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IMPROVING PATIENT SAFETY THROUGH POLICY: IS PAYMENT REFORM UP TO THE TASK?

Andrew M. Ryan*

I. THE SCOURGE OF HOSPITAL ACQUIRED CONDITIONS

Hospital acquired conditions (HACs) are adverse events experienced by patients as a result of the care they receive. HACs lead to substantial patient harm and health system spending. For example, postoperative venous thromboembolism, ventilator-associated pneumonia, and central line-associated bloodstream infections (CLABSI) increase the probability of inpatient mortality by 10.4%, 14.4%, and 18.5% and are associated with increases in spending of \$8,000, \$21,000, and \$17,000 per hospitalization, respectively.¹ Together, HACs contribute to more than 90,000 deaths² annually and annual spending in excess of \$30 billion.³

II. USING PAYMENT REFORM TO IMPROVE QUALITY

Evidence of the societal burden of HACs ignited the quality movement in health care.⁴ Two key reports from the Institute of Medicine—*To Err is Human*⁵ and *Crossing the Quality Chasm*⁶—addressed medical errors and shortcomings in patient safety as systematic problems in U.S. health care. Quality improvement interventions,

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1. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, PUB. NO. 16-0006-EF, 2013 ANNUAL HOSPITAL-ACQUIRED CONDITION RATE AND ESTIMATES OF COST SAVINGS AND DEATHS AVERTED FROM 2010 TO 2013 5 (Oct. 2015), https://www.ahrq.gov/sites/default/files/publications/files/hacrate2013_0.pdf.

2. R. Monina Klevens et al., *Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002*, 122 PUB. HEALTH REP. 160, 160 (2007).

3. R. DOUGLAS SCOTT II, THE DIRECT MEDICAL COSTS OF HEALTHCARE-ASSOCIATED INFECTIONS IN U.S. HOSPITALS AND THE BENEFITS OF PREVENTION 1, 7–8 (Mar. 2009), https://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf.

4. Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851, 1855, 1857 (1994).

5. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 3–4 (Linda T. Kohn et al. eds., 2000).

6. COMM. ON QUALITY HEALTH CARE IN AM., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 2–4 (2001).

such as the Michigan Keystone Initiative⁷ and efforts from the Institute for Healthcare Improvement,⁸ were launched to combat these widespread shortcomings. However, until recently, few policy initiatives have specifically targeted HAC reduction. This changed as a result of two key developments. First, advances in data storage and computing allowed researchers to move beyond primary data collection and single-site studies to leverage massive administrative claims data to evaluate quality performance across hospitals.⁹ This in turn allowed policymakers to create new programs measuring and profiling the relative quality of hospitals. Second, researchers developed measures of HACs that could be calculated using administrative claims.¹⁰ While the use of claims-based measures of HACs remains controversial, their development paved the way for policies that employ hospital-level profiling of patient safety.

Once hospital quality performance could be profiled, payers could begin to link reimbursement to quality through new programs. Financial incentives to improve health outcomes and reduce spending growth (known as value-based payments) have been applied widely in the hospital setting. Nonetheless, how these programs can be designed to improve care remains unclear.¹¹ Early results from the Hospital Quality Incentive Demonstration—Medicare’s first experience tying hospital quality performance with reimbursement—suggested that modest financial incentives for clinical process measures could improve quality of care.¹² Subsequent research, however, challenged whether these improvements translated into improvements in patient outcomes and reductions in spending.¹³ More recent evidence indicates that Hospital Value-Based Purchasing, the first nationwide value-based payment program initiated by the Centers for Medicare

7. Peter Pronovost et al., *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU*, 355 *NEW ENG. J. MED.* 2725, 2726 (2006).

8. *Healthcare-Associated Infections*, INST. FOR HEALTHCARE IMPROVEMENT, <http://www.ihl.org/explore/HAI/Pages/default.aspx> (last visited Oct. 29, 2018).

9. Gary I. Cohen & Gabrielle Rocque, *Measuring Quality of Care: Past, Present, and Future*, *ASCO DAILY NEWS* (May 26, 2016), <https://am.asco.org/daily-news/measuring-quality-care-past-present-and-future>.

10. See generally Lisa I. Iezzoni, *Assessing Quality Using Administrative Data*, 127 *ANNALS INTERNAL MED.* 666 (1997).

11. Andrew M. Ryan & Cheryl L. Damberg, *What Can the Past of Pay-for-Performance Tell Us About the Future of Value-Based Purchasing in Medicare?*, 1 *HEALTHCARE* 42, 43 (2013).

