR is intended to encourage coordination of care between all healthcare providers involved in the care of a patient. Various studies in cross-cutting settings have demonstrated that such coordination may help reduce unplanned readmissions. Readmission measures are being developed, or are already implemented, across multiple care settings, including hospitals, inpatient rehabilitation facilities, skilled nursing facilities, long-term care hospitals, home health agencies, and at the physician group level.

#### Comment #4

\*note: this comment contains 8 questions; a response is provided after each question

1) Pt ID#XXX: Provider #XXXXXX is the psychiatric unit inside [redacted]. This patient was actually in for 1 long admission but was transferred from the floor to the psychiatric unit and back again. The hospital has the patients be discharged from the hospital and admitted to the psychiatric unit and then discharged from there to be admitted back to the floor. I am sure this gets them more money somehow. How can this be readmissions? They never left the original facility, only moved up to another floor. Also isn't psychiatric an exclusion?

#### **Response:**

Medicare claims indicate that this patient was discharged from an acute hospital five times in 2012 (see below). Our calculation for your facility identified the first three of these as index discharges with the first and second being followed by a readmission. Your comment however helped us identify an error in our code and with this correction we would include only the first two of these as index discharges with both being followed by a readmission. A detailed description of how this was determined both for the calculation you received and for the new corrected calculation follows.

## Original Calculation:

The first three of the hospitalizations below were included as index discharges in the readmissions measure because they satisfied our definition of index discharges (please see a full list of the exclusion criteria on slide 4 of the linked document:

| Hospital ID | Admission | Discharge | Primary ICD9 |
|-------------|-----------|-----------|--------------|
| XXXXXX      | 5/9/2012  | 5/24/2012 | 531.40       |
| XXXXXX      | 6/1/2012  | 6/8/2012  | 780.2        |
| XXXXXX      | 6/22/2012 | 6/25/2012 | 403.91       |
| XXXXXX      | 6/25/2012 | 7/2/2012  | 296.30       |
| XXXXXX      | 7/2/2012  | 7/30/2012 | 038.3        |

https://www.dialysisdata.org/sites/default/files/SRRMeasureSpecifications.pptx).

You are correct that discharges with a psychiatric-related primary diagnosis are not considered index discharges; in your case, only the June 25–July 2 hospitalization included a psychiatric-related primary diagnosis (ICD-9 296.30). This hospitalization was therefore not counted as an **index discharge**; however, the psychiatric diagnosis exclusion criterion applies only when identifying index discharges, not readmissions. Therefore, the June 25–July 2 hospitalization was still considered a **readmission** following the June 22–25 hospitalization.

The July 2–30 hospitalization was excluded entirely from the measure. It was not considered an index discharge because the patient died during the hospitalization. It was not considered a

readmission for the June 25-July 2 hospitalization because this hospitalization involved a psychiatric diagnosis and was therefore not considered an index discharge.

## Corrected Calculation:

As indicated above, your comment has helped identify an error in the code that creates the measure—the June 22 –25 hospitalization, which resulted in the patient being transferred to the psychiatric unit—should not have been included in your SRR calculation as an index admission because it ended in a transfer. I It should instead have been considered a single hospitalization in conjunction with the June 25–July 2 hospitalization. Then, because the June 25–July 2 hospitalization involved a primary psychiatric diagnosis, the combined hospitalization is not eligible to be considered an index discharge. It is, however, counted as a readmission following the June 8 discharge. Thank you for helping us identify this problem.

 Pt ID#XXX: Pt was discharged on 9/26/12 following a GI Bleed. Then readmitted on 9/27/12 with an MI. Aren't GI Bleed and MI considered "High Risk"?

#### **Response:**

To clarify, a high-risk diagnosis is not a basis for exclusion, but rather is adjusted for in the SRR model. Furthermore, we defined "high-risk" discharges as those where, among the dialysis population, the primary diagnosis very commonly leads to a readmission within 30 days of discharge—the "risk" here refers to the likelihood of 30-day readmission, and not necessarily to the risk of death. Neither gastrointestinal bleeding nor myocardial infarction is so highly related to readmission as to be on the list of high-risk diagnoses, which can be found in the Detailed Methodology at

https://www.dialysisdata.org/sites/default/files/SRR\_Detailed\_Methodology.pdf.)

3) Pt ID#XXX: Pt was ours until 4/15/12 then transferred to [another facility] then was readmitted on 4/27/12. We had no control of this nor were we involved in it.

#### Response:

Our database does indicate that this patient was transferred between discharge and readmission. CMS has defined the measure such that the patient's readmission is attributed to the discharging facility is, even if that patient transferred to another facility before readmission. We will look into the possibility of handling cases such as this differently in the calculation of the measure, and we appreciate your help in bringing this issue to our attention.

