Evaluation of Improvement Capability Grants: Lessons from the Field: Part 1

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COLMR

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Many dedicated staff on the site visit & analysis teams

Systems Redesign

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Why do we care about improvement capability?

- USH goal for VHA is continuous improvement
- VHA strives to continue to move to higher levels of performance in terms of being Veteran-centered, data driven & team-based
- To accomplish this goal, the system needs to have the capacity & will to continuously change & improve

Priority of capability to continuously improve in VHA is reflected, e.g., in

- FY13 Senior Executive Performance Plan under the critical element of Leading People
  - **"CE 2b: Culture of Continuous Improvement and Learning**: The Senior Executive demonstrates strong commitment to ongoing, real-time learning to ensure the sustainability of quality improvement and *patient-driven* model engineering and redesign efforts."

To bring VHA to the next level of performance

- Systems thinking & improvement knowledge, skills & experience are important tools for the continuous improvement needed
- Yet in FY2008, few staff in our medical centers had this expertise & few medical centers had a strong improvement culture

Q1. In the past year, have you been involved in a team to improve work processes or outcomes?

- Yes
- No

Q2. In what role were you usually involved ?

- Not involved in this type of team
- Team member
- Team leader
- Improvement advisor/facilitator/coach

Improvement Capability Grants (ICG) to address the gaps

- VHA Systems Redesign (SR) developed the ICG initiative to:
  - Fund innovative, creative, & practical approaches to creating improvement capability that engages leadership & front line staff together in activities that improve day-to-day function of every aspect of VA care

SR competitively awarded 30 grants

- RFP with broad guidelines to encourage local strategies
- Grants awarded to VISNs & medical centers
  - 10 grants in 2009 to 7 medical centers & 3 VISNs
  - 20 grants in 2010 to 18 medical centers & 2 VISNs
- Three-year grants with total possible funding of $450K-500K/year
- All grants now completed

Grantees developed local approaches to building improvement capability

- Activities clustered in 4 categories:
  - Training in improvement methods = 9 grants
  - Targeted clinical improvement projects = 9 grants
  - Combined training & improvement projects = 8 grants
  - Building infrastructure such as a registry or resource center = 4 grants

COLMR commissioned to evaluate the ICG initiative

- Did the sites carry out their grant initiatives as proposed & meet their short-term objectives?
- Did the sites' initiatives achieve intended program aims & build to the long-term goals of broader improvement capabilities & the development of learning organizations?
- What factors contributed to success or hindered progress in each site?

Site visits with all grantees

- COLMR two-person teams conducted site visits with the 30 grantees at 6 month intervals
  - Grantees included VISNs & individual facilities
  - 34 sites reported here
- Currently conducting
  - One-year follow-up visits with 2009 sites
  - End of grant visits with 2010 sites

Majority of sites showed good progress in building improvement capability

- Based on ratings of 3-4 (mostly/fully) on 0-4 scale:
  - 74% met their grant objectives
  - 65% spread grant activities beyond the original pilot area or clinical focus
  - 68% planned to sustain grant activities after grant funding ends

Key factors in developing improvement capability that builds a culture of improvement

- Improvement training linked with application to improvement projects
- Data & skills to analyze
- Strong improvement infrastructure
- Front-line staff engagement
- Middle manager engagement
- Senior leadership engagement
- Strategic alignment with organizational priorities

Q3. Roughly how many staff in your facility have been trained in systematic improvement methods beyond employee orientation?

- More than 100
- 50-100
- 10-49
- 0-10
- Don’t know

Q4. Is there an explicit expectation that people trained will participate in improvement projects when they return?

- Yes, for all trainees
- Yes, for some trainees
- No
- Don’t know

Improvement training linked with application

- Neither training nor conducting projects alone is sufficient
  - High volume of projects does not build capability unless coupled with skill building
  - Heavy reliance on improvement experts without engaging staff has little sustained impact
  - Without opportunity to apply skills learned, trained staff do not retain skills

Improvement training linked with application

- ICG sites with combined training & projects foci had greater success
  - Trainees work on projects during or immediately after training
  - There is ongoing support for use of new skills by supervisors and improvement advisors
- But this isn't easy

Data & skills to analyze

- Information is critical for improvement
  - Systematic data on processes & performance are critical in diagnosing problems, identifying potential solutions & monitoring progress
- Application of data is particularly important in four areas:
  - Selecting & directing projects
  - Tracking progress in meeting goals
  - Sharing & discussing at levels of the organization
  - Monitoring to detect performance changes

Q5. How deep is the improvement expertise in your medical center? Select all that apply

- A few people in an improvement/quality-related office
- People across the facility with expertise to coach teams
- Don’t know

Strong improvement infrastructure

- Challenges
  - Insufficient improvement resources
    - Level of expertise
    - Collateral duties
    - Working alone
  - Staff trained without plans for projects or support when they return
- Structural & functional depth is needed

Strong improvement infrastructure

- Capacity is needed in five key areas
  - Staff with the expertise & experience to oversee improvement work
  - Sufficient numbers of systems redesign resources
  - A clear plan, defined expectations & ongoing support at all levels
  - Clear linkages between training & projects for staff to apply when return from training
  - Orientation for new staff & refresher training for existing staff

An improvement culture consists of:

- Engaged staff with improvement skills
- Infrastructure of expert skills, structures & culture to support improvement
- Senior leaders engaged in system improvement

Q6. How would you rate the improvement culture in your facility?

- Minimal
- Developing
- Mature
- Don’t know

Recap of lessons & preview of Part 2

- Improvement training linked with application to improvement projects
- Data & skills to analyze
- Strong improvement infrastructure

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- Front-line staff engagement
- Middle manager engagement
- Senior leadership engagement
- Strategic alignment with organizational priorities

Strengthening organizations to implement evidence-based clinical practices

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Objectives: Despite recognition that implementation of evidence-based clinical practices (EBPs) usually depends on the structure and processes of the larger health care organizational context, the dynamics of implementation are not well understood. This project's aim was to deepen that understanding by implementing and evaluating an organizational model hypothesized to strengthen the ability of health care organizations to facilitate EBPs.
Conceptual Model: The model posits that implementation of EBPs will be enhanced through the presence of three interacting components: active leadership commitment to quality, robust clinical process redesign incorporating EBPs into routine operations, and use of management structures and processes to support and align redesign.
Study Design: In a mixed-methods longitudinal comparative case study design, seven medical centers in one network in the Department of Veterans Affairs participated in an intervention to implement the organizational

Key words: evidence-based clinical practice, hand hygiene, implementation, innovation, organizational change

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model over 3 years. The network was selected randomly from three interested in using the model. The target EBP was hand-hygiene compliance. Measures included ratings of implementation fidelity, observed hand-hygiene compliance, and factors affecting model implementation drawn from interviews.
Findings: Analyses support the hypothesis that greater fidelity to the organizational model was associated with higher compliance with hand-hygiene guidelines. High-fidelity sites showed larger effect sizes for improvement in hand-hygiene compliance than lower-fidelity sites. Adherence to the organizational model was in turn affected by factors in three categories: urgency to improve, organizational environment, and improvement climate.
Implications: Implementation of EBPs, particularly those that cut across multiple processes of care, is a complex process with many possibilities for failure. The results provide the basis for a refined understanding of relationships among components of the organizational model and factors in the organizational context affecting them. This understanding suggests practical lessons for future implementation efforts and contributes to theoretical understanding of the dynamics of the implementation of EBPs.

