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Standardized Clinical Assessment And Management Plans (SCAMPs) Provide A Better Alternative To Clinical Practice Guidelines

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Abstract

Variability in medical practice in the United States leads to higher costs without achieving better patient outcomes. Clinical practice guidelines, which are intended to reduce variation and improve care, have several drawbacks that limit the extent of buy-in by clinicians. In contrast, standardized clinical assessment and management plans (SCAMPs) offer a clinician-designed approach to promoting care standardization that accommodates patients' individual differences, respects providers' clinical acumen, and keeps pace with the rapid growth of medical knowledge. Since early 2009 more than 12,000 patients have been enrolled in forty-nine SCAMPs in nine states and Washington, D.C. In one example, a SCAMP was credited with increasing clinicians' rate of compliance with a recommended specialist referral for children from 19.6 percent to 75 percent. In another example, SCAMPs were associated with an 11–51 percent decrease in total medical expenses for six conditions when compared with a historical cohort. Innovative tools such as

SCAMPs should be carefully examined by policy makers searching for methods to promote the delivery of high-quality, cost-effective care.

The great degree of variability in US medical practice leads to higher costs without measurable differences in outcomes.[1,2] Efforts to reduce this variability and thereby rein in the overuse of resources and improve the quality of care have largely focused on clinical practice guidelines.[3–5] Created by professional societies to standardize practice and promote evidence-based medicine, these guidelines have several shortcomings that can trigger clinician resistance.[6,7]

Most clinical practice guidelines acknowledge the limitations of the evidence they present, make recommendations that are graded based on the strength of evidence supporting them, and permit variation. However, payers and regulatory agencies often translate guidelines into rigid decision support tools and use adherence to them as a measure of the quality of care.[8]

This official sanctioning of “best practices” can be at odds with an appropriate consideration of patients’ individual differences and personal preferences, and patients can perceive it as representing a rationing of care. What's more, when medical decisions are driven by guidelines, physicians sometimes perceive that their autonomy is being eroded,[9] which is an increasingly recognized source of clinician dissatisfaction.[10]

The way in which clinical guidelines are developed can raise concerns about their validity and whether they were subject to external influence.[11,12] Clinical studies that form the foundation of guidelines also have limitations. For example, randomized controlled trials, considered the gold standard for medical evidence, derive their scientific validity from testing hypotheses in selected, homogeneous subject populations. However, real patients are diverse and have complex comorbidities, which makes it difficult to translate trial results into practice. Prospective cohort studies also have limitations since they focus on narrow populations and can be inefficient in their examination of less common outcomes.

Another characteristic of clinical studies may also weaken the validity of clinical guidelines. These studies typically exclude from analyses any “outliers”—practices that deviate from the research protocol or patients who have unusual outcomes—even though such deviations and anomalies can be valuable sources of innovation and information.[13]

Furthermore, whether derived from trials or cohort studies, the medical evidence that forms the basis for clinical practice guidelines has a surprisingly short shelf life. One meta-analysis found that systematic reviews of randomized trials had a median “survival time” of 5.5 years before needing an update, with 23 percent requiring an update within two years.[14] Another study reported that about half of the guidelines published by the Agency for Healthcare Research and Quality needed updating within 5.8 years.[15]

In short, clinical practice guidelines are limited in their ability to deliver what our health care system needs: a way to promote greater care standardization that accommodates

patients' differences, respects providers' clinical acumen, and keeps pace with the rapid growth of medical knowledge.

Standardized Clinical Assessment And Management Plans

Standardized clinical assessment and management plans (SCAMPs) represent a promising alternative to, and improvement on, clinical practice guidelines. SCAMPs are a practical and flexible tool for narrowing practice variability while still permitting providers to exercise their clinical acumen and adapt treatment pathways to individual patients' needs. In essence, SCAMPs are flexible and continuously improving care guidelines created by clinicians to examine and repeatedly modify existing practice methods.