4) Pt ID#XXX: Pt was ours until 9/10/12 then transferred to [another facility] then readmitted on 9/14/12. Again how is there our responsibility?

#### **Response:**

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Our database does indicate that this patient was transferred between discharge and readmission. CMS has defined the measure such that the patient's readmission is attributed to the discharging facility is, even if that patient transferred to another facility before readmission. We will look into the possibility of handling cases such as this differently in the calculation of the measure, and we appreciate your help in bringing this issue to our attention.

5) Pt ID#XXX: Pt had metastic CA before admission for dialysis and it continued to spread afterwards. She had numerous admissions secondary to it but the CA was not the first listed diagnosis code.

#### **Response:**

The measure is of necessity based on the data available to us on the hospital claims. We recognize that there may be some cases where the hospital claim does not allow us to properly identify exclusion diagnoses. We will take this issue into consideration as we further refine the measure.

6) Pt ID#XXX: Pt was admitted twice with MI. Again isn't this "high risk"?

#### **Response:**

No, MI is not defined as a "high-risk" diagnosis for this measure. .. To clarify, a high-risk diagnosis is not a basis for exclusion, but rather is adjusted for in the SRR model. Furthermore, we defined "high-risk" discharges as those where, among the dialysis population, the primary diagnosis very commonly leads to a readmission within 30 days of discharge—the "risk" here refers to the likelihood of 30-day readmission, and not necessarily to the risk of death. Neither gastrointestinal bleeding nor myocardial infarction is so highly related to readmission as to be on the list of high-risk" diagnoses, which can be found in the Detailed Methodology at <u>https://www.dialysisdata.org/sites/default/files/SRR\_Detailed\_Methodology.pdf</u>.

7) Pt ID#XXX: Crown Web has this number listed as "no record found". I also could not find any patient with this birthdate. These admissions need to be removed from our list since not our patient.

## Response:

A review of the dialysis facility claims data indicated your facility submitted dialysis claims for this patient for the month of August 2012 as well as two week-long periods in June and July of 2012. *Note: UM-KECC will follow up with this facility to clarify the issue.* 

8) Pt ID#XXX: The ID number and birthdate are correct for one of our patients, however only the admissions to provided #XXXXXX are for our patient. Even through the number and birthdate are the same for the other admissions, the ones to provider numbers XXXXXX and XXXXXX are definitely NOT our patient. I checked chart records and billing sheets and he was definitely here in this dialysis facility when he was supposed to be at those facilities. Please correct this and remove them from our list.

#### Response:

A review of the hospitalization claims data for this patient verified the hospitalizations listed in your report. *Note: UM-KECC will follow up with this facility to clarify the issue.* 

#### Comment #5

\*note: this comment contains 6 questions/comments; a response is provided after each question

Given that there is no formal mechanism for our organization to comment we are using this venue to comment on behalf of the 2200 dialysis clinics and 170,000 ESRD patients that DaVita Healthcare Partners serves.

1) We believe admissions and readmissions are important in ESRD, we believe the dialysis unit has limited ability to impact those outcomes for all causes. Based on 2011 Medicare Claims data, ESRD patients had an admission rate of 1.88 admits/pt. The percentage of those admissions attributable to factors the dialysis unit can control were low, namely 5% for vascular access infection, and 27% for ALL CV disease which includes fluid overload, CAD, AMI, and many others which the nephrologists will have some control over. A significant majority then of admissions and presumably readmissions are due to other end organ manifestations of chronic disease, many of which are beyond the ability of the dialysis unit to manage. Further 17 percent of patients had a readmission within 3 days post discharge meaning that the dialysis unit would not have time to even try to intervene.

#### **Response:**

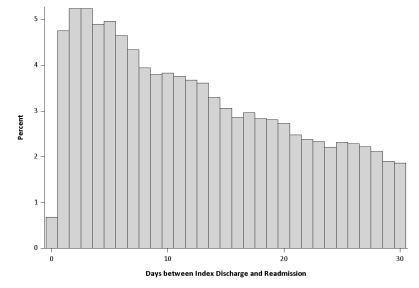
Three main factors have led CMS to develop the SRR as an all-cause measure. First, in April 2012, CMS convened a Technical Expert Panel (TEP) to review the SRR measure; this panel comprised nephrologists, dialysis facility medical directors, dialysis nurses, dialysis patients and statisticians. A significant point of discussion was whether the SRR should be a cause-specific measure. After the TEP failed to reach a consensus on a list of diagnoses under the control of the dialysis facility, The TEP voted that the measure be all-cause. Second, a cause-specific measure would deviate from other CMS-implemented readmission measures (e.g., the Hospital-Wide Readmission measure [NQF #1789]) as well as the CMS-implemented dialysis hospitalization measure (Standardized Hospitalization Ratio [NQF #1463]). Third, limiting the measure to specific causes would limit its stability, given the small size of many dialysis facilities (median facility size in 2013 was 62 patients).