12. Peter K. Lindenauer et al., *Public Reporting and Pay for Performance in Hospital Quality Improvement*, 356 *NEW ENG. J. MED.* 486, 487 (2007).

13. Andrew M. Ryan, *Effects of the Premier Hospital Quality Incentive Demonstration on Medicare Patient Mortality and Cost*, 44 *HEALTH SERVS. RES.* 821, 822 (2009); Ashish K. Jha et al., *The Long-Term Effect of Premier Pay for Performance on Patient Outcomes*, 366 *NEW ENG. J. MED.* 1606, 1607 (2012).

and Medicaid Services (CMS), did not document, track, or report process, patient experience, or mortality over the short term or long term.¹⁴ However, evidence from the Hospital Readmission Reduction Program (HRRP)—which penalized hospitals with high rates of readmission within 30 days for discharge—suggests that the program has worked to reduce readmissions.¹⁵

Given the lackluster results from other value-based payment programs, the apparent success of the HRRP is an important policy development. It suggests that, if designed appropriately, national payment reform can improve quality of care. The HRRP appeared to succeed while other programs failed due to a larger financial incentive, a simpler incentive design, and a penalty-based design.¹⁶ Together, this evidence suggests that while financial incentive programs do not always work, well-designed incentive programs have the potential to improve patient and system outcomes.

III. FINANCIAL INCENTIVES AND HOSPITAL ACQUIRED CONDITIONS

The first major policy effort to reduce HACs came in 2008, when CMS ceased paying hospitals for the incremental costs of treating certain HACs. The program initially targeted “never events,” including foreign objects left in patients after surgery, Stage 3 or 4 pressure ulcers after admission, and death or disability associated with intravascular air embolism.¹⁷ It then expanded to include additional conditions, including catheter-associated urinary tract infection (CAUTI), manifestations of poor glycemic control, falls, trauma, and surgical-site infections after certain procedures.¹⁸ This program relied on claims submitted to CMS by hospitals to identify the presence of HACs.

Overall, it is unclear whether this program has improved patient safety. One evaluation found that the program was associated with

14. Andrew M. Ryan et al., *Changes in Hospital Quality Associated with Hospital Value-Based Purchasing*, 376 *NEW ENG. J. MED.* 2358, 2359 (2017) (discussing the long term); Andrew M. Ryan et al., *The Early Effects of Medicare’s Mandatory Hospital Pay-for-Performance Program*, 50 *HEALTH SERVS. RES.* 81, 84 (2015) (discussing the short term).

15. Rachael B. Zuckerman et al., *Readmissions, Observation, and the Hospital Readmissions Reduction Program*, 374 *NEW ENG. J. MED.* 1543, 1551 (2016).

16. Tim Doran et al., *Impact of Provider Incentives on Quality and Value of Health Care*, 38 *ANN. REV. PUB. HEALTH* 449, 460 (2016).

17. Grace M. Lee et al., *Effect of Nonpayment for Preventable Infections in U.S. Hospitals*, 367 *NEW ENG. J. MED.* 1428, 1429 (2012).

18. Sanjay Saint et al., *Catheter-Associated Urinary Tract Infection and the Medicare Rule Changes*, 150 *ANNALS INTERNAL MED.* 877, 879 (2009).

reductions in CLABSI and CAUTI, but not with reductions in injurious falls, or pressure ulcers.¹⁹ Another evaluation found no impact of the program on CLABSI, CAUTI, or ventilator-associated pneumonia.²⁰ The researchers posited that, among other challenges, incentives in the program may not have been sufficiently large to motivate behavior change.²¹ Taken together, research suggests that the incentives embodied in the CMS non-payment for HAC policies were not sufficient to substantially improve patient safety.

The Hospital Acquired Condition Reduction Program (HACRP) was created by the Patient Protection and Affordable Care Act (ACA) to enhance the pressure on hospitals to reduce HACs. The statute that created the program—specified in Section 3008 of the ACA—was quite vague, assigning the Department of Health and Human Services the responsibility for determining features of the program, which would begin no later than fiscal year (FY) 2015.²² The program regulations were ultimately codified under the FY 2014 final rule for the Inpatient Prospective Payment System.²³ Under this rule, starting in 2015, acute care hospitals in the worst quartile of HAC rates have been penalized 1% of Medicare payments.²⁴ The HACRP profiles HAC rates using two domains: Domain 1 is the PSI-90 composite, and Domain 2 is the Healthcare-Associated Infections tracking system provided by the Centers for Disease Control and Prevention's National Healthcare Safety Network.²⁵ In FY 2015, Domain 2 measures included CLABSI and CAUTI measures. The two domains are assigned points and combined using a weighted average. In FY 2015, Domain 1 received 35% of the weight and Domain 2 received 65%. Over time, Domain 2 will receive a larger relative weight.