Clinical practice guidelines are often associated with the concept of "best practice"—ideal patient management that draws on current medical understanding and consensus. However, we contend that the word *best* can be misleading and paralyzing because it implies a value judgment that overlooks changes in medical knowledge, therapeutic options, and patient populations and can discourage both the use of clinical acumen and necessary practice variation.[16]

We argue that a more useful concept for standardizing care is "sound practice," a synthesis of current medical knowledge and best clinical judgment that embraces improvement. In fostering sound practice, therefore, SCAMPs are an improvement on clinical practice guidelines that are based on best practice.

Similar to a practice guideline, each SCAMP sets forth a standard care pathway for a diverse patient population with a particular condition—for instance, chest pain or high cholesterol. Recommendations on medical management are structured as decision trees, providing guidance for decision making.

In contrast to a practice guideline, each SCAMP collects targeted clinical data about the patients, their conditions, their testing and treatment choices, and their outcomes through the use of the electronic health record or a paper form filled out by the clinician. In this way, the SCAMP directly measures the use of resources in the care of the patient.

Providers using a SCAMP can divert from it at any time to provide individualized patient management, and they are asked to supply their rationale for doing so through the electronic or paper forms. As a result, a SCAMP actively invites and captures clinician diversions, which—as noted above—are a rich source of information and innovation.

Developing A SCAMP

The first SCAMPs were conceived, designed, and implemented by physician and nursing leaders of the Cardiovascular Program at Boston Children's Hospital in 2009, with early support from other pediatric cardiologists.[17]

The care of children with heart disease is both risky and costly, and it is characterized by considerable variation and uncertainty in practice.[18,19] SCAMPs can be used in specialized fields of medicine such as pediatric cardiology, where limited clinical data are available to

inform decision making. They are also useful in standardizing treatment for patients with conditions for which randomized trial data are limited or out of date, a common phenomenon given the rapid pace of knowledge generation.

The development and subsequent modification of a SCAMP involves an eight-step process that is carried out by a multidisciplinary group of clinicians.[20] It typically takes three to six months before a SCAMP can be implemented. Each round of SCAMP analysis and modification usually takes another one to two years.

First, the clinician group formulates a background position paper on a particular disorder, examining the medical literature and relevant professional society guidelines to establish a foundation for sound clinical practice.[21] If necessary, the group conducts a focused retrospective study to analyze current practice. The group that designed the SCAMP on pediatric chest pain at Boston Children's Hospital conducted a study of patients previously evaluated for this condition at the hospital to help determine which characteristics associated with chest pain corresponded with clinically significant cardiac abnormalities.[22]

Second, the group reaches consensus about which patients to include in the SCAMP, what clinical assessments to use, and how to structure the treatment algorithm. This step is modeled on the processes and standards that professional societies use to create practice guidelines.[23]

Third, the group formulates “plausible findings” that highlight knowledge gaps and help identify data to be collected. For instance, although it is well known that childhood obesity rates are rising, the relationship between elevated weight and pediatric chest pain is not well established. A plausible finding in a SCAMP for pediatric chest pain might be that chest pain during exertion in children with a body mass index greater than 25 is less likely to have a cardiac basis than chest pain in children with a body mass index between 20 and 25. With the inclusion of this plausible finding, the patients’ body mass indexes, whether their chest pain is associated with exertion, and the ultimate results of their clinical workups would become required SCAMP data elements.

Fourth, data forms (see online Appendix Exhibit 1A)[24] and electronic tools are developed to implement the SCAMP and collect targeted clinical data, information on resource use, and reasons for clinicians’ diversions from the SCAMP recommendations.

Fifth, the SCAMP is piloted at a few sites before being deployed on a larger scale throughout a network of practices or institutions. Patient enrollment begins when a data coordinator, with the help of electronic and manual screening tools, identifies an eligible patient and notifies the clinician.

The coordinator then supplies the needed SCAMP data form, in either electronic or paper format, to the clinician prior to the patient's initial visit. During the visit the clinician confirms the patient's eligibility to be part of the SCAMP. Starting with this first visit and continuing in follow-up encounters, the clinician provides care to the patient according to the SCAMP treatment algorithm, asking pertinent questions, acquiring required data

elements, and using his or her best clinical judgment about whether to follow the SCAMP recommendations.

