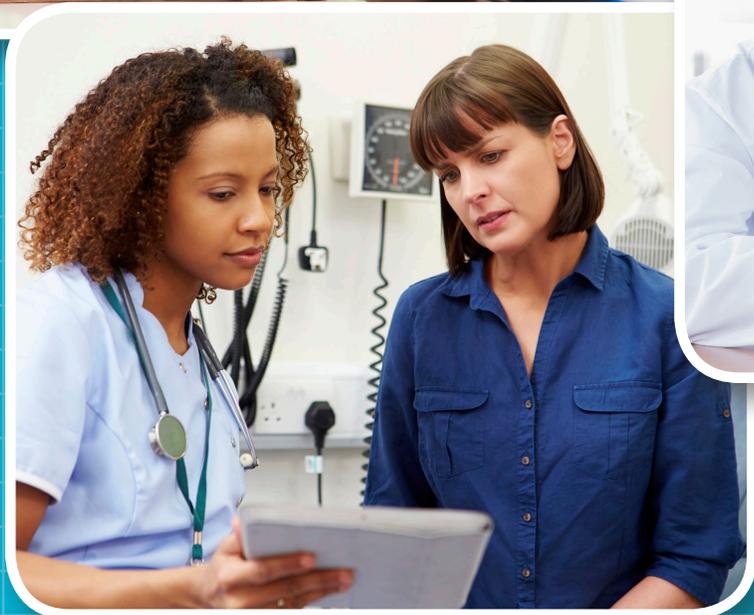
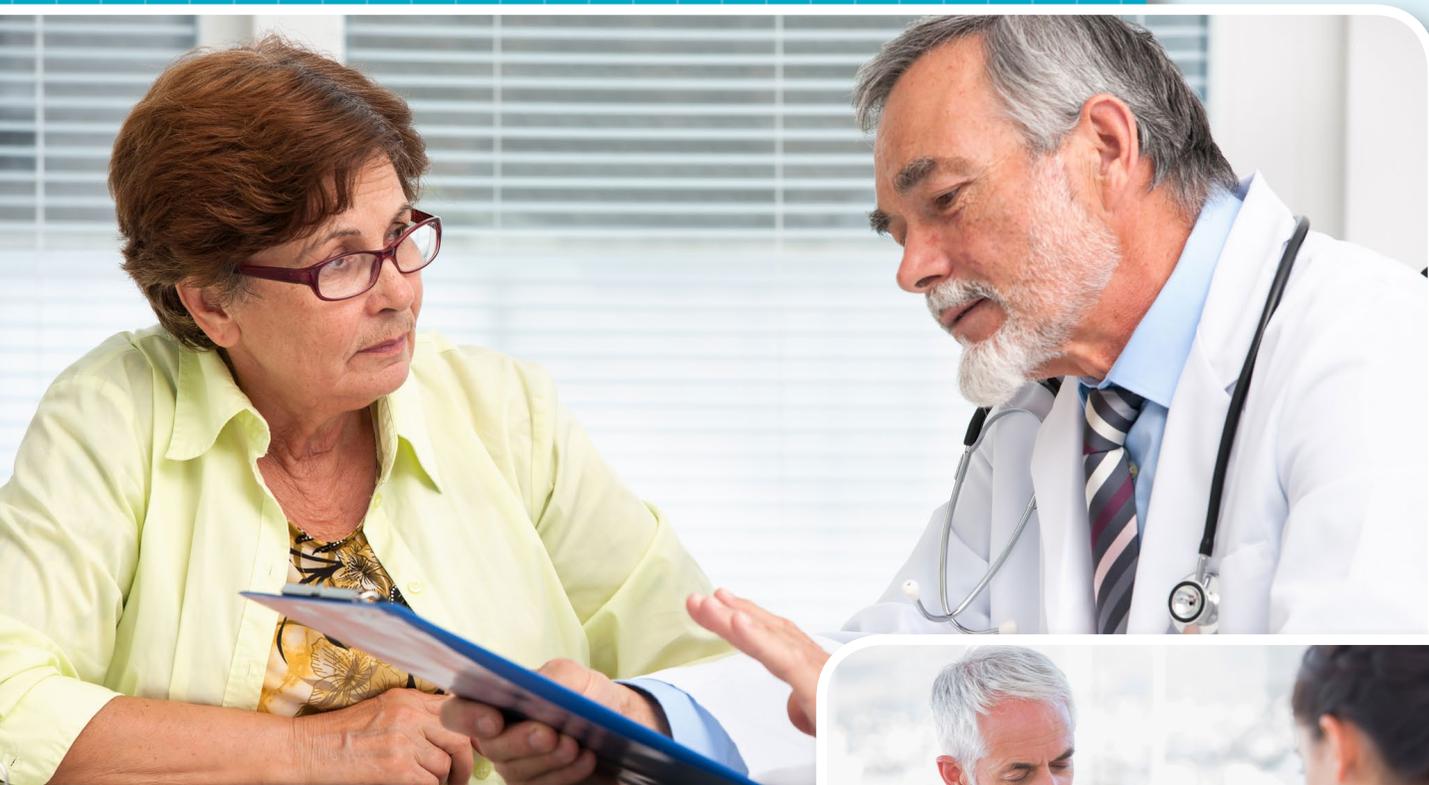


# Advances in Patient Safety and Medical Liability



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## Preface

Since the Institute of Medicine report “To Err is Human” was issued in 2000, the Agency for Healthcare Research and Quality (AHRQ) has served as the lead Federal agency to fund research and the development of tools and resources to improve patient safety. Through these activities, AHRQ seeks to prevent, mitigate, and decrease medical errors, patient safety risks and hazards, and quality gaps associated with health care and their harmful impact on patients. While we have made great strides in reaching this goal, and health care providers continue their efforts to deliver high-quality, evidence-based care, patients continue to be harmed by the health care system.

To address the need to improve patient safety and the medical liability system, the AHRQ Patient Safety and Medical Liability (PSML) Initiative was established in October 2009. Funding was intended to address four goals: (1) putting patient safety first by reducing preventable injuries, (2) fostering better communication between doctors and patients, (3) ensuring fair and timely compensation for medical injuries while reducing malpractice litigation, and (4) reducing liability premiums.