19. Teresa M. Waters et al., *Effect of Medicare's Nonpayment for Hospital-Acquired Conditions: Lessons for Future Policy*, 175 JAMA INTERNAL MED. 347, 350 (2015).

20. See Lee et al., *supra* note 17, at 1435.

21. *Id.*

22. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18001).

23. Hospital Inpatient Prospective Payment Systems, 78 Fed. Reg. 50495, 50496 (Aug. 19, 2013) (to be codified at 42 C.F.R. pts. 412, 413, 414, 419, 424, 482, 485, and 489).

24. Amanda Cassidy, *Medicare's Hospital-Acquired Condition Reduction Program*, HEALTH AFF. HEALTH POL'Y BRIEF (Aug. 6, 2015), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=142.

25. See *id.* "PSI-90 composite" is the shortened name for the Patient Safety of Selected Indicators Composite created by the Agency for Healthcare Research and Quality. *PSI 90 Fact Sheet*, AGENCY FOR HEALTHCARE RES. & QUALITY, https://www.qualityindicators.ahrq.gov/news/psi90_factsheet_faq.pdf (last updated Aug. 31, 2016). The name of the composite has since been modified to the Patient Safety and Adverse Events Composite because the composite now accounts for "patient harm resulting from a patient safety event." *Id.*

The design of the HACRP is more similar to the HRRP than to Hospital Value-Based Purchasing: it is penalty-based, and the performance criteria are based on absolute levels of performance for a relatively narrow set of measures. As a result, there is some reason for optimism that the HACRP may also improve care, reducing HACs and improving patient safety. Nonetheless, there are a number of controversies and challenges surrounding the program that have the potential to undermine its impact on patient safety.

IV. MEASURING HOSPITAL ACQUIRED CONDITIONS USING ADMINISTRATIVE DATA IS FRAUGHT WITH CHALLENGES

A key difference between a hospital readmission and an HAC is observability. Notwithstanding some controversy about hospitals' use of "observation" as a substitute for an inpatient admission,²⁶ the presence of a readmission within thirty days of discharge from a prior admission is exceedingly clear to both patients and to CMS. The same is not true for an HAC. HACs, by definition, occur as a result of care received during a hospitalization. They typically will not be the main reason why a patient was admitted to the hospital. Consequently, they will rarely be the principal diagnosis for the admission. Instead, HACs are typically determined on the basis of secondary diagnoses. Because principal diagnoses determine payment, through classification into Diagnosis Related Groups (DRGs), hospitals and CMS pay close attention to how principal diagnoses are coded. While used to classify patients into a higher severity level (based on the MS-DRG classification),²⁷ secondary diagnoses are less central to hospital payment. As a result, the information contained in secondary diagnoses has traditionally been less complete and less reliable.

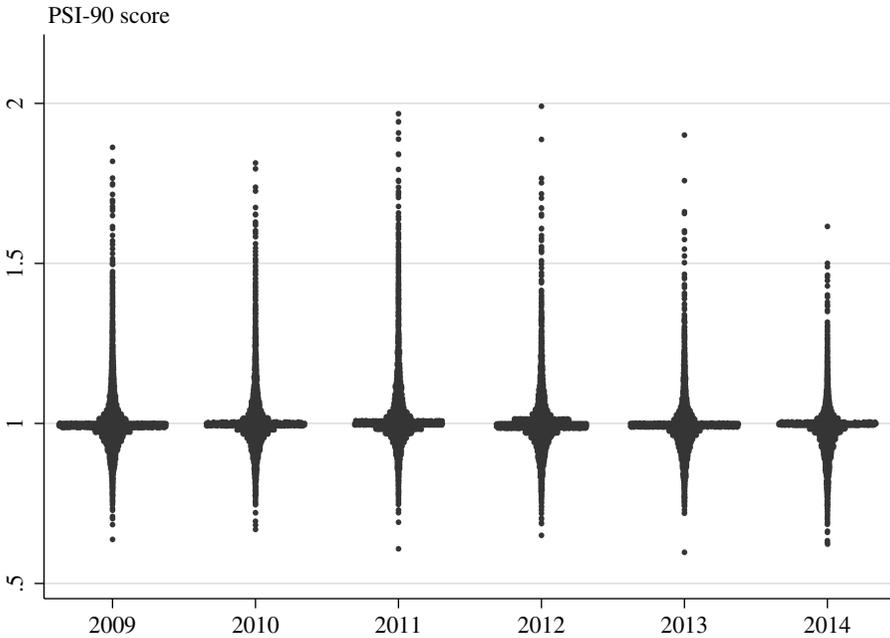
From the perspective of measuring HACs, this creates two problems. First, because secondary diagnoses are not coded as diligently, a patient could experience an HAC that does not make it onto the claim sent by hospitals to CMS. Second, comorbidities that are coded as secondary diagnoses may either be a result of care received in the hospital (an HAC) or may instead be "present on admission"