Sixth, a data coordinator gathers clinical data from the forms the clinicians have filled out on patients and extracts additional relevant information from their electronic health records. Diversions and clinicians' reasons for individualized management are also captured. All of this information is stored in a database.

Seventh, after a set time period—typically six to twelve months—has passed or a minimum number of patients—usually 200—have been enrolled, SCAMP data are analyzed by a statistician. This analysis focuses on plausible findings, adherence to the treatment algorithm, and the clinical and cost-effectiveness of the recommendations. The statistician's report is reviewed by the clinical group and also shared with the larger group of clinicians participating in the SCAMP to ensure transparency.

Eighth and last, persuasive data from the above analysis and from new medical literature are used by the clinical group to modify the SCAMP.

This process of developing, implementing, and modifying a SCAMP helps rapidly optimize clinical decision making and care delivery based on existing standards of medical management. Clinical decisions involving less-established diagnostic and therapeutic options may require more rigorous evaluation through effectiveness trials. Data collected through SCAMPs highlight these areas of uncertainty and provide useful preliminary information to inform trial design.

Three Interconnected Aims

SCAMPs have three explicit goals: reduce practice variation, optimize resource use, and improve patient care.

REDUCING PRACTICE VARIATION

Clinicians who use SCAMPs adhere to their recommendations at a rate exceeding 80 percent (Exhibit 1), even though clinicians are free to use their own clinical judgment in place of the SCAMP's recommendations. This high rate of adherence demonstrates that SCAMPs reduce practice variation while permitting individualized patient management.

When clinicians do exercise their own judgment, the SCAMP collects information about why they chose not to follow its recommendations. Analyzing such diversions shows that most of them occurred because a patient's comorbidities or other circumstances made the SCAMP treatment algorithm not optimal for that patient.[25]

Tracking and understanding these diversions is critical to revising the SCAMP. For instance, the treatment algorithm for the SCAMP for pediatric patients with a dilated aorta specified that they be referred to a genetic specialist. However, many providers using the SCAMP chose to not make this suggested referral.

Analysis of SCAMP data on patients who were referred to a genetic specialist showed that the majority of these referral visits were not yielding important new clinical information. Revising the SCAMP's criteria for a genetic specialist referral so that the recommendation applied not to all patients but only to those who had a dilated aorta as well as other symptoms that suggested an underlying genetic disorder—such as eye abnormalities, joint dislocations, or a family history of similar disease—increased clinicians' buy-in. As a result, adherence to this recommendation improved from 19.6 percent to 75.0 percent ($p < 0.0001$).

In some cases, diversions are found to be unjustified, highlighting opportunities for targeted education to address gaps in providers' knowledge. In the SCAMP on hypertrophic cardiomyopathy—a genetically linked disease that can lead to sudden death—many providers were scheduling follow-up visits more frequently than recommended when testing showed that a patient carried a gene mutation associated with the disease.

This increased follow-up rate was found to stem from heightened parental and provider anxiety over disease progression in cases where the patient was known to have the gene mutation. Teaching providers that the mutation's presence does not alter the disease progression helped reduce the rates of follow-up visits for these patients in a safe and evidence-based way. This knowledge gap might have gone unrecognized had the SCAMP not captured the common diversion from its recommendations and the clinicians' rationale for diverting.

OPTIMIZING RESOURCE USE

SCAMPs reduce the unnecessary use of resources, which has a substantial impact on the cost of care.[26] To facilitate a financial analysis, Boston Children's Hospital statisticians have begun to capture all medical expenses pertinent to a SCAMP condition during a predefined time period. For six such episodes of care, the implementation of a SCAMP was associated with an 11–51 percent decrease in total medical expenses (Exhibit 2), with an overall cost reduction of 27.5 percent and estimated savings of $702,000 for a cohort of roughly a thousand patients when compared to historical controls.

IMPROVING PATIENT CARE

Some SCAMPs have demonstrated both reduced practice variation and improved patient outcomes. The preferred treatment for children with congenital aortic stenosis—narrowing of the heart's aortic valve—is balloon valvuloplasty via catheterization, or repair of the aortic valve using a balloon inserted with a catheter. The use of a SCAMP on this intervention at Boston Children's Hospital increased the frequency of "ideal" outcomes from 40 percent to 69 percent and reduced "inadequate" outcomes from 30 percent to 9 percent (Exhibit 3).