Regarding your concern with short-turnaround readmissions, the first few days after discharge represent the time during which the patient is most vulnerable. As indicated in Figure 1, about 16% of readmissions occur in the first 3 days after index discharge. However, the question as to whether this period should be included or excluded from the SRR is a difficult one that relates to policy issues and the aims and purposes of the measure. As most dialysis facilities presently operate, they typically do not see patients after hospital discharge until the patient comes for the first post-discharge dialysis session, often two or three days later; understandably, the management of dialysis facilities argue that they have no way at present to address early readmissions to the hospital.

On the other hand, including readmissions within the first few days after discharge may be appropriate to encourage closer cooperation between the dialysis facility and the hospital in the process of hospital discharge. One concern is that some hospitals may not be as cognizant of ESRD care as are dialysis facilities, and patients are sometimes discharged having received inadequate ESRD care. This would be an extension of the paradigm of measures being constructed to affect processes and encourage coordination of care, with the aim of developing a new norm. Whether or not this is a part of the measure's purpose is a policy issue.

It is clear that the very high rate of very early readmissions should be addressed in some way, and this raises the policy issue. If it is not included in a dialysis facility measure, then perhaps it should be included in an additional measure on hospitals. It should also be noted that adjusting for hospital effects as we've proposed in our measure avoids full attribution of the readmission to a dialysis facility in situations where care cannot be coordinated. Additionally, hospitals are currently held responsible for 30-day readmission rates through the Hospital Readmission Reduction Program following discharge for specific conditions. A Hospital-Wide Readmission (HWR) measure is additionally implemented in the Hospital Inpatient Quality Reporting Program (IQR) and is publicly reported on Hospital Compare.

Table 1 illustrates the change in SRR if the first three days post-discharge are dropped from the measure. The correlation between the two versions of the measure is 0.96. Table 1 also describes flagging rates for the SRR with and without readmissions over the first three days. The percentage agreement between the two versions of the measure is 97.3%. Approximately 0.8% of dialysis facilities were classified as "As Expected" when early readmissions were included and "Worse than Expected" when early readmissions were removed; 0.7% of dialysis facilities moved in the other direction. These changes are relatively small but significant for the affected facilities. In the light of these small changes and keeping simplicity of the measure in mind, we recommend including all readmissions in the measure.



#### Distribution of Days between Index Discharge and Readmission, 2012

Change in Dialysis Facility Categorization, when Readmissions in the First Three Days Are Excluded versus Included (2012)

|                      | Significantly worse | Non-significant | Significantly better | Total        |
|----------------------|---------------------|-----------------|----------------------|--------------|
| Significantly worse  | 154 (2.7%)          | 32 (0.6%)       | 0                    | 186 (3.2%)   |
| Non-significant      | 50 (0.9%)           | 5370 (93.4%)    | 45 (0.8%)            | 5465 (95.0%) |
| Significantly better | 0                   | 31 (0.5%)       | 70 (1.2%)            | 101 (1.8%)   |
| Total                | 204 (3.5%)          | 5433 (94.5%)    | 115 (2.0%)           | 5752         |

**Early Readmissions Excluded** 

2) All cause readmission markers are appropriate for hospitals where care coordination and data are available. Dialysis units do not receive timely data, nor are hospitals required to provide data to dialysis units to coordinate care. Despite a large, dedicated effort we were unable to obtain relevant and timely patient data following discharge within one year, let alone within the few days required to coordinate care.

#### **Response:**

We appreciate your description of the current practice. However, one goal for developing this measure is to encourage more timely conversations and care coordination between dialysis facilities and hospitals. There is a similar measure for hospitals relating to readmission, so there is motivation for them to also seek to improve communications. CMS believes care transition is important and can be improved by focused intentional communication between hospitals and dialysis facility staff.

3) The use of a percentage is also troubling. We have seen in our special needs plan that in some cases as we reduce total hospitalizations the readmission percentages grow. Some very sick patients contribute the vast majority of readmissions and it is difficult to impact that. These patients contribute disproportionately to the numerator, such that reducing hospitalizations for the whole unit actually increases the readmission rate.