Under the PSML initiative, AHRQ funded 13 planning grants and 7 demonstration grants. This initiative aimed to help States and health systems seek comprehensive solutions that improve patient safety and address the underlying causes of the malpractice problem.

Advances in Patient Safety and Medical Liability presents contributions and findings from several of these projects to illustrate that, despite the complexity of this work, this initiative has contributed important insights to guide future research. In addition to a prologue, the volume includes two commentaries and nine papers, organized into two primary themes: improving communication and improving patient safety. Topics include the role of the patient and family in supporting improved care and patient safety; shared decision-making initiatives; the use of reporting systems; the harmful impact of institutional silence when patient harm occurs; implementation of disclosure, apology, and offer programs; safety culture and disclosure culture surveys; medication safety initiatives; and more.

Many of the activities and findings from the PSML initiative will serve as the groundwork for future patient safety and medical liability projects, as these grants sustained successful implementation and maintenance of their interventions. The papers presented in this volume offer new insights, raise new questions, and identify new areas for further exploration. We hope that this contribution to the field will more firmly establish the importance of emerging research in patient safety and medical liability.

Sharon B. Arnold, PhD  
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Specifically, we thank Karen Migdail for her helpful guidance throughout the publication process, as well as Michelle Pillen, Susan Ridgely, Michael Greenberg, and Robin Campbell for their advice and constructive suggestions regarding the development of this work. We thank Sharon Arnold, Jeff Brady, Erin Grace, and Margie Shofer for their review of the manuscripts and participation in the publication process.

Thank you to our colleagues in AHRQ's Office of Communications, including Joel Boches for preparing cover designs, and Sandra Cummings, Karen Fleming-Michael, and Farah Englert for their work in the development and clearance of this publication.

We are indebted to our peer reviewers for their time and diligent feedback. Most of all, we thank the participating authors and their research teams who patiently and willingly shared their stories and their work with the aim of advancing the research base in this field. We hope that this collection of manuscripts will inform and benefit future investigators and researchers who seek to improve the safety of health care and patient outcomes.

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# Prologue

**Kenneth Sands, Alan Woodward, and Melinda Van Niel**

Research in patient safety and medical liability in recent years has widened our definition of these terms. Patient Safety improvement is no longer a preventive strategy to protect medical facilities from lawsuits – it is a serious and wide-reaching effort to measurably improve the safety culture among staff in medical institutions, to find lasting and systemic prevention strategies for adverse events, and to work with patients—and with their families and caregivers—as equals to both address their care needs and to earnestly reconcile when their care does not go as planned. Working with patients as partners has become increasingly important in our rapidly changing medical landscape. Patients are experts in their own care and their own needs. Too often, we medical professionals ignore their expertise and opinion. In addition, caregivers and family members have knowledge and perspectives about the patient and his or her condition that can contribute to better care and improved patient safety. Transparency between and among medical colleagues and a supportive just culture<sup>1</sup> are also central aspects to improving safety and creating a climate less prone to medical liability in health care facilities.

The articles included in this publication demonstrate a wide variety of studies that investigate the importance of openness and collaboration with medical colleagues and patients before, during, and after patient care. Many of the papers reveal the merits of involving patients as team members from the planning stages for their care, with programs like shared decision-making and team building. Several authors also demonstrate the need for internal transparency with regard to near-miss reporting and medication discrepancies during transfers to improve safety. And finally, there are several illuminating studies on working with patients when things go wrong, including communication and resolution programs (CRPs) and other disclosure strategies.

Patient safety, as a field, has come a long way in a short time, but there is still significant progress to be made. The National Patient Safety Foundation was formed fewer than 20 years ago, and in many places in the country, patient safety is not a central component of health care operations, but instead it is a patch to reflexively plug problematic holes in a system. Likewise, initiatives to address medical liability have only taken the progressive turn noted by our fellow authors in this publication in the last 20 years, and programs that embrace transparency and prevention of adverse event recurrence like CRPs are still few and far between. In order to create true progress in patient safety and medical liability and spread adoption of these successful programs, committed stakeholders must join together to press these programs forward. Our experience in Massachusetts has demonstrated that understanding the barriers and concerns of the stakeholders involved and working with those stakeholders to remove those barriers and collaboratively move toward safer, more transparent care together represent the best way to achieve lasting success.<sup>2</sup> Engaging traditionally opposing sides and finding common ground and a higher purpose are strong drivers toward change, and the absence of this buy-in from all constituents – patients, physicians, insurers, attorneys, and others – stops rapid progress and adoption of programs that are demonstrated to show significant benefit for all stakeholders.

Likewise, additional research in patient safety and medical liability is crucial to overcome barriers and demonstrate value. The studies described herein are at the forefront of their field;

this research is important pioneering work that must be continued to remove roadblocks such that prevent widespread adoption of these progressive patient safety and medical liability improvement measures.

Studying patient safety and medical liability takes diligence and patience, as the challenges of researching lawsuits, claims, and other patient harm include long resolution time (for example, the average medical malpractice lawsuit that goes to trial in the United States takes about 3.5 years to resolve),<sup>3</sup> different insurance models (i.e., captive vs. commercial) that have the loci of control outside or inside the medical facility itself, and the common fear that engaging patients in dialogue around harm, safety, or even fallibility will create increased legal activity from patients. We must continue our research efforts to address these concerns and demonstrate that for each of the variables listed above, time and again, engaging with patients for safety in their care only improves their care and increases the quality of service that we, as health care professionals provide.

Additional research in patient safety and medical liability will also continue to emphasize the value in creating a culture of safety and in engaging with patients to improve quality of care. Using measures of patient experience such as the Consumer Assessment of Healthcare Providers and Systems Hospital Survey (HCAHPS),<sup>4</sup> and patient-reported outcomes will assist health care facilities in composing a complete picture of patient safety by better understanding how patients feel physically and emotionally after the care they receive. In addition, using tools to measure staff and clinician experience through culture of safety surveys,<sup>5</sup> and human resources (HR) metrics such as staff turnover and retention, will give health care facilities a 360-degree view of where their patient safety culture stands and areas in which they can improve.