Data demonstrate that "ideal" outcomes lead to a lower likelihood of future aortic valve surgery.[27] The success of the SCAMP in achieving these better outcomes is predicted to reduce total cardiac medical expenditures per patient by 33 percent over the ensuing ten years (Exhibit 2).

Importantly, in no case has a SCAMP been demonstrated to reduce the quality of care delivered to an enrolled patient. A rigorous pre-post comparison conducted on the first six SCAMPs by an adjudication committee convened to review SCAMP use and diversions[25] did not identify any increase in adverse events attributable to SCAMP implementation.

ALIGNING STAKEHOLDERS' INTERESTS

Multiple stakeholders throughout the US health care system have endorsed the implementation of SCAMPs. Insurance companies recognize the use of SCAMPs as a way to eliminate unnecessary care while improving quality. A consortium of Massachusetts payers, including Blue Cross Blue Shield of Massachusetts, Tufts Health Plan, Harvard Pilgrim Health Care, and MassHealth, provided early and important funding for SCAMPs through the Payer-Provider Quality Initiative at Boston Children's Hospital.

Strong support from hospitals in California, Connecticut, Maine, Massachusetts, New Hampshire, Pennsylvania, Rhode Island, Vermont, Wisconsin, and Washington, D.C., has facilitated the dissemination of SCAMPs (Appendix Exhibit 2A).[24] These institutions recognize that using SCAMPs can cut into revenues through reduced use of resources. Nonetheless, the hospitals embrace the use of SCAMPs in their efforts to improve patient care. Furthermore, the hospitals believe that losses in revenue may be offset by future financial alignment with payers through revised payment models and incentives based on SCAMPs (discussed below).

Providers who choose to use a SCAMP tend to find the experience highly satisfactory. A survey of clinicians at Boston Children's Hospital in 2010 found that the approval ratings of SCAMPs exceeded those of other tools used to standardize and improve care, such as practice guidelines and care pathways.[28]

A second survey, conducted eighteen months later and involving clinicians from six different institutions, found that SCAMPs were preferred by 72 percent of providers, with clinical practice guidelines a distant second, preferred by only 12 percent of respondents (unpublished data). We have observed that providers' satisfaction with using a SCAMP tends to improve with increased understanding of the SCAMP's goals.

Perhaps most important, we are actively exploring patients' perceptions of SCAMPs. Preliminary results from a 2011–12 survey of 400 patients and parents of patients demonstrate that SCAMPs do not interfere with patient satisfaction with their providers or the care that they receive (unpublished data).[29]

The Impact Of SCAMPs

Since early 2009 more than 12,000 patients (Appendix Exhibit 3A) have been enrolled in forty-nine SCAMPs (Appendix Exhibit 4A) in pediatric and adult medicine. The SCAMPs target conditions ranging from common outpatient complaints such as hyperlipidemia to advanced surgical procedures such as the repair of complex congenital heart disease. Twenty-two SCAMPs have undergone review and algorithm modification after an analysis of collected data. Twenty-four new SCAMPs are in development (Appendix Exhibit 5A).[24]

Nineteen health care institutions currently collect SCAMP data (Appendix Exhibit 2A).[24] Six of these—Boston Children's Hospital; Brigham and Women's Hospital, also in Boston; Children's National Medical Center, in Washington, D.C.; Lancaster General Hospital, in Lancaster, Pennsylvania; Children's Hospital of Wisconsin, in Milwaukee; and the Pediatric Endocrine Society, based in McLean, Virginia—have formally agreed to collaborate on implementing and analyzing SCAMPs.

The fact that so many institutions have implemented SCAMPs for such a wide range of conditions demonstrates the scalability of the SCAMP approach and reflects the broad buy-in that it has achieved from multiple stakeholders.

Policy Implications And Opportunities

The success that SCAMPs have achieved so far may have important policy implications.

