

March 20, 2020

Via Email and U.S. Mail

Thomas J. Donovan, Esq.
Director of Charitable Trusts
New Hampshire Department of Justice
33 Capitol Street
Concord, H 03301-6397

Re: GraniteOne Health/Dartmouth-Hitchcock Health Acquisition Transaction

Dear Director Donovan:

The following is in response to your February 28, 2020 second request for additional information in connection with the Joint Notice filed under RSA 7:19-b by GraniteOne Health (GOH), Catholic Medical Center (CMC), Monadnock Community Hospital (MCH), Huggins Hospital (HH) and their affiliates regarding their proposed transaction with Dartmouth-Hitchcock Health (D-HH) (the “Joint Notice”). The responses follow each specific request of your February 28th letter, and in some cases refer to documents appended to this response. The parties reserve the right to supplement these responses if additional information becomes available after their submission.

69. CMC, MCH and HH each remain responsible to complete community health needs assessments and to develop strategic plans to address those needs. CITE. But D-HH approval is required for those entities to address those community needs or further the strategic plan. How will conflicts be addressed when the D-HH system priorities conflict with those developed by CMC, MCH or HH through the needs assessment and strategic planning processes?

Addressing community health needs is both a goal and a responsibility of D-HH GO and of each System member. System member management and boards are primarily responsible for developing and executing plans to meet the needs of their respective communities because they are best-positioned to identify those needs and develop a delivery strategy informed by their knowledge of community resources and characteristics. D-HH and GOH have not experienced, nor do they envision experiencing in the future with D-HH GO, a conflict with a System member regarding strategies to address community needs. Because there is a high degree of consistency among the identified health needs of the communities D-HH and GOH serve, the integrated D-HH GO System can more effectively address community needs by (i) pooling resources in more focused ways, (ii) sharing learning and best practices, and (ii) distributing effective programs across the System. In the unlikely event that a conflict arises between the D-HH GO System and one of the System members, then D-HH GO will exercise its limited fiduciary duty to the System member and develop a mutually-acceptable resolution that does not impair or prevent the System member from fulfilling its legal obligation to address community health needs.

70. The transaction contemplates that the budgets for CMC, MCH, and HH receive approval by the board of directors of D-HH GO. What specific financial commitments for community benefits will D-HH GO require of those hospitals to address community needs, apart from unreimbursed Medicare and Medicaid costs?

The budget process for the current D-HH System is, and for the future D-HH GO System will be, a “bottom-up” approach. Community needs and benefit strategies are identified and discussed among System member and D-HH GO leadership at the Member Leadership Council meetings. As noted in the previous response, community needs are relatively uniform across the System and the Member Leadership Council meetings are an opportunity to identify best practices and develop strategies among System members for the efficient delivery of quality services addressing community needs. The cost and budgeting of the community services to be provided by each System member is an iterative process and ongoing conversation between and among System members and D-HH GO leadership so that costs and programming are well-vetted by the time they are presented in a budget for approval.

Each of D-HH GO and the System members recognize that, as a 501(c)(3) charitable hospital, each System member hospital has a legal obligation under federal and state law to assess and address community needs. D-HH GO will review the community needs assessments and benefit plans of each System member and will ensure that the budgets and community benefit plans of each member are aligned and prudent given the resources available and the required services. The parties also recognize that their legal obligations to benefit their communities extend far beyond the provision of uncompensated Medicare and Medicaid services. The D-HH System is in the process of standardizing robust charity care and financial assistance policies among its member hospitals, which will continue under the D-HH GO System. As described thoroughly in the Combination Agreement, the Joint Notice and our responses to your inquiries, the parties are deeply committed to re-investing in their facilities, their infrastructure and their clinical programming (including medical training, education and research) to improve the quality and efficiency of, and access to, their health care services.

71. In addition to debt financing activities, what back-office services or functions may be centralized as a result of the transaction?

The parties intend, over time, to lower the costs of providing care and to promote the more efficient use of System resources. One of the ways to accomplish this will be the consolidation of back-office functions and reduction of operational and administrative expenses, where it makes sense to do so.

[The remainder of the response to Question 71 is exempt from RSA 91-A, as Confidential, Competitively-sensitive and Financial in nature for which we request redaction from public disclosure:]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

72. If the proposed transaction is able to reduce the growth in health care costs, do the parties anticipate passing on that efficiency to insurers and consumers in the form of smaller price increases?

The economics of non-profit health care delivery bear little resemblance to a for-profit business, which can pass manufacturing or distribution efficiencies and supply savings on to customers in the form of price reductions. Rates under Medicare and Medicaid are set by the federal and state government. Incremental cost savings or increases have not been particularly influential on rate negotiations with commercial payers, of which there are relatively few in the New Hampshire

market and who typically establish rates within a narrow negotiable band. The parties currently participate in, and hope to more broadly and successfully participate in after the Combination, risk-based or value-based contracting under which savings can be shared and future costs reduced.

Under the nonprofit health care services model, the parties will ensure that their patients (consumers) enjoy the benefits of costs reductions through D-HH GO's anticipated re-investment of those savings into new or improved services, such as behavioral health services, and health care facilities designed to enhance access and quality of care for patients. The Combination Agreement and the Joint Notice and its attachments reflect the parties' detailed plans for reinvesting health cost savings into improved access and quality of care, and new service offerings.

73. If additional fees or costs increase costs for any of the member hospitals, do the parties anticipate passing on those higher costs to insurers and consumers in the form of higher price increases?

The economics of the health care delivery system described in our response to Question 72 similarly apply to "passing on" higher costs. With the exception of the limited effect of the cost reports of critical access hospitals, the federal and commercial payer reimbursement programs typically do not permit the passing on of costs. This is particularly true for nonprofit hospitals, which have a mission-driven and legal obligation to care for patients and provide services even when those patients are unable to pay. The cost of these care obligations typically is absorbed by the nonprofit hospitals and addressed through careful fiscal and clinical delivery methods, rather than being recovered through increased rates under Medicare/Medicaid and commercial payer reimbursement contracts. In fact, the parties are experiencing higher costs and lower net reimbursement under most of their reimbursement arrangements.

74. Do the parties expect, after the transaction, that CMC, MCH and HH will have the same overall volume of service, a larger volume of service or a smaller volume of service? Do the parties expect that the volume of certain services will increase while the volume of other services will decrease? If so, please explain the changes expected and what will cause those changes.

The parties expect that the overall volume of services and patient cases will increase at CMC, MCH and HH for a number of reasons. The proposed Combination integration strategy is built around three interrelated components:

(1) Enhancing and expanding clinical program offerings at CMC and rural member facilities, including MCH and HH. Initially, the clinical areas for enhancement and expansion include behavioral health; pediatric emergency, urgent care and neonatology; spine services and pain management; heart and vascular; orthopedics; trauma; oncology; and obesity management and bariatrics. See Chartis Integration Report, Joint Notice at [Appendix I\(2\)](#). More specifically

to MCH and HH, the parties intend to assess the feasibility of deploying general and orthopedic surgical services in order to expand access to surgical procedures appropriate in a critical access hospital setting and to optimize the hospitals' operating room capacity; deploy specialists for outpatient services and minor surgical procedures in urology and geriatrics; enhance cancer treatment services at both HH and MCH with particular attention to initiating chemotherapy infusion services at HH; and supporting appropriate services in ophthalmology, bariatrics and behavioral health. *See* Article V generally and Section 5.3.4 specifically of the Combination Agreement at Appendix I(1) of the Joint Notice.

(2) Developing additional clinical capacity and effectively managing patient care across the System, including in rural locations. *See* Chartis Integration Report, Joint Notice at Appendix I(2). The parties intend to expand CMC's capacity in a number of ways including enhanced operational efficiencies to improve patient throughput and efficiencies, expand upon its outpatient strategy including use of the D-HC ambulatory surgical center to do more complex cases in a safe, more cost effective ambulatory setting and expanding inpatient beds with the proposed patient tower expansion to the north of the campus. Rural hospitals – with the exception of hospitals within the D-HH system – have seen declines in volumes. By supporting necessary staffing, enhancing specialty services and coordinating care so that patients are returned to their local hospital as soon as possible after meeting acute care needs, the current excess capacity at MCH and HH will be better utilized resulting in increased volumes.

(3) Integrate quality, academics, and other infrastructure to drive value as a System. These efforts include aligning quality processes and infrastructure, expanding and developing new residency and fellowship programs, adding workforce development initiatives, and expanding upon innovative value-based care payment plans. These are foundational building blocks to expanding services and capacity.

New volumes are expected to come from multiple sources. The parties seek to address at CMC the complex health needs of the more than 10,000 patients who travel to Boston each year for medical services. Patients in southern New Hampshire presently traveling to DHMC or other more distant hospitals will have an opportunity to receive higher acuity care at CMC following the Combination. Finally, New Hampshire's aging population will increase the demand for health services. The population of those aged 65 or older is expected to increase 91% by 2040, at which point 25% of New Hampshire's population will be 65 or older (compared to 20% for the nation overall). *See* p. 2 at the Chartis Integration Report, Joint Notice at Appendix I(2) (*citing* US Census Bureau Data (Weldon Cooper Center Analysis, 2016). Because the elderly use nearly 2.5 times the volume of inpatient hospital services as those in the next oldest age group, the aging of the population will fuel demand for new and expanded services. *Id.* *citing* Healthcare Cost and Utilization Projection (Statistical Brief #235, 2018).