#### **Response:**

The SRR may be used in conjunction with the Standardized Hospitalization Ratio (SHR). The latter is a NQF approved standardized measure of the rate of hospitalizations by patients at a dialysis facility, and has been regularly reported for several years. Readmissions are, of course, a subset of hospitalizations, so they are a part of the SHR measure as well. The SRR, however, concentrates on the specific issues associated with a discharge from and potential readmission to the hospital. Measuring readmissions at the dialysis facility level offers substantial opportunities for coordination of care between hospitals, patients, nephrologists and other dialysis facility staff, and the measure provides a direct indication of how the dialysis facility performs in comparison to the national norm, taking account important patient characteristics. It should be noted, however, that a dialysis facility might have a low SHR and yet have a high SRR. This suggests that overall use of hospitals is being well handled, but that improvement in the readmission process may nonetheless be possible. For this and related reasons, we suggest that the SHR and SRR should be considered together.

Your concern about very sick patients potentially skewing a facility's readmission measure was a concern raised during CMS' Technical Expert Panel (TEP) for the SRR. We have addressed this concern by limiting the number of hospital discharges a patient can contribute to the measure in a given year. This exclusion is outlined in the Detailed Methodology document (available at <u>https://www.dialysisdata.org/sites/default/files/SRR\_Detailed\_Methodology.pdf</u>). We considered allowing a maximum of six readmissions per patient-year (<1% of our 2009 test population); however, this more stringent definition led to only small changes in the identification of outlier facilities (i.e., facilities who performed much better or much worse than the national average). Specifically, there was 99.0% agreement in the rate of facility outlier identification when using a cap of six compared with a cap of 12 readmissions. This is an issue that we will continue to monitor, especially with respect to small volume facilities.

4) Within this report, we do not see any difference based on incidence or prevalence. That may be in the statistical model but what factors are adjusted for is not called out either in descriptive next nor displayed in any table in the report. Similarly, there is reference to planned versus unplanned. There are no definitions provided as to what is planned or unplanned. For example, is a scheduled AVF placement following a discharge for an incident patient with a catheter planned or unplanned? Those definitions should be provided. We also note that no details are provided on readmission types. In order to affect readmissions it would be helpful to list dialysis specific types like vascular access related. Without that level of detail the units will not know what programs to concentrate on. Per the point above, ESRD related readmits that the unit has control over would be better than all cause.

## Response:

The Detailed Methodology document (available at

<u>https://www.dialysisdata.org/sites/default/files/SRR\_Detailed\_Methodology.pdf</u>), which is referenced on page 3 of each facility's report, outlines the risk adjustors included in the SRR model. One of the adjustors in the model is the amount of time a patient has been on dialysis as of the date of hospital discharge. Regarding your second point, the Detailed Methodology also contains the full set of definitions of planned and unplanned readmissions.

To your third point, the discharge-level reports provide the ICD-9 code associated with the patient's primary diagnosis at both the index hospital discharge and at the readmission discharge.

5) With regards to the statistical model used to risk adjust this measure, there is no detail or peer reviewed reference included in this report. The model does not include other important variables. Recently the NQF noted that socioeconomic status may affect quality outcomes. This is the case with this measure, a factor which is not taken into account in the model. We have trended public data for readmissions currently distributed by KECC on behalf of CMS against census data for income; a measure of socioeconomic status (SES). We note that units in locations with high degrees of poverty were more likely to have higher readmit rates, while units in lower poverty locations were more likely to have lower rates. We see similar trends for urban vs rural and hospital based vs non hospital based units. But this report does not seem to take that into account.

#### **Response:**

We again refer to the Detailed Methodology document (available at <u>https://www.dialysisdata.org/sites/default/files/SRR\_Detailed\_Methodology.pdf</u>), which includes various details of the measure calculation as well as references to relevant peer-reviewed literature, including the paper published in 2013 on the Standardized Readmission Ratio (He K, Kalbfleisch JD, Li Y, Li Y. Evaluating hospital readmission rates in dialysis facilities; adjusting for hospital effects. Lifetime Data Anal. 2013;19(4):490–512.)

Regarding your second point on socioeconomic status, we would like to note that the NQF's new recommendations regarding risk adjustment for patient demographics (such as socioeconomic status) are not final, and CMS will consider their risk adjustment strategies in light of that final report. We have done studies for SES using average salary by zip code as a proxy for socioeconomic status. Using that indicator, we don't see a strong dependence of the readmission measure on socioeconomic status. We are also investigating the feasibility of other

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measures of socioeconomic status. Properties of the dialysis facility such as urban vs. rural and hospital based vs. non hospital based are typically not adjusted for in quality measures, though this is a policy issue. The question arises as to whether one should hold urban and rural facilities to a different standard.

6) In summary we believe that you will not receive many comments on this dry run due to the data issues above. If implemented it is likely that this all cause measure will have limited impact due to large number of readmits beyond the dialysis units control. Lastly the report does not provide sufficient data to allow the units to take action on the readmits they may control, nor provides adequate detail into methodology to be credible to unit staff and physicians.