26. See Zuckerman et al., *supra* note 15, at 1544; Amber K. Sabbatini & Brad Wright, *Excluding Observation Stays from Readmission Rates—What Quality Measures Are Missing*, 378 *NEW ENG. J. MED.* 2062, 2062 (2018).

27. The MS-DRG classification system is used by CMS to group patients into groups of diagnoses, adjusted by severity, which is then used to pay hospitals under the Inpatient Prospective Payment System. For instance, hip replacement or joint replacement without a major condition category (i.e., a lower severity case) would be classified to MS-DRG 470, while joint replacement with a major condition category (i.e., a higher severity case) would be classified to MS-DRG 469.

when a patient arrives at the hospital. Until recently, there was no way to distinguish between these possibilities. To address this issue, beginning in FY 2008, CMS required hospitals to document whether each secondary diagnosis was present-on-admission. These present-on-admission indicators have helped, but not fully addressed challenges measuring HACs.²⁸

FIGURE 1. VARIATION IN PSI-90 SCORES



Source: Authors' analysis of MedPAR claims, 2009-2014

Despite the challenges associated with measuring HACs using claims, efforts to profile and reward hospital performance on HACs have continued. The AHRQ PSI, and the composite measure PSI-90, represent the state of the art in HAC measurement. The PSI-90 includes the HACs that are most reliably identified in claims. Version 5.0 of the PSI-90 includes CLABSI, pressure ulcer, iatrogenic pneumothorax, postoperative hip fracture, pulmonary embolism or deep

28. Hamsa Bastani et al., *Evidence of Upcoding in Pay-for-Performance Programs 2* (July 13, 2015) (Research Paper) (on file with Stanford University Graduate School of Business), <https://www.gsb.stanford.edu/faculty-research/publications/evidence-upcoding-pay-performance-programs>; Margriet Fokkema et al., *The Impact of the Present on Admission Indicator on the Accuracy of Administrative Data for Carotid Endarterectomy and Stenting*, 58 J. VASCULAR SURGERY 32, 35-37 (2014).

vein thrombosis, postoperative sepsis, postoperative wound dehiscence, or accidental puncture or laceration. To arrive at a hospital-level metric, these measures are risk- and reliability-adjusted and weighted based on the frequency with which these HACs occur.²⁹ Version 6 of the PSI-90 introduced three new measures (perioperative hemorrhage or hematoma, postoperative acute kidney injury, and postoperative respiratory failure), eliminated one measure (CLABSI), and re-weighted the indicators based on their relative harm.³⁰ Figure 1 shows a “turnip plot” hospital-level distribution of performance on the PSI-90 between 2009 and 2014. Substantial variation in hospital performance over time on the PSI-90 suggests possible improvement for many hospitals.

Despite the technical sophistication of the PSI-90, many have criticized the validity of the measure.³¹ Underlying these critiques is the insight that claims are particularly ill-suited to identify the clinically complicated and often ambiguous HACs.³² The greater nuance in the ICD-10 classification may help to alleviate some of these challenges, but it is too early to tell.³³

Perhaps recognizing this, hospital performance on the PSI-90 received a weight of only 35% in the first year of the HACRP and is scheduled to decline further. Instead, the Centers for Disease Control and Prevention’s National Healthcare Safety Network Healthcare-Associated Infection measures are weighted more heavily in the program. Instead of being calculated through claims, these measures require hospitals to document the presence of specific HACs within a separate data-entry platform. While this system allows for more clinical nuance, it is subject to many concerns raised about the PSI-90.³⁴ For instance, hospitals often considered to have the highest technical quality (i.e., academic medical centers and those engaged in

29. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, PUB. NO. 15-M053-4-EF, *PATIENT SAFETY INDICATORS* (2015), https://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/PSI_Brochure.pdf.

30. *PSI 90 Fact Sheet*, *supra* note 25.

31. Bradford D. Winters et al., *Validity of the Agency for Health Care Research and Quality Patient Safety Indicators and the Centers for Medicare and Medicaid Hospital-Acquired Conditions: A Systematic Review and Meta-Analysis*, 54 *MED. CARE* 1105, 1105 (2016).