75. Do the parties expect their overall payer mix to change as a result of the affiliation? In what way?

The primary drivers of payer mix changes in any health services market are demographics and clinical service offerings. Due to demographics, we expect to see increases in our Medicare payer mix as the population ages. This is unrelated to the proposed Combination and a change that both D-HH and GOH are experiencing today. Through the Combination we will increase clinical service offerings in the communities served by GOH as described in our Joint Notice and accompanying reports, work plans and other materials. We do not expect these services to have a dramatic impact on our current payer mix, a majority of which already is comprised of government payers. As we improve access and expand pediatric and behavioral health services, however, we are likely to see some growth in our Medicaid payer mix despite the fact that D-HH’s pediatric specialty programs already care for a majority of New Hampshire’s Medicaid pediatric patient population. To the extent that fewer patients need to travel to Boston for less convenient and more costly care after the Combination, and because those patients tend to have a higher commercial payer mix, we may see some small increase in our commercial payer mix as more care stays within our state.

76. After the transaction, will D-HH GO negotiate joint or separate contracts with health insurers?

Following the Combination, each of the System members will negotiate health insurer payor contracts independently rather than jointly through D-HH GO.

The only type of payor contracts that might be negotiated as a System through D-HH GO are risk-based and value-based care contracts which should lead to reductions in patient care costs. See p. 58, Value-Based Care of the (*Confidential*) Chartis Integration Report, Joint Notice at [Appendix I\(2\)](#); see also [Appendix C](#) of the Chartis Integration Report for a detailed workplan.

77. List the current number of licensed beds and staffed beds at each New Hampshire general hospital.

Given that the parties do not have access to the proprietary information of each hospital in New Hampshire, including staffing strategies, the parties interpret this question as seeking to elicit “the current number of licensed beds and staffed beds at each New Hampshire general hospital *within the proposed combined system.*” (Emphasis and content added). This list is as follows:

	<u>Licensed</u>	<u>Staffed</u>
Alice Peck Day Memorial Hospital (D-HH)	25	23
Cheshire Medical Center (D-HH)	169	98
Mary Hitchcock Memorial Hospital (D-HH)	396	396

New London Hospital (D-HH)	25	25
Catholic Medical Center (GraniteOne)	330	261
Huggins Hospital (GraniteOne)	25	17
Monadnock Community Hospital (GraniteOne)	25	18

78. How will the extensive coordination required by D-HC "to ensure respect for the ERDs" as reflected in the response to Request 54, affect D-HH's ability to promote its secular mission to "provid[e] each person the best care, in the right place, at the right time, every time." Will that coordination result in any change to clinical practices at D-HC?

The integration of the D-HH and GOH Systems will not adversely affect, impede, or hinder D-HH’s ability to promote its secular mission to “provid[e] each person the best care, in the right place, at the right time, every time.” (Quotation marks and brackets in original). Indeed, one of the principles guiding the evolution of the parties’ relationship and operation of the combined system expressly acknowledges “that D-HH is New Hampshire’s only academic health system whose mission includes delivering innovative, high quality care across a broad range of services to patients and families regardless of where or how a patient chooses to utilize the health system.” *See* Combination Agreement at §2.7. The parties also acknowledge that “the provisions specific to CMC [compliance with Catholic moral teaching, the ERDs, or Canon Law] will neither be imposed upon nor mandatory for other System Members, who will not be precluded from providing services or conducting research and medical education activities prohibited by Catholic moral teaching, the ERDs or Canon Law, including, among other things, the provision of reproductive health services.” *Id.*

As more fully set forth in the parties’ responses to Requests 54 and 59, Dartmouth-Hitchcock Clinic (“DHC”), a subsidiary of D-HH, and Alliance Health Services (“AHS”), a subsidiary of CMCHS, have entered into contractual arrangements over a period of years during which they have gained experience in reconciling their respective missions. For example, one administrative practice for coordinating the provision of secular health care with CMC’s Catholic health care mission is for DHC to report annually to CMC the number, nature, and DHC location at which procedures inconsistent with the ERDs are performed. *See id.* at §4.2.2(e)(iii). In this and other ways, the parties will ensure CMC’s compliance with the ERDs while also ensuring that DHC will continue to offer services that do not align with those directives but which patients demand and choose to utilize. Accordingly, there will be no change in clinical practices at DHC as a result of the proposed transaction.

79. What is the 2017 Advisory Board study referred to in response to Request No. 29? Please supply a copy of that study.

To understand the demands of future orthopedic and spine care, CMC relied on estimates provided by the Advisory Board. To clarify, the Advisory Board did not produce a formal report for CMC but rather provided raw estimates (based on 2017 data) of future inpatient and outpatient volumes for three southern New Hampshire counties (Hillsborough, Merrimack, and Rockingham). The data show that from 2017 to 2027, spine and pain care is expected to grow 2.3% (inpatient) and 31% (outpatient); similarly, orthopedic need is expected to grow 7% (inpatient) and 29% (outpatient). The underlying data are confidential pursuant to certain agreements by and between the Advisory Board and CMC.

80. What studies demonstrated a need for D-HC to construct a new outpatient surgical center in Manchester?

Industry projections from sources such as the Advisory Board and Sg2 project a continued shift of surgical procedures from hospital inpatient and outpatient settings to Ambulatory Surgical Centers (ASCs). Medicare and commercial payer payments for surgical cases are moving from hospital based rates to outpatient and ambulatory based rates, and many commercial payers are steering patients away from hospitals to ASCs through pre-authorization processes and benefit design incentives.

A majority of D-HC's commercial patients are included under D-HC's risk contracts with insurers under which D-HC is accountable for the quality and total cost of care for those patients. Having the ability to offer more services at its new ASC will enable D-HC to offer high quality care at a lower cost which will benefit consumers and improve D-HC's performance under its risk contracts.

D-HC currently has limited ambulatory surgery capacity that is insufficient to meet growing demand. Additionally, D-HC's new surgical center in Manchester will be able to accommodate extended stay (up to 23 hours) patients. This means that patients can have appropriate procedures done in an ASC when their physician may feel that the recovery time needed is longer than is available at a typical ASC. This will enable more patients to be cared for in an ASC rather than in a more costly hospital setting. D-HC also will be able to offer a broader scope of surgical services to all patients at its new ASC, regardless of their ability to pay, than other local ASCs currently offer.

CMC plans to continue its relationship with its existing joint venture surgical center. D-HC's new ASC will enable more of CMC's patients to access ASC services in the community.

What are the plans with respect to CMC's future relationship with its existing joint venture surgical center?

Through a subsidiary, Alliance Ambulatory Services, CMC is a 50% governance member and a 43.5185% economic interest member in the Bedford Ambulatory Surgical Center (“BASC”). CMC intends to continue its relationship with its existing joint venture with physicians in the BASC. From CMC’s perspective, the relationship with the BASC and the proposed D-HC Manchester ASC are complementary and will enhance an overall outpatient strategy for CMC for a number of reasons. As stated in the Joint Notice and applicable supporting Appendices (*see* Appendices I(1) and I(2)), the proposed Combination will enable CMC patients to seek care at the proposed ambulatory surgical center that is being built in Manchester at the D-HC Manchester campus. These two ambulatory centers will be offering different kinds of services which will enable the two to complement each other offering more outpatient opportunities for patients in the southern region or who are seeking similar care in Boston. More specifically, the D-HC ASC is intended to be an extended stay ambulatory center. A long-stay ambulatory surgical center is one that enables up to 23 hour stays for patients enabling higher acuity outpatient procedures or offering an outpatient setting for more complex patients. Currently, these cases and patients are seen at CMC in an inpatient setting or a hospital-based outpatient setting which adds additional risks and costs to the procedures. The parties expect to treat these patients at the D-HC ambulatory center resulting in inpatient capacity improvements at CMC and an overall lower cost of procedure for patients and payors. At the BASC, procedures generally are performed within a 12-hour stay. Services at the BASC are focused primarily on orthopedics and sports medicine, ear, nose and throat, gastroenterology, and limited plastic and general surgery. The D-HC ASC will offer additional outpatient services not provided by the BASC, including a newly designed, medical infusion suite and a fixed MRI, cardiovascular services, dermatology, endoscopy, general surgery, medical infusion, including dedicated pediatric infusion space, podiatry, rheumatology and spine services. *See:* <https://www.dartmouth-hitchcock.org/hitchcock-way.html>. Finally, there are differences in payor considerations as well. The BASC does not currently accept Medicaid patients. The D-HC ASC will accept Medicaid patients ensuring that this segment of the population is granted greater access to high quality outpatient care.

81. How will this transaction effect existing efforts of D-HH and CMC to provide cardiac, labor and delivery and other OB-Gyn services in New Hampshire's north country?

The proposed Combination will enhance existing efforts. Currently, D-HH and GOH are the only two healthcare systems in the State of New Hampshire dedicated to supporting rural healthcare both within and outside of their respective systems. In New Hampshire’s North Country, such support has included cardiac care, oncology, dermatology, and other clinical services either on-site or through telehealth. By pooling these resources together, the Combination will generate opportunities to further enhance these services with staffing and to develop more robust and internal (rather than contracted) telehealth initiatives. As the two

primary acute care transfer centers in the State, the parties will have opportunities to better coordinate cases to ensure that patients are sent to the most appropriate place of care in terms of quality, convenience and cost. D-HH GO will continue to provide coordination support and educational services for maternal and neonatal care needs in the North Country. D-HH GO also will have opportunities to expand the New England Alliance for Health (NEAH) and explore greater opportunities in the North Country to establish improved inpatient capacity management, post-acute care management and regional transportation for patients and providers.

82. What steps do the parties plan to take to address unmet physical health needs in the community, such as poorly controlled asthma and diabetes?

Effectively managing patients with chronic diseases such as diabetes, asthma and behavioral health are important from a community health standpoint as well as a means to reduce total cost of care. D-HH GO has identified a set of targeted behavioral health initiatives in its regulatory submission. Both D-HH and GOH have chronic disease management programs aimed at asthma and diabetes. Through the Combination we will be able to integrate these programs, share best practices, and improve data analytics which will enable us to better target interventions.

