Please find our responses to the Steering Committee's reasons for not endorsing 0136 heart Failure: Detailed Discharge Instructions (HF-1)

1. Evidence lacking for relationship to outcomes and continued gaps in performing this measure

Of the many potential outcomes of poorly managed heart failure patients, readmissions and death are the most costly for the heart failure patient and society. Heart failure is a major and growing public health problem in the United States that currently affects approximately 5.7 million Americans.[1] It is the leading cause of hospitalization in persons older than 65 years, and more than half of hospital inpatients older than 65 years with congestive heart failure were readmitted within 6 months of hospital discharge.[2] Although recent data would suggest that heart failure outcomes may be improving,[3] it remains a condition with serious morbidity and mortality. Indeed, despite modest declines in 30-day mortality in the US, these mortality rates remain high.[4] Furthermore, these modest declines in mortality have been accompanied by increases in readmission rates.[4] Studies have shown that educating heart failure patients on diet, weight monitoring, activity levels, discharge medications, worsening symptoms, and follow-up appointments and plans can impact readmission rates.[2,5]

We used the 2009 calendar year data set from the clinical data warehouse which can be linked to the CMS Fee-for-Service Claims database to obtain information regarding readmission. The linkage process produced a data set of 319,878 eligible patients for HF-1 from 3,256 hospitals. The 2009 data was used due to time constraints in providing a response to the NQF Steering Committee. The 2009 data set showed that the readmission rate was significantly lower among patients who fulfilled measure eligible criteria for inclusion, were alive at the time of discharge and received all six discharge instructions (26.3%), than those who failed the measure (27.4%), p-value <0.001. Further analysis, using multivariate procedures (which could control for other factors) is needed to confirm this result. These results are similar to those of VanSuch et al. in that those who received all six components of HF-1 were noted to have increased time to readmission in heart failure patients who were instructed in all six components of HF-1.[5]

We also analyzed the performance of hospitals in completion of HF-1. Although the publicly reported data shows hospital performance rates to have gradually increased over the past few years, there still remains a substantial gap in performance. Based on a preliminary analysis using the same 2009 data set as described above, a national average of 86% of eligible patients (275,817/319,878) passed our discharge instructions measure. Patients who

"passed" the measure received discharge instructions on all six components. Note that this number has slightly improved in subsequent quarters which are not analyzed here. Although this measure "pass" rate may appear relatively high, only 25% of hospitals (1 in 4 hospitals) provided instruction in all six heart failure components to 80% of their eligible heart failure patients. This estimate was based on a subset of 2,697 hospitals with a denominator of at least 25 eligible patients (we excluded hospitals with denominators less than 25 patients from this specific sub-analysis as their rates were deemed unstable). This illustrates that a considerable number of hospitals that still do not provide their patients with comprehensive written discharge instructions consistent with HF-1. Moreover, in a prior univariate analysis of 2009 data (n = 624,579 patients with documented Race, not linked to the claims data set), fewer Native Americans received instruction on all six components (76.3%) compared to the other racial/ethnic groups (Caucasian 86.3%, African-American 86.3%, Hispanic 86.6%, and Asian/Pacific Islander 87.0%), suggesting that there may be important disparities which warrant continued attention.

Finally, HF-1 continues to be part of CMS' Value Based Purchasing Program for the Inpatient Quality reporting program.

2. Literacy level is not addressed.

We acknowledge that literacy level is not measured in 0136 Heart Failure: Detailed discharge instructions. However, the unit of analysis in this measure is the hospital and not individual patient literacy of the English language, medical knowledge of the pathophysiology of heart failure, and/or health literacy (the knowledge necessary to successfully navigate a healthcare system), aspects of literacy that enable a heart failure patient to prevent exacerbations with the assistance of his/her providers. This measure assesses how successful hospitals are in educating patients on heart failure at the time of discharge. As with any new concept or lesson, repetitive instructions provide opportunities for the patients and caregivers to learn unfamiliar knowledge characteristic of a new chronic disease; this measure assesses how well hospitals engage in providing education to heart failure patients. Naylor et al. showed that comprehensive instructions and planning (e.g., diet, activity, medications, follow-up appointments, etc.) can lead to increased times to readmission when provided by Advanced Practice Nurses (APN) trained on heart failure guidelines.[6] Although this study highlights the importance of coordinating comprehensive care through APN's it also highlights the importance of the responsibility hospitals have to consistently provide comprehensive discharge instructions, an initial critical step in the continuous education of

heart failure patients. This measure is consistent with ACCF/AHA and Heart Failure Society of America clinical guidelines that strongly support the role of patient education.[7,8]

3. No assessment of whether the instructions were reviewed with the patient and that the patient had good understanding of the instructions.

We acknowledge that our measure does not specifically capture if a patient understood the contents of HF-1. As discussed above the unit of analysis is the hospital. Further, studies to assess knowledge of heart failure in heart failure patients provided verbal and written instructions, showed less than 50% of the patients who were educated on heart failure stating they knew anything about heart failure; the results suggest that despite being "educated" on heart failure, patients still did not consider themselves to have comprehensive knowledge of this subject.[9] Despite these findings in the literature, our discharge instructions measure is comprehensive, covering the most important dimensions of heart failure patient self-care that may result in improving outcomes and decreasing readmissions: activity, diet, physician follow-up, medications, weight monitoring, and what to do if heart failure symptoms worsen. To "pass" the measure chart documentation must clearly indicate the patient received written instruction that addresses ALL of these areas or the case will fail the measure. Standards are set for what content must be included (e.g., instruction to follow-up with the physician on an "as needed" basis only is not acceptable, instructions on what to if symptoms worsen must be specific to heart failure symptoms), and in the area of discharge medications the abstractor is asked to compile a list of all discharge medications for comparison against the list sent home with the patient. Documentation must clearly convey that the patient/caregiver was given a copy of the material to take home (abstractors cannot assume that a copy of a form included in the medical record was actually received by the patient, without substantiating documentation).

There are areas in our measure specifications for improvements. Clearly, the ultimate value of discharge materials is only as good as the patient's understanding of the material which can be attained, according to Stromberg, by identifying and removing barriers to learning.[9] Once barriers to learning are identified and removed confirmation of patient understanding of instruction content could be collected, and in times where the patient may be unable to provide such confirmation (e.g., mental incapacity, language barrier), confirmation from a caregiver would suffice. Criterion could be changed to require that both verbal and written instructions be given to the patient, thereby overcoming the obstacles with written discharge instructions that often come with patients handicapped in terms of literacy level, vision, ability to comprehend the written word, etc. Abstraction guidelines for follow-up instruction

could be fortified to require that follow-up instructions note the timeframe for the next appointment, to deepen patient understanding of the importance of follow-up with a physician. Use of referrals to heart failure outpatient clinic programs could be incorporated into element guidelines. Such programs offer a multidisciplinary approach and provide heart failure-specialized, quality education, often one-on-one, in order to help patients fully understand the importance of diet, medications, etc. Outpatient heart failure clinics find ways to overcome barriers to patient adherence and active participation in treatment. Studies have shown that outpatient heart failure clinics are effective in reducing the number of hospitalizations and reducing lengths of stay. All of these ideas for improvement are being considered for revision in the next CMS/TJC specifications manual (for January 2013+ discharges).

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