A SYSTEMATIC APPROACH TO IMPROVING PATIENT SAFETY: THE PATIENT SAFETY CHAIN MODEL

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ABSTRACT

We propose that top leadership influences the creation of a safety culture. This leads to adoption of patient safety initiatives, and ultimately to positive patient safety outcomes. Structural equations modeling for a 212 multiple-respondent hospital sample lends empirical support to this patient safety chain model.

Keywords*:* healthcare operations, operations safety, medical errors, operational failures

INTRODUCTION

This paper builds on prior literature by testing the existence of a sequence of events that lead to improvements in patient safety for hospitals. Although no empirical evidence currently exists in the literature to support a patient safety chain model, the prevailing research tends to substantiate such a concept. We propose that improving patient safety begins with top management's support of such efforts through the use of transformational leadership (TFL), and that hospitals wishing to make these improvements will need to focus their energies towards this top link in the chain. We further propose that TFL will lead to a chain of events whereby it influences the creation of a patient safety culture (PSC), which then leads to the adoption of patient safety initiatives (PSI), and ultimately results in positive improvements in patient safety outcomes (PSO).

Although patient safety is not a new concept, the first report issued by the Institute of Medicine (IOM, 2000), broke the silence that had originally surrounded medical errors and their consequences. Their findings indicated that as 58% of the 98,000 error-related deaths may be preventable. Consequently, the IOM recommended rigorous and widespread changes in healthcare processes. In addition, in November of 2000, The Leapfrog Group was established by a coalition of major employers in order to initiate breakthrough improvements in safety and reduce preventable medical errors. The Leapfrog Group and the IOM reports, along with the adoption of patient-safety standards and patient safety goals by the Joint Commission have put serious pressure on hospitals to develop PSI (activities designed to prevent or ameliorate adverse outcomes or injuries stemming from the process of health care). Nonetheless, hospitals have been slow in meeting patient safety goals and inconsistent in implementing safety systems (Longo et al., 2007), despite the unprecedented focus on patient safety over the last eight years.

Prior to the first IOM report (2000), most efforts to reduce errors and improve patient safety focused on individuals rather than systems or processes (Woodhouse et al., 2004). Although humans often play a role in the occurrence of errors, the first IOM report used the popular adage of Alexander Pope – to err is human – to make the point that blaming individuals for being human is not an effective way to improve patient safety. Recent evidence now suggests that the majority of errors more accurately stem from system and process failures as opposed to human failures (Reason, 1990; Gaba et al., 2003). With this new focus on systems and processes has come the identification of more effective methods for improving patient safety, including redesigning the hospital work environment, modifying systems and processes to make them more redundant, and implementing PSIs.

LITERATURE REVIEW AND HYPOTHESES

The Multifactor Leadership Theory (Bass and Avolio, 2000) is a widely applied leadership model in the management literature and proposes three distinct leadership styles: TFL (based on charisma), transactional leadership (based on rewards and punishments), and laissez-faire leadership (lack of leadership). TFL has been proposed and supported as the most successful among the three leadership styles (Tichy and Ullrich, 1984; Bass, 1990; Bass and Avolio, 2000; Bass and Riggio, 2006). The charismatic-inspiration dimension of the TFL style, which emphasizes leadership behaviors that provide "followers with a clear sense of purpose that is energizing and a role model for ethical conduct which builds identification with the leader and her/his articulated vision" (Bass and Avolio, 2000; p. 29), most closely matches Kotter's (1990) task requirements needed to facilitate organizational change. This leadership style is therefore proposed as necessary for creating and promoting a culture that emphasizes patient safety.

High reliability organizational theory (HROT) is based on the idea that errors can be prevented through leadership practices and improved system design (Perrow, 1984). High reliability organizations (HROs) refer to organizations or systems that operate in complex and hazardous conditions and yet consistently achieve nearly error-free performance. They are termed "high reliability organizations" because they seem to operate in a more reliable fashion than other similar organizations. Classic examples of HROs include the aviation industry, the nuclear power industry, and some sections of the military. Failure rates in these industries are much lower than those found in healthcare. HROT has identified senior leadership behavior and attitudes as being linked to high reliability (Roberts 1990; Roberts et al., 2001). Moreover, it is believed that HROs have less error because they have embraced the notion of a "safety culture," or a "culture of reliability," and argue that creating redundancy of systems, training, and learning can result in improvements in safety, even for a complex, tightly coupled system (Roberts, 1990; Gaba, 2001; Ruchlin et al. 2004). The theories of leadership and safety culture derived from studies of HROs are being applied to hospitals as they work towards PSO (Reason, 2000).