83. In what nationally recognized quality or safety surveys will each of the hospitals participate after the transaction? Will all the D-HH GO hospitals participate in the Leapfrog Hospital survey?

84. In 2019, CMC received a Leapfrog Hospital Safety Grade C, Dartmouth-Hitchcock Medical Center (DHMC) received a C, and Cheshire received a B. These Safety Grade differentials cannot be explained based on high acuity patient differentials. Explain the reasons for the higher rates of infection and how this transaction involving two lower performing hospitals will result in them offering better quality care.

85. What are the parties' plans to ensure continued or improved patient experience at the member hospitals?

86. What are the parties' plans for improving health care outcomes? For example, what steps will the parties take to reduce preventable hospitalizations and re-admissions?

The following is a consolidated response to Questions 83-86:

The parties anticipate that after the transaction all D-HH GO hospitals will participate in the following nationally recognized quality and safety surveys: a) all CMS Hospital Compare metrics; b) CMS Star Rating for Quality and Safety; c) CMS Star Rating for Patient Experience; d) U.S. News and World Report Hospital Ratings; and e) Medicare Beneficiary Quality Improvement Project (MBQIP). Additionally, D-HH GO Critical Access Hospitals will participate in the CMS National Rural Health program. **(Request 83).**

Like more than half the hospitals in the United States, the D-HH GO hospitals are unlikely to participate in the Leapfrog Hospital Survey for several reasons, not the least of which is the well-documented criticism of Leapfrog’s flawed methodology that “advantage[s] HHS [Hospital Safety Scores] for hospitals participating in the Leapfrog Hospital Survey in ways unrelated to representations of valid hospital safety.” See *Medical Care*, Volume 55, Number 6, p. 606 (June 2017), Smith, et. al., “*Dissecting Leapfrog - How Well Do Leapfrog Safe Practices Scores Correlate With Hospital Compare Ratings and Penalties, and How Much Do They Matter?*” (**Attachment 1**). Leapfrog’s flawed methodology utilizes “data ... drawn from different sources depending on whether the hospital completed the proprietary Leapfrog Hospital Survey” and a number of “process and structural measures that are self-reported and non-audited,” both of which raise serious questions about the reliability of Leapfrog’s results. See *Journal of the American Medical Association Surgery*, Volume 149, Number 5, p. 413 (May 2014), Gonzales and Ghaferi, “*Hospital Safety Scores, Do Grades Really Matter?*” (**Attachment 2**). The data also are not risk-adjusted.

For example, rather than attributing CMS’s compulsory and publicly reported standardized infection ratios (SIRs) for certain hospital acquired conditions to *all* hospitals, Leapfrog punitively attributed those SIRs only to a certain cohort – those hospitals that did not complete its 2013 survey. *Id.* at 613. Participating hospitals, on the other hand, were permitted to use self-reported rates. *Id.* Given that “most hospitals report *perfect scores* for most SPS [Safe Practices Score] measures (emphasis added) ... Leapfrog’s methodologies, in combination with strongly positively skewed self-reports of SPS measures ... cast doubt on the utility of SPS and, more generally, the HSS and grades.” See Attachment 1.

The parties take issue not only with Leapfrog’s methodologies but also with the Charitable Trusts Unit’s characterization of CMC and DHMC as “two lower performing hospitals” based on the results of those flawed methodologies. (**Request 84**). As the peer-reviewed literature cited above establishes, Leapfrog’s hospital grades do not correlate with the more reliable, validated, undifferentiated, publicly reported data on which CMS’s Hospital Compare and Star Ratings are based. For example, despite receiving a C grade from Leapfrog, CMC is rated as a 4-star hospital by CMS. In 2020, DHMC improved from a 3-star to a 4-star hospital, placing it in the upper quartile of academic medical centers in the country. U.S. News and World Report ranks DHMC as the top hospital in New Hampshire based, in part, on its low mortality rate despite its high case mix index, a measure of the severity of patient acuity (DHMC and CMC have the two highest severity indices in the State). Furthermore, U.S. News ranks DHMC in the top decile nationally in 7 of 12 specialties and 8 of 9 complex procedures. CMC ranked second in the State by U.S. News and World Report and, more recently, Newsweek World’s Best Hospitals lists DHMC and CMC as the top first and third hospitals in the State of New Hampshire. These ratings and accolades do not comport with what the public might expect from C grade hospitals, revealing the confusion caused by, and deficiencies in, the Leapfrog model.

As set forth in section 5.3.6 of the Combination Agreement, the parties will continue to improve patient experience and outcomes by deploying their integrated quality improvement resources to monitor adherence to System-wide, data-driven quality, safety, and patient experience goals, against which performance will be measured regularly and reflected on scorecards to promote accountability. (**Requests 85, 86**). In order to facilitate this work the parties will convene a System Quality Management Council, modeled on the D-HH Quality Management Council, on which each System member will be represented. This council will be responsible for patient care and process improvement goal-setting, data-driven performance measurement, and implementation of best practices. The parties will utilize the System's Analytics and Value Institutes to tailor care quality and process improvement initiatives to local needs and expand access to proven training programs for System providers and other health care professionals. The System will enable the parties to spread the high cost of such tools and infrastructure across multiple System members, most of whom alone are financially incapable of making such investments.

Best practices will be implemented and derived from the data and packaged as "care bundles" for implementation by System members, driving standardization of care pathways, care quality, and patient experience. For example, the parties will establish best practice "infection prevention bundles," a set of process steps that should be executed every time a patient is exposed to the risk of a particular hospital acquired condition ("HAC"), such as Central Line Associated Bloodstream Infection ("CLABSI") or Catheter Associated Urinary Tract Infection ("CAUTI"). These bundles are well established, revised annually, and taught to and managed by unit level "champions," who audit the processes and provide immediate peer-to-peer training if a deviation in the bundle execution occurs. Finally, Mary Hitchcock Memorial Hospital is the only hospital in New Hampshire that has not incurred a penalty for patient readmissions since the inception of CMS's Hospital Readmissions Reduction Program in 2012. As demonstrated by their proven ability to establish annual goals for year over year improvement, the parties are committed to continuous learning and adjusting processes to improve performance.

87. Both the Notice Document and the response to Request 1 identify cost savings possible if patients were to receive care in New Hampshire as opposed to hospitals in Boston. What evidence exists that more patients will choose to receive, in New Hampshire, the types of care noted in response to Request 1, based upon cost savings, if those types of care become available?

There is little evidence that patients will choose care in New Hampshire based solely on cost. Patients make their care decisions based on multiple factors including physician attitude, competency, facility quality and safety, patient and care giver convenience, health insurance networks and provider referrals. This informed and comparative consumerism is a trend throughout the country. New Hampshire insured patients likely will not make a choice based on cost, or at least not solely on cost. They will make a choice based on convenience (for themselves and their families) and perceived reputation. Through the Combination, D-HH GO

will be a powerful brand as the New Hampshire-based academic system. D-HH GO also will work with New Hampshire payors to establish incentive programs for New Hampshire patients to be incentivized to select care based on cost and quality. By enhancing and expanding capacity at CMC, the proposed Combination will create a new opportunity which does not exist today for payors to develop these kinds of cost-reducing incentive programs.

88. What if any projections exist as to the additional number of patients who may be able to receive service through clinical trials as a result of this transaction? What additional revenues are projected for D-HH GO to receive as a result of increased clinical trials?

The number of additional patients who may participate in clinical trials, and the revenue to be derived, as a result of this transaction are not known at this time.

89. With respect to the response to Request 2, what if any additional amount will CMC be able to charge as facility fees or as medical education payments from commercial payers and Medicare? Will any southern New Hampshire D-HH staff or services migrate to CMC to permit charging of facility fees?

Forming D-HH GO will not, in and of itself, increase CMC's facility fees. Because the parties have agreed to not contract jointly (except on value-based care arrangements), CMC's facility fees will be determined through the same negotiation process that CMC currently participates in with commercial payors. As it relates to Medicare, CMS is no longer approving new hospital-based outpatient programs.

Given the D-HH GO foundational goal of lowering the cost of healthcare for patients, payors, and employers, D-HH will not be migrating staff or services to CMC to facilitate billing a facility fee. In the D-HH GO Clinical Integration Strategy, the parties outlined their plans to redirect care to facilities with a lower cost basis. Specifically, D-HH GO will redirect appropriate patients to CMC who would otherwise receive care at DHMC, which is more expensive, and D-HH GO will redirect appropriate patients who are currently seen in CMC's hospital outpatient facility to D-HH's ambulatory surgery center in Manchester. Enacting these initiatives will help patients, payors, and employers realize approximately \$8M in savings per year (*see* Appendix B of D-HH Go Clinical Integration Strategy, Joint Notice, Appendix(I)(2)).

As it relates to residency programs, under D-HH GO, if D-HH residency programs are brought to CMC, then Medicare will reimburse CMC for part of the cost of operating those graduate medical education (GME) programs. However, the net increase in Medicare payments for GME programs may not increase. Because D-HH currently is capped at the number of GME residency positions it has, if it receives a waiver allowing it to increase the number of positions at CMC, then the total amount of GME payments to D-HH GO will increase. Alternatively, if D-HH GO transfers existing residency programs from DHMC to CMC (i.e. no increase in total residency

positions), then GME payments to DHMC will decrease and GME payments to CMC will increase. However, as an academic medical center, DHMC is reimbursed at a higher rate for GME programs than CMC is, thus transferring residency programs from DHMC to CMC will likely result in lower total GME payments. Because neither commercial payors nor Medicaid reimburse for medical education, changes to CMC's GME composition will have no effect on commercial rates or Medicaid payments.

90. Will D-HH GO migrate any services to a different cost basis for reimbursement by Medicare? This could include either services that are free-standing becoming hospital outpatient facility based or other shifts to help support the expansion at CMC of D-HC Manchester?