Fortunately, over the past several years, many valuable tools have been built to help support positive changes in patient safety and medical liability through low- or no-cost measures. Organizations on both a national and local scale have created toolkits to help facilities implement programs like CRPs (see the AHRQ CANDOR Toolkit<sup>6</sup> and the Massachusetts Alliance for Communication and Resolution following Medical Injury Implementation Guide<sup>7</sup>) and shared decision-making (see the AHRQ SHARE Program toolkit<sup>8</sup>) and have also built communities of stakeholders already doing the work who can provide support and encouragement to those who are at the beginning of their journey. These toolkits and communities were built with the express purpose of helping these concepts spread quickly, without reinventing the wheel and with low barriers to entry. We encourage you to take advantage of these valuable resources.

Patient safety and medical liability is a dynamic field, and we hope that in the next several years the concepts presented in these articles will be rapidly adopted to help ensure that we take the best care of our patients that we can. This, in turn, will enable staff and clinicians to feel secure and supported and our systems to be as close to error-free as possible. We must continue to build on those concepts tested here and help make the case for more honest, transparent partnership with patients before, during, and after their care and more open engagement with our staff around problems and solutions. This way forward will lead to delivering care and handling unexpected outcomes in a way that supports iterative improvement, so that all of the care delivered in the future is care of which we can be proud.

# Planning and Implementing the Patient Advocacy Reporting System<sup>®</sup> in the Sanford Health System

James W. Pichert, Wendell W. Hoffman, David Danielson, Cindy Baldwin, Craig Uthe, Meghan Goldammer, Thomas F. Catron, Sue Garey, Jan Karrass, Peggy Westlake, Rhonda Ketterling, William O. Cooper, and Gerald B. Hickson

## Abstract

**Background.** Patient complaints can help health care organizations identify physicians whose behaviors undermine a culture of safety and increase lawsuit risk. In 2010, the Sanford Health System (SHS) sought to plan and implement the Vanderbilt Center for Patient and Professional Advocacy's (CPPA) Patient Advocacy Reporting System<sup>®</sup> (PARS<sup>®</sup>), which effectively addresses "high-risk" physicians identified via analysis of unsolicited patient complaints. More than 1,400 SHS-affiliated physicians provide care for a large patient volume outside major metropolitan areas, and SHS sought ways to enhance its culture of safety using the PARS tool and process for promoting professional self-regulation. This study describes planning for SHS's PARS program launch and results of ongoing implementation through August 2016.

**Methods.** This retrospective, descriptive, planning and implementation project began with application of CPPA's Project Bundle assessment tool, which directed development of key people, processes, and systems until PARS launch-readiness was achieved. SHS patient complaint databases were coded and analyzed to calculate a "Risk Score" for all affiliated physicians. SHS peer physicians were trained as "messengers" to share local and national PARS data comparisons with physicians whose Risk Scores exceeded intervention thresholds. Six rounds of annual interventions have been completed.

**Results.** Planning efforts resulted in a successful SHS PARS launch and ongoing implementation. The peer physician messengers have delivered PARS data with high fidelity to intervention elements over the past 6 years to 124 high risk physicians; 60 percent have improved, 7 percent have departed, and 33 percent are so far unimproved. Overall, recipients' Risk Scores have declined 24 percent ( $p < .001$ ). SHS's return on investment in PARS exceeds \$4 for every \$1 spent.

**Discussion.** SHS and CPPA participated in a collaborative, comprehensive planning effort that has resulted in successful and sustained PARS implementation throughout SHS's multi-State regional facilities. Lessons learned and limitations are discussed.

**Conclusion.** First, the Project Bundle offers health care leaders a useful pre-launch heuristic for identifying needs and addressing readiness of quality/safety and/or risk-prevention projects. Second, PARS works to reduce patient dissatisfaction and overall claims-related expenditures via interventions involving high-risk physicians in a large, geographically complex health care system.

## Introduction

Patients and families are well positioned to help identify physicians whose behaviors undermine a culture of safety and increase lawsuit risk.<sup>1</sup> If patient complaints—a proxy for malpractice claims—are reported, addressed via service recovery efforts, recorded, analyzed, aggregated, and used to provide feedback to the health care professionals involved, risk can be reduced.<sup>2,3,4,5,6</sup> Specifically, research demonstrates a small proportion of physicians in any medical group are associated with disproportionate numbers of patient/family complaints.<sup>2,6,7, 8,9,10,11,12,13,14</sup> Research also demonstrates strong relationships between physicians' unsolicited patient complaints, malpractice claims, and other risk management actions.<sup>7,8,15,16,17,18</sup>

Taking advantage of patients' perspectives, the Vanderbilt Center for Patient and Professional Advocacy (CPPA) developed the evidence-based Patient Advocacy Reporting System<sup>®</sup> (PARS<sup>®</sup>) to: (1) promote professional accountability and self/group regulation; (2) optimize service recovery to address patient dissatisfaction; (3) identify physicians at increased risk for malpractice claims and effectively reduce their risk; (4) implement system-wide surveillance for behaviors that undermine a culture of safety, and (5) promote behavioral and practice/system changes that enhance a culture of safety.

CPPA currently partners with more than 140 hospitals nationally to implement PARS, resulting in a national comparative database of unsolicited patient complaints and shared operational best practices. CPPA continuously works with patient relations directors and representatives to achieve and maintain best practices in centralizing and increasing the recording of patient and family complaints for both immediate service recovery and pattern identification.<sup>6,19</sup> CPPA codes, aggregates, and analyzes unsolicited patient complaint narratives recorded by patient relations staff. The data are used to calculate a Risk Score for all affiliated physicians. The Risk Score is based on a proprietary algorithm in which complaints about physicians filed in more recent years have greater impact than those from previous years. As a result of these efforts, CPPA creates evidence-based, actionable reports that include local and national peer comparisons from the PARS national database (described below), and extracts the text of relevant patient complaints.<sup>5,6,7,11,12,13,14,20</sup>

The PARS process of tiered interventions is depicted in Figure 1.<sup>2,3,21</sup> PARS interventions are physician driven and have been implemented by trained peer physician “messengers” with excellent fidelity.<sup>3</sup> High risk physicians—those whose PARS Risk Scores are associated with malpractice claims risk, generally those in the top 3-8 percent of a medical group's members<sup>4</sup>—are recommended to be recipients of an Awareness Intervention. In these, a messenger physician colleague meets with a high-risk physician recipient to share PARS data (i.e., local and national comparisons, aggregated coded complaints, and full narratives). Most physicians take self-corrective actions that address behavioral and systems issues that dissatisfy patients and are associated with risk.<sup>3</sup>



**Figure 1. PARS Model of Tiered Interventions**

Source: Adapted from Hickson, Pichert, Webb, et al., 2007. Used with permission.