ADDED TOOLS FOR REFORM

First, SCAMPs could provide the critical tools needed by the Centers for Medicare and Medicaid Services and other payers to guarantee the success of various patient care and payment reforms that are now under way. SCAMPs can be rapidly developed and efficiently deployed across a wide range of care delivery settings by relatively small groups of clinicians. They provide actionable information quickly and include an examination of the costs of care as a critical outcome. SCAMPs accomplish these goals without unduly restricting a clinician's ability to provide care, thus avoiding concerns about imposed rationing.

Although other efforts to standardize care and reduce resource use have struggled to keep multiple stakeholders' incentives aligned, SCAMPs have earned buy-in from providers, hospitals, and major payers. SCAMPs may also help new accountable care organizations, which will require tools to evaluate and optimize care management on a large scale to generate meaningful cost savings. Successful accountable care organizations are likely to be learning organizations whose providers are able to articulate, evaluate, and change care delivery on an ongoing basis, a process that SCAMPs demonstrably facilitate.

One example of the way in which SCAMPs support the learning process is the improvement in the SCAMP recommendation for referrals to genetic specialists for patients with a dilated aorta, mentioned above. Another example comes from a SCAMP on transposition of the great arteries, a serious congenital cardiac abnormality that requires immediate surgical intervention after birth if the patient is to survive.

Cardiac magnetic resonance imaging was recommended by the SCAMP at the twelve-year follow-up visit for all patients who had undergone this surgery. However, some providers were diverting from this recommendation and not having patients obtain the imaging. An exploration of these diversions led to the proposal that probably only high-risk patients—that is, those who had transposition of the great arteries and had experienced challenges during their surgical intervention—would benefit from magnetic resonance imaging. The

SCAMP was revised so that imaging was no longer recommended for low-risk patients, leading to a reduced burden on patients and to cost savings in their management.

APPROPRIATE RESOURCE USE

Second, the use of SCAMPs by providers offers a cost-effective means of ensuring the appropriate use of resources, especially when compared with tools such as prior authorization. In addition, the framework that a SCAMP uses to manage an episode of care provides a longitudinal view of patient care and outcomes that is helpful in defining episodes that are appropriate for economic evaluation, an important step in attaining optimal care.

When Boston Children's Hospital statisticians analyzed the SCAMP on transposition of the great arteries, no new major cardiac problems were discovered in patients over five years old. Thus, the SCAMP episode of care that previously covered these patients from infancy into adulthood was divided into an early episode, aimed at detecting new cardiac problems within the first five years, and a late episode, focused on the management of known problems. Being able to accurately predict providers' use of resources and payers' expenditures in this way, which SCAMPs can accomplish readily, has considerable systemwide benefits that may lead to substantial administrative simplification.

COMPLEMENT TO COMPARATIVE EFFECTIVENESS RESEARCH

Third, SCAMPs should be recognized as an alternative to tools such as clinical practice guidelines and a complement to efforts in comparative effectiveness research. As mentioned above, payers and regulatory agencies use strict adherence to practice guidelines as a measure of care quality. Guidelines are thus often seen to discourage individual variation and to compel clinicians to conform, though they may not have been designed to be used in this way. SCAMPs can incorporate and iteratively improve on elements of practice guidelines while giving providers flexibility and obtaining relatively high adherence rates. In this way SCAMPs and similar tools may offer a superior approach in the effort to reduce practice variation when compared to guidelines, especially in areas where strong evidence is lacking.

SCAMPs also align well with comparative effectiveness research, which aims to examine medical management options and define effective care delivery strategies. And SCAMPs can complement patient-centered outcomes research, which explicitly acknowledges individual patients' differences in desired treatments and health outcomes.

Policy makers and the Patient-Centered Outcomes Research Institute should ensure that funding available for comparative effectiveness research is sufficiently flexible to support novel clinically integrated learning systems like SCAMPs, given their ability to deliver timely, actionable, and patient-centered information. Furthermore, a formal cost-benefit analysis of SCAMPs compared to other clinical research tools in achieving health care optimization may be warranted.