No, D-HH GO will not migrate services to settings that result in a higher cost basis for reimbursement by Medicare. Please see response to Question 89.

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The foregoing responses are submitted by the undersigned on behalf of the respective, and to their knowledge are true and complete.

GRANITEONE HEALTH and ITS MEMBERS

DARTMOUTH-HITCHCOCK HEALTH

By: *Jason E. Cole*

Name: Jason E. Cole

Title: Vice President & General Counsel,
duly authorized.

By: *John P. Kacavas*

Name: John P. Kacavas

Title: Chief Legal Officer & General Counsel,
duly authorized.

INDEX OF ATTACHMENTS:

NO.	DESCRIPTION
1.	Article: <i>Dissecting Leapfrog - How Well Do Leapfrog Safe Practices Scores Correlate With Hospital Compare Ratings and Penalties, and How Much Do They Matter?</i>
2.	Article: <i>Hospital Safety Scores, Do Grades Really Matter?</i>

Attachment 1

Article

Dissecting Leapfrog - How Well Do Leapfrog Safe Practices Scores Correlate With Hospital Compare Ratings and Penalties, and How Much Do They Matter?

Dissecting Leapfrog

How Well Do Leapfrog Safe Practices Scores Correlate With Hospital Compare Ratings and Penalties, and How Much Do They Matter?

Shawna N. Smith, PhD,* †‡ Heidi A. Reichert, MA,* Jessica M. Ameling MPH,*
and Jennifer Meddings, MD, MSc* †§||

Background: Voluntary Leapfrog Safe Practices Score (SPS) measures were among the first public reports of hospital performance. Recently, Medicare's Hospital Compare website has reported compulsory measures. Leapfrog's Hospital Safety Score (HSS) grades incorporate SPS and Medicare measures. We evaluate associations between Leapfrog SPS and Medicare measures, and the impact of SPS on HSS grades.

Methods: Using 2013 hospital data, we linked Leapfrog HSS data with central line-associated bloodstream infection (CLABSI) and catheter-associated urinary tract infection (CAUTI) standardized infection ratios (SIRs), and Hospital Readmission and Hospital-Acquired Condition (HAC) Reduction Program penalties incorporating 2013 performance. For SPS-providing hospitals, we used linear and logistic regression models to predict CLABSI/CAUTI SIRs and penalties as a function of SPS. For hospitals not reporting SPS, we simulated change in HSS grades after imputing a range of SPS.

From the *Department of Internal Medicine; §Department of Pediatrics and Communicable Diseases, University of Michigan Medical School; †Institute for Healthcare Policy and Innovation, University of Michigan; ‡University of Michigan Institute for Social Research; and ||Ann Arbor VA Medical Center, Ann Arbor, MI.

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Reprints: Shawna N. Smith, PhD, Department of Internal Medicine, University of Michigan Medical School, 2800 Plymouth Road, Building 16, Ann Arbor, MI 48109. E-mail: shawnana@umich.edu.

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Results: In total, 1089 hospitals reported SPS; >50% self-reported perfect scores for all but 1 measure. No SPS measures were associated with SIRs. One SPS (feedback) was associated with lower odds of HAC penalization (odds ratio, 0.86; 95% confidence interval, 0.76–0.97). Among hospitals not reporting SPS (N=1080), 98% and 54% saw grades decline by 1+ letters with first and 10th percentile SPS imputed, respectively; 49% and 54% saw grades improve by 1+ letter with median and highest SPS imputed.

Conclusions: Voluntary Leapfrog SPS measures skew toward positive self-report and bear little association with compulsory Medicare outcomes and penalties. SPS significantly impacts HSS grades, particularly when lower SPS is reported. With increasing compulsory reporting, Leapfrog SPS seems limited for comparing hospital performance.

Key Words: health policy, safety, hospital-acquired conditions, readmission

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Available metrics for comparing hospital safety have expanded in recent years. These measures have transitioned from voluntary self-report to compulsory national collection of standardized instruments, such as those on the Centers for Medicare & Medicaid Services (CMS) Hospital Compare website.¹

Figure 1 illustrates the timeline of hospital and patient safety measure development. The Leapfrog Group, founded in 2000 by employers to encourage transparency of hospital performance, provided the earliest measures.² In 2001, they launched the Leapfrog Hospital Survey, a voluntary instrument covering hospital and patient safety process and outcome measures. In 2004, Leapfrog added self-reported Safe Practices Score (SPS) measures³ built from 34 National Quality Forum-endorsed practices to reduce risk of patient harm in acute-care hospitals.⁴ Leapfrog SPS measures focus on implementing structures or protocols reflective of accountability, rather than objective outcomes. SPS initially included 27 measures, and were trimmed to 8 in 2013 (Supplemental Table 1, Supplemental Digital Content 1, <http://links.lww.com/MLR/B359>). In 2012, SPS was bundled with other process and outcome measures to inform a more consumer-friendly composite Hospital Safety Score (HSS) rating hospitals on a scale ranging from 0 to 4, and providing a single corresponding letter grade of “A” (best), “B,” “C,” “D,” or

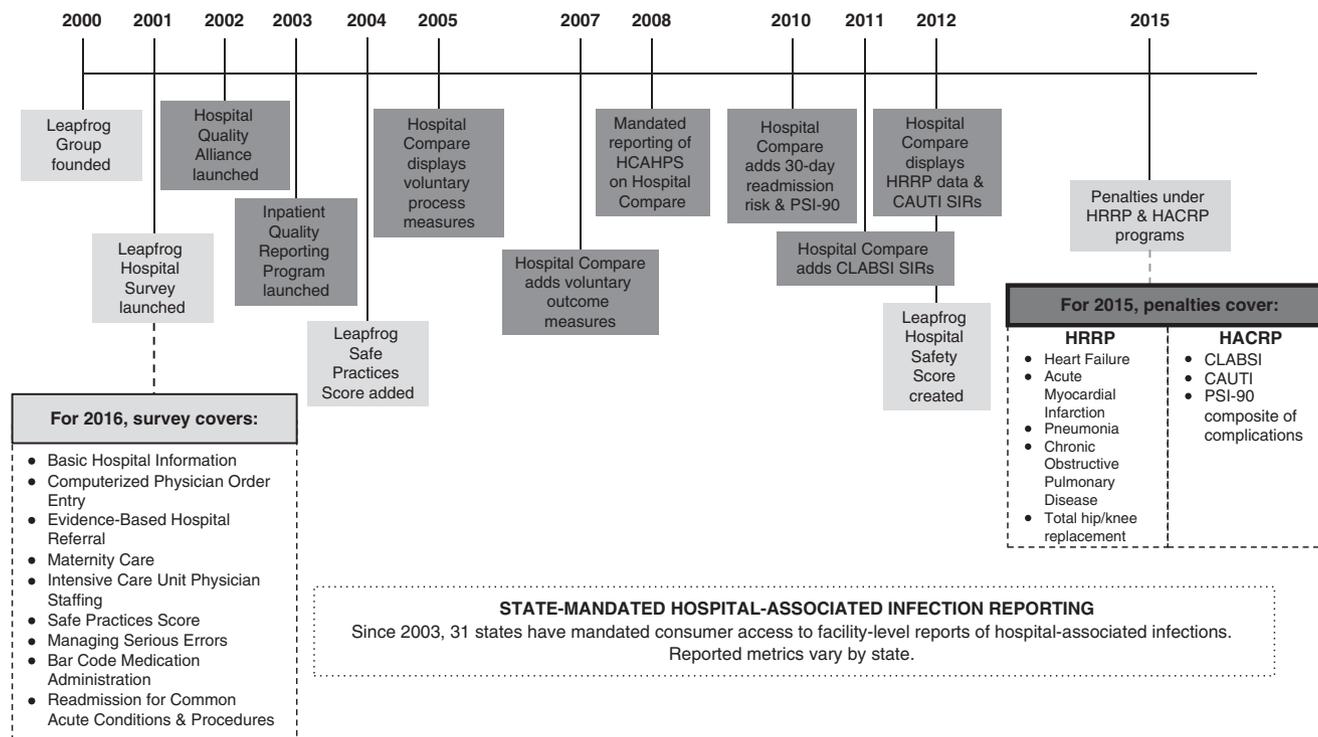


FIGURE 1. Timeline for collection of voluntary and compulsory patient safety metrics and content overview. CLABSI indicates central line-associated bloodstream infections; CAUTI indicates catheter-associated urinary tract infections; HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems; HRRP, Hospital Readmission Reduction Program; HACRP, Hospital-Acquired Condition Reduction Program; PSI-90, Patient Safety Indicators #90; SIR, standardized infection ratio.

“F” (worst) (Supplemental Table 2, Supplemental Digital Content 2, <http://links.lww.com/MLR/B360>).⁵ Hospital self-reports on the 8 SPS measures are available for consumers to compare across hospitals on the HSS website⁶; they also account for a substantial portion of the HSS (22.6% of total score; 45% of “Process and Structural Measures” domain).

Over time, compulsory measures of hospital quality and patient safety were developed. In 2002, the Hospital Quality Alliance, a public-private partnership, formed to support hospital quality improvement and improve consumer health care decision-making.⁷ Their efforts created the Hospital Compare website,¹ a consumer-facing website focused on improving consumer decision-making by providing hospital performance and safety metrics. Hospital Compare first mandated reporting in 2008, requiring hospitals to report patient satisfaction and mortality measures or face a 2% reduction in CMS’ annual payment update.⁸ Hospital Compare measures now include hospital-associated infections and complications, including central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), and the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSI).