One of the pressing issues in health care today is that promising research findings about best clinical practices are often not widely used, despite extensive efforts to influence their use. Early, provider-focused efforts to introduce evidence-based clinical practices (EBPs) were not consistently successful. Most efforts focused on unidirectional translation of evidence delivered to individual providers in the practice setting (Grol & Grimshaw, 2003; Wensing, Wollersheim, & Grol, 2006), but targeting diffusion efforts only to individuals generally fails because providers do not act in isolation. Although there is now recognition that implementation or uptake of EBPs is complex, the organizational processes and dynamics of successful implementation are not well understood (Feldstein & Glasgow, 2008; Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004; Nembhard, Alexander, Hoff, & Ramanujam, 2009). To improve the implementation of new practices, we need to learn to build organizations with structures, processes, and cultures that can accommodate the complexity of implementing EBPs in daily operations. The growing number of frameworks that lay out the range of theoretical perspectives and complex array of dimensions to be considered in implementing new practices (Damschroder et al., 2009; Feldstein & Glasgow, 2008; Greenhalgh et al., 2004; Grol, Bosch, Hulscher, Eccles, & Wensing, 2007; Nembhard et al., 2009) provide important steps forward. However, further work is needed to deepen our knowledge of how those dimensions and factors interact in different contexts.

The aim of this study was to contribute to that knowledge by implementing and evaluating an organizational model that we expected to strengthen the ability of health care organizations to implement EBPs. In a mixed-methods longitudinal comparative case study design, seven medical centers in one network in the Department of Veterans Affairs (VA) participated in an intervention to implement the organizational model. The network, or the Veterans Integrated Services Network, was selected randomly from three interested in using the model. The network directors recommended hand-hygiene compliance as the target EBP for the study.

Conceptual Framework

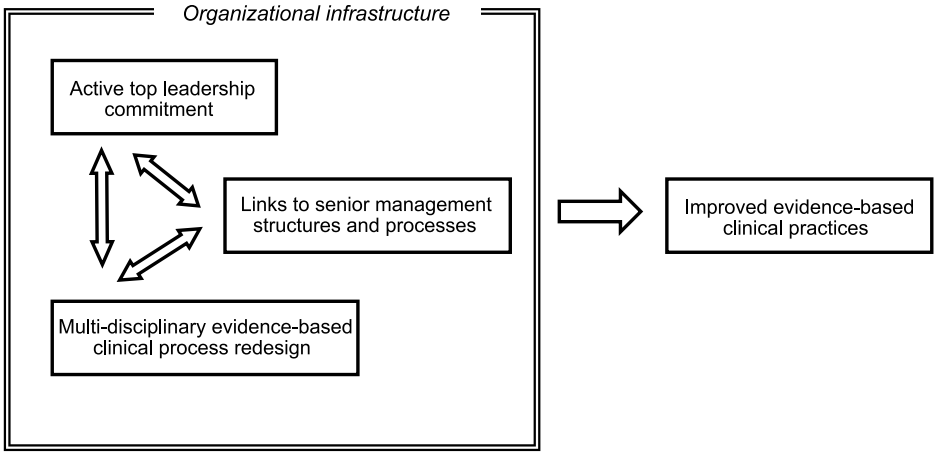
The organizational model being tested is grounded in the organizational transformation model (OTM) developed in the evaluation of the Robert Wood Johnson Foundation's Pursuing Perfection (P2) initiative (Lukas et al., 2007). According to Lukas et al. (2007), OTM was based theoretically in research on complex organizational change (Greenhalgh et al., 2004; Grol et al., 2007; Poole & Van de Ven, 2004), microsystem effectiveness (Donaldson & Mohr, 2001; Nelson et al., 2002), and organizational diffusion of innovation (Rogers, 1995). It was based empirically in the experiences of the P2 health care organizations. The key drivers of change identified in OTM are those that emerged as most important as the P2 organizations worked to transform their systems to provide perfect patient care (Lukas et al., 2007).

Our aim was to build from, although not precisely replicate, OTM in two ways. First, we applied it to EBPs. Our expectation was that the organizational elements that drive organizational transformation would facilitate the change required to implement EBPs. Second, we applied it in an intervention. Because OTM was based on an observational study, we wanted to test its usefulness as an implementation strategy by intentionally introducing it to organizations.

The organizational model used in the study is a consolidated version of OTM that posits that the implementation of EBPs will be enhanced through the presence of three critical organizational components that are interactive and synergistic. Figure 1 presents these elements in highly simplified form. We recognize that organizations are dynamic and that change is complex and iterative with multiple feedback connections and is influenced by many factors not shown. We chose a simplified figure to focus on the model elements that we expect are key drivers and

Figure 1

Organizational model for implementing evidence-based clinical practices



which medical center leaders can influence and control. The complexity of the larger context is depicted as a box in the background to represent the array of other organizational factors that act on and are influenced by the model components. Not only were the three model components identified as critical in OTM, but each separately is supported in the literature. Therefore, in describing each component, we cite examples of other prior research.

The three components are as follows:

Active top leadership commitment. Organizational change is more likely when senior leaders promote change and foster a learning environment (Beer, Eisenstat, & Spector, 1990; Lukas et al., 2007; Sirio et al., 2003). Senior leaders orchestrate transformation by promoting conditions for change, by specifying the direction in which the organization should move, and then by spreading the lessons of both successes and failure (Beer et al., 1990). By spending their own time on activities that directly support continuous improvement and quality of care, senior leaders demonstrate the personal commitment and investment needed for sustained improvement (Sirio et al., 2003).

Clinical process redesign. The success and the speed of adoption of EBP are related to (among other things) an infrastructure dedicated to process redesign (Bradley, Webster, et al., 2004). Clinical redesign serves several functions. First, it provides a vehicle for building EBPs reliably into routine work rather than layering them on top of existing work as added demands (Bradley, Holmboe, et al., 2004). Second, it facilitates change by engaging front-line staff, including physicians, in high-priority problem solving around a concrete, meaningful issue (Beer et al., 1990; Sirio et al., 2003). Third, successful redesign builds momentum for further change and improvement. Short-term experiences working in teams and seeing success motivate staff to go further with improvement.

Links to senior management structures and processes. By itself, the redesign process runs the risk of becoming a quality improvement project that, like many before, is not sustained or spread. To counter this threat, the organization's structures and processes must reinforce the need for change and enhance staff motivation to strive for improvement. More specifically, in organizations with successful change efforts, improvement initiatives are aligned with system strategies and priorities, and staff are held accountable and rewarded for alignment with goals and starting change processes (Beer et al., 1990). Senior management provides the needed infrastructure resources of staff time, equipment, and data systems (Lukas et al., 2008) and addresses integration across organizational boundaries (Greenhalgh et al., 2004). Finally, senior management creates opportunities to communicate improvement successes and failures so that redesign efforts build a culture of a learning organization (Bradley, Webster, et al., 2004; Tucker & Edmondson, 2003).

