## **GUEST EDITORS' PAGE**









Time to Reconsider

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ver the last decade, the U.S. Centers for Medicare and Medicaid Services (CMS) has focused on several initiatives to reduce 30-day readmissions among the Medicare population. The intended objective has been to reduce health care expenditures for avoidable repeat hospitalizations under the presumption that gaps in quality of care are largely responsible for recidivist and costly care decisions. Heart failure (HF) has served as the nexus of these efforts based on its high prevalence, need for hospitalization, and costs of care among Medicare beneficiaries (1-3). Effective strategies to prevent HF readmissions have been assumed by health policy experts to be underutilized due to lack of incentives to improve quality of care. The Patient Protection and Affordable Care Act established the Hospital Readmissions Reduction Program (HRRP) with public reporting of hospital-based, 30-day, riskstandardized readmission rates and financial penalties for hospitals with higher than expected readmissions (1,2). The 30-day risk-standardized

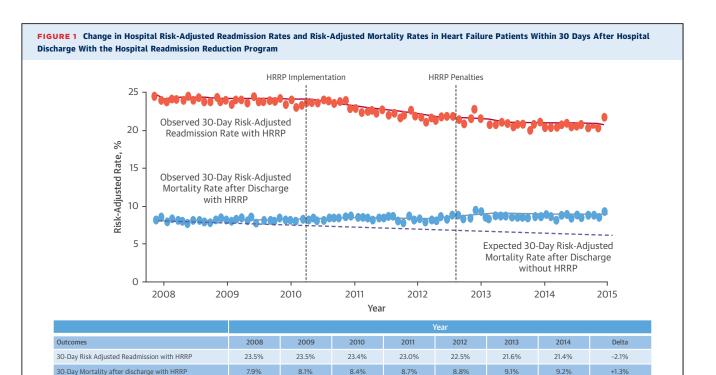
From the <sup>a</sup>Ahmanson-UCLA Cardiomyopathy Center, Ronald Reagan-UCLA Medical Center, Los Angeles, California; <sup>b</sup>Cardiovascular Center, Tufts Medical Center, Boston, Massachusetts; and the <sup>c</sup>Division of Cardiology, Northwestern University Feinberg School of Medicine, Chicago, Illinois. Dr. Fonarow has served as a consultant to Amgen, Janssen Pharmaceutical, Medtronic, Novartis, and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. readmission rate for hospitals based on claims data has been portrayed as a highly reliable and actionable measure of care quality and has been utilized as the basis for rendering financial penalties for poor outcomes (4). Hospital 30-day risk-standardized readmission data began to be reported by CMS starting in 2010. Beginning October 1, 2012, using claims data from July 2008 through June 2011, CMS levied financial penalties against hospitals, with penalties initially up to 1% of total Medicare reimbursement, rising up to 3% in subsequent years (1,2).

From inception, the HRRP has been beset with 3 predominant questions:

- 1. Is it a reliable quality metric that meets both content and face validity?
- 2. Are the penalties levied in a manner that is fair and achieves meaningful quality improvement?
- 3. Has there been unintentional harm in the deployment of this process (5-14)?

Because deaths without hospitalization favorably affect the HRRP metric, it should be considered a metric of utilization, not quality. Further, the HRRP readmission model performs poorly, with C-statistics well below acceptable discrimination standards (14). As the model is risk-adjusted based on administrative claims, concerns have been raised that it cannot adequately adjust for illness severity or medical complexity, and is subject to variation in coding (10-14). Regarding equity, academic centers

-1.3%



Linear trends in mean monthly 30-day risk-adjusted readmission rates and 30-day risk-adjusted mortality rates after discharge from hospitalization for heart failure shown for 3 periods: January 2008 through March 2010, April 2010 through September 2012, and October 2012 through December 2014. The vertical dashed lines denote April 1, 2010, to reflect the passage of the Affordable Care Act and implementation of the Hospital Readmissions Reduction Program (HRRP); and October 1, 2012, to reflect the implementation of HRRP penalties, respectively. Risk adjustment included patient age, sex, comorbidities, season, and hospital length of stay. Adapted with permission from Dharmarajan et al. (19).

7.2%

and safety-net hospitals that disproportionately take care of high-acuity patients are more likely to be affected by inadequate risk-adjustment (7-12). Evidence has emerged that readmission rates are largely driven by factors not captured or adjusted for in the model, including health literacy, race/ ethnicity, and socioeconomic status. Hospitals in lower socioeconomic regions are more likely to have higher 30-day risk-standardized rehospitalization rates irrespective of the quality of care provided (10,11).