In 2012, Hospital Compare began reporting data from 2 new CMS value-based purchasing programs. The Hospital Readmission Reduction Program (HRRP) aims to decrease unplanned 30-day readmissions following select procedures for certain conditions.⁹ The Hospital-Acquired Conditions Reduction Program (HACRP) targets reduction in incidence of hospital-acquired conditions (HACs) including CLABSI,

CAUTI, and serious complications of treatment.¹⁰ In 2015, hospitals whose HACs or readmissions during the evaluation period exceeded expected values could be penalized up to 1% (under HACRP) or 3% (under HRRP) of total hospital Medicare reimbursement.

It is unclear how well Leapfrog’s voluntary SPS correlates with more recent compulsory Medicare metrics displayed by Hospital Compare. Prior work demonstrated Leapfrog’s voluntary nature overrepresents “high-quality” hospitals,¹¹ and tied Leapfrog-led implementation efforts with improved process quality and decreased mortality rates¹² and surgical death¹³; however, SPS measures have shown no relationship with all-cause or surgical mortality^{14,15} or trauma outcomes, including hospital-associated infections.¹⁶ Given these mixed findings, this paper addresses 2 objectives: first, among hospitals reporting SPS, evaluate how well Leapfrog’s SPS correlates with compulsory outcomes and penalties for readmission and complications publicly reported on Medicare’s Hospital Compare; and second, among hospitals not reporting SPS, evaluate the potential impact of SPS on Leapfrog’s HSS grades using imputed SPS measures to simulate new HSSs.

METHODS

Data Sources

For all analyses, we combined data from 4 sources: (1) the Spring 2014 Leapfrog HSS dataset, which includes

hospital grades, SPS measures as reported in the 2013 Leapfrog Hospital Survey, and all other HSS components listed in Supplemental Table 2; Supplemental Digital Content 2 (<http://links.lww.com/MLR/B360>); (2) Hospital Compare data on CLABSI and CAUTI in 2013¹⁷; (3) Hospital Compare data on penalties assessed under the HRRP and HACRP in 2015¹⁷; and (4) hospital characteristics from the 2013 American Hospital Association (AHA) Survey Database.

Objective 1: Do Leapfrog SPS Measures Predict Publicly Reported Outcomes and Penalties?

Predictor Variables

Our predictor variables were Leapfrog SPS measures (Supplemental Table 1, Supplemental Digital Content 1, <http://links.lww.com/MLR/B359>) for hospitals that reported SPS measures. We selected 5 individual SPS measures (indicated in bold in Table 1) as representative of direct pathways from standards of care to study outcomes, as well as total SPS. AHA data were used to control for hospital characteristics: bed size (<50, 50–200, and >200 beds); ownership (public, private nonprofit, private for-profit); Council of Teaching Hospitals membership; and safety-net status, defined as ≥ 1 standard deviation more Medicaid patients than state average.

Dependent Variables

We examined 4 publicly reported outcome variables: CLABSI and CAUTI standardized infection ratios (SIRs), and penalization under HRRP or HACRP.

CLABSI and CAUTI SIRs

Hospital Compare CLABSI and CAUTI SIRs were reported to the National Health and Safety Network (NHSN) from April 1, 2012 to March 31, 2013. SIRs are risk-adjusted measures dividing the number of observed infections by the number of predicted infections calculated from CLABSI or CAUTI rates from a standard population throughout a baseline time period.^{18–20} SIRs >1.0 indicate more infections observed than predicted, whereas SIRs <1.0 indicate fewer observed than predicted.²¹

Penalties

The 2015 HRRP penalties covered readmissions from July 1, 2010 to June 30, 2013. Readmissions penalties are calculated via the readmissions adjustment factor (RAF), which incorporates a risk-adjusted excess readmission ratio and diagnosis-related group payments for all included conditions.²² The 2015 HAC penalties used CLABSI and CAUTI rates from January 1, 2012 to December 31, 2013, and PSI-90 from July 1, 2011 to June 30, 2013. HAC penalties were computed from the average decile of performance for the NHSN CAUTI and CLABSI rates, weighted at 65%, plus the decile of performance for the PSI-90, weighted at 35%.¹⁰ For both programs we examined a binary measure of penalization.

Analysis Strategy

To examine the relationship between Leapfrog SPS measures (individual and total) and CLABSI and CAUTI SIRs, we looked at bivariate correlations and used linear

regression to evaluate the effect of SPS on outcomes, controlling for hospital characteristics. For penalties, we computed point-biserial correlations between SPS measures and penalty indicators, and then used binary logistic regression to evaluate effect of SPS on odds of penalization, controlling for hospital characteristics. All analyses were performed using Stata MP Version 14.1²³ and a 0.05 two-sided significance level.

Objective 2: How Much Can Voluntary SPS Measures Impact HSS Grades?

Predictor Variables

Imputed SPS measures were our main predictors of interest. Because we were interested in their impact on HSS grades for hospitals that did not report them, 4 sets of SPS measures were imputed for hospitals, based on the distribution of SPS measures for hospitals that did report: lowest SPS measures (first percentile); low (10th percentile); median (50th percentile); and highest (100th percentile). As control inputs, we also included hospital data as observed for all other HSS components listed in Supplemental Table 1, Supplemental Digital Content 1 (<http://links.lww.com/MLR/B359>) as provided in the HSS database.

Dependent Variable

Our dependent variable was overall HSS, which ranges from 0 to 4; and corresponding HSS grades, which range from “A” to “F.”

Analysis Strategy

We simulated change in the HSS and corresponding grades after imputing SPS measures using the methodology reported by Leapfrog for their Spring 2014 HSS.²⁴ HSS comprise weighted z-scores (trimmed at 99th percentile, or $z = \pm 5$) across 2 domains: Process and Structural Measures (50% of total HSS); and Outcomes (remaining 50%). SPS measures account for 8 of 15 Process measures, or 22.6% of the total score. Hospitals that do not report SPS have other Process measures upweighted proportionally by Leapfrog. To simulate new scores imputing missing SPS measures at lowest, low, median, and highest levels, we converted the 8 SPS measures into z-scores, trimmed as appropriate, and recalculated weights for Process measure scores including SPS measures, before recalculating the Process domain score and subsequent total HSS. No changes were made to Outcome domain scores. Simulated scores for different values of SPS were then compared with original scores to evaluate change in score and letter grade.

Study Population

Supplemental Figure 1, Supplemental Digital Content 3 (<http://links.lww.com/MLR/B361>) illustrates the study flow diagram. In total, 2530 hospitals were included in the Spring 2014 HSS database. In total, 2178 had AHA data; either CLABSI or CAUTI SIR; and either HRRP or HACRP penalty data. The 1098 hospitals (50.4%) provided SPS and were included in our objective 1 analyses; 1080 (49.6%) declined to report SPS and were used for objective 2 analyses.

The University of Michigan Institutional Review Board deemed this study exempt from oversight.

RESULTS

Summary Statistics

Distributional statistics for SPS measures (Table 1) show highly skewed distributions for all individual measures. For all but 1 measure (SPS #1), the median score is also the highest score, indicating that at least 50% of hospitals self-report perfect data. First percentile values generally correspond to receipt of 1/3 of possible points for an individual measure; and 10th percentile values to 3/4 of possible points. Mean total SPS was 444.40; 213 hospitals (19.4%) reported a perfect 485.

With respect to hospital characteristics, outcomes and grades (Table 2), the 2178 hospitals included 279 (12.8%) teaching hospitals and 305 (14.0%) safety-net hospitals. Ownership was predominantly private, not-for-profit

(70.3%); the majority had >200 beds (60.7%). Average CLABSI SIR across all hospitals was 0.55, similar to the national baseline of 0.54, and average CAUTI SIR was 1.03 compared with the national baseline of 1.07.²⁵ Of note, NHSN SIRs analyzed here had baselines from 2008, with declines reflecting both improvements in care and NHSN definition changes. NHSN used 2015 data to rebaseline SIRs in January 2017.²⁶ In total, 1875 hospitals (86.1%) received a penalty under HRRP in 2015, and 582 (26.7%) were penalized for HAC. Compared with hospitals declining SPS, those providing SPS were larger ($P < 0.001$) and more for-profit ($P = 0.001$). CAUTI and CLABSI SIRs and penalization rates did not vary significantly by SPS provision. However, hospitals that provided SPS were graded significantly higher than hospitals that declined; 510 (46.5%) hospitals providing SPS received an “A” grade, compared with 193 (17.9%) hospitals declining SPS ($P < 0.001$).

TABLE 1. Descriptive Statistics and Distributions for Leapfrog SPS Measures

SPS Measures	Mean (SD)	Potential Range	Distribution (Scores Used for Imputation in Objective 2)			
			lowest (1%)	low (10%)	median (50%)	highest (100%)
#1: Culture of safety <u>leadership</u> structures and systems	111.28 (12.72)	0–120	51.43	94.29	111.43	120.00
#2: Culture measurement, <u>feedback</u> and intervention	18.09 (4.49)	0–20	0.00	15.56	20.00	20.00
#3: Teamwork <u>training</u> and skill building	34.97 (8.55)	0–40	4.00	20.00	40.00	40.00
#4: <u>Risks and hazards</u>	110.30 (17.31)	0–120	43.64	87.27	120.00	120.00
#9: Nursing workforce	92.31 (14.02)	0–100	38.10	76.19	100.00	100.00
#17: Medication reconciliation	31.93 (5.34)	0–35	11.67	25.67	35.00	35.00
#19: <u>Hand hygiene</u>	27.65 (4.54)	0–30	12.00	21.00	30.00	30.00
#23: Health care–associated complications in ventilated patients	18.42 (2.88)	0–20	6.67	13.33	20.00	20.00
Total SPS	444.40 (54.47)	0–485	Total score not used in imputations			

Measures in bold are examined as predictors or publicly reported outcomes and penalties under objective 1; all SPS measures except Total SPS are used for simulating new Hospital Safety Scores under objective 2. Underlined terms correspond to SPS measure descriptors displayed in Figure 2. SPS indicates Safe Practices Score.

