Conflict of Interest Disclosures: None reported.

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Editor’s Note
Risks Associated With Catheters
When I was an intern, we frequently placed urinary catheters in hospitalized patients. For some diagnoses, like congestive heart failure, we believed placement of a urinary catheter was almost mandatory to accurately measure fluid output during diuresis. We were well meaning and thought more monitoring of intake and output meant better care. The problem was that we focused more on getting information than how it actually added value to our clinical assessment, and we did not consider the possible and likely complications of catheter placement. In most cases, the risks of catheter placement outweigh any possible benefits.

We are familiar with the dramatically increased risk of infection in patients with urinary catheters. But their immobilizing effects are equally serious. Saint et al1 has described the urinary catheter as a 1-point restraint that renders the hospital patient bedbound. Hospital immobility leads to more weakness and hospital-acquired disability, a syndrome in which older patients leave the hospital with new and often permanent disabilities in their basic activities of daily living, even when their medical diagnoses are successfully treated. This disability renders patients in need of institutional long-term care or care by family or friends. There is emerging evidence that the urinary catheter is an instigator of hospital-acquired disability.2

It is best to avoid placing urinary catheters. However, when catheters are placed, Leis et al3 describe a pragmatic and innovative approach to help us remove them as expeditiously as possible. By empowering nurses to remove urinary catheters that are no longer needed, they were able to markedly reduce the number of days patient spent with these catheters. This is a promising innovation. We need more team-based interventions that improve patient care and safety.

Kenneth E. Covinsky, MD

Conflict of Interest Disclosures: None reported.


HEALTH CARE REFORM
Changes in Discharge Location and Readmission Rates Under Medicare Bundled Payment
Patients are often referred for postacute care after hospitalization to improve outcomes and reduce readmissions. The use of postacute care has grown rapidly, with costs doubling since 2001.1,2 Although such care can take place at home, skilled nursing facilities, or inpatient rehabilitation facilities, facility-based care is more expensive,3,4 but whether it is more effective remains unknown.

In 2013, NYU Langone Medical Center (NYULMC) joined the national Bundled Payment for Care Improvement (BPCI) model for patients with Medicare fee-for-service insurance undergoing cardiac valve replacement, major joint replacement in the lower extremities, or spinal fusion.5 The BPCI model held NYULMC accountable for costs incurred from the index admission to 90 days after discharge. To control these costs, NYULMC attempted to shift referrals from facility-based to home-based postacute care. In the context of this shift in referrals, we examined the change in hospital readmission rates.

Methods | We used complete claims data provided by Medicare. We divided the study period into 3 phases. Medicare provided baseline data from July 1, 2009, through May 30, 2012, for 3070 patients. Because of superstorm Sandy, NYULMC was closed from October 29 through December 27, 2012. From January 1 through September 30, 2013, NYULMC began preparations for BPCI, but cost incentives were not in effect (preparation period). From October 1, 2013, through August 31, 2014, cost incentives took effect (risk-bearing period) (1594 patients). Inclusion criteria were determined by the BPCI model. This study was approved by the institutional review board of the NYULMC; the institutional review board of the NYU School of Medicine waived the need for patient authorization and consent.

Data were assessed from July 1, 2009, to December 31, 2014. For each condition, we examined whether the risk-bearing period was associated with discharge to postacute care in a facility. We also examined whether the BPCI period was associated with 30-day readmission for each condition. For all models, we used generalized estimating equations, controlled for age, race, sex, and major complications or comor-
### Table. Characteristics of Bundled Payment for Care Improvement Episodes by Surgical Procedure