32. Jennifer A. Meddings et al., *Hospital Report Cards for Hospital-Acquired Pressure Ulcers: How Good Are the Grades?*, 159 *ANNALS INTERNAL MED.* 505, 508, 512 (2013).

33. Amy K. Rosen et al., *Using Estimated True Safety Event Rates Versus Flagged Safety Event Rates: Does It Change Hospital Profiling and Payment?*, 49 *HEALTH SERVS. RES.* 1426, 1439 (2014). ICD-10 is the 10th revision of the International Statistical Classification of Diseases. Beginning in October 2015, CMS has used the ICD-10 for documentation related to all claims.

34. Keith F. Woeltje et al., *Data Requirements for Electronic Surveillance of Healthcare-Associated Infections*, 35 *INFECTION CONTROL HOSP. EPIDEMIOLOGY* 1083, 1085 (2014).

quality improvement initiatives) have been more likely to perform poorly on these measures.³⁵ In addition, the extremely low event rates for the CLABSI and CAUTI outcomes suggest that these measures have limited ability to discriminate across hospitals. A single CLABSI or CAUTI frequently pushes hospitals into the penalty range under the HACRP.³⁶

V. MEASUREMENT ISSUES IN THE HOSPITAL ACQUIRED
CONDITION REDUCTION PROGRAM MAY LEAD TO
HETEROGENEITY IN HOSPITALS' RESPONSES

Under the HACRP, hospitals have the opportunity to improve measured performance through both clinical and administrative activities. For instance, Sanjay Saint et al. identified a number of specific clinical improvements that hospitals could employ to reduce urinary tract infections. These include using indwelling urinary catheters only when medically indicated; inserting and maintaining indwelling catheters using the proper technique; developing systems to encourage the removal of catheters when they are no longer indicated and educating clinicians about the appropriate use and interpretation of urinalysis and urine culture.³⁷ Related strategies, such as improving hand hygiene, performing subclavian vein insertion, and reducing non-essential central venous catheters, have been developed to reduce CLABSI.³⁸

However, hospitals also have the potential to improve measured performance through narrowly focusing on administrative activities to improve performance and avoid penalties under the program. This includes increases in coding comorbidities as “present on admission” and an overall increase in coded severity to make patient populations look sicker under risk-adjustment. Recent evidence suggests that improvement in pneumonia mortality is due in large part to re-classifying index admissions.³⁹ Increases in hospitals' coding of patient severity is also responsible for much of the improvement observed

35. Ravi Rajaram et al., *Hospital Characteristics Associated with Penalties in the Centers for Medicare & Medicaid Services Hospital-Acquired Condition Reduction Program*, 314 JAMA 375, 375–77 (2015).

36. Richard L. Fuller et al., *Is the CMS Hospital-Acquired Condition Reduction Program a Valid Measure of Hospital Performance?*, 32 AM. J. MED. QUALITY 254, 254 (2017).

37. See Saint et al., *supra* note 18, at 878.

38. Elizabeth Pfoh et al., *Interventions to Improve Hand Hygiene Compliance: Brief Update Review*, in RAND CORP., AHRQ PUB. NO. 13-E001-EF, MAKING HEALTH CARE SAFER II: AN UPDATED CRITICAL ANALYSIS OF THE EVIDENCE FOR PATIENT SAFETY PRACTICES 67 (2013).

39. Michael W. Sjoding et al., *Gaming Hospital-Level Pneumonia 30-Day Mortality and Readmission Measures by Legitimate Changes to Diagnostic Coding*, 43 CRITICAL CARE MED. 989, 994 (2015).

under the HRRP.⁴⁰ Together, this suggests that hospitals may engage in improvements in clinical care along with administrative changes in response to incentive programs such as the HACRP, resulting in different implications for patient and system outcomes.

VI. EVOLUTION OF POLICY THROUGH CONTINUED RULEMAKING

Whatever limitations may be present in HACRP as currently constituted, policy can evolve to address them. Both Hospital Value-Based Purchasing and the Hospital Readmission Reduction Program have undergone substantial revision in subsequent rule-making for the Inpatient Prospective Payment System. Only by acquiring more evidence can we understand the conditions under which financial incentives will improve quality and spending. Ultimately, the success of the HACRP will be tied to the ability to accurately and effectively measure HACs while minimizing gaming and unintended consequences. Without achieving this balance, the HACRP is unlikely to substantially improve patient safety.

40. Andrew M. Ibrahim et al., *Association of Coded Severity with Readmission Reduction After the Hospital Readmissions Reduction Program*, 178 JAMA INTERNAL MED. 290, 291 (2018).