Methods

The study is a mixed-methods longitudinal comparative case study based on a 3-year intervention in which one VA network implemented the organizational model in support of redesign efforts to improve hand-hygiene practices, the designated EBP. The mixed-methods data collection strategy was judged to be an appropriate methodological

fit given the intermediate level of theory development: There was prior work related to the research question, but the theory on which the project was based was not mature (Edmondson & McManus, 2007).

Research Objectives

The study addressed three questions:

1) ***Is the organizational model implemented with high fidelity to the model design?*** For this study, fidelity is defined as elements of the organization model were in place and being used as intended. We assessed the extent of fidelity for two reasons. First, it serves as an independent variable in evaluating the effectiveness of the organizational model in improving hand-hygiene compliance: Medical centers may not have fully implemented the model and thus reduced its effectiveness. Second, it serves as the dependent variable in assessing factors that affect the success of implementation.
2) ***Are medical centers that implement the model with high fidelity more successful in improving performance of a targeted EBP?*** The study tested the hypothesis that medical centers that implement the organizational model more fully would show stronger improvement and performance in hand-hygiene compliance in comparison with their own performance before model implementation and with medical centers only using a few elements of the organizational model.
3) ***Why is the organizational model implemented more fully in some sites than others?*** Anticipating that the model might be implemented with greater fidelity in some contexts than others, the study was designed to examine the factors affecting implementation and thus increase our understanding of the dynamics of implementation.

The Intervention

The intervention consisted of both research team activities to introduce and support the organizational model and the local implementation of the organizational model.

Study sites. The participating medical centers were varied, ranging from large urban highly-affiliated tertiary facilities to small medical centers in rural areas; six were acute inpatient facilities and one was primarily a long-term care facility. All medical centers were part of the same network, an important structural and reporting feature of the VA health care system.

Operational elements of the organizational model. Organizational interventions are most likely to be successful when they can be tailored by local staff to local conditions (Berwick, 2003). Therefore, for each of the three model components, we identified key elements drawn from OTM and other literature, as outlined in Table 1. We asked the participating medical centers to identify the details of the structures and processes they would use to put each element into place. This operationalization of the model allowed us to distinguish between local tailoring that was consistent with the key elements and therefore reflected high fidelity and variation that reflected only partial implementation of the model.

Clinical focus on hand-hygiene compliance. In collaboration with participating network leaders, we selected hand-hygiene compliance as the clinical focus across all sites. Basic hand hygiene is one of the most fundamental, widely publicized and effective processes shown to reduce hospital-associated infections (Lautenbach, 2001; Newell, Edelman, Scarbrough, Swan, & Bresnen, 2003). However, research indicates that compliance with hand-hygiene guidelines is highly variable and often lower than expected. Although hand-hygiene compliance may seem to be a simple individual practice, in fact, it requires complex system changes to improve across an organization. Because hand hygiene is important in all aspects of hospital functioning, it offered many opportunities for redesign that would engage staff.

Activities to introduce and support the organizational model. In a 3-day visit to each site, a two-person research team conducted a preimplementation assessment, introduced the organizational model, and began working with local project leads to develop a detailed implementation plan. Over the remaining 2 ½ years of the project, the team used site visits at 4- to 6-month intervals to monitor model implementation and to address issues that arose. In addition, at the request of the local redesign leads, it conducted periodic informal telephone calls and, after the first year, quarterly calls with medical center leadership. Two network-wide activities complemented these local efforts: a shared learning group convened via telephone for members of all clinical redesign teams and an in-person quarterly consortium for medical center directors convened by the network senior leaders to stimulate opportunities for information exchange, dialogue, and shared problem solving. These activities were consistent across the seven sites.

Data Sources

The comparative case study drew on three data sources:

Organizational model implementation fidelity ratings. At the end of each site visit, the two-person team, which remained consistent visit to visit when possible, rated implementation fidelity in terms of the extent to which the elements of the organizational model were in

Table 1

Organizational model for implementing evidence-based clinical practices: components and elements

1. Active top leadership commitment
   Leadership vision and direction, constancy of purpose, use of own time
   - Set high local expectations of improvement in measures in target clinical area
   - Set local expectations for becoming a learning organization
   - Convey quality as a high priority by the way leaders use their own time, for example, participating in an improvement team or on a quality oversight committee
2. Links to senior management structures and processes
   Alignment and accountability
   - Appoint strong clinician and administrator to lead local improvement efforts in the target area, with charge that they will establish a multidisciplinary redesign team; appoint an improvement advisor to support the redesign team (see below)
   - Create incentive and reward structures to encourage use of evidence-based practices and, where needed, fundamental redesign of clinic processes
   - Establish structures to link the improvement efforts to senior management such that senior management gives the initiative high priority and holds the design team accountable
     - Reporting relationship to senior leadership team
     - Member of senior management and chief or comparable service line leader in the targeted area designated as formal champions to advocate for redesign and help the design team solve problems

   Integration and resource support
   - Link improvement efforts to senior management such that senior management facilitates cooperation across organizational boundaries and provides other resources to design team, for example, protected time to work on initiative; staff, equipment, and space as needed; IT support as needed

   Communication
   - Celebrate and broadcast successes and share failures to learn from them
   - Use lessons from this redesign to spread processes, redesign skills and values to other parts of the organization
3. Clinical process redesign
   - Create a collaboratively functioning redesign team that is multidisciplinary and crosses organizational lines to include all owners of processes that touch the target clinical area
     - Provide training/refresher in QI techniques as needed to team members
   - Analyze performance and processes and identify areas for improvement
     - Review performance data to identify areas for improvement
     - Aim for system redesign that builds evidence-based practices into daily work not just add them on; take away old actions
     - Set goals and measures and map processes and activities expected to improve measures to reach the goals
     - Identify new parts of organization that need to be involved—add team members as needed
   - Monitor, analyze, and modify or extend improvement processes (ongoing)
   - Report progress, including problems, to senior leadership regularly
   - Spread successful improvement efforts to other parts of the organization
   - Monitor successful areas to ensure that improvements are sustained

place and used as intended. Using a structured tool, each team member independently rated the presence of each element, both assigning a quantitative score of 0 (*no evidence of the element present*) to 4 (*element in place and consistently being used as intended*) and providing narrative evidence to support each score. After the independent ratings, the site-visit team members compared ratings and developed a consensus score for each element. By measuring implementation after each round of interviews, we were able to track changes over time.

Observations of hand-hygiene compliance. Observations of adherence to national hand-hygiene guidelines were conducted by the sites using local data collection instruments and practices. Core data elements were constant across sites, but observers varied. This approach was consistent with the study intent of building on local processes that would be sustained after the research project. To some extent, this compromised cross-site comparisons of raw rates of adherence. However, our main focus was on within-site changes over time. With one exception, there were no major changes in data collection approach over the study period. In most sites, observation data were collected monthly between the last quarter of 2006 and the third quarter of 2008.