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study Period&lt;sup&gt;a&lt;/sup&gt;</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline</td>
<td>Risk-Bearing</td>
<td>P Value</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Cardiac valve surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of episodes</td>
<td>644</td>
<td>342</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>317 (49.2)</td>
<td>156 (45.6)</td>
<td>.28</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>78.1 (8.4)</td>
<td>76.9 (8.2)</td>
<td>.02</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRG with MCC, No. (%)</td>
<td>415 (64.4)</td>
<td>175 (51.2)</td>
<td>&lt;.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major joint replacement in the lower extremities</td>
<td>1908</td>
<td>1024</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of episodes</td>
<td>1286 (67.4)</td>
<td>671 (65.5)</td>
<td>.30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>74.7 (8.9)</td>
<td>72.1 (8.6)</td>
<td>&lt;.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRG with MCC, No. (%)</td>
<td>120 (6.3)</td>
<td>38 (3.7)</td>
<td>.004</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinal fusion</td>
<td>518</td>
<td>228</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of episodes</td>
<td>300 (57.9)</td>
<td>134 (58.8)</td>
<td>.83</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>73.1 (9.0)</td>
<td>70.7 (9.3)</td>
<td>.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>35 (6.8)</td>
<td>16 (7.0)</td>
<td>.90</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DRG, diagnosis related group; MCC, major complication or comorbidity.

<sup>a</sup> Described in the Methods section.

### Figure. Change in Proportions of Patients Discharged to Postacute Care Facilities

Patients are grouped by surgical procedure. Q indicates quarter.
bidity (as determined by a principal diagnosis related group) during the index admission, with clustering at the physician level.

Results | Patient characteristics appear in the Table. Discharge rates to postacute care facilities fell from 454 of 644 patients (70.5%) in the baseline period to 72 of 342 patients (21.1%) in the risk-bearing period (adjusted odds ratio [AOR], 0.11; 95% CI, 0.08-0.15) for cardiac valve surgery, from 1289 of 1908 patients (67.6%) to 343 of 1024 patients (33.5%) (AOR, 0.26; 95% CI, 0.22-0.31) for major joint replacement in the lower extremities, and from 209 of 518 patients (40.3%) to 68 of 228 patients (29.8%) (AOR, 0.69; 95% CI, 0.48-0.97) for spinal fusion surgery (Figure). In these same cohorts, readmission rates were unchanged in patients undergoing cardiac valve surgery (117 [18.2%] vs 54 [15.8%]; AOR, 0.93; 95% CI, 0.67-1.31; P = .69), significantly decreased in patients undergoing joint replacement (152 [8.0%] vs 51 [5.0%]; AOR, 0.66; 95% CI, 0.47-0.92; P = .01), and unchanged in patients undergoing spinal fusion (51 [9.8%] vs 26 [11.4%]; AOR, 1.19; 95% CI, 0.71-1.99; P = .50). Mean length of stay decreased for all conditions from baseline to the risk-bearing period.

Discussion | We achieved absolute 49% and 34% reductions in rates of discharge to postacute care facilities among patients undergoing cardiac valve surgery and major joint replacement in the lower extremities, respectively, with no corresponding increase in readmission rates. Readmission rates were similarly stable in patients undergoing spinal fusion, for whom rates of admission to postacute care facilities were unchanged.

Our findings suggest that institutions may be able to shift some patients from facility-based to home-based postacute care without adversely affecting hospital readmission rates or the length of hospital stay. Although we did not investigate the mechanism for the major decrease in rates of referral to facility-based postacute care, the inpatient rehabilitation facility owned by NYULMC closed during the risk-bearing period. Such a dramatic decrease may not have occurred without the change in availability of inpatient beds.

A limitation of the study is that we did not examine outcomes such as functional status or quality of life, which merit further investigation. An additional limitation is that the disease burden in the population may have changed during the study period, although we adjusted for the presence of major complications or comorbidities. Our findings raise questions about the value of providing postacute care services in facilities where care is more costly and potentially more disruptive to the lives of patients and families.