TABLE 2. Descriptive Statistics for Hospital Characteristics, Hospital Compare CLABSI and CAUTI SIRs, Penalization, and HSS Grades for Spring 2014, Overall and by Provision of Leapfrog SPS

	n (%) or Mean (SD)			Test Statistics and P for Difference
	Overall (N = 2178)	Provided SPS (N = 1098)	Declined SPS (N = 1080)	
American Hospital Association hospital characteristics				
Teaching hospital? (1 = Yes)	279 (12.8)	150 (13.7)	129 (11.9)	$\chi^2_1 = 1.43$ $P = 0.23$
Bed size				
<50	18 (0.8)	9 (0.8)	9 (0.8)	$\chi^2_2 = 21.09$ $P < 0.001$
50–200	837 (38.4)	370 (33.7)	467 (43.2)	
>200	1323 (60.7)	719 (65.5)	604 (55.9)	
Ownership				
Public	249 (11.4)	94 (8.6)	155 (14.4)	$\chi^2_2 = 34.31$ $P = 0.001$
Private, not-for-profit	1531 (70.3)	761 (69.3)	770 (71.3)	
Private, for-profit	398 (18.3)	243 (22.1)	155 (14.4)	
Safety-net hospital? (1 = Yes)	305 (14.0)	146 (13.3)	159 (14.7)	$\chi^2_1 = 0.92$ $P = 0.34$
Outcome variables				
Hospital Compare SIR				
CLABSI	0.55 (0.51)	0.55 (0.50)	0.56 (0.52)	$t = -0.23$ $P = 0.82$
CAUTI	1.03 (0.88)	1.05 (0.87)	1.01 (0.89)	
Penalized in 2015 under ...				
HRRP	1875 (86.1)	942 (85.8)	933 (86.4)	$\chi^2_1 = 0.16$ $P = 0.69$
HACRP	582 (26.8)	306 (28.0)	276 (25.7)	
HSS grades assigned in Spring 2014				
A	703 (32.3)	510 (46.5)	193 (17.9)	$z = 15.79$ $P < 0.001$
B	588 (27.0)	299 (27.2)	289 (26.8)	
C	748 (34.3)	251 (22.9)	497 (46.0)	
D	119 (5.5)	35 (3.2)	84 (7.8)	
E	20 (0.9)	3 (0.3)	17 (1.6)	
F	20 (0.9)	3 (0.3)	17 (1.6)	

Test statistics include χ^2 (with degrees of freedom) for nominal variables, t -tests for continuous variables, and nonparametric trend tests (z -distribution) for ordinal variables.

CAUTI indicates catheter-associated urinary tract infection; CLABSI, central line-associated bloodstream infection; HACRP, Hospital-acquired Condition Reduction Program; HRRP, Hospital Readmission Reduction Program; HSS, Hospital Safety Score; SIR, standardized infection ratio; SPS, Safe Practices Score.

Objective 1: Do Leapfrog SPS Measures Predict Publicly Reported Outcomes and Penalties?

Bivariate correlations between SPS measures and outcomes were consistently weak (range, -0.05 to 0.05 , Supplemental Table 3, Supplemental Digital Content 4, <http://links.lww.com/MLR/B362>).

CLABSI and CAUTI SIRs

Figure 2A presents standardized regression coefficients and 95% confidence intervals from linear regression models predicting CAUTI and CLABSI SIRs, controlling for hospital characteristics (full model results in Supplemental Table 4, Supplemental Digital Content 5, <http://links.lww.com/MLR/B363>). Neither individual nor total SPS were significant predictors of CLABSI or CAUTI SIRs.

As sensitivity analyses, negative binomial models of observed infections were also estimated with an exposure for number of catheter days. These models also revealed no associations. We also compared the CAUTI/CLABSI SIRs self-reported in Leapfrog Hospital Survey with these same hospitals' CAUTI/CLABSI SIRs reported on Medicare's Hospital Compare. Note that Leapfrog uses CLABSI and CAUTI SIRs reported in the Leapfrog Hospital Survey as the

primary data source for the HSS, and Hospital Compare SIRs as a secondary data source. This analysis revealed similar CLABSI SIRs, but significantly lower CAUTI SIRs, even after accounting for Leapfrog's trimming of extreme values, with a mean CAUTI rate 0.47 reported in the Leapfrog Hospital Survey, compared with 1.05 in Hospital Compare (Supplemental Figure 2, Supplemental Digital Content 6, <http://links.lww.com/MLR/B364>).

Penalties

Figure 2B presents standardized odds ratios and 95% confidence intervals from binary logit models predicting penalization under HRRP or HACRP, controlling for hospital characteristics (full model results in Supplemental Table 5, Supplemental Digital Content 7, <http://links.lww.com/MLR/B365>). No SPS measures were significantly associated with penalization under HRRP, net hospital characteristics. One SPS (culture of measurement, feedback, and intervention) was significantly associated with penalization under HACRP, with a standard deviation increase in measure score decreasing odds of penalization by a factor of 0.87 (95% CI, 0.76–0.98). On average, this equates to a 2.7 percentage point decrease in probability of penalization. Sensitivity analyses used censored

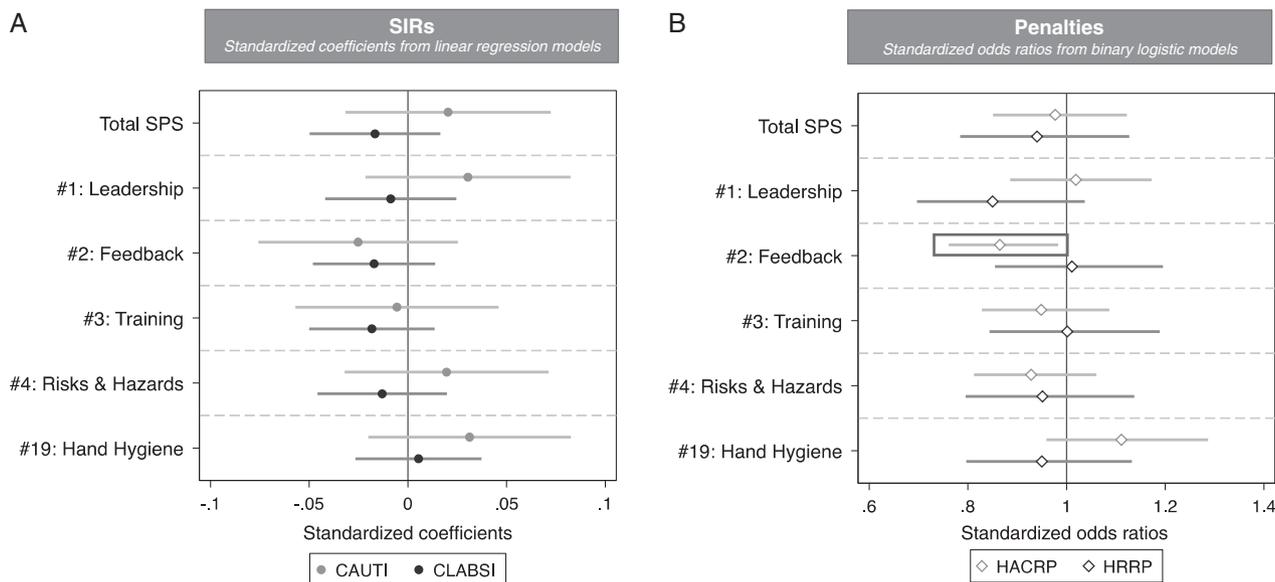


FIGURE 2. Is there an association between Leapfrog SPS and rates of CLABSI and CAUTI reported by Hospital Compare, or penalization for excessive readmission or hospital-acquired conditions? (A) SIRs: Standardized coefficients from linear regression models and (B) Penalties: Standardized odds ratios from binary logistic models. Coefficients and 95% confidence intervals from multivariate regression models, by individual and total SPS. Standardized coefficients presented for all SPS measures, indicating the change in dependent variable for a SD change in SPS measure. SIR models estimated as linear regression models. Penalty models estimated as binary logistic models, with odds ratios presented here. All models include controls for hospital size, ownership, teaching status, and safety-net status. CAUTI indicates catheter-associated urinary tract infection; CLABSI, central line-associated bloodstream infection; HACRP, Hospital-acquired Condition Reduction Program; HRRP, Hospital Readmission Reduction Program; SIR, standardized infection ratio; SPS, Safe Practices Score.

linear regression models to examine associations between SPS and HRRP RAF (range, 0.97–1.00) and HACRP total HAC score (range, 1–10). Correlations remained very small (range, –0.01 to 0.07) and only 1 SPS measure showed a significant association in either model (Supplemental Table 6, Supplemental Digital Content 8, <http://links.lww.com/MLR/B366>).

Objective 2: How Much Can Voluntary SPS Measures Impact Leapfrog’s HSS Grades?

With lowest SPS (first percentile; Fig. 3, Panel 1) imputed, hospitals saw grades decline by 0.8 points (of 4), on average. In total, 1062 (98%) of hospitals’ grades declined by ≥ 1 letter grade and very few hospitals (N=16; 1.5%) received a grade higher than D. Imputing 10th percentile grades for SPS (Fig. 3, Panel 2) resulted in a 0.24-point average decline in score, with 588 (54%) of hospitals’ grades declining by ≥ 1 letter grade. Alternatively, 9 hospitals’ (8%) grades improved by 1 letter grade.

Imputing median SPS (Fig. 3, Panel 3) resulted in a small improvement of 0.16 points, on average, in HSS, which improved grades for 528 hospitals (49%) by ≥ 1 letter. Imputing highest SPS (Fig. 3, Panel 4) resulted in only marginally more improvement, improving scores by 0.18 points, on average, and improving grades by ≥ 1 letter grades for 586 hospitals (54%).