Semi-structured interviews during site visits. The site visits were designed to collect data on the course of

the intervention and to provide feedback to the medical centers. Semi-structured interviews were conducted by the two-person teams, with the medical center leadership including the director, the chief of staff, the nurse executive, and the associate director; the clinical redesign team members, leaders, and project improvement advisor; and selected front-line staff. Questions were designed to evaluate the use and dynamics of organizational model elements and site-specific tailoring. Interview protocols were reviewed after each wave of site visits and refined to capture emerging issues. Each site was visited five or six times with an average total of 37 interview sessions conducted over the study, many with multiple informants. Detailed interview notes were written up and circulated within the site-visit team for review and clarification. Using Nvivo 2.0 (QSR International 2006, Melbourne, Australia), the qualitative coding team reviewed and independently coded transcripts for sites they did not personally visit. The initial coding list was developed on the basis of the broad concept areas of the organizational model followed by more specific codes as they evolved. After each round of site visits, the codes were reassessed and refined for continued content validity. Initial reliability of the coding protocol was assessed by an inter-rater coding comparison, resulting in 70% agreement. To maintain a high level of coding reliability, the coding team held quarterly meetings to review the codes and compare coding.

Measures and Analyses

To answer three study questions, we developed and analyzed three sets of measures:

Ratings of implementation fidelity. We used the fidelity ratings to analyze the extent of organizational model implementation from two perspectives. First, we used the quantitative ratings as summary indicators of the extent to which the key elements of the organizational model were in place and to track changes over time. To create summary fidelity scores for each site visit, we aggregated the scores on each element to the level of the three model components and calculated an unweighted mean for each on the 0 to 4 scale. Means of component scores were used rather than individual elements to weight each component equally. The overall fidelity rating is an unweighted average of the three component scores. For the analyses reported here, we focused on ratings of fidelity at the final site visit and overall change between first and last visit. Second, we used the narrative evidence given to support each rating to capture qualitatively an operational picture of what the ratings meant.

Hand-hygiene compliance scores. For each observation period, we calculated the percent of hand-hygiene compliance at the site level. The effect size of improvement in compliance was calculated by comparing the baseline 3- and 6-month periods to the last 3- and 6-month periods of the study. To evaluate the statistical significance of changes in proportion adherence over time, we ran a weighted least squares regression model with time (i.e., month) as the independent variable and adherence proportion as the dependent variable. The sample size in each data collection period was used as the weight. Our interest is in the statistical significance of the coefficient associated with time. To evaluate the practical significance of the change preintervention and postintervention, we examined the effect size associated with the change in proportion adherence in the first 3-month period of data collection (denoted by p_1) and the last 3-month period (p_2). Effect size was calculated as follows: $2 \times \arcsin(\mathrm{sqr}(p_2)) - 2 \times \arcsin(\mathrm{sqr}(p_1))$. Using Cohen's criteria, an effect size of .2 is interpreted as small, .5 as medium, and .8 as large (Cohen, 1977).

Factors affecting model implementation. Factors affecting the extent of implementation of the organizational model were identified qualitatively through interviews. The analysis was designed to understand the impact of the organizational context on model implementation in each site and to examine patterns of similarity and difference across sites, especially between high-fidelity and lower-fidelity groups. Following the procedures described by Miles and Huberman (1994), we conducted thematic analyses of the interview notes, identifying both within-site patterns and across-site differences. We used an explanation-building strategy, focusing on understanding each case first before conducting cross-site comparisons and then cycling back and forth between the individual site cases and the cross-site comparisons. Cross-site matrices were used to compare and to contrast evidence of activities, processes, and structures across sites.

Findings

Is the Organizational Model Implemented With High Fidelity to the Model Design?

Overall fidelity ratings ranged from 1.42 to 3.95 at the end of the study, indicating considerable variability in fidelity to the model design. As shown in Table 2, sites clustered in two groups by implementation ratings, both overall and by the individual components: Sites were grouped into high implementation fidelity (four sites) and lower implementation fidelity (three sites). In the lower-fidelity group, implementation scores were 2.50 or less across dimensions, indicating that elements were partially present (2 = *partially present*). In the high-fidelity

Table 2

Ratings of fidelity to the organizational model

Facility	Fidelity: leadership	Fidelity: management links	Fidelity: redesign efforts	Fidelity: overall	Fidelity: overall change from baseline	Fidelity rank order
A	**4.00**	**4.00**	**3.85**	**3.95**	**2.82**	**1**
B	**4.00**	**3.20**	**2.95**	**3.38**	**2.11**	**2**
C	**3.75**	**2.60**	**3.35**	**3.23**	**1.99**	**3**
D	**3.00**	**3.00**	**3.50**	**3.17**	**1.84**	**4**
E	2.00	2.20	2.25	2.15	1.21	5
F	2.50	1.80	1.65	1.98	0.41	6
G	2.50	1.25	0.50	1.42	−0.05	7

Note. Bold font indicates data for high implementation fidelity sites (facilities A–D).

group, scores were above 3.0 on the overall ratings, indicating that the elements were mostly or fully present (3 = *mostly present*, 4 = *element in place and consistently used as intended*). Sites with the highest final ratings were also those with the largest changes in implementation scores over the project, as shown in Table 2. At baseline, implementation scores were closely clustered between 1.13 and 1.57, indicating that the differences in final scores were not simply a reflection of preexisting differences among sites.

Qualitative analyses supported the quantitative differences between the two groups. Although the high-fidelity sites did not fully implement every element of the organizational model and the lower-fidelity sites were strong on some elements, the overall patterns of behavior and activities in the three model components are clearly different in the high and lower groups:

Active top leadership commitment. In the high-fidelity group, senior medical center leaders were supportive of and involved in hand-hygiene improvement efforts. Perhaps most important, senior leadership involvement and support was consistent across settings and over time. Senior leaders set clear expectations about target levels of compliance and sent the message that current practices were deficient. They received regular briefings about compliance levels and improvement progress. They served as role models and champions for hand-hygiene compliance. They also created opportunities for communication to emphasize awareness. In the lower-fidelity group, senior leaders either did not see hand hygiene as a high priority or expressed support but were not consistent in their involvement. In some cases, they modeled good hand hygiene and, for example, addressed it if it came up on patient safety and environment of care rounds, but they generated little sense of urgency for improvement.

Clinical process redesign. In the high-fidelity group, clinical redesign was characterized by energetic, visible, multidisciplinary improvement teams. Sites with solid quality improvement approaches tended to involve staff affected by redesign efforts across disciplines and divisions on their teams. High-functioning teams had strong team leaders with excellent project management skills and often had experienced quality improvement experts serving as team members or dedicated to the team. Team leaders in some sites were paired with clinical leads who used their professional collateral to help move the project forward. Finally, all teams in the high-fidelity group went beyond basic process redesign methods to explore higher reliability interventions as compliance improved or plateaued. In the lower-fidelity group, clinical process redesign was often more ad hoc. Teams, if appointed at the beginning of the project, never really got off the ground or fell away to just the skeleton of a team because team members could not find time to meet or were not released from clinical duties to participate. Teams collected data but did not use it to help understand possible sources of noncompliance or the impacts of their intervention activities. Often lower-fidelity sites felt their teams lacked the leadership, the authority, or the infrastructure to accomplish their goals.