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Author Contributions: Ms Chung had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Jubelt, Goldfeld, Horwitz.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Jubelt.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Jubelt, Goldfeld, Chung.
Administrative, technical, or material support: Jubelt, Chung, Horwitz.
Study supervision: Blecker, Horwitz.
Conflict of Interest Disclosures: Dr Horwitz reports receiving funding from the Centers for Medicare & Medicaid Services (CMS) to develop and maintain quality measures. No other disclosures were reported.

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Association of Postdischarge Spending and Performance on New Episode-Based Spending Measure

The Centers for Medicare & Medicaid Services (CMS) is incentivizing hospitals to provide high-quality, low-cost care. As part of these efforts, CMS recently added the Medicare Spending per Beneficiary (MSPB) metric to its Hospital Value-Based Purchasing (HVBP) program, marking the first time that most US hospitals have received financial penalties or rewards based on their performance on a risk-adjusted, price-standardized 30-day episode-based measure of Medicare spending along with quality measures. The factors that influence or determine hospital performance in this metric have not yet been thoroughly investigated. We evaluated whether hospital performance was driven by spending before, during, or after hospitalization.

Methods | We determined hospital performance on the MSPB measure in fiscal year (FY) 2014 and 2015, using publicly available data on CMS’s Hospital Compare. The MSPB metric is...
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Abbreviations: HVBP, hospital value-based purchasing; MSPB, Medicare Spending per Beneficiary; SNF, skilled nursing facility.

* Low Cost indicates the MSPB score is equal to or lower than the mean of hospital scores in the first decile. Medium Cost indicates that the MSPB score is less than or equal to the 50th percentile of scores and greater than the mean of scores in the first decile. High Cost indicates that the MSPB scores are greater than the 50th percentile. Other includes spending in carrier costs, home health agency, outpatient, hospice, and durable medical equipment.

Fiscal Year 2015 HVBP uses MSPB performance data from Calendar Year 2013. P values are from t tests comparing the average spending levels between high- and low-cost hospitals. P < .001 for all comparisons.

Table. Components of Unadjusted Total Episode Payments, by MSPB Category in Fiscal Year 2015 HVBP

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>MSPB Category, $ (%)</th>
<th>Medium Cost (n = 1630)</th>
<th>High Cost (n = 1429)</th>
<th>Difference (High Minus Low)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low Cost (n = 132)</td>
<td>0.51-0.84</td>
<td>0.85-0.99</td>
<td>1.00-2.13</td>
</tr>
<tr>
<td>Preadmission</td>
<td>372 (3)</td>
<td>547 (3)</td>
<td>615 (3)</td>
<td>243</td>
</tr>
<tr>
<td>Index admission</td>
<td>7556 (60)</td>
<td>9618 (55)</td>
<td>10 006 (50)</td>
<td>2450</td>
</tr>
<tr>
<td>Postdischarge care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNF</td>
<td>1485 (11)</td>
<td>2824 (17)</td>
<td>3473 (18)</td>
<td>1988</td>
</tr>
<tr>
<td>Readmission</td>
<td>1325 (11)</td>
<td>1931 (11)</td>
<td>2995 (15)</td>
<td>1670</td>
</tr>
<tr>
<td>Other</td>
<td>1786 (15)</td>
<td>2345 (14)</td>
<td>2819 (14)</td>
<td>1033</td>
</tr>
<tr>
<td>Subtotal</td>
<td>4596 (37)</td>
<td>7100 (42)</td>
<td>9287 (47)</td>
<td>4691</td>
</tr>
<tr>
<td>Total</td>
<td>12 523 (100)</td>
<td>17 265 (100)</td>
<td>19 908 (100)</td>
<td>7385</td>
</tr>
</tbody>
</table>

Abbreviations: HVBP, hospital value-based purchasing; MSPB, Medicare Spending per Beneficiary; SNF, skilled nursing facility.

Results | Among 3194 hospitals in HVBP in 2015, preadmission, index admission, and postdischarge spending made up 3%, 53%, and 44% of average total episode spending of $18 247. The SNF and readmission payments accounted for 38% and 30% of postdischarge payments, respectively.