From the perspective of total quality management (TQM), medical errors can be considered defects. Therefore, it seems logical to draw on the principles of TQM to develop methods that may be used to improve patient safety. McFadden et al. (2004) was the first to develop a coherent set of PSIs that were drawn from the TQM and aviation safety literature. Lukas et al. (2007) argue that using traditional TQM techniques will not yield sustainable change without being supported by the culture and structure of the larger organization. Therefore, a culture emphasizing patient safety should be a driving force behind the implementation of PSI. The literature also suggests that implementing safety practices leads to positive safety performance in healthcare (Katz-Navon et al. 2005). Therefore, the theoretical and empirical evidence suggests the following hypotheses:

H1: TFL will be positively associated with PSC.
H2: PSC will be positively associated with the use of PSI.
H3: PSI will be positively associated with positive PSO.

We would expect that TFL affects the implementation of PSI indirectly through the creation of a PSC. However, it is unlikely that all of the effects of TFL on PSI can be explained by this indirect relationship because there are other likely organizational mechanisms through which top leadership would affect PSI. Similarly, we expect that the impact of a PSC will lead to positive PSO via culture's impact on the implementation of PSIs. Finally, we expect TFL to improve PSO by "trickling down" through its influence on creating a culture of patient safety, which in turn should increase the implementation of PSIs, which in turn will improve safety outcomes for patients. Therefore, we hypothesize the following:

H4: PSC will partially mediate the relationship between TFL and PSI.
H5: PSI will partially mediate the relationship between PSC and PSO.
H6: PSC and PSI will partially mediate the relationship between TFL and PSO.

METHODS

We employed a survey methodology to collect data used to test our research hypotheses, using the hospital organization as the unit of analysis. To obtain a list of US hospitals, we utilized a directory of 6000 medical organizations posted on the website *Hospitallink.com*. We targeted only hospitals for our sample, eliminating from the initial list non-hospital organizations and healthcare associations. From additional links we were able to obtain the telephone numbers for the remaining organizations. An initial questionnaire was tested in a pilot survey sent to several hospital Quality Directors in our local area. Phone interviews were also initially conducted to improve the clarity and reduce any ambiguity of the questions.

For each of the hospitals in the dataset, we attempted to contact via telephone the Quality Director, Risk Manager, Director of Nursing, and Information Systems Director. Calls were conducted with the intent to receive multiple responses from each hospital. Hospitals may have been omitted from the final sample if personal contact with the appropriate personnel was not achieved. By calling the hospitals directly, we were able to ensure that the surveys were emailed to the appropriate individuals and that email addresses were accurate and current. Hospital personnel with whom we were able to speak personally received our survey via an email attachment. Three rounds of email reminders spaced approximately 3 weeks apart were sent out.

Completed surveys were received from 371 hospitals for a response rate of 59.3%. To improve reliability, we limited our final dataset to those hospitals for which we received completed surveys from at least two separate respondents, thus yielding a final sample of 212 hospitals. Comparing characteristics of this sample of 212 multiple-respondent hospitals with the hospitals with only one respondent, there were no statistically significant differences in terms of number of beds (mean = 162.82 vs. 140.31, respectively; $t = -1.09$; $p = .28$) or number of full-time equivalent (FTE) employees dedicated to error prevention (mean = 3.33 vs. 2.15, respectively; $t = -1.91$; $p = .06$). The responses received from multiple raters from each hospital were averaged for each item. All inter-rater reliability values were significant at the $p < .005$ level, with an average intra-class correlation coefficient value of 0.71.