Links to senior management structures and processes. In the high-fidelity group, there were explicit strategies to link improvement efforts to senior management. A member of the leadership team was explicitly identified as an executive champion or coach to work actively with the hand-hygiene redesign team as a liaison and a mentor. Sometimes the executive champion served as members of the redesign team but if not was connected as part of his or her ongoing management responsibilities. In addition to the designated executive champion, the whole leadership team remained aware of most of the improvement efforts by, among other things, regularly reviewing the hand-hygiene compliance data. As part of the data review, there were clear lines of accountability for performance

that did not meet the target, although there was variation among sites in their consistency in dealing with weak performance. Across high-fidelity sites, data and redesign progress were generally discussed by senior leaders in a forum where issues and problems could be assigned to appropriate managers to solve. Medical center managers provided resources, such as time and staff, for the hand-hygiene improvement efforts as well as for incentives and rewards. Attention to hand hygiene was regularly rewarded and hand-hygiene success generally celebrated. In the lower-fidelity group, executive champions were less consistently identified and involved or, in some cases, served as champions in name only. In addition, reporting hand-hygiene data tended to be reviewed by standing performance improvement or patient safety committees buried several layers below leadership, which diluted the ability of the team to get sufficient leadership attention. Sometimes hand-hygiene performance data were reported to leadership, but there was no constructive follow-up action when performance was low. The result of such disconnection was that project teams felt they did not get consistent direction, cross-department issues went unresolved, and hard-won successes were not recognized.

Are Medical Centers That Implement the Model With High Fidelity More Successful in Improving Performance of a Targeted EBP?

Analyses support the hypothesis that greater fidelity to the model is associated with higher adherence to hand-hygiene guidelines, as shown in Table 3 where the sites are divided between high and low fidelity in the same way they were in Table 2. In the four high-fidelity sites, the effect sizes were much larger (.48 to .92) than that in the lower-fidelity sites (−.22 to .14). This is true even in facility C when a 6-month preperiod and postperiod are used (thus reducing the effect of the extremely low adherence rate in the 3-month preperiod). For the most part, effect sizes suggest a moderate effect. For the four high-fidelity sites, the monthly increase in the percent adhering was statistically significant. In the three lower-fidelity sites, the monthly change was not statistically significant.

Why Is the Organizational Model Implemented More Fully in Some Sites Than Others?

As expected, the extent of implementation fidelity was affected by the context in which the organizational model was implemented in each medical center. Organizational factors were identified inductively from the accounts of implementation experiences provided in the medical center staff interviews. They were analyzed as force fields with some factors exerting positive influence and others negative influence. We grouped the emergent factors in three categories: urgency to improve hand-hygiene compliance, organizational environment, and improvement climate. Where there are systematic differences between high-fidelity and lower-fidelity groups, they are noted. Although we present the factors separately, in practice, they are overlapping and interrelated.

Urgency to improve hand-hygiene compliance.

Organizational change is difficult, and without a strong impetus to move from the status quo, it is not likely to happen. As described above, not all the medical center leaders in the study accorded hand hygiene high priority for improvement. Four factors were most salient in determining whether they felt an urgency to improve hand-hygiene compliance.

1) Infection control problems. An important impetus for change is a serious clinical problem or a performance gap—in the case of hand hygiene, an infection

Table 3

Hand-hygiene compliance ordered by fidelity ranking

Facility	Adherence preperiod	Adherence postperiod	Effect size: 3 months before and after	Effect size: 6 months before and after	Regression model: time coefficient	Regression model: time coefficient *p* value	Regression model: r^2
A	**67.6**	**92.9**	**.67**	**.69**	**1.29**	**.00**	**.72**
B	**74.2**	**91.5**	**.48**	**.40**	**0.98**	**.00**	**.57**
C	**37.4**	**80.9**	**.92**	**.22**	**1.41**	**.01**	**.36**
D	**81.7**	**96.8**	**.52**	**.53**	**0.97**	**.00**	**.53**
E	69.1	75.2	.14	.07	0.20	.11	.62
F	61.5	68.3	.14	−.27	−0.40	.47	.03
G	80.1	70.8	−.22	−.29	−0.47	.17	.08

Note. Bold font indicates data for high implementation fidelity sites (facilities A–D).

outbreak. However, in the absence of an immediate or recent infection control problem, hand hygiene was not a natural top priority for many sites.

2) External pressures for hand-hygiene compliance. External pressures are commonly cited as an impetus for change, particularly in the absence of a strong internal reason for change. In this case, The Joint Commission (TJC) was a motivator in several sites because they had upcoming surveys, and TJC gave considerable attention to hand hygiene in the latest survey round. New attention to Methicillin-resistant Staphylococcus aureus (MRSA) outbreaks in the health care environment also served as a pressure to change. Partway through the project, VA central office issued a directive requiring attention to MRSA. Several sites combined their hand-hygiene and MRSA initiatives, which gave added attention to hand hygiene.
3) Source of the intervention. The source of the intervention in all sites was the network office. The network director and the chief medical officer—the leaders up the corporate ladder—sponsored this project. However, the responses to that source differed. For leaders in some medical centers, this gave the project legitimacy and, as a result, they pursued the project consistently and thoroughly. For others, the network sponsorship compromised the project because it did not emerge from local priorities or local identification of a problem.
4) Competing priorities. Perhaps even more than that in the private sector, VA medical center leaders, who work in a national health care system, are bombarded with competing priorities from the network, the VA central office, and the Congress. Although all study sites faced this dynamic, they varied in the ways in which they responded to the myriad of demands. High-fidelity sites were able to focus despite the noise. They set priorities among competing pressures and had structures in place to enable them to delegate responsibilities but at the same time, by monitoring them, not let go of priorities. In two lower-fidelity sites, attention swung from one priority to another, and staff seemed overwhelmed by competing forces. A third lower-fidelity site faced particular problems with performance measures.

Organizational environment. In addition to factors that affect the urgency to change, aspects of the broader organizational environment may influence model implementation. In some study sites, two factors were important: changes in leadership with the result that priorities were recast away from hand-hygiene improvement and budgetary pressures that made the resource requests for hand-hygiene efforts, although low, a barrier to improvement.

Improvement climate. An organization's experience with quality improvement and the values of improvement in the organization affected implementation through both their receptivity to the organizational model and the skills they brought to the initiative. Three improvement climate factors influenced implementation:

1) Staff skills in and experience with quality improvement. Fidelity to the clinical redesign component of the organizational model was facilitated by staff capability with systematic quality improvement methods and projects. High-fidelity sites had a track record of having done improvement work before, with staff seeing the benefits of their work and getting recognition for their efforts, thus creating high staff morale around improvement. Lower-fidelity sites had neither the skills nor such a track record. As a result, improvement efforts were inconsistent and not given enough attention, often leading to poor results and low morale. Clinical redesign efforts were seen as extra work or unwelcome assignments.
2) Organizational values for improvement. Beyond specific team skills and experience, an improvement climate reflects the values of an organization in fostering a culture that aims to embed quality and performance improvement in the way work is done. Medical centers varied in the extent to which quality improvement was core to their organizational values, with high-fidelity sites being more likely to have organizational values for improvement. In contrast, in other sites, systematic continuous improvement efforts were not built into their way of doing things.
3) Psychological safety. Closely tied to organizational values, the concept of psychological safety is the extent to which staff feels safe speaking out and taking the risks associated with improvement, including both the initiative to try new ways of doing things and the chance of failing. High-fidelity sites were more likely to exhibit characteristics of psychological safety.

Practice Implications and Discussion

This project offers multiple lessons for practitioners. First, improvement of the targeted evidence-based practice, hand-hygiene compliance, is enhanced by the presence of three components in the organization that leaders and managers can affect: active leadership commitment to improving the targeted practices, robust clinical process redesign to engage staff and to incorporate EBPs in routine operations, and links to management structures and processes to support, to align, and to integrate redesign. Medical centers with high fidelity to these components had consistently higher hand-hygiene scores at the end of the project and greater before and after improvement than medical centers with lower-fidelity. The premise underlying the study is that the presence of these components will facilitate the implementation of other evidenced-based practices also.