A total of 135 hospitals (4%) were low-cost hospitals in 2015, 1630 (3%) were medium cost, and 1429 (45%) were high cost (Table). Patients admitted to high-cost hospitals spent an average of $7385 more than patients in low-cost hospitals ($19 908 vs $12 523; P < .001). This difference was driven primarily by payments for postdischarge care. Patients at high-cost hospitals spent an average of $4691 more on postdischarge care than those

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at low-cost hospitals ($9287 vs $4596; \textit{P} < .001). In contrast, patients at high-cost hospitals spent only $2450 more on the index admission ($10 006 vs $7556; \textit{P} < .001). Changes in hospitals’ MSPB performance over time were also driven largely by changes in postdischarge payments (Figure). On average, hospitals whose performance on MSPB got worse, determined by changes in classification (low, medium, or high cost) from FY 2014 to FY 2015, spent $1238 more on postdischarge care, whereas hospitals whose performance improved spent $297 less on postdischarge care (\textit{P} < .001).

**Discussion** | Compared with low-cost hospitals, high-cost hospitals had significantly higher preadmission and index admission spending, but the largest differences were in postdischarge spending. The CMS effort to hold hospitals financially accountable for readmissions is not new, but holding hospitals accountable for spending on other types of postdischarge care is a departure from past practice.\textsuperscript{5} Our findings suggest that hospitals that can reduce postdischarge spending will perform well on CMS’ new spending measure.

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**Author Contributions:** Mr Das had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

- **Study concept and design:** All authors.
- **Acquisition, analysis, or interpretation of data:** All authors.
- **Drafting of the manuscript:** Das.
- **Critical revision of the manuscript for important intellectual content:** All authors.
- **Statistical analysis:** Norton, Chen.
- **Administrative, technical, or material support:** Das, Miller.
- **Study supervision:** Norton, Chen.

**Conflict of Interest Disclosures:** None reported.

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**Role of the Funder/Sponsor:** The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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**Invited Commentary**

**Accountability of Hospitals for Medicare Beneficiaries’ Postacute Care Discharge Disposition**

The Centers for Medicare & Medicaid Services have introduced the Medicare Spending per Beneficiary demonstration to bring more accountability to patient care by focusing hospitals on lowering spending across the continuum of care. This metric reflects consensus from policymakers and health care professionals that hospitals and health systems should be held accountable for spending and outcomes that occur after discharge.

From a health system’s perspective, the following 3 levers can reduce per capita spending on health care: decreasing the volume of services, lowering the price of each service, and/or substituting lower-cost treatments or services (eg, generic pharmaceuticals). In this issue of \textit{JAMA Internal Medicine}, Das and colleagues\textsuperscript{1} note that only 3% of total Medicare spending per beneficiary relates to preadmission costs, leaving inpatient hospital and postacute care costs as the only vehicles for reducing costs. Because hospital reimbursement rates are based on prospective payments by diagnosis related group and because hospitals’ ability to decrease inpatient length of stay without increasing adverse outcomes is being reached, opportunities for inpatient savings are also limited.