FAIR DISTRIBUTION OF COSTS AND SAVINGS

Finally, as many participants in payment reform discussions recognize, the fair distribution of the costs and savings resulting from optimizing patient care is critical to the success of any clinical standardization tool. We are convinced that clinicians and hospitals will welcome the opportunity to forgo the unnecessary use or overuse of resources if they can recover, rather than absorb, the operational costs associated with implementing tools such as SCAMPs. As with the adoption of electronic health records, the federal government and private payers could support the adoption of SCAMPs and similar systems.

Alternatively, a shared-savings structure could provide the necessary incentives for redesigning health care. This model might assume that systems such as SCAMPs would reduce expenditures by 8 percent across an at-risk population. Two percent could be shared between hospitals and participating providers. Payers could return the remaining 6 percent to society in the form of reduced premiums or investments in the information technology and personnel required to sustain SCAMPs.

Conclusion

Stakeholders have called for flexible, reliable, and scalable approaches that will improve quality, reduce variability, preserve innovation, and identify and purge unnecessary resource use in health care and that will also gain buy-in from patients and providers. Because SCAMPs provide a methodology through which these goals can be achieved, they could represent a breakthrough in the struggle to optimize resource use and to define and implement effective care.

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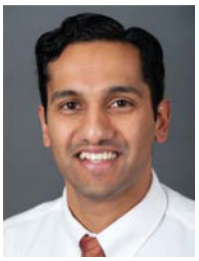
Biography



Michael Farias is a senior resident in pediatrics in the Boston Combined Residency Program.

In this month's *Health Affairs*, Michael Farias and coauthors describe standardized clinical assessment and management plans, or SCAMPs, which they contend offer a preferred alternative to standard clinical practice guidelines. SCAMPs, designed by clinicians, promote care standardization and reduce practice variation, but they still accommodate patients' individual differences, respect providers' clinical acumen, and keep pace with the rapid growth of medical knowledge. The authors describe results from forty-nine SCAMPs involving roughly 12,000 patients since 2009 and recommend that SCAMPs be given serious consideration by policy makers searching for methods to promote the delivery of high-quality, cost-effective care.

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29. We conducted a survey of 200 SCAMP and 200 non-SCAMP patients or parents of patients in 2011–12 in the Boston Children's Hospital outpatient cardiology clinic and found no significant difference in satisfaction across fourteen measures of satisfaction. These data are being prepared for publication.

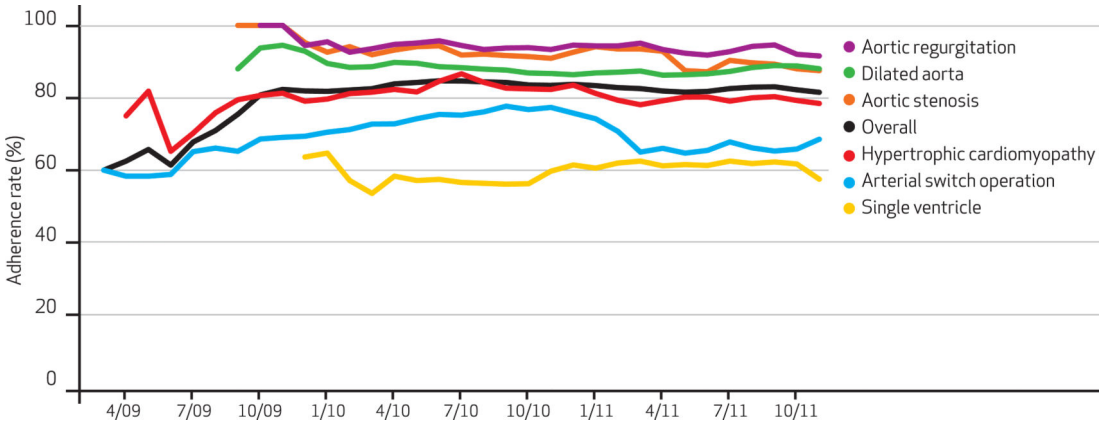

Exhibit 1.