Second, the three components interact to create synergies that contribute to improved performance. Links to

management structures and processes are critical to turn personal leadership support into management actions, to align the redesign teams with organizational priorities, to hold the team accountable, and to provide practical support.

Third, implementing the OTM components is not always easy. Fidelity of implementation to the organizational model varied despite an intervention strategy that was consistent across sites, indicating that existing features and resources must be taken into account to successfully change an organization. Although each medical center had its own array of factors that affected fidelity, some factors were common across sites. Sites that were best able to achieve implementation of the organizational model—and through that implementation to improve performance in hand hygiene—were those that shared the urgency to improve compliance with hand hygiene, had a positive improvement climate including staff experience and skills with quality improvement and organizational values for improvement, and to a lesser extent had no major aspects of the organizational environment that interfered with implementation, such as leadership changes or severe budget constraints. These factors suggest dimensions that a medical center might assess to determine the features on which it should build and those which must be overcome to implement the model components successfully.

In addition to having implications for practice, the study also contributes to research on organizational change and implementation science. First, it provided an opportunity to test under new conditions an abbreviated version of the OTM that was developed observationally from the Robert Wood Johnson Foundation's P2 initiative (Lukas et al., 2007). Our findings provide further validation for OTM: Although our model was not identical, the underlying concepts are the same. Second, the organizational model presented here complements other organization theories of implementation effectiveness. For example, Helfrich, Weiner, McKinney, and Minasian (2007) and Weiner, Lewis, and Linnan (2009) posit that implementation effectiveness begins with organizational readiness for change, which influences implementation policies and procedures that in turn influence implementation climate that leads to implementation effectiveness. The organizational model presented here offers additional understanding of and strategies for creating strong implementation policies and procedures and implementation climate through, for example, its emphasis on links to management structures and processes. The model is also consistent with the conclusions that implementation policies and procedures need to be highly contextual to successfully affect implementation climate (Helfrich et al., 2007) and that antecedent conditions in an organization—its existing features and resources—must be taken into account in successful transformation (Harrison & Kimani, 2008). Going further, it offers strategies for addressing the context, both through the elements of the organizational model and by offering an approach for understanding factors contributing to implementation success.

As in most research projects, this study was not without limitations. An early design decision to build the project structure on local site capabilities presented research challenges, notably from the decision to rely on site staff rather than researchers to collect data on hand-hygiene compliance. Our aim was to work with sites on a data collection processes that would continue after the research project, an aim consistent with TJC requirements for hand-hygiene monitoring and with our broader intent to build lasting structures and processes into the site's infrastructure. Because of this decision, there was a common core of data collected, but it varied in terms of the observer and in the number and frequency of observations.

As we have highlighted, the study was conducted in the Department of Veterans Affairs. Although VA has some unique characteristics, it also shares many features with private-sector hospitals and health care systems. In this instance, the commonalities of organizational structures and clinical operations across medical centers offer a firm basis for generalizing study results to other health care settings, especially because the model studied was originally developed from experiences in private-sector systems. From this understanding, we can both draw practical lessons for future implementation efforts and contribute to the theoretical understanding of the dynamics of the implementation of EBPs.

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Transformational change in health care systems: An organizational model

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Background: The Institute of Medicine's 2001 report *Crossing the Quality Chasm* argued for fundamental redesign of the U.S. health care system. Six years later, many health care organizations have embraced the report's goals, but few have succeeded in making the substantial transformations needed to achieve those aims.
Purposes: This article offers a model for moving organizations from short-term, isolated performance improvements to sustained, reliable, organization-wide, and evidence-based improvements in patient care.
Methodology: Longitudinal comparative case studies were conducted in 12 health care systems using a mixed-methods evaluation design based on semistructured interviews and document review. Participating health care systems included seven systems funded through the Robert Wood Johnson Foundation's *Pursuing Perfection* Program and five systems with long-standing commitments to improvement and high-quality care.

Key words: alignment, health system change, integration, organizational change, transformation

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Findings: Five interactive elements appear critical to successful transformation of patient care: (1) *Impetus* to transform; (2) *Leadership* commitment to quality; (3) *Improvement initiatives* that actively engage staff in meaningful problem solving; (4) *Alignment* to achieve consistency of organization goals with resource allocation and actions at all levels of the organization; and (5) *Integration* to bridge traditional intra-organizational boundaries among individual components. These elements drive change by affecting the components of the complex health care organization in which they operate: (1) *Mission, vision, and strategies* that set its direction and priorities; (2) *Culture* that reflects its informal values and norms; (3) *Operational functions and processes* that embody the work done in patient care; and (4) *Infrastructure* such as information technology and human resources that support the delivery of patient care. Transformation occurs over time with iterative changes being sustained and spread across the organization.
Practice Implications: The conceptual model holds promise for guiding health care organizations in their efforts to pursue the Institute of Medicine aims of fundamental system redesign to achieve dramatically improved patient care.

In 2001, the Institute of Medicine (IOM) released the report *Crossing the Quality Chasm: A New Health System for the 21st Century*. Highly critical of the U.S. health care system, the IOM argued that current systems of care fail to provide Americans with the high-quality health care system they need, want, and deserve. To achieve safer, high-quality care, intensive efforts are needed at all organizational levels to fundamentally redesign systems of care (IOM, 2001). Today in 2007, many health care systems are striving to respond to the challenges of the *Quality Chasm*. Few, however, have succeeded in making substantial transformations to achieve the IOM aims. Using traditional quality improvement (QI) techniques, many have attained short-term improvements in targeted areas through hard work and focused attention. However, few QI efforts have yielded sustained system change because they were not supported by the culture and structure of the larger organization (Repenning & Sterman, 2001; Rondeau & Wagar, 2002). Transformational change, by contrast, is pervasive and involves not only structures and processes but also the inherent culture and values of the health care organization (NHS Institute for Innovation and Improvement, 2006).

The question, then, is how can health care systems transform to provide consistently safe, high-quality care for patients? We address this question by identifying factors critical to successful system redesign, or transformation, from the experiences of 12 health care systems striving to provide superior—and in some cases, perfect—patient care. Our work stems from the national evaluation of the *Pursuing Perfection* (P2) Program, a major initiative of the Robert Wood Johnson Foundation (RWJF) created in 2001 in response to the *Quality Chasm*. P2 health care organizations sought to achieve dramatic improvements in patient outcomes by pursuing perfection in all major care processes, with technical assistance from the Institute for Healthcare Improvement (IHI), the national program office for P2.