#### **Response:**

In 2011 dialysis, patients were admitted to the hospital twice on average and spent an average of 12 days in the hospital, accounting for approximately 38% of Medicare expenditures for ESRD patients (USRDS, 2013). Furthermore, 36% of hemodialysis patients discharged from the hospital had an unplanned readmission within 30 days (USRDS, 2013). In cross-cutting settings, some studies confirm that about 25% of unplanned readmissions are preventable, and preventability varied widely across diagnoses, and readmissions were more likely to be preventable for patients with more severe conditions (van Walraven et al., 2011).

In the dialysis setting, care coordination strategies, including appropriate hand-off and timely pre- and post-discharge communication among care providers have emerged as a potentially effective means to reduce unplanned readmission among the ESRD patients. A recent study in the ESRD population found that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmission (Chan et al, 2009). A recent multi-unit qualitative study by Reilly et al (2013) found that a lack of care coordination between in- and outpatient dialysis units post-discharge is associated with increased readmission rates. Other articles concerning the dialysis setting (e.g. Castner, 2011; Wish. 2014, Plantinga and Jarr, 2009) discuss the importance of dialysis facility and physician communication with the discharging hospital in order to ensure appropriate coordination of care such as reconciliation of post-discharge medications and treatment orders.

Clinical studies in the non-ESRD populations have also demonstrated that improved care coordination and discharge planning can reduce readmission rates; see a variety of studies in the non-dialysis-setting and the non-ESRD population evaluated post-discharge interventions (Dunn, 1994; Bostrom, 1996; Dudas, 2001; Azevedo, 2002; Coleman, 2004; Coleman, 2006; Balaban, 2008; Braun, 2009) or a combination of pre- and post-discharge interventions (Naylor, 1994; McDonald, 2001; Creason, 2001; Ahmed, 2004; Anderson, 2005; Jack, 2009; Koehler, 2009; Parry, 2009). Readmission measures have been developed in various care settings, including hospitals and skilled nursing facilities.

As detailed in the aforementioned Detailed Methodology document as well as the paper published in 2013 on a peer reviewed statistical journal (He et al., 2013), we have proposed a standardized readmission ratio (SRR) measure that aligns with the U.S. healthcare system moving toward a paradigm of shared accountability across providers from different care settings. Specially designed for the vulnerable ESRD population, our measure will not only encourage improvement in transition of care across various settings, but also serve as a strong motivation for facilities to coordinate treatment with the discharging hospital to reduce readmission rates. Moreover, our measure encourages facilities to review their current readmission practices and identify potential problems, with goal of improving care and reducing costs.

#### Comment #6

\*note: this comment contains 12 questions/comments; a response is provided after each question

1) How are bedded outpatients/observation admissions counted in the SRR?

#### **Response:**

Observation stays are excluded from this measure. To provide some idea of the scope of this issue, approximately 250 (0.03%) of the more than 700,000 dialysis patient hospitalizations occurring each year in 2009 – 2012 are observation stays.

2) Any measure that reflects on dialysis facilities should be modifiable by dialysis facilities. If a discharged patient is readmitted prior to being seen at the dialysis facility, the facility has not had the opportunity to intervene to prevent the readmission. This serves for both readmissions within 48 hours as well as readmissions from other healthcare settings (e.g., if a dialysis patient is receiving dialysis at a rehabilitation center rather than at their home facility following hospital discharge). For an ESCO, where there are funds allocated to expand the reach of the facility reliably and consistently beyond the dialysis unit, this does not matter, but for individual facilities, the metric as written does not support the reality of the dialysis facility role.

#### **Response:**

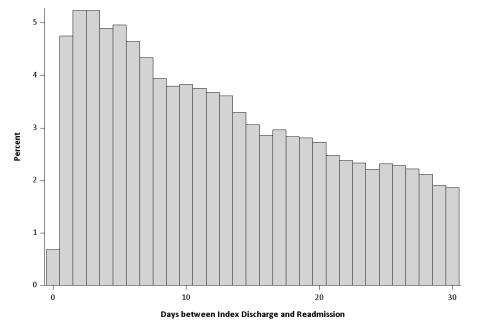
Regarding your concern with short-turnaround readmissions, the first few days after discharge represent the time during which the patient is most vulnerable. As indicated in Figure 1, about 16% of readmissions occur in the first 3 days after index discharge. However, the question as to whether this period should be included or excluded from the SRR is a difficult one that relates to policy issues and the aims and purposes of the measure. As most dialysis facilities presently operate, they typically do not see patients after hospital discharge until the patient comes for the first post-discharge dialysis session, often two or three days later; understandably, the management of dialysis facilities argue that they have no way at present to address early readmissions to the hospital.