DISCUSSION

The Leapfrog group has been a vanguard in developing and publicizing novel measures to inform patient choice. As

the market of measures has grown more crowded, their niche is increasingly delineated by 2 proprietary measures: 8 National Quality Forum-inspired SPS measures; and the HSS and corresponding grade, with Leapfrog SPS as its sole proprietary component. This study reports 2 major findings. First, there is a lack of meaningful association between voluntary SPS measures and compulsorily-reported patient outcomes and Medicare penalties for complications and readmissions. Second, the highly positively skewed voluntary SPS measures strongly impact the Leapfrog HSS beyond compulsory scores, so that imperfect SPS scores often result in lower grades.

Several mechanisms could underlie the lack of association between SPS and outcomes and penalties, yet lack of variation within SPS measures (Table 1) is responsible for much of the limited predictive ability. The observed lack of variation, meanwhile, could be due to selection effects; hospitals able to reliably report high scores may be more likely to volunteer. Alternatively, given that hospitals have a clear incentive to score themselves highly, participating hospitals may inflate their SPS reports, resulting in the skewed distributions and undermining the measures’ predictive value. As Leapfrog’s SPS focuses on processes and protocols linked to accountability (eg, protocols for handwashing for SP #19) rather than hard outcomes (eg, handwashing compliance), hospitals also have a strong incentive to produce protocol documents that meet Leapfrog documentation standards but may do little to impact clinical practice or patient outcomes.

Even with accurate data, however, SPS measures may not impact the outcomes highlighted in this study. Although

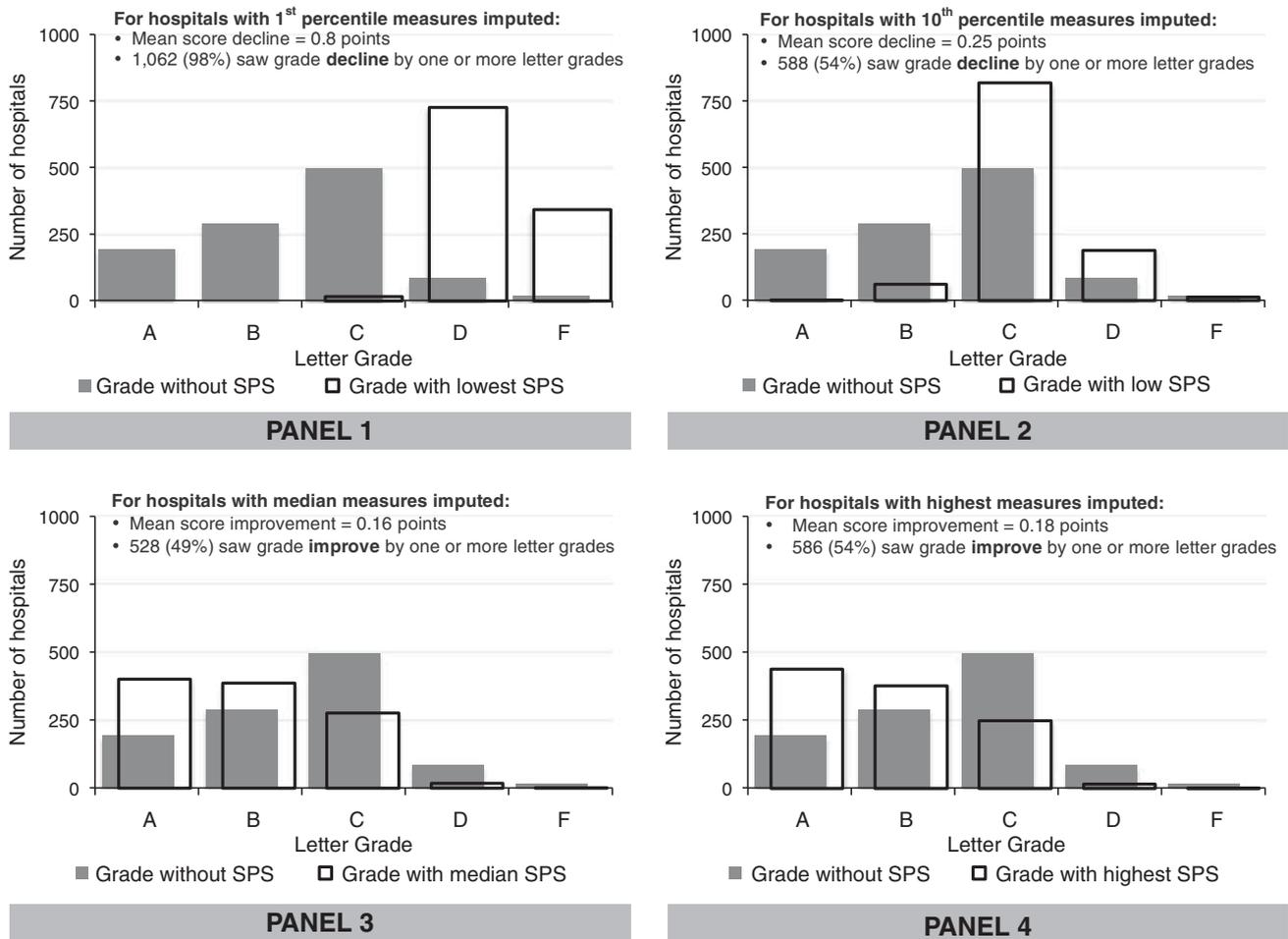


FIGURE 3. How much impact do voluntary SPS have on Leapfrog Hospital Safety Score letter grades? Change in letter grades (A through F) after imputing first percentile (Panel 1), 10th percentile (Panel 2), median (Panel 3), and highest (Panel 4) SPS measures. SPS indicates Safe Practices Score.

prior work has argued that SPS measures are more likely to be associated with complications than mortality,¹⁴ hospital variation in validity of CLABSI and CAUTI reports potentially correlates meaningfully with SPS measures. For example, hospitals with better reporting might also have higher SPS, which could cancel out more conventional negative associations.

Our analyses also show that Leapfrog SPS measures, when provided, can substantially impact a hospital’s HSS and grade—however, again due to the highly skewed distributions of the SPS measures, on average, there is more potential for low scores to negatively impact a hospital’s grade than for high scores to improve a grade. Indeed, as most hospitals report perfect scores for most SPS measures, hospitals accurately reporting scores that fall in the lower half of the potential distribution end up with z-scores for these measures that are strongly negative (up to the trim point of -5). Given the composite weight of these measures—nearly $\frac{1}{4}$ of the total HSS—low (or even lower than perfect) SPS can take a hospital’s grade from “A” to “B,” or even “C.” For hospitals that are uncomfortable with or unable to report very high SPS, the

current Leapfrog methodology thus presents a strong incentive against reporting SPS.

Alternatively, hospitals that improve SPS and/or report high, or even perfect, scores gain relatively modest advantages in their HSS. Perversely, there were 24 hospitals whose HSS declined after the highest SPS were imputed. This result is a function of the Leapfrog methodology converting highly skewed distributions into z-scores—in these cases, the most positive z-scores allowable by the SPS distribution were lower than the positive z-scores they had received for other Process measures; including SPS resulted in downweighting of these larger z-scores, and thus a lower grade. Leapfrog’s methodology, in tandem with the highly skewed SPS, results in a system that punishes hospitals whose scores fall at the lower end of the distribution far more significantly than it rewards those hospitals falling at the highest end.

Our study has several important limitations. First, we assess associations only among hospitals with all metrics of interest available; broader inclusion may have revealed more associations between SPS and outcomes. Second, we assess relationships between SPS and outcomes at 1 timepoint, thus

ignoring potential for association over time, or correspondence between change in SPS and change in patient safety outcomes. Third, our simulations rely on an implied counterfactual that all other observed process and outcome measures would remain the same in presence of imputed levels of SPS.

Leapfrog has faced prior criticism for using methods that advantage HSS for hospitals participating in the Leapfrog Hospital Survey in ways unrelated to representations of valid hospital safety.²⁷ This study revealed another way that Leapfrog Hospital Survey participation potentially advantaged hospitals. Rather than use Hospital Compare's publicly reported CLABSI and CAUTI SIRs for the HSS for all hospitals, these SIRs were only used for hospitals who did not complete the 2013 Leapfrog Hospital Survey; participating hospitals were allowed to use self-reported rates instead. Our comparisons of these self-reported SIRs with the Hospital Compare SIRs found that while CLABSI SIRs were largely similar across data sources for hospitals participating in the Leapfrog Hospital Survey, self-reported CAUTI SIRs were substantially lower than Hospital Compare CAUTI SIRs. This resulted in an advantage for hospitals that participated in the Leapfrog Hospital Survey, as they received credit for a lower SIR; it also disadvantaged hospitals that did not participate in the Leapfrog Hospital Survey by artificially deflating the mean of the distribution with which these hospitals' SIRs were compared.

Improving the Leapfrog HSS

Leapfrog's mission to grade hospitals in a manner that is both methodologically rigorous and results in accessible comparisons is undoubtedly laudable. However, the lack of association between Leapfrog's proprietary, and voluntary, SPS and the compulsory metrics reported on Medicare's Hospital Compare website raises questions about the internal consistency of Leapfrog's HSS. Recent press releases highlighting Fall 2016 Leapfrog grades^{28,29} illustrate the score's 2 audiences: for consumers attempting reconciliation of safety-related metrics, the HSS offers a comprehensive measure incorporating proprietary process measures and important outcomes; for hospital administrators, an "A" grade from Leapfrog offers consumer-friendly marketing opportunities. For both groups, however, the composite is only meaningful if it is internally consistent, that is, if process measures correlate in meaningful ways with important outcomes. For consumers, important outcomes reflect personal health needs and concerns; if SPS does not provide a direct pathway from experience to outcome, its value is unclear. For administrators, important outcomes are increasingly defined by policies that incentivize or penalize certain metrics; SPS that adds more noise than signal to composite measures undermine any value-added proposition.