As a large, growing, geographically complex, multi-hospital, multi-outpatient-facility system, Sanford Health System (SHS) leadership sought tools and processes for continuing its tradition of promoting safety, quality, and risk reduction and doing so reliably. SHS expressed interest in PARS beginning in 2009 after learning CPPA had by that time supported several thousand initial and follow-up interventions nationally on physicians with high Risk Scores (“high risk” professionals) and that reductions in overall patient concerns and malpractice claims rates had resulted.<sup>3,4,5,6</sup> SHS then applied for and was awarded an AHRQ planning grant in collaboration with CPPA.

Successful PARS planning and implementation deserve and require considerable thought and collaborative effort. Leadership of both SHS and CPPA were substantially involved in both the planning study and the move to implement PARS throughout SHS. Collaborative decisionmaking was guided by CPPA’s “Project Bundle” (Table 1), a heuristic for assessing an organization’s readiness to launch and implement PARS.<sup>2,22</sup> The bundle includes three major categories—people, processes, and systems—and 10 subcategories. The tool simply but effectively reminds leaders and project initiators of essential elements that influence PARS success. Leaders, stakeholders, and other decisionmakers use professional judgment to reflect on each essential element’s capacity and ability to support PARS (or other safety, quality, or risk prevention projects). The bundle first helps identify project-critical elements deemed not sufficiently present or robust enough for program implementation. Those elements undergo development until launch readiness is mutually deemed sufficient to proceed. Perfection is not required, but willingness and commitment to improve current practices and sustain best practices are essential. The bundle also guides program planners’ and organizational leaders’ ongoing post-launch decisionmaking and development efforts when project goals are not being achieved.

**Table 1. PARS-Specific Project Bundle: Characteristics of Organizations With Successful PARS Programs <sup>2</sup>**

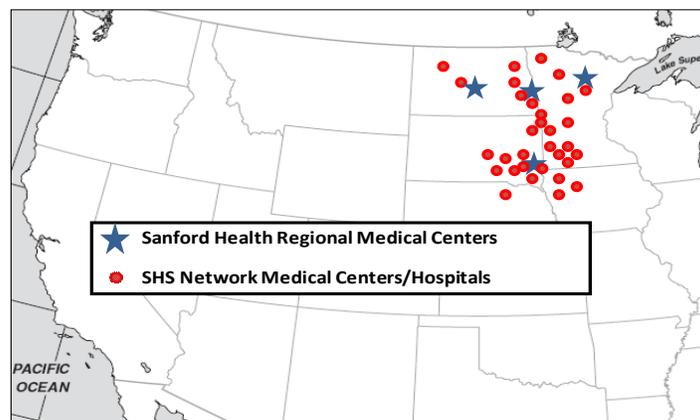
|                  |  |
|------------------|--|
| <b>People</b>    | 1. <b>Leadership commitment</b> to PARS. Leaders are prepared to address <i>any</i> and <i>all</i> professionals or other colleagues (regardless of seniority, rank, or financial considerations) whose behaviors appear to undermine a culture of safety.   |
|                  | 2. <b>Project champion(s)</b> . These persons are trusted with key data and a commitment to confidentiality and have a history of persevering and inspiring others to overcome barriers to achieving aims.   |
|                  | 3. <b>An implementation team—a “messenger committee” of medical group members, patient relations representatives, legal and human resources experts, risk managers, physician and nursing leaders, and key administrators</b> . Important team member characteristics include a reputation for trustworthiness and commitment to confidentiality; clinicians who are in practice or not far from it, willing to undergo training, able to communicate distressing information non-judgmentally, and are willing to hold accountable those unwilling or unable to make changes. |
| <b>Processes</b> | 4. <b>Clearly articulated organizational values and goals</b> that align with PARS.  |
|                  | 5. <b>Policies and procedures</b> that address expectations for professional conduct and professional accountability.  |
|                  | 6. <b>A tiered model for interventions</b> (Figure 1) when unsolicited patient and family complaints are aggregated over time.   |
|                  | 7. <b>Resources</b> appropriate and sufficient to create (or improve) and sustain best practices in service recovery (e.g., patient relations staff, training, software for documenting and aggregating patient/family complaints). Also resources for professional assessment and wellness services, coaching/shadowing, practice redesign assistance, and other forms of support for high risk professionals.  |
| <b>Systems</b>   | 8. <b>Measurement tools, data and metrics</b> for capturing, monitoring, reporting, and securely transferring data files to CPPA containing patient/family complaints, staff complaints, selected clinical metrics, affiliated physicians, and locations to assess risk.   |
|                  | 9. <b>Processes for reviewing the data</b> prepared by the CPPA PARS team, including individual points, trend lines, aggregated local comparisons, national comparisons.   |
|                  | 10. <b>Multi-level professional training for leaders and peer messengers about PARS science and politics</b> for long-term implementation, management, and sustainability.   |

The project had two major goals. The first was to assess SHS’s PARS readiness during a pre-launch planning and development phase. The second was to assess results of the PARS post-launch implementation phase, now in its sixth year. This paper will describe the pre-launch planning steps taken to increase the chances of PARS program success, changes in Risk Scores for recipients of PARS interventions, and evidence of return on investment for PARS program implementation. The methods employed during the pre-launch planning phase are presented and then followed by the methods used during the implementation phase. The results section is

similarly organized. Key project bundle elements addressed during each phase are highlighted in each section.