On the other hand, including readmissions within the first few days after discharge may be appropriate to encourage closer cooperation between the dialysis facility and the hospital in the process of hospital discharge and care transition. One concern is that some hospitals may not be as cognizant of ESRD care as are dialysis facilities, and patients are sometimes discharged having received inadequate ESRD care. This would be an extension of the paradigm of measures being constructed to affect processes and encourage coordination of care, with the aim of developing a new norm. Whether or not this is a part of the measure's purpose is a policy issue.

It is clear that the very high rate of very early readmissions should be addressed in some way, and this raises the policy issue. It should also be noted that adjusting for hospital effects as

we've proposed in our measure avoids full attribution of the readmission to a dialysis facility in situations where care cannot be coordinated. Additionally, hospitals are currently held responsible for 30-day readmission rates through the Hospital Readmission Reduction Program following discharge for specific conditions. A Hospital-Wide Readmission (HWR) measure is additionally implemented in the Hospital Inpatient Quality Reporting Program (IQR) and is publicly reported on Hospital Compare.

Table 1 illustrates the change in SRR if the first three days post-discharge are dropped from the measure. The correlation between the two versions of the measure is 0.96. Table 1 also describes flagging rates for the SRR with and without readmissions over the first three days. The percentage agreement between the two versions of the measure is 97.3%. Approximately 0.8% of dialysis facilities were classified as "As Expected" when early readmissions were included and "Worse than Expected" when early readmissions were removed; 0.7% of dialysis facilities moved in the other direction. These changes are relatively small but significant for the affected facilities. In the light of these small changes and keeping simplicity of the measure in mind, we recommend including all readmissions in the measure.



Distribution of Days between Index Discharge and Readmission, 2012

|                      | Early Readinissions Excluded |                 |                      |              |
|----------------------|------------------------------|-----------------|----------------------|--------------|
|                      | Significantly worse          | Non-significant | Significantly better | Total        |
| Significantly worse  | 154 (2.7%)                   | 32 (0.6%)       | 0                    | 186 (3.2%)   |
| Non-significant      | 50 (0.9%)                    | 5370 (93.4%)    | 45 (0.8%)            | 5465 (95.0%) |
| Significantly better | 0                            | 31 (0.5%)       | 70 (1.2%)            | 101 (1.8%)   |
| Total                | 204 (3.5%)                   | 5433 (94.5%)    | 115 (2.0%)           | 5752         |

Early Boodmissions Evoluded

# Change in Dialysis Facility Categorization, when Readmissions in the First Three Days Are Excluded versus Included (2012)

3) Similar to access related infections (where the metric is all access rather than just fistulas), the number of readmissions should be based on the total number of patients, not just the number of admissions. If I have a dialysis facility with 50 patients, and there is one patient who is readmitted repeatedly and no one else is hospitalized, my performance will appear awful while, in actuality, I may be running the best unit in the country, albeit with one difficult patient. This is important as well as it seems that this denominator decision is the only reason to have both an SHR and an SRR, which are otherwise redundant in as much as facility steps to intervene are likely to affect both metrics similarly (which is the goal of the QIP). There clearly are arguments which are very valid for having both metrics and having the SRR numerator and denominator as stated currently in the MJF, but the current SRR proposed is very vulnerable to one or 2 individual patients, making it a far less robust measure of true quality.

#### **Response:**

First, the utility of the SRR depends in part on the extent to which it measures a different aspect of facility performance from the SHR. As indicated on the Measure Information (MIF), the 2009 SHR and SRR are correlated at a level of 0.53 (p < .0001), demonstrating that the measures are related but do not completely overlap. Furthermore, sensitivity analyses of the 2012 version of these measures show that dialysis facilities may be categorized differently on their performance on each of the two measures—specifically, we find that 106 facilities that perform "Worse than Expected" on the SRR measure perform "As Expected" on the SHR measure. In addition, 205 facilities that perform "As Expected" on the SRR measure perform "Worse than Expected" on the SHR measure. This means that a facility's SRR can be very high even if the facility is handling hospitalizations very well. Conversely, SHR can be high even if the facility is managing readmissions well. Together, these results emphasize that SRR and SHR are indeed separate measures of a facility's performance on patient hospital utilization.

To your second point, please note that the SRR does exclude hospitalizations for a patient after his/her 12<sup>th</sup> hospital discharge in the year.

4) I am concerned that the denominator is overly adjusted, such that you may be adjusting away what we are in fact most interested in but also, in some ways, insufficiently adjusted based on coding habits.