Therefore, hospitals must focus on postacute care as the most viable lever for reducing spending. Some of this focus requires greater preoperative planning for elective admissions to reduce risks of readmission and to speed recovery. However, the greatest opportunity is during the postacute care period. Savings can be achieved in any or all of 3 ways. First, change patients’ discharge location to a less costly service (eg, from an inpatient rehabilitation facility to a skilled nursing facility or from a skilled nursing facility to a home health agency). Second, reduce the amount and duration of postacute care services provided. Third, narrow the network of choices (ie, preferred provider networks within a given type) to lower-cost agencies with higher levels of performance.
Postacute care has been one of the fastest-growing components of Medicare spending in the past decade. From 2001 to 2013, annual Medicare spending increased from $12 to $29 billion (7.6% annual growth) for care in skilled nursing facilities, from $9 billion to $18 billion (5.9% annual growth) for home health agency care, and from $4.5 billion to $6.8 billion (3.5% annual growth) for care in inpatient rehabilitation facilities. More than 40% of all patients in Medicare fee-for-service plans who were discharged from acute care hospitals received postacute care. As Das and colleagues\(^1\) note, postacute care expenditures represent a growing share of all 90-day episode costs, which is one reason why the Centers for Medicare & Medicaid Services added the spending metric to the hospital value-based purchasing program.\(^1\) Indeed, the finding by Das et al that patients served by hospitals with high per-beneficiary spending levels spent $4691 on postacute care services vs $2450 by those with low per-beneficiary spending levels reinforces the importance of controlling postacute care expenditures. Furthermore, that temporal changes in per-beneficiary spending levels between hospitals with higher and lower levels of spending were mostly owing to reductions in skilled nursing facility and readmission costs reinforces the point.

Under the bundled payment program, hospitals can achieve reductions in spending levels by reducing the use of costly postacute care services. Changing the acuity mix of patients by targeting a younger patient population in select service lines facilitates deflection of patients to home health agencies or directly home rather than to skilled nursing facilities as suggested by Jubelt and colleagues\(^2\) in this issue of *JAMA Internal Medicine*. This change in patient case mix makes achievement of lower per-beneficiary spending possible while reducing the rate of rehospitalizations. This solution is not sustainable or generalizable. Nonetheless, it highlights policymakers’ challenges in designing case-mix adjustment models and quality metrics sensitive to changes in acuity of patient care.

Previous research on relationships between hospital and postacute care facilities and the effect of these relationships on rehospitalization\(^3\)\(^-\)\(^5\) shows that, since 2000, after the introduction of prospective payment for skilled nursing facilities and home health agencies, the 30-day rehospitalization rates from skilled nursing facilities did not increase as much in those areas that lost fewer hospital-based facilities compared with those areas that lost more such facilities. Because hospitals with their own nursing facilities discharge more than 45% of their patients to them, greater integration between hospitals and free-standing nursing facilities can be reasoned to reduce errors and rates of rehospitalization.\(^5\) Testing of this assumption found that hospitals that concentrated their discharges in fewer skilled nursing facilities experienced lower rates of rehospitalization after controlling for geographic, hospital, and facility characteristics and patient characteristics and selection.\(^3\) Finally, the choice of skilled nursing facilities matters because they vary widely in their rehospitalization rates. Patients discharged to skilled nursing facilities with historically lower readmission rates are less likely to return to the hospital regardless of the rehospitalization rate of the hospital that discharged them.\(^6\) This evidence suggests that some hospitals identify and preferentially discharge their patients to better-performing facilities. Hospitals can also work to improve the transfer of patients to select skilled nursing facilities regardless of their historic readmission rate and, in turn, improve the performance of the skilled nursing facilities. Whether this pattern of findings would apply to home health agencies, which also have considerable variation in their 30-day rates of rehospitalization, remains to be seen.

This pattern of findings with respect to rehospitalization from skilled nursing facilities suggests the following recommendations:

- First, to meet the challenge of fiscal and clinical responsibility that new reimbursement models impose, hospitals should develop preferred provider networks that can mimic a virtual hospital-based skilled nursing facility with rapid exchange of medical record information, constancy of care paths across settings, and active control of the discharge and admission processes, perhaps even with shared staff. Whether this development is accomplished by ownership of the facility or via contractual arrangements should be locally determined because no universal solutions are available and the quality of local facilities varies.\(^7\)
- Second, appropriate financial arrangements will be necessary, including shared risk between the hospital and skilled nursing facility, because these business relations take time to evolve. Premature switching to another partner can be costly given the level of investment necessary to achieve smooth clinical and administrative communication processes.
- Third, the competitiveness of the local hospital market, the influence of Medicare Advantage plans in the area, and the level of adoption of the operating principles of accountable care organizations should greatly influence hospitals’ strategies, namely, building a preferred postacute care provider network.