## Methods

**Setting.** SHS is a relatively young system, formed in November 2009 via merger of mature regional systems with 100+ year histories centered in Sioux Falls, SD (hereafter “SHS South”) and Fargo, ND (hereafter “SHS North”) (Figure 2). SHS is one of the largest health systems in the Nation with 43 hospitals and nearly 250 clinics in nine States and three countries. SHS’s 27,000 employees include more than 1,400 physicians practicing in 80 specialty areas of medicine. SHS is committed to continuously raise its high standards for delivering compassionate, comforting care for patients, promising both patients and staff “a flawless experience that inspires.”



**Figure 2. Sanford Health Medical Center Sites in the North (Fargo, Bismarck) and South (Sioux Falls, Bemidji) Regions**

**Planning Phase.** Evaluating “readiness” began with identifying and then addressing gaps in the project bundle elements. CPPA and SHS leaders continuously reviewed and, based on mutual experience and professional judgment, addressed the robustness of each bundle element via structured site visits, face-to-face meetings, frequent conference calls and email communications, training sessions, and discussions with all levels of SHS leadership and participants. The iterative nature of actions undertaken and length of time required to assure sufficient presence of each element prior to launching the PARS program are summarized in the Appendix Table, which indicates the people-specific, process-specific, and systems-specific methods and timeline. The methods used to address the various bundle elements are presented in the Appendix Table in order to illustrate how common program development and implementation challenges may be addressed, they reflect experiences similar to those employed by other organizations adopting PARS, they signal need for organizational commitment, and they are consistent with CPPA’s experience implementing a system for addressing co-worker concerns.<sup>22</sup> These processes and activities resulted in the initial SHS PARS launch in late 2011.

**Implementation Phase.** As background, the Vanderbilt Center for Patient and Professional Advocacy (CPPA) currently works with more than 140 hospitals and medical groups

(“participating health care organizations”) across 17 States to identify affiliated physicians who are associated with disproportionate levels of patient and family complaints relative to peers. CPPA maintains an electronic database containing securely transferred patient complaint and medical/surgical specialty data for more than 28,000 physicians with active practices who are credentialed at participating organizations.<sup>2,3,5</sup> CPPA data analysis identifies physicians whose patient/family-reported complaints show them to be outliers from both their local peer groups and physicians from the other medical centers represented in the database.<sup>11,12,13,14</sup> The Vanderbilt University Medical Center (VUMC) institutional review board approved a retrospective review of the patient complaint data from SHS and other participating health care organizations.

**Complaint Data.** Patient complaint data were obtained from the SHS North and South regions’ Offices of Patient Relations (“OPR”). The OPRs collected and recorded each patient or family complaint, identified the physician(s), if any, associated with alleged concerns, and created a narrative electronic report (“report”) describing the issue(s). Reports were securely submitted to CPPA for entry into the PARS database for analysis. This study focused on complaints recorded between August 16, 2007 and August 15, 2016.

**Coding System, Database, and Risk Scores.** Trained research coders reviewed each SHS patient complaint report, identified distinct concerns embedded within them, and assigned each complaint a code. One report might contain several complaints (e.g., “doctor was very late for my appointment,” “did not do a thorough exam,” “did not let me know my test results”). All complaints were coded using a standardized system that sorted complaints into six categories: accessibility, billing, care and treatment, communication, concern for patient and family, and environmental. The system’s inter-rater and test-retest reliabilities have been previously established through related research.<sup>20</sup> Coded data are used to calculate a Risk Score for all affiliated physicians. The Risk Score is based on a proprietary algorithm in which complaints about physicians filed in more recent years have greater impact than those from previous years.

**Intervention Process.** The principle underlying the PARS process is that identifying unnecessary variations in professionals’ behavior/performance and support system reliability is necessary, but not sufficient to increase patient safety, reduce malpractice claims, improve reliability, and increase professional accountability. In addition, the organization must support a systematic approach to promoting change in behavior or performance through peer-driven (at least initially), evidence-based, tiered conversations (Figure 1).<sup>2,6,21,23</sup>

Figure 1 reflects that the majority of health care professionals exhibit exemplary behavior, perform consistently well, and need only be given appropriate recognition and feedback about progress toward goals. The Pyramid’s first intervention level suggests that when what appears to be a single slip or lapse occurs, all that may be needed is an informal, non-authority conversation between peers, what we call a “Cup of Coffee” conversation.<sup>24,25</sup> Note, however, that single incidents involving alleged violations of law, regulation, or policy (e.g., sexual boundary violations, practicing impaired, harassment) are mandated to be immediately referred to appropriate leadership and/or offices, agencies, and/or law enforcement for evaluation and consideration of corrective/disciplinary action. Other serious breaches of normative behavior

that impact the work environment may be considered sufficiently egregious that they should be urgently addressed by the individual's authority figure/supervisor or institutional authority.

If a documented pattern of concerning behavior/performance appears to have emerged, the PARS process calls for a Level 1 "Awareness" intervention. Awareness interventions are designed to be confidential, nondirective, non-punitive, evidence-based conversations in which a peer professional (most often) delivers observations/data that the recipient's behavior/performance appears to vary from group expectations. If the pattern persists despite two or three rounds of Awareness interventions, the next step in the process is a Level 2 "Guided Intervention by Authority." These involve an individual up the recipient's chain of command (e.g., Department Chair, Chief Medical Officer [CMO], Chief of Staff, or other) and development of a specific action plan. Consistent with bylaws or other governing documents, the organization's disciplinary process and higher levels of administration are involved in rare Level 3 "Disciplinary" interventions.<sup>6,21,24,25</sup>

For peer-based comparisons involving patient complaints, CPPA used SHS patient complaint data to calculate a Risk Score for each SHS-affiliated physician. The Risk Score is based on a proprietary algorithm in which complaints about physicians filed in the most recent year have greater impact than those reported during the 3 previous years. The Risk Score is presented in PARS feedback materials created for each SHS physician whose score exceeds CPPA's threshold for assessment and further analysis.<sup>3,4,6,17</sup> Details about the PARS intervention process and supporting feedback materials have been published and discussed elsewhere.<sup>3,6</sup>

## Results

First, results of the planning phase are described in terms of the three major Project Bundle elements (Table 1) used to direct development efforts during the planning phase. Then we present outcomes achieved to date during PARS implementation.