7.9%

7.8%

30-Day Mortality after discharge without HRRF

Regarding unintended consequences, the concerns are substantial. Studies have demonstrated that 30-day readmission rates have a poor or even inverse correlation with process-based quality measures and with 30-day risk-standardized mortality rates (6,15,16). As the financial penalties were applied disproportionately on academic medical centers and safety-net hospitals, it has resulted in more barriers to provide care for vulnerable and sicker populations, depleting hospital resources available to improve care for the very populations who are at the highest risk of poor outcomes (10,11). Most worrisome is a concern that pressure to reduce readmissions may have potentially encouraged inappropriate care strategies. These may have included discouraging appropriate triage for emergency care, coercing clinicians into delaying necessary hospital readmissions beyond discharge day 30, and increasing the use of observation stays without admitting patients, even when admission was clinically indicated (13). There is a concern that well-intentioned metric-focused clinicians might have avoided initiating therapies known to improve intermediate- and long-term outcomes based on a misperception those therapies may threaten short-term stability (13). At the system level, hospitals have clearly focused resources on the 30-day readmission measure, but this may detract from meaningful HF quality-improvement efforts and considerations of patient safety and access to care. Such paradoxical and potentially detrimental clinician and health system behavior in the face of the

6.7%

artificial short-term goal of cost saving coupled with strong financial disincentives is disconcerting (6,13,15,16).

Recent publications have reported that the HRRP has been successful in reducing 30-day readmission rates (17,18). Representatives from CMS have stated that payment reforms aimed at reducing avoidable readmissions have had a measurable effect on provider behavior and have resulted in improved care. Yet, these studies have focused only on temporal changes in readmission rates without assessments for any unintended consequences, which would be critical before reaching any conclusions. A new analysis, which included Medicare beneficiaries hospitalized with HF along with other conditions covered by the HRRP from 2008 to 2014, reported that reductions in hospital 30-day readmissions were weakly but statistically significantly correlated with reductions in 30-day mortality rates after discharge (19). This would be reassuring and validating if it is fully credible. However, as the potential effect of HRRP goes beyond hospitals where readmissions may have fallen, the assessment for unintended consequences needs to consider the effect on all patients and all hospitals exposed to the policy. The other side of the statistical correlation reported is that hospitals with no change or increasing 30-day readmissions rates, and thus facing greater HRRP financial penalties, had increases in 30-day post-discharge mortality. Moreover, with HRRP implementation nationally, 30-day risk-adjusted post-discharge mortality in Medicare beneficiaries hospitalized with HF increased from 7.9% in 2008 to 9.2% in 2014 (19). This represents a 1.3% absolute increase and 16.5% relative increase in 30-day risk-adjusted mortality (Figure 1). In the decade prior to HRRP, 30-day riskadjusted mortality rates in HF patients had steadily decreased by 16.4% (20). Had 30-day mortality continued to decline at the same rates as observed prior to HRRP, mortality could have been expected to be 33% lower for HF patients than what was actually observed. The potential adverse effect of HRRP implementation was not just confined to the first 30 days post-discharge, as there were also temporal increases in 90-day post-discharge mortality for HF patients (19).

These changes in HF mortality cannot be dismissed as slight or due to a change in comorbidities (which were not fully captured in a weak risk adjustment model) (19). It is interesting that the declines in 30-day readmission after HRRP

implementation are accepted as evidence of the success of the program, but the reversal in more than a decade of declines in 30-day mortality for HF is dismissed. Furthermore, the HRRP has created additional financial incentives for hospitals to document more comorbid conditions and greater complexity (up-coding), which is further facilitated by electronic health records, to improve riskadjusted rates (21). Thus, it is also possible that this strategy has artificially made the reductions in risk-standardized 30-day readmission appear greater than they actually were and has artificially underestimated the increases in risk-adjusted mortality for HF that may have occurred. To evaluate whether temporal shifts in administrative coding or medical complexity of patients hospitalized with HF may be contributing to these findings, studies utilizing actual clinical, vital sign, and laboratory data must be performed.

Even without accounting for the previously declining mortality trends and the potential effect of coding, in 2014 alone, an estimated 5,008 excess HF patient deaths were associated with HRRP implementation (compared with risk-adjusted 30-day mortality rates, which remained at 2008 pre-HRRP levels). We cannot fully assign causation to the HRRP, but given the number of patients potentially affected, this is anything but a slight increase in mortality. No level of reduction in readmissions or cost savings should be considered adequate justification for this level of potential harm. Rather than providing any measure of reassurance, available evidence suggests that the HRRP policies targeting readmissions after HF hospitalization were associated with the serious unintended consequence of higher mortality. We acknowledge that these assertions are not yet fully proven, but the logic upon which these concerns are based is at least as cogent as that upon which the HRRP was launched. Our concerns, if corroborated, should prompt immediate consideration for reassessment and revision of the HRRP. If harm has been the consequence of the HRRP, we are obliged to exercise appropriate due diligence. Primum non nocere.

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