The key constructs in our conceptual framework are *TFL, PSC, PSI, and PSO.* The questionnaire items were drawn from the literature discussed above. *TFL* was measured by eight items asking the respondent to assess the frequency with which each item described the top leadership (CEO) at their hospital. This scale was derived from prior literature on the charisma-inspiration TFL scale of Bass (1990, 1999), and Bass and Avolio (2000). The *PSC* constructs were measured by six items drawn from the literature on patient safety. *PSI* was measured by seven items asking the respondent to assess the level of implementation of each of seven critical success factors derived from prior literature (McFadden et al 2004). Finally, *PSO* was measured by five items based on the work of McFadden et al. (2006a) and Stock et al. (2007).

The Cronbach's alpha scale reliability values for these five constructs consisted of a range of .83 to .93, which is beyond the minimum acceptable level of .60 for exploratory research (Flynn et al., 1990) and .70 for general research (Nunnally and Bernstein, 1994). We used Harman's one-factor test to check for the presence of common method bias (Podsakoff and Organ, 1986). Harman's one-factor test resulted in five factors accounting for 58% of the variance, of which the first factor accounts for about 38%. Because a single factor did not occur and no factor accounted for most of the variance, the single method of data collection was an acceptable risk (Podsakoff et al., 2003).

In addition to the variables presented above, we also examine three control variables that could have an impact on the study variables – size of hospital (in terms of beds), number of FTEs, and type of hospital (teaching vs. non-teaching). However, an analysis of variance showed no significant differences between any of these variables. These controls were therefore removed from further analyses to both maximize statistical power and eliminate the possibility of biased parameter estimates due to the inclusion of unnecessary control variables (Becker, 2005)

RESULTS

The hypothesized structural model was a mediated model consisting of paths between the four study variables, whereby TFL was hypothesized to influence PSC, PSC was hypothesized to partially mediate the relationship between TFL and PSI, and PSI was hypothesized to partially mediate the relationship between PSC and PSO. Additionally, an indirect relationship was also hypothesized between TFL and PSO, as partially mediated through both PSC and PSI. We assessed mediation by comparing the fit of three alternative models using EQS 6.1. The initial model was tested by fitting the least constrained model to the data, which was the partially mediated model that included all possible direct and indirect effects from TFL throughout the patient safety chain.

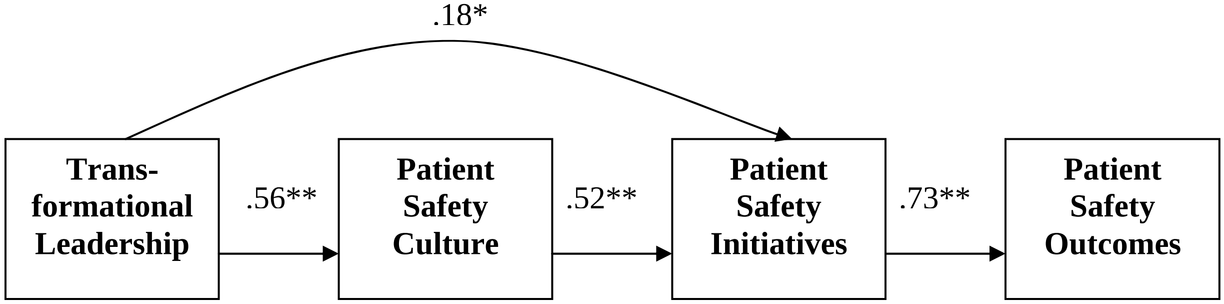
All of the measures used in this study displayed acceptable psychometric properties, with the lowest reliability estimate being .83 for PSO. Correlations among the study variables were strong, with the strongest (r = .62) between PSI and PSO. Multicollinearity was not a concern, however, as all tolerance levels were well above the accepted cut-off value of .10 (Hair, Black, Babin, Anderson, and Tatham, 2006), ranging from .59 to .97.

The measurement model, which included four latent constructs representing TFL, PSC, PSI, and PSO, fit the data well [$\chi^2(293, N = 212) = 469.20, p < .001$; Comparative Fit Index (CFI) = .95; Bentler-Bonett Non-Normed Fit Index (NNFI) = .94; root mean square error of approximation (RMSEA) = .05; standardized root mean residual (SRMR) = .05]. These results provide evidence that the model meets Hu and Bentler's (1999) conservative two-index presentation criteria for good model fit.