#### **Response:**

Our risk adjustment is intended to give a fair comparison of a given facility compared to the national level after properly adjusting for the case-mix in that facility. Thus, the adjustments were chosen to reflect important comorbidities and characteristics of patients in a given facility, and were assessed with respect to their association with the readmission outcome. We have, however, avoided conditioning on facility practices that reflect choices in care provided and that may result in better or worse outcomes. This is done to avoid adjusting away choices that may account for important differences in facility outcomes.

5) I am uncertain of the validity of the methods behind the double random effects model (stage 1) and how this is impacted by communities where there is only 1 major hospital and/or 1 major dialysis facility versus those where there are many of one or both. This is not addressed in the methods paper as best I could discern.

#### **Response:**

In our analysis, hospitals are included as random effects, and this assumption tends to smooth the effects of hospital. Thus, it is assumed that the hospital effects arise from a normal model with unspecified variance; data from a given hospital alters this prior distribution to reflect a higher or lower readmission rate. If there is only one hospital and one dialysis facility separate from the others, the hospital effect is taken to arise at random from the population of hospital effects. It is this assumption that allows the model to deal effectively with the situation where there is a single hospital associated with one dialysis facility. The issue of incentive for collaboration is not really affected by this adjustment as discussed in the sensitivity analysis. The two-stage model is a statistical method described in He at al. (2013) that overcomes some numerical problems caused by the large number of facilities and hospitals and the relatively sparse connections between them. In the first stage, both dialysis facilities and hospitals are represented as random effects, and regression adjustments are made for patient-level characteristics. From this stage, we obtain the estimated standard deviation of the random effects of hospitals. The second stage is a binary logistic mixed-effects model, in which facilities are fixed effects and hospitals are modeled as random effects with the standard deviation specified as equal to its estimate from the first stage.

In our analysis, hospitals are included as random effects, which has the effect of shrinking estimates of hospital effects toward the national mean readmission rate. This shrinkage means that there is still incentive for facilities to work with hospitals to improve readmission rates. Also, as noted above, including random effects for hospital addresses the problem of facilities that are the only major dialysis facility in the area and have only one major hospital to which its

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patients are admitted. In such a case the estimated hospital effect will borrow information from the national mean.

6) Variables included in the model reduce my confidence in validity. For example, I do not think that the BMI off of the 2728 should be used for anything as the data quality is poor and potentially uninterpretable given the heterogeneity of weight (wasting and anorexia, edema, etc...) at the time of dialysis initiation. Also, I am not sure that BMI at baseline can be reconciled with a readmission at a future time point that may be years later, even if statistically significant. Additionally, some of the results are unexpected. For example, a 75+ year-old individual fares better than a 25-45 year-old individual. Admittedly, this is a model of readmission, so there may be peculiarities (is this an example of the semi-competing risk of death?). Similarly, >6 years treated with dialysis fares better than 3-6 years, which fares worse than 1-2 years. Is there a system in place for model refinement as coding catches up with the 'risk factors'?

#### **Response:**

We appreciate your bringing this issue to our attention. We will investigate the effects of adjusting for prevalent BMI in the model, and will consider a revision to the measure depending on the results of that analysis.

7) The correlations presented in 2b2.3 on the MJF do not enhance confidence in the validity of the measure. Hospitalization is required for rehospitalization, so a poor correlation here is not possible. The correlations with access and URR are statistically significant but of very low magnitude and the correlation with the SMR also is not very impressive.

#### **Response:**

As hospitalization is a major issue in the management of ESRD patients, there is a strong case for face validity of the SRR measure. This face validity of the SRR measure is also supported by its association with other known quality measures, which include both dialysis facility outcomes and practices. When looking at 2009 data, the measure is positively correlated with the oneyear SHR for hospital admissions (r = .53, p < .0001), the one-year Standardized Mortality Ratio (r = .19, p < .0001) and the vascular access quality measure for percentage of patients with a catheter (r = .11, p < .0001). This relationship indicates that higher values of SRR are associated with increased use of catheters and higher rates of hospitalization and mortality. The SRR is negatively correlated with a quality measure of dialysis adequacy, the percentage of patients having a Urea Reduction Ratio (URR) of at least 65% (r = -.05, p = .001) and a vascular access measure, percentage of patients using a fistula (r = -.09, p < .0001). That is, higher values of SRR are associated with lower rates of URR and fistula use. The correlations with the process measures are relatively small, and another view of this can be obtained by relating the process measures to readmission at the patient level. When a catheter is present in the period preceding the index hospitalization, this is associated with a 12% increase in the odds ratio for readmission. If URR is at least 65%, this is corresponds to an increase in the odds ratio of 23%.

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Both of these effects are highly significant and give another view of the association seen at the facility level.