The evaluation, which was aimed toward understanding the factors that contributed to (or impeded) the health care systems' abilities to achieve their goals, drew upon theoretical constructs and disciplinary perspectives regarding complex organizational change (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004; Grol, Bosch, Hulscher, Eccles, & Wensing, 2007; Poole & Van de Ven, 2004). The initial conceptual framework was based on research on microsystem effectiveness—including concepts of communication, coordination, organizational culture, and management support and involvement (Donaldson & Mohr, 2001; Nelson et al., 2002)—and on organizational diffusion of innovation (Rogers, 1995). This framework reflected IHI's intervention strategy to focus first on achieving perfect patient care in two clinical areas, then expand to five areas, and finally expand to all areas. We also used the IOM's *Quality Chasm* aims (IOM, 2001) and the Malcolm's Baldrige National Quality Program guidelines (2005) as frames of reference because many study systems used them. The data collection strategy, however, was designed to capture key system experiences, dynamics, and learnings that were not necessarily emphasized in the original frameworks. The factors reported here are those that emerged from the data as most important in the systems that we studied.

This article offers a conceptual model for understanding how organizations move from short-term performance improvements to sustained, organization-wide patient care improvements. The elements identified as critical to successful transformation have been

studied before. Our contribution lies in bringing them together and sometimes extending their conceptual basis, to show how they behave and interact in health care systems striving for perfection.

Methods

Using a mixed-methods evaluation design, we conducted comparative case studies in 12 health care systems over 3.5 years.

Study Sites

Participating health care systems included seven systems that received RWJF funding (*P2 systems*) and five systems that were selected initially to provide a basis for distinguishing the effects of P2 participation from other improvement efforts in the health care environment (*expanded-study systems*). The 12 systems are described in Table 1. The P2 systems were selected competitively by RWJF, with each receiving $2.4 million in funding over 4 years in addition to ongoing technical support from IHI. The P2 systems are named in Table 1 because their identities have been widely publicized. However, they are identified as Sites A–G throughout the article to protect the confidentiality of their interviews. The expanded-study systems were selected to exemplify organizations of different size and complexity with long-standing commitments to QI, as recognized through public ratings and professional networks. Two systems received small P2 planning grants but were not selected for implementation funding. Expanded-study systems are identified throughout the article as Sites H–L.

Data Sources

We used *semi-structured interviews* to conduct more than 750 sessions in the 12 systems over the 3.5-year study period (2002–2005). We visited each system up to seven times, conducting 5 to 21 interview sessions each time, as shown in Table 1. Interviewees were selected to obtain perspectives from across the organization and included the following: the CEO; clinical executive staff; senior QI manager(s) and staff; members of interdisciplinary QI project teams (e.g., middle managers, improvement staff, physicians, nurses, and other frontline staff); representative frontline physicians and nurses affected by improvement initiatives; and managers responsible for information technology, human resources, customer service, and other business functions. Many interview sessions involved multiple participants. Except for the interdisciplinary team interviews, individuals generally were interviewed with their peers. Although we recognized the drawbacks of group interviews, we opted to talk with more people than would have been possible with only individual interviews because of the project's broad scope. Two- or three-person teams conducted interviews of 1 to 2 hr in length. Altogether seven team members participated in interviews, rotating their assignments to visit as many systems as possible while also ensuring that at least one team member was present at consecutive visits for each system. Detailed interview notes were taken and subsequently transcribed. Materials provided by the systems also were reviewed, including strategic plans, improvement team workplans, team and organizational performance measures, and communication materials.

Analytic Approach

We conducted longitudinal comparative case studies, using an explanation-building analytic strategy applied to build, test, and refine our conceptual model. After the first three waves of interviews, we coded and sorted the interview transcripts into descriptive meta-matrices organized by domains specified in the earliest conceptual model and by new themes that emerged from the site visits. Consistent with Miles and Huberman's (1994) guidelines for comparative case studies, we first created individual site matrices and analyzed them separately before seeking cross-site explanations and then cycled back and forth between analytic strategies to understand both case dynamics and the effects of key variables. For each emerging domain, we added questions to the interview guides for subsequent rounds to enable further definition and refinement of domains. This iterative process followed Denzin's interpretive synthesis approach of collecting multiple instances and inspecting them for essential elements (Miles & Huberman, 1994). As we gained deeper understanding of each system's approach to improvement and transformation over time, we were able to validate domains and interactions between elements. We further refined the model by presenting it iteratively to the study systems for feedback, validation, and revision.

Finally, as the basis for a summary rating of model presence in each system, each team member independently rated the system on each model element on a 1 to 5 scale (1 = *no or negligible evidence of that dimension present*, 5 = *fully present*). Cross-member ratings were reasonably consistent, with consistency defined as all ratings being within one or two adjacent points on the scale. We aggregated scores across elements and averaged them across raters to create a summary score of the extent of model presence in each site.

Table 1

Description of study systems and data collection

P2 Systems	Site Description	Number of Site Visits	Interview Sessions/Site Visit
Cambridge Health Alliance	Academically affiliated public health care system in Cambridge, MA, area with 3 community hospitals, 20 primary care sites, and a city public health department; 200–300 hospital beds and approximately 3,500 employees; ethnically diverse patient population with approximately 60% uninsured	7	7–18
Cincinnati Children's Hospital Medical Center	Pediatric academic medical center in Cincinnati, OH, serving approximately 30 regional counties; 300–400 beds and approximately 6,000 employees; diverse racial and socioeconomic patient population with 40% of children below the federal poverty level	6	11–16
Hackensack University Medical Center	Academically affiliated hospital subsidiary of a health system, which includes 6 other satellite locations serving patients in the greater metropolitan New Jersey and New York area; 600–700 beds with approximately 7,000 employees and approximately 1,500 affiliated physicians; approximately 5% of the county population is below the U.S. poverty line, 4% receive Medicaid, and 6% receive uncompensated care; approximately 25% of the population is from ethnic minority groups	7	8–16
HealthPartners	Nonprofit integrated care delivery and financing system headquartered in the Minneapolis/St. Paul, MN, area with 2 hospitals and approximately 50 clinics and practice locations; 1000 beds, 9,000 employees, and over 10,000 contracted providers for approximately 700,000 members and 100,000 fee-for-service patients including recent immigrants from Africa and Asia; approximately 20% of patients are insured through Medicare/Medicaid.	7	8–13
McLeod Regional Medical Center	Nonprofit, academically affiliated multifacility health care provider in Florence, SC, serving rural Pee Dee county with 500–600 beds, approximately 400 medical staff and 4,000 employees, approximately 25% of the population is below the poverty line, and almost half are from ethnically diverse backgrounds	7	8–13
Tallahassee Memorial Hospital	Flagship hospital of a nonprofit integrated health care system including the hospital, a home health agency, and more than 10 primary care clinics serving the metropolitan Tallahassee, FL, area and surrounding rural counties; around 800 beds and almost 4,000 employees; mixed demographic patient population with approximately 25% below the poverty line	7	7–13
Whatcom County/ Peace Health	County-wide collaboration of health care providers, including St. Joseph Hospital, part of the academic and religiously affiliated Peace Health system, a number of community health centers and physician group practices and a nonprofit insurer in rural Washington state; the hospital has 200–300 hospital beds and approximately 1,700 employees including 300 medical	7	9–12

(continues)

Table 1

Continued

	Site Description	Number of Site Visits	Interview Sessions/Site Visit
	staff; the patient population is overwhelmingly Caucasian, and more than 60% are insured through government health care programs		
Expanded-Study Systems			
H	Physician-led integrated health care system in a relatively rural part of a midwestern state, part of a larger academically affiliated medical system; hospital has 300–400 beds and almost 200 physicians serving patients with a median household income of approximately $30,000 and little ethnic diversity	5	8–12
I	Religiously affiliated medical system of approximately 20 hospitals and 2 nursing homes in 4 Midwestern states with approximately 5,000 affiliated physicians and 24,000 employees	2	15–21
J	Hospital that is part of a nonprofit, academically affiliated regional health care system in a rural area of a midwestern state; the hospital serves patients from 32 counties with approximately 400 beds and 400 affiliated physicians	3	10–16
K	Academically affiliated health system including multispecialty group practices, approximately 30 ambulatory care facilities, and a major hospital with 900–1,000 beds and a staff of approximately 4,000 (including 1,000 physicians) located in a midwestern urban area serving a patient population consisting of approximately 90% African Americans	3	13–18
L	Academically affiliated nonprofit health care system consisting of approximately 20 hospitals, 2,000–2,500 beds, approximately 2,500 employees serving patients in 1 urban area and several rural areas in a western state	1	5

Note. P2 = Pursuing Perfection.