Some of the deficiencies of the Leapfrog HSS have straightforward remedies. For example, Leapfrog should use Hospital Compare's CLABSI and CAUTI SIRs for all hospitals, rather than self-reported rates. Other deficiencies will require Leapfrog to align broader incentive structures with reporting accuracy, rather than opportunity for leniency. In the context of the HSS, where nearly all inputs now stem

from compulsory, standardized measures, voluntary SPS self-reports represent a rare locus of hospital control.

Although Leapfrog currently incorporates methods for encouraging data accuracy, including requiring a letter of affirmation and flagging potentially erroneous or misleading reports,³⁰ auditing processes are crucial for ensuring that variation in these measures reflects true differences in process best practice. Just as we would not expect drivers to turn themselves in for speeding, we should not expect hospitals to accurately self-report failure to protocolize safe practices. Leapfrog has recently implemented new efforts to externally validate data,³⁰ which may help to incentivize accurate reporting. As a further step, Leapfrog should consider asking hospitals to report information about the survey completion process, including potential conflicts of interest, for example, which administrators spearheaded Leapfrog survey response? What direct access to clinical practice do they have? And what stake (if any) do they have in the hospital's grade? To the extent that mechanisms of safe practices go beyond minimally implemented protocols, Leapfrog may also want to consider adding more objective safe practice measures to their survey.

Finally, Leapfrog should ensure that "honest" hospitals are not unfairly disincentivized to report less-than-ideal SPS measures. Given the strongly skewed distributions observed in recent SPS data, methods other than *z*-scores should be considered for making data commensurate.

CONCLUSIONS

In dissecting Leapfrog's Safe Practices Score measures and HSS and grades, our study finds little association between self-reported SPS measures and publicly reported outcomes and penalties data. Further, we find that Leapfrog's current methodologies, in combination with strongly positively skewed self-reports of SPS measures, punish low SPS reports substantially more than they reward high SPS. These concerns cast doubt on the utility of SPS and, more generally, the HSS and grades.

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Attachment 2

Article

Hospital Safety Scores, Do Grades Really Matter?

VIEWPOINT

Hospital Safety Scores

Do Grades Really Matter?

Andrew A. Gonzalez, MD, JD, MPH

Department of Surgery,
Center for Healthcare
Outcomes & Policy,
University of Michigan,
Ann Arbor.

Amir A. Ghaferi, MD

Department of Surgery,
Center for Healthcare
Outcomes & Policy,
University of Michigan,
Ann Arbor.

Since the 1999 Institute of Medicine report "To Err is Human: Building a Safer Health System," hospital safety has emerged as a central issue for patients, payers, and policy makers. Based on estimates from that report, medical errors result in 44 000 to 98 000 deaths every year in the United States, making them the third leading cause of death—ahead of breast cancer, AIDS, and motor vehicle crashes.¹ As a result of that report and growing scrutiny from the media and patient advocacy groups, hospitals nationwide have redoubled their efforts at improving patient safety.

Aiming to enhance hospital accountability and to accelerate improvements in safety, The Leapfrog Group, a national consortium of large employers and health care purchasers, launched the Hospital Safety Score in 2012.² Based on input from an expert panel, The Leapfrog Group consolidated a variety of proprietary and publicly available hospital safety data into a single composite score. In designing the composite score, 50% of the weight was applied to measures of processes of care (eg, timely administration of perioperative antibiotics) and hospital structure (eg, computerized physician order entry). The remaining 50% of the weight was applied to outcome measures (eg, rates of selected hospital-acquired conditions, such as iatrogenic pneumothorax).² Hospitals were then rated and given a safety letter grade ranging from A to F, which reflects how safe hospitals are for patients.

Dissemination of the Hospital Safety Score is a key component of The Leapfrog Group's strategy. In addition to making these ratings freely available on the Internet, The Leapfrog Group is also leveraging modern smartphone technology to help patients identify the safest hospitals and to allow hospitals to advertise their safety ratings. The latest release includes a free downloadable mobile application that allows users to view a hospital's overall safety grade and relative performance on patient safety measures. In addition, users are provided with links to hospital websites, the ability to call hospitals directly from the mobile application, and integration with social media such as Twitter and Facebook.

To examine the extent to which the Hospital Safety Score directs patients to hospitals with better outcomes, we linked Leapfrog's final grade to patient outcomes using the 2009-2010 national Medicare Provider Analysis and Review files. Hospital Safety Scores were downloaded directly from the Hospital Safety Score website (www.hospitalsafetyscore.org). We extracted hospital name and zip code variables from the American Hospital Association's 2009 annual survey of hospitals to facilitate linking patient-level data with Hospital Safety Scores. This algorithm successfully matched

2483 of the 2620 (94.8%) hospitals evaluated by The Leapfrog Group.

Our study population included both medical and surgical hospital admissions. For medical admissions, we assessed 30-day mortality and 30-day readmission rates for acute myocardial infarction, congestive heart failure, and pneumonia (n = 2 369 533). For surgical admissions, we assessed the same outcomes among patients undergoing coronary artery bypass grafting, hip fracture repair, and colectomy (n = 829 731). In the surgical cohort we also assessed rates of major complication and failure to rescue (patient fatality after a major complication) using methods described elsewhere.³ Outcomes were adjusted for patient age, race, socioeconomic status, and comorbidities using standard regression-based methods.³ In addition, all SEs were "clustered" to account for any intrahospital correlation of patient outcomes. This technique adjusts the 95% CIs to allow for arbitrary correction of error terms within individual hospitals. All analyses were completed using Stata 12 (StataCorp).

As seen in the Figure, patients treated at hospitals receiving safety grades of D or F (n = 145) had slightly higher 30-day mortality for both medical and surgical admissions. In the surgical cohort, hospitals with safety grades of D or F had significantly higher rates of failure to rescue, but similar rates of complications. Despite worse outcomes in hospitals with safety grades of D or F, the safety composite score did not discriminate outcomes in the remaining hospitals. Specifically, there was negligible difference in mortality or complication rates among hospitals receiving A, B, or C grades. There were no statistically significant differences across grades for readmission rates in either the medical cohort (21.0% to 21.3%, $P = .23$) or the surgical cohort (14.8% to 15.2%, $P = .12$).

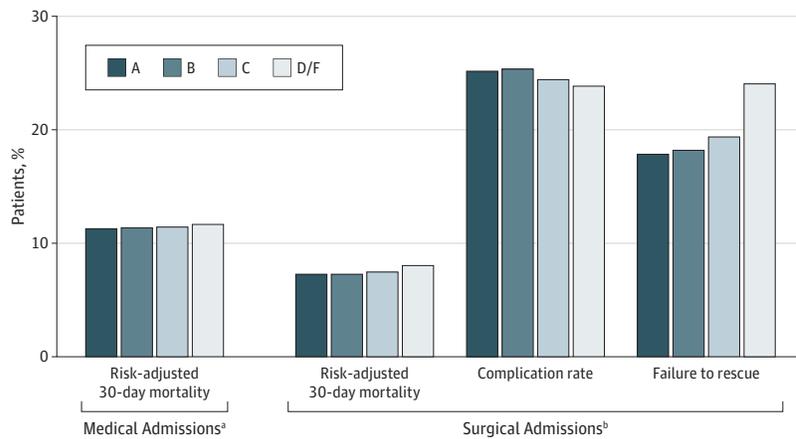
There are several potential reasons why the Hospital Safety Score may fail to discriminate outcomes among the large majority of hospitals with nonfailing grades. First, previous studies comparing administrative data to expert medical record reviews have described only a weak association between patient safety indicators, such as iatrogenic pneumothorax, and patient outcomes.⁴ Second, two-thirds of the process and structural measures are self-reported and non-audited, raising questions concerning completeness and accuracy. Further contributing to possible measurement error, data are drawn from different sources depending on whether the hospital completed the proprietary Leapfrog Hospital Survey.

Apart from the reliability of its component measures, the value of the Hospital Safety Score may be further limited by the variable clinical relevance of those

Corresponding

Author: Andrew A. Gonzalez, MD, JD, MPH, Center for Healthcare Outcomes & Policy, 2800 Plymouth Rd, North Campus Research Complex, Bldg 16, Room 100-14, Ann Arbor, MI 48109 (aagonzal@umich.edu).

Figure. Risk-Adjusted Rates of Adverse Outcomes by Leapfrog Hospital Safety Score Letter Grade

^a $P < .001$.^bMortality, $P < .001$; complication, $P < .11$; failure to rescue, $P < .001$.

measures. For example, numerous studies have raised doubts as to the extent to which process measures tracked by the Centers for Medicare & Medicaid Services, such as foreign objects retained after surgery, are associated with patient outcomes.⁵ These measures encompass relatively rare events more reflective of patient illness severity and hospital case mix than true signals of quality. For this reason, starting in 2013, the Centers for Medicare & Medicaid Services no longer reports many of these measures on its website (<http://medicare.gov/hospitalcompare/search.html>).

In drawing further attention to patient safety, Leapfrog's Hospital Safety Score may ultimately enhance safety by increasing accountability and accelerating safety initiatives within hospitals. From a patient perspective, the Hospital Safety Score may be useful be-

cause it distills a variety of somewhat confusing measures into a single, easily understandable letter grade. Finally, as suggested by the analysis herein, the grading system may be valuable in helping patients to identify and avoid the few hospitals with potential safety problems.

Nonetheless, our findings raise questions about the informational value of these measures for the 94.2% of hospitals with non-failing grades. Outcomes-based measures that include mortality, major complications, and failure to rescue may ultimately be more useful in guiding patients to institutions where they can expect better end results. In the meantime, our results suggest that The Leapfrog Group might consider moving to a pass/fail system rather than letter grades.

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