Regardless of how a network is constructed, hospitals and their postacute care partners should be expected to deliver value to the patients in exchange for effectively restricting their choices. One cost-reduction solution is to reduce the use of skilled nursing facilities among patients who could safely receive postacute care at home, but patients want—and tend to trust—hospitals’ advice on which postacute care provider to use, as witnessed by the high rate of loyalty of patients to hospital-owned postacute care services. That implicit trust must be rewarded by hospitals’ assuming ongoing responsibility long after the arbitrary 30-day rehospitalization period ends. Indeed, consistent evidence suggests that transfer to a poor-quality skilled nursing facility increases the likelihood that patients will inadvertently become permanent residents—something that is a particular problem for Medicare beneficiaries who are dually eligible for Medicaid.\(^4\)

In the face of rapidly evolving Medicare reimbursement models, including increases in Medicare Advantage membership, accountable care organizations, and bundled payments, not to mention the penalties exacted for rehospitalizations, hospitals face a bewildering choice of options. However, all of the options require that hospitals embrace the postacute care experience of their patients by assuming responsibility directly or jointly with trusted partners. During the next decade, hospitals’ reputations and measured quality may
be based as much on patients’ experience after discharge as during a hospital stay.

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Conflict of Interest Disclosures: Dr Mor reported performing research in a related area to that of several different paid activities; periodically serving as a paid speaker at national conferences where he discusses trends and research findings in long-term and postacute care but never any specific product or service provider; founding and previously owning stock of unknown value and sitting on the board of PointRight, Inc, an information services company that provides advice and consultation to various components of the long-term care and postacute care industries, including suppliers and insurers, and sells information on the measurement of nursing home quality to nursing homes and liability insurers; chairs the independent quality committee for HRC Manor Care, Inc, a nursing home chain, for which he receives compensation ranging from $20 000 to $40 000 per year; serving as chair of a scientific advisory committee for NaviHealth, a postacute care service organization, for which he also receives compensation ranging from $20 000 to $40 000 per year; serving as a compensated speaker at the nonacademic National Long Term Care Quality Meeting in 2014; serving as a technical expert on several Centers for Medicare & Medicaid Services quality measurement panels; and serving as a member of the board of directors for Tufts Health Plan Foundation, Hospice Care of Rhode Island, and the Jewish Alliance of Rhode Island. No other disclosures were reported.

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Results | A total of 371 trials randomizing 590 040 participants were included for analysis. Overall, 212 trials (57.1%) excluded patients with KD. Patients with KD were more likely than patients without KD to be excluded from North American and Canadian trials vs European trials (84 of 129 [65.1%] vs 107 of 206 [51.9%]), were more likely to be included in trials that tested medications vs those that tested procedures (142 of 200 [71.0%] vs 32 of 94 [34.1%]), were more likely than patients without KD to be included in industry-funded trials vs government-funded trials (111 of 172 [64.5%] vs 49 of 101 [48.5%]), and were more likely than patients without KD to be included in trials of patients with heart failure vs trials of patients with acute coronary syndrome (91 of 144 [63.2%] vs 120 of 244 [53.6%]). The Figure shows the exclusion of patients with KD by specific categories of treatment and diagnosis. There were no significant differences in representation of patients with KD in trials testing an intervention that was a class I or II recommendation vs representation of patients with KD in all trials (Table).

Of 212 trials excluding patients with KD, 111 (52.4%) used serum creatinine levels as the exclusion threshold, 21 (9.5%) used estimated glomerular filtration rate, 22 (10.4%) used creatinine clearance thresholds, 60 (28.3%) used renal replacement therapy of any form, and 36 (17.0%) used non-specific qualitative exclusion criteria. Only 156 (42.0%) and 84 (22.6%) trials, respectively, reported at least 1 measure of