**People.** The first important result of the planning phase occurred when highest level SHS leadership, Physician Board of Governors, and Board of Trustees signaled their commitment to the project by providing endorsements and support for PARS as a proactive risk reduction strategy. Then, at the end of the planning period, SHS made a financial commitment as well, signing a multi-year PARS implementation contract. The four SHS-affiliated co-authors (WH, DD, CB and RK) served throughout the planning process and initial PARS implementation as project champions, providing essential institutional memory and access to other leaders. SHS's North- and South-centered geography required regional PARS peer messenger committees, Co-Chairs, and administrative point persons so each could take regional ownership. A single individual (DD) with system-wide responsibilities was appointed as a co-chair on both committees to coordinate training; facilitate safe, secure document distribution; review data; promote system-wide consistency; and serve as a focal point for questions or issues that arose throughout the process. SHS's Medical Director for Clinical Services (CU) now serves those roles as the Medical Director for Sanford PARS.

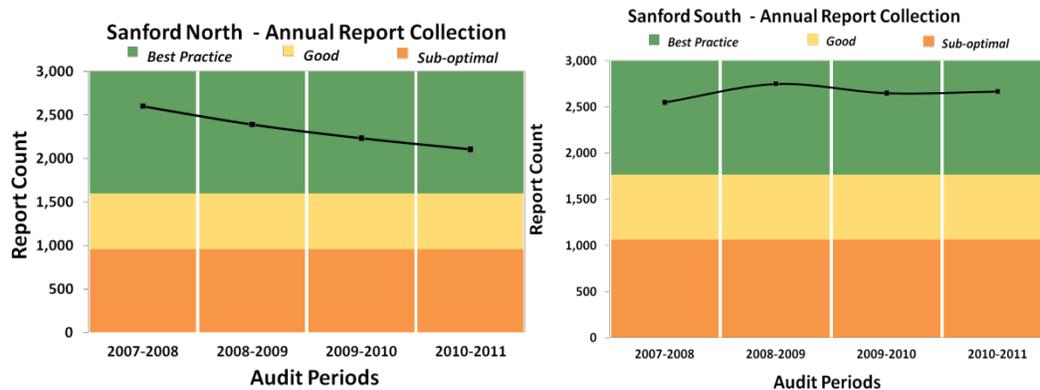
**Process.** SHS's published values, goals, and codes of professional conduct aligned with PARS principles (<http://www.sanfordhealth.org/about>). In addition, results of the planning phase

included SHS's leadership adoption of the CPPA intervention model (Figure 1) and receipt of training in its implementation. Legal issues were far less straightforward. Significant planning was devoted to addressing legal issues, including messenger committee structure, State-to-State variations in Peer Review laws and protections, language to be included on PARS work products, safety-related professional legal language, and procedures to be taken when Level 1 "Awareness" interventions did not reduce patient complaints. A novel aspect of this project was development of a secure system by which peer messengers could share awareness intervention data electronically with a high-risk colleague who worked at a significant distance from the messenger, not uncommon within SHS.

**Systems.** Another key planning phase result was achieved when SHS's OPRs and Information Technology (IT) teams expressed willingness to support PARS. While the SHS North and South flagship hospitals had reliable systems and dedicated staff for patient advocacy, SHS's small-town locations were just beginning in 2010 the work of adopting a unified process for systematically receiving and addressing patient concerns about their health care experiences. Therefore, CPPA provided training, "Getting the Most from Your Patient Relations Department and Service Recovery Program"<sup>19</sup> to all SHS North and South OPR staff, focusing on best practices in complaint reporting and service recovery. Meetings supplemented with email and phone communications with SHS database managers and IT support personnel resulted in smooth, secure data transfer. As a result of the PARS planning process, SHS patient advocates now enter all patient comments in electronic complaint capture software.

CPPA and SHS North and South OPR leaders collaborated on qualitative and quantitative assessments of complaint reports (e.g., includes clearly identifiable physicians, number of codable complaint(s), and needed attachments). One goal was an overall 80 percent rate of uniquely identified physicians associated with physician-related concerns (some patients simply do not recall which physician(s) they saw, and the physicians' identities cannot be determined from a review of records). During the pre-launch planning period, SHS North had an 84 percent physician identification rate, and SHS South had a 77 percent rate, both of which were deemed sufficient for launching PARS. Each OPR has since achieved and exceeded the 80 percent goal. The second goal, to demonstrate sufficient complaint capture relative to organization size well in advance of PARS' launch, was also achieved by 2011 during the planning phase project period (Figure 3). SHS complaint capture has continuously stayed well above each region's Best Practice baseline through the 2016 intervention cycle.

Prior to being shared with high-risk physicians, PARS intervention data underwent multi-level reviews, including six quality checks by CPPA staff, faculty, and physicians, plus local reviews by SHS co-chairs and the assigned messenger physician.<sup>3,6</sup> In order to move forward with an intervention, the co-chairs and messenger physicians must agree the data are sufficiently compelling that the high-risk colleague stands out from his or her peers. CPPA recommends and trains committee chairs not to pair messenger and recipient physicians with known conflicts of interest (e.g., direct competition for patients or resources), poor prior relationships, or a social relationship that makes the messenger role just too uncomfortable. Finally, 12 physicians from SHS South and 7 from SHS North completed CPPA's PARS Messenger training, described elsewhere.<sup>3,6</sup>



**Figure 3. Annual SHS Complaint Report Capture, June 2007–July 2011, plotted as a function of CPPA pre-PARS launch indicators of readiness**

**Patient Complaints and Risk Scores During the Implementation Phase.** The first round of PARS Interventions occurred in both the North and South regions in October-November 2011. As of 2016 a total of 124 SHS physicians have received awareness interventions, including five currently receiving interventions guided by authority (Level 2 on the Promoting Professionalism Pyramid, Figure 1). Messengers’ fidelity to intervention elements exceeds 95 percent compliance. Overall, Risk Scores of physicians receiving interventions have declined 24 percent ( $p < 0.001$ ). Sixty percent of the physicians have succeeded in substantially reducing their Risk Scores, 33 percent remain unimproved, and the rest (7 percent) have departed SHS (similar to physician turnover elsewhere). These results are similar to those achieved in other studies.<sup>3,5</sup>

**SHS Return on Investment (ROI) in PARS.** ROI evaluation compared SHS’s pre- and post-PARS intervention paid claims and claims-related expenses. The analysis used dollars spent per insured physician pre- and post-PARS within the statute of limitations period, adjusting for time (CPI) and published statewide market experience.<sup>26,27</sup> Based on CPPA research, 25 percent of any savings were attributed to PARS.<sup>4,6</sup> The remainder was attributed to SHS’s other safety, quality, and risk prevention initiatives. PARS contract charges for the intervention period were then applied to calculate SHS’s system-wide ROI of 4 to 1. ROI remained positive when sensitivity analyses (e.g., 10 percent impact attributed to PARS) were conducted.