The partially mediated model provided excellent fit to the data, but Wald statistics indicated the direct paths between TFL and PSO and between PSC and outcomes should both be removed. The path coefficients for these relationships were also not significant. Therefore, a second model was tested with these two paths eliminated, such that any effects of TFL and PSC on PSO were indirect through the other variables in the chain. Eliminating these paths resulted in no significant changes in model fit, thereby identifying this second model as the more parsimonious of the two. A final model tested the fully mediated patient safety chain by constraining all but the direct paths from TFL to PSC, from PSC to PSI, and from PSI to PSO. The second model fit the data better than the fully mediated model [$\Delta\chi^2(1, N = 212) = 5.66, p < .05$] and was thus retained as the final model.

Fig. 1 presents the final model. Examination of the paths in the model indicated support for the direct effects put forth in H1, 2, and 3. Support was also found for the partially mediated relationship between TFL and PSI through PSC, as predicted in H4. The relationship between PSC and PSO, however, was fully mediated through PSI rather than partially mediated as predicted in H5. Whereas indirect effects were significant, no direct effects were found between TFL and PSO. This indicated that all influence from TFL on outcomes (H6) was fully mediated through the other two variables in the model. In sum, the overall pattern of results provides support for the patient safety chain presented, suggesting that increases in patient safety are largely (standardized total effect = .73) attributable to increases in the implementation of PSI, which are sparked by a culture of patient safety as influenced by TFL.

Fig. 1. Final path model for the patient safety chain with standardized coefficient



DISCUSSION

This is the first study to provide empirical evidence for the existence of a patient safety chain, which is a set of cause-and-effect linkages that lead to improvements in patient safety in hospitals. Specifically, this study found that improving patient safety begins at the top of the organization with a hospital CEO who possesses a TFL style, and it empirically demonstrates that the charismatic-inspirational leader exerts significant influence on creating a culture of safety within the hospital, which leads to the implementation of PSI, and ultimately to improved PSO. These PSO include the reduction in the frequency, severity, and impact of errors, as well as heightened awareness and understanding of errors.

This study has major implications for healthcare leaders. It provides empirical support that the CEO's leadership style drives PSO, suggesting that hospitals desiring to make patient safety improvements need to focus their attention on this top "link" in the chain. Our findings support both full and partial mediation as part of the patient safety chain model. Specifically, TFL has a direct effect on creating a culture of patient safety and on the actual implementation of PSI. In addition, it has an indirect effect on the implementation of initiatives as mediated through culture, and ultimately an indirect effect on improved PSO as mediated through culture and initiatives. Therefore, these results indicate that the characteristics of charismatic-inspirational leaders lead them to make organizational safety culture a top priority and to devote the necessary resources to PSI in order to realize maximal improvements in PSO.

Healthcare CEOs interested in improving PSO at their hospitals should actively seek feedback on their leadership styles as a critical first step. They must also recognize the need to follow a systematic approach in order to achieve the desired outcomes in the area of patient safety. This involves not only enhancing their TFL style, but also using this style to create a culture of safety. Creating a safety culture means that patient safety is the top priority, and leadership provides a caring and safe environment free of blame, with open communication and collegiality and the commitment and drive to be a safety-centered institution. This enhances the likelihood of actual implementation of a variety of PSI designed to reduce the frequency, severity and impact of errors.

The Joint Commission has exerted considerable pressure and placed a great deal of emphasis on the improvement of patient safety in hospitals. In fact, hospital accreditation has been increasingly tied to PSO. Nonetheless, research indicates that hospitals have been slow and inconsistent in meeting patient safety goals (Longo et al., 2007) and "few have succeeded in making substantial transformation needed to achieve these aims" (Lukas et al. 2007). In order to strengthen the quality of care nationwide, it is imperative that hospitals develop effective solutions to decrease the frequency and severity of medical errors. This paper provides the basis for a systematic approach to addressing patient safety that leads to improved PSO. We believe this study provides practical guidance for both managers and researchers in addressing this very important national issue.

References are available from the first author upon request.