The correlation with the SMR is of a reasonable size and suggests that about 4% of the variation in the standardized mortality rates can be accounted for by the readmission measure; the magnitude of association with SMR is similar to associations reported by other measure developers. The overall reliability of the measure is about 56%. This can also be viewed as a measure of validity since it implies that 56% of the variation in the SRR can be attributed to underlying differences between and among the dialysis facilities.

8) The exclusion of PPS-exempt cancer hospital discharges from the denominator lacks validity, especially as these 171 discharges are above and beyond discharges for a primary diagnosis for cancer (exclusion #4). I do not see that there is a legal requirement to exclude these discharges from a metric, as the metric does not apply to the cancer hospitals but rather to dialysis facilities. I do see this as unfairly benefitting facilities that admit specifically to PPS-exempt cancer hospitals rather than cancer centers that are parts of full service institutions. This fails the smell test.

#### **Response:**

This exclusion is applied to be consistent with the existing hospital-wide all-cause unplanned readmission measure. The rationale for such an exclusion is based on clinical reasoning. Specifically, "These hospitals care for a unique population of patients that cannot reasonably be compared to the patients admitted to other hospitals." We will review the suitability of this exclusion in the light of these comments.

9) The numerator is determined by planned admissions, but uses codes from a non-ESRD population. There should be validation of these codes in the ESRD population. This may be able to be done with detailed examination of samples of patient-level data from the dry run.

#### **Response:**

We would like to clarify that the diagnosis codes we used have been consistent with CMS' existing hospital readmission measure definitions.

10) There is a very fine line here between over- and under-adjusting as you clearly do not want to adjust away the factors that are modifiable.

## **Response:**

Thanks for this comment. This has been our aim in determining adjustment factors and we appreciate suggestions we may consider for improving our approach.

11) The planned admissions list is extracted entirely from the general population. Given that we are dealing with a very specific population for this metric, although this may introduce some differences

with general population measures, I would strongly suggest aligning this list better with dialysis patients. For example, where does a PD catheter placement or omentectomy fall into this list? Vascular access creation? Transfusion for a transfusion dependent patient (which is typically done in hospitals)? I think that it is notable that, as stated in appendix B page 6 of the MIF, there was no input in development of list from people who routinely care for dialysis patients. This seems to be a direct threat to validity for an ESRD measure. That said, in looking at the detailed data for my unit, in a relatively small sample, the planned readmission was picked up appropriately.

#### **Response:**

The list of planned readmissions underwent thorough clinical review for the existing hospitalwide readmission measure, and then further review by a nephrologist.

In regards to vascular access, access procedures that are planned are much more likely to be performed in an outpatient setting rather than as a planned readmission, except during the initial access creation. This is supported by the data, which show that in 2009, 78.9% of all arteriovenous fistula (AVF), AV graft and peritoneal dialysis (PD) catheter placements among ESRD patients occurred in the outpatient setting. Among our sample of 2009 hospitalizations, only 1.9% of unplanned readmissions included such a placement. Thus, there would be no disincentives introduced for most planned access procedures.

Those access procedures performed during an inpatient hospitalization, even planned AVF creation and PD catheter placement, do not necessarily represent events that should be encouraged if, for example, they reflect poor management of an existing access. It is likely not possible to identify clinical practices and other factors that may contribute to access loss (and which, therefore, represent "poor management") from administrative data. For example, the absence of an inpatient diagnosis of an infection or other access complication may not necessarily indicate that an inpatient access placement does not result from suboptimal management of an existing access.

Access-related complications (as captured by complication of device, implant or graft) represent one of the most common causes of hospitalization among dialysis patients, and potentially one of the areas of ESRD patient care that dialysis facilities are most able to influence. A potentially important goal for a dialysis facility readmission measure is to incentivize practices that may help to avoid unnecessary inpatient hospitalizations that involve or result from dialysis access complications. In the absence of sufficient information to suggest that an inpatient access procedure is a planned event that could not have been avoided through facility management of an existing access, we recommend that readmissions involving access procedures be treated as unplanned readmissions and therefore not be excluded from the measure.

12) There needs to be clarification of how unsuccessful kidney transplants are handled in the 6 months following the transplant. My suggestion is that these should not reflect on the dialysis facility (but

rather reflect the transplant) and be excluded from the numerator and denominator. In essence, for the purposes of assignment, they are considered to have a modality of transplant rather than dialysis. In data from my unit, this made a difference, adding 3 readmissions to our numerator.

#### **Response:**

We will clarify this issue in our methods document and will share your comment with CMS. We will examine this issue further, possibly including a covariate in the model that indicates that the patient is within 6 months of a failed transplant.