## Discussion

This article presents a study of the planning process leading to successful initiation and ongoing implementation of the Vanderbilt CPPA PARS program in the Sanford Health System. Steps taken to increase the probability of PARS program success revolved around attention to key elements of a Project Bundle. These steps proved effective: Risk Scores declined for the majority of PARS intervention recipients, and the program’s positive ROI supports PARS’ sustainability.

The planners learned important lessons worth consideration before health care leaders launch PARS or other safety, quality, or risk prevention initiatives. The most important lessons are organized around the Project Bundle’s three major elements.

**People-Related Lessons.** Project planning and implementation required commitment of both titled leadership (e.g., CMOs, Department Chairs) and influential physicians whose opinions shape what really happens “on the ground.” These leaders must be willing to have the PARS process address every physician who appears to have a pattern of concerning behavior/performance, regardless of status or stature. Messenger committee members must be willing to deliver PARS data in a timely fashion, and all involved must be willing to give high risk professionals opportunities to self-correct in the earliest stages of intervention.

**Process-Related Lessons.** Organizational values must deem patients to be valuable health care team members. Partnership with Legal Affairs and Human Resources is essential to help craft and implement committees, policies, and procedures that provide peer review protections and fully align PARS within (and make PARS integral to) the organization. The organization must be willing to consistently and reliably implement the model of tiered interventions. Finally, the organization must be committed to employ the right number of Patient Relations Representatives and to invest in training in best practices for service recovery and documentation of patient/family complaints.

**Systems-Related Lessons.** Partnership with the Patient Relations teams and their database managers is essential, first for promoting institutional efforts to have a common, system-wide database. Patient Relations leaders need to receive regular feedback regarding best practices in complaint capture and narrative records so that high standards are sustained. Training for peer messengers must include practice delivering peer-comparative data and responding to recipients’ comments, questions, concerns, and emotions. In addition, there must be multi-level, regularly scheduled sharing of PARS progress and aggregated data to keep all levels of leadership aware of and up to date on the program to promote long-term implementation and sustainability.

**Limitations.** This study has limitations. First, SHS has unique characteristics as a large, multi-State, multi-facility, predominantly rural health care provider, so generalizability is unknown. Nevertheless, one reason this study was conducted was to assess and demonstrate PARS’ viability in just such a system. SHS, like all PARS partner sites, was self-selected and thus is motivated to provide high quality patient experiences and mitigate risk exposure and thus is motivated to capture complaints and record service recovery activities.<sup>19</sup> Second, we did not measure potential confounding physician characteristics (e.g., years in practice, clinical volume), aspects of the practice environment (e.g., local physician group characteristics) or patient characteristics (demographics, payer, and case mix) that may be associated with patient complaints and lawsuit risk.

The literature rightly directs much attention to systems issues but less to individual professional accountability. This study focused on use of the PARS tool for analysis of individual physicians’ relative risk. We acknowledge that promoting safety also requires attention to systems failures and team functioning. We would argue that all three—self- and group-regulation, support systems, and teamwork—are must-haves for a strong patient safety culture. While this study highlighted individual accountability, if PARS data reveal multiple high-risk members of a division, department, or location in a large system, that group’s risk may not be a function of the individual; it may instead signal systems and/or team issues. For example, patient complaints about surgeons’ communication and respectfulness have been shown to be related to surgical

complications, which may indicate that similar behaviors toward colleagues may negatively impact high-complaint surgeons' team functioning.<sup>28,29</sup>

## Conclusion

This project resulted in the successful launch, implementation, and sustainability of the CPPA PARS program at SHS after the conclusion of the planning grant. The project demonstrated how in 1 year, a large multi-State health care system became prepared to implement an intervention process that promotes professional self-governance, fosters a fair and just culture of safety and kindness, and reduces avoidable lawsuit risk. By sustaining the PARS program, SHS has:

- A process for supporting fair, constructive, peer-delivered, evidence-based, peer-comparative self- and group regulation
- Ongoing training for cohorts of “messengers”
- A tiered approach to addressing unnecessary variation in other domains
- Consistent data monitoring that is applied to both rural and metropolitan sites
- Reduced patient complaints about most physicians identified as high risk
- A positive return on investment

The results of this work have at least six implications. Our first conclusion is that the plan to assess, develop, and implement SHS's PARS-related infrastructure could serve as a model for other large, multi-site institutions. Second, the Project Bundle tool provides leaders a useful heuristic for identifying and addressing pre-launch needs of other potential quality, safety, and/or risk prevention projects. Third, by attending to the Project Bundle's elements, the SHS champions succeeded in demonstrating that potential pre-launch issues due to SHS's size and complexity could be addressed and overcome, thus making the case for ongoing PARS program funding. SHS PARS implementation is now in its 6th year past the AHRQ-funded planning period and continues. Fourth, results on individual physicians receiving PARS interventions are positive and consistent with results achieved elsewhere, and fifth, the experience shows that a positive return on investment in PARS can be achieved in a geographically widespread health care system.

Finally, these findings have potential national significance. As U.S. medical centers continue to combine into major systems, the need for plans for promoting system-wide consistency in professionalism and professional self-regulation will expand. SHS and CPPA learned a great deal from this project, and we conclude that the experience can generalize to other dynamic health care systems, so long as the necessary people, processes, and systems are in place.