Providers' Adherence To Testing Recommendations Of The First Six Standardized Clinical Assessment And Management Plans (SCAMPs), Twelve-Month Rolling Adherence Rate, March 2009–November 2011

SOURCE Authors' analysis. **NOTES** The first six SCAMPs (for arterial switch operation, hypertrophic cardiomyopathy, dilated aorta, aortic regurgitation, aortic stenosis, and single ventricle) focus on pediatric cardiac disease and were the first SCAMPs designed and implemented by the Department of Cardiology at Boston Children's Hospital. This analysis excludes adherence to magnetic resonance imaging recommendations in arterial switch operation, hypertrophic cardiomyopathy, dilated aorta, and aortic stenosis because these recommendations were not universally relevant in early implementation of the SCAMPs.

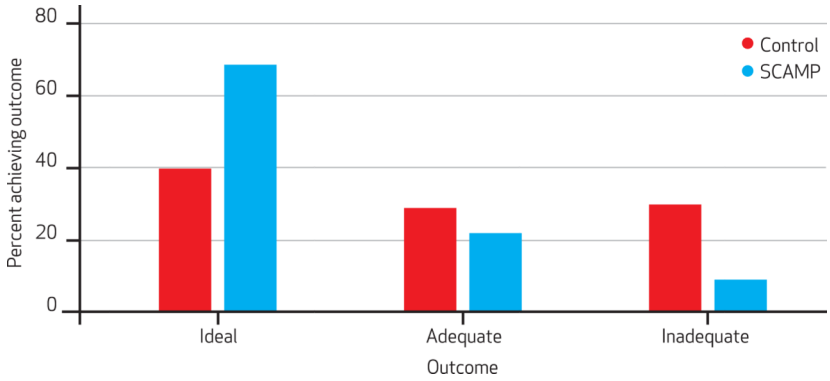

Exhibit 3.

Impact Of The Use Of A Standardized Clinical Assessment And Management Plan (SCAMP) On Catheterization Intervention On Aortic Stenosis In Children

SOURCE Authors' analysis. **NOTES** The percentages are for SCAMP patients (n = 23) and historical controls (n = 92). Outcomes were ideal (≤35 mmHg residual gradient across stenotic aortic valve and none to trivial residual aortic regurgitation), adequate (≤35 mmHg residual gradient and mild residual aortic regurgitation), or inadequate (>35 mmHg residual gradient, moderate to severe residual aortic regurgitation, or both).

EXHIBIT 2

Cost Reduction Per Episode Of Care With The Use Of A Standardized Clinical Assessment And Management Plan (SCAMP)

	Condition					
	Chest pain	**Arterial switch operation**	**Hypertrophic cardiomyopathy**	**Aortic stenosis treated in clinic**	**Aortic regurgitation**	**Aortic stenosis treated in catheterization lab**
NUMBER OF EPISODES						
Control	406	158	99	51	107	— [a]
SCAMP	399	188	226	83	111	14
AVERAGE COST PER EPISODE OF CARE						
Control ($)	1,506	2,384	1,638	5,406	2,064	34,100
SCAMP ($)	1,200	2,111	1,306	2,661	1,464	22,743
Reduction with use of SCAMP (%)	20	11	20	51	29	33

SOURCE Authors' analysis.

NOTES Costs were calculated by multiplying charges by a ratio of costs to charges; the ratio was 0.625. Costs were shown or predicted to decrease across episodes of care in six SCAMPs when SCAMP patients (n = 1,021) were compared to historical control patients (n = 821) from the year prior to SCAMP implementation. We employed a microcosting methodology in which standardized charges were assigned to each clinical, procedural, or testing component making up the episode of care. See Gold M, Siegel J, Russell L, Weinstein M, editors. Cost-effectiveness in health and medicine. New York (NY): Oxford University Press; 1996. Episodes of care for all conditions except aortic stenosis treated in the catheterization lab began at the patient's initial visit to an outpatient clinic and ended one year later; all costs were based on observed use. The episode of care for aortic stenosis treated in the catheterization lab began at the time of the balloon valvuloplasty via catheterization and lasted for ten years. The results in this case were projected based on the predicted need for valve replacement as a function of observed clinical parameters immediately following the valvuloplasty (see Note 27 in text).

[a] Not applicable.