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## Appendix

# PARS Program Planning Methods and Procedures Timeline

| Timeline and Events   | Corresponding Project Bundle Element(s)   |
|---|---|
| <b>November 2009.</b> MeritCare (Fargo, ND) and Sanford Health (Sioux Falls, SD) systems combine to form SHS.   | Background  |
| <b>March 2010.</b> Gerald Hickson, MD, presents PARS to first combined SHS Board of Governors (physician leadership) retreat.   | 1 - Leadership commitment   |
| <b>June 2010.</b> Business Associates Agreement signed by Vanderbilt CPPA with SHS to permit the exchange of data.  | 1 - Leadership commitment   |
| <b>July 2010.</b> Vanderbilt CPPA leadership introduce PARS to SHS Leaders and discuss its relationship to SHS goals and values.  | 1 - Leadership commitment<br>4 - Goals, values                                    |
| <b>August 2010.</b> Vanderbilt CPPA receives four back-years of patient complaint data from Fargo, ND hospital (North) and Sioux Falls, SD hospital (South) to be coded in the PARS program; South complaints were largely scanned handwritten reports, North's were electronic.  | 7 - Pt Relations and IT resources<br>8 - Measurement tools                        |
| <b>September 2010.</b> Vanderbilt CPPA begins receiving monthly deliveries of patient complaint data for PARS coding—South complaints are largely handwritten, North's are electronic. Plans are implemented for system-wide electronic reporting. Based on CPPA PARS team feedback, complaint reporting nomenclature is standardized across SHS. | 7 - Pt Relations and IT resources<br>8 - Measurement tools                        |
| <b>October 2010.</b> Local institutional IRB forms approved. Focused discussion of conduct policies and intervention model with SHS Champions and Legal Affairs.  | 4 - Goals, values<br>5 - Conduct policies<br>6 - Intervention model               |
| SHS physician messenger candidates representing North and South are nominated and selected.   | 2 - Champions<br>3 - Messengers   |
| SHS demographic data needed to develop complaint benchmarking estimates are assembled (facility locations, number of beds, number of physicians).   | 8 - Measurement tools   |
| <b>November 2010.</b> Vanderbilt CPPA leadership conduct initial Physician Messenger Training in SHS North (9 physicians) and South (12 physicians). All participants agree to continue as messengers.  | 2 - Champions<br>3 - Messengers<br>6 - Intervention model<br>10 - Leader training |
| CPPA team initiates relationship-building, learning about and discussions with North and South Patient Relations offices and IT support team.   | 7 - Pt Relations and IT resources<br>8 - Measurement tools                        |

**Appendix. Timeline and Events (continued)**

| <b>Timeline and Events</b>   | <b>Corresponding Project Bundle Element(s)</b>  |
|--|---|
| <b>December 2010.</b> Post-site visit Assessment Report provided to SHS leadership.  | 10 - Ongoing Leader follow-up, training   |
| Discussion of SHS organizational structure and patient complaints committee formation.   | 1 - Leadership commitment<br>6 - Intervention model   |
| Sample documentation and guidance shared for developing patient complaints committees and content of letters to physicians.  | 2 - Champions<br>3 - Messengers<br>6 - Intervention model   |
| At Enterprise Risk Management day-long retreat, SHS champions lead discussion about PARS.  | 1 - Leadership commitment<br>4 - Goals, values  |
| <b>January 2011.</b> Coding, analysis, and feedback related to patient complaints continues.   | 7 - Pt Relations and IT resources<br>8 - Measurement tools  |
| <b>March 2011.</b> SHS PARS champions present PARS® program to leadership and receive 2012 budget approval by AHRQ.  | 1 - Leadership commitment<br>10 - Ongoing Leader follow-up, training  |
| <b>April 2011.</b> Unnamed Physician List distributed to SHS North and South Patient Relations (PR).   | 8 - Measurement tools   |
| South begins 100% complaint reporting via a software system.   | 7 - Pt Relations resources  |
| SHS complaint reports are reviewed and feedback provided to PR teams.  | 7 - Pt Relations and IT resources<br>8 - Measurement tools  |
| <b>May 2011.</b> SHS PR teams supply additional complaint report text and attachments. Following additional coding, complaint data are ready for analysis to identify physicians with high risk scores.  | 7 - Pt Relations and IT resources<br>8 - Measurement tools  |
| <b>June 2011.</b> South and North Patient Relations and risk management representatives visit CPPA to learn about best practices in complaint collection, CPPA complaint coding, and CPPA data processing.   | 7 - Pt Relations and IT resources<br>8 - Measurement tools  |
| AHRQ grant extension requested and approved for ongoing data analysis and PARS launch readiness.   | 1 - Leadership commitment   |
| Complaint data coding continues for all SHS complaints   | 7 - Pt Relations resources<br>8 - Measurement tools   |
| <b>August 2011.</b> SHS commits to using the PARS program over the next 4 years by signing a contract with Vanderbilt CPPA.  | 1 - Leadership commitment<br>10 - Ongoing Leader follow-up, training  |
| SHS identifies Senior VP of Clinical Risk Management, who has a system-wide “presence” and reasonable “need to know,” to serve/collaborate with physician messenger co-chairs. Process for Provider Quality Analysis & Research Committee (PQARC), chairs/co-chairs is documented. | 2 - Champions<br>6 - Intervention model<br>9 - Process for reviewing PARS data  |
| Champions update SHS Leadership and Messengers regarding process of providing PARS intervention folders to PQARC chair/co-chairs, committee chairs’ reviews of PARS data, and ongoing Messenger training.  | 1 - Leadership commitment<br>2 - Champions<br>3 - Messengers<br>6 - Intervention model<br>9 - Process for reviewing PARS data |

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| <b>SHS PARS Program Launch</b>   |
| <b>September 2011.</b> IRB continuing review forms were approved. CPPA prepares initial PARS intervention folders.   |
| <b>November 2011–Present.</b> CPPA conducts site visits to SHS North and South to update SHS Messengers and Leadership about PARS progress, provide intervention folders to messenger committee co-chairs, and offer additional messenger training. Interventions on 124 SHS physicians with high risk scores have been conducted to date; follow-up results are positive. |