Model Overview: Framework for Organizational Transformation

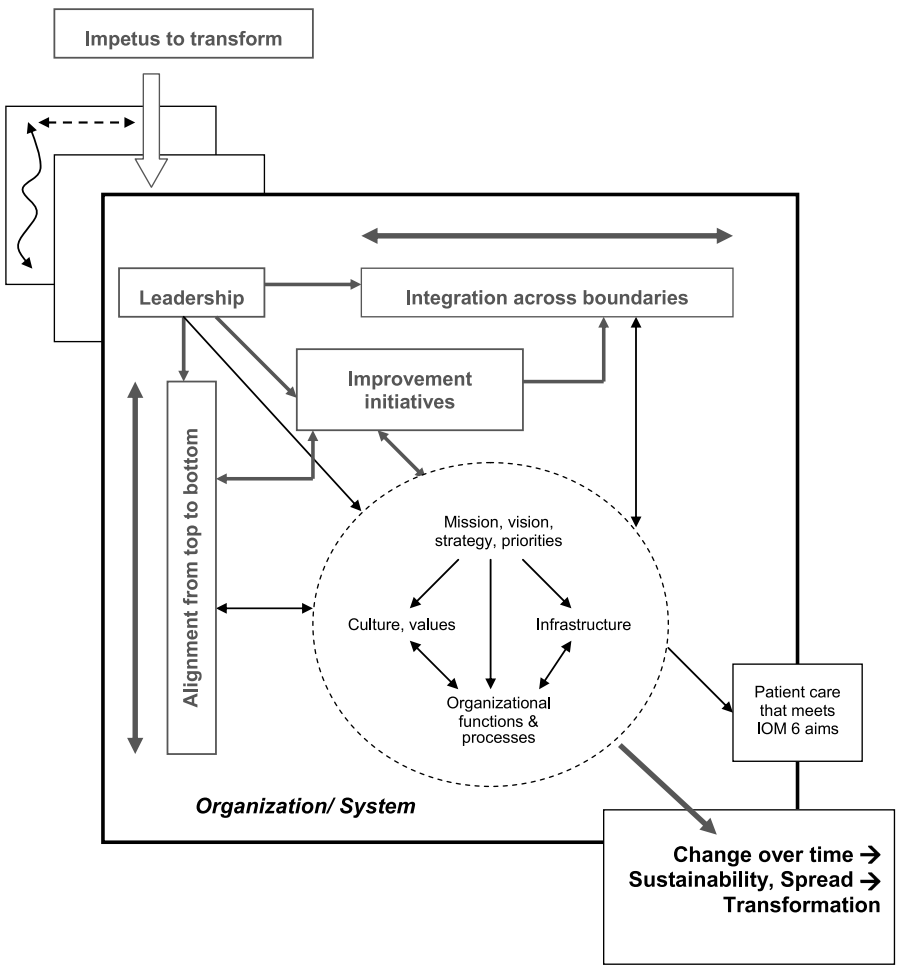
In the P2 program, RWJF and IHI translated the *Quality Chasm*'s aims into a standard of perfect patient care, emphasizing patient-centered care driven by the needs and preferences of patients rather than by professional or organizational judgments. Although none of the 12 study systems achieved perfect care for all patients during the 4-year grant period, most made substantial progress in improving clinical performance in targeted areas, and some made notable strides in redesigning systems to support broader organizational changes.

From our analyses of all 12 site experiences, we identified five elements, or key drivers, that appear critical to a health care organization's success in moving to sustained, highly reliable, evidence-based improvements that ultimately lead to patient care transformation across the organization. Through the comparative case study analysis, we recognized experiences of the expanded-study systems that fit the same model as those of the P2 systems. Although some factors played out differently in the expanded-study sites, the same factors appeared critical to transformation. Therefore, we present findings from all 12 systems together rather than contrasting them as would be done with a usual comparison group.

The five critical elements, shown in Figure 1, include the following: (1) *Impetus* to transform; (2) *Leadership* commitment to quality; (3) *Improvement initiatives* that

Figure 1

Key elements of organizational transformation to deliver high-quality patient care



actively engage staff in meaningful problem solving; (4) *Alignment* to achieve consistency of organization-wide goals with resource allocation and actions at all levels of the organization; and (5) *Integration* to bridge traditional intra-organizational boundaries between individual components.

In highlighting these factors, we run the risk of presenting them as isolated and static. In reality, these elements effect the transformation by driving change in complex and dynamic health care organizations. As illustrated inside the dotted circle in Figure 1, we define the organization—or network of organizations comprising the system—in terms of four basic components: (1) *Mission, vision, and strategies* that set its direction and priorities; (2) *Culture* that reflects its values and norms; (3) *Operational functions and processes* that embody the work that is done in patient care; and (4) *Infrastructure* such as information technology, human resources, fiscal services, and facilities management that support the delivery of patient care. Changes in these four components reflect the transforming health care system. Transformation occurs over time, as illustrated by the shadow boxes and diagonal line, leading to changes that spread across the organization and are sustained.

We expand here on the five model elements and their interactions, providing examples to illustrate each element in practice and how it interacts with other parts of the organization.

Key Drivers: Elements of the Model

Impetus to Transform

Each study system had a strong impetus to change. In Figure 1, impetus appears outside the organization to

emphasize external pressures for change that often were strongest. However, in some cases, impetus for change came from within the organization and often was stimulated by multiple factors.

Among P2 systems, each reported that its P2 grant was a major driving force behind its improvement efforts. Although most systems had well-defined improvement programs in place by the time that P2 began, the program brought renewed focus. For systems with serious financial challenges, P2 funding contributed importantly to their improvement efforts. For all P2 systems, however, the prestige and visibility engendered by P2 seemed more important than the financial gain. As one senior manager in Site F said,

> Pursuing Perfection gives legitimacy to the [clinical improvement] efforts... by building a coalition of people... and hopefully having a lasting impact. It provides a focus and gives a framework for changing culture in different parts of the organization... P2 challenges us to think about the next level. We are better thinkers than before...

Among the expanded-study systems, the impetus for change varied. For example, in Site I, the impetus was the recognition by system leaders that organizational performance had plateaued and that the Baldrige Award criteria provided a framework for linking clinical improvement efforts with the organization's business strategy. The Baldrige application process, with its deadlines and feedback opportunities, also created a powerful urgency to change. In contrast, in Site J, medical errors created urgency. The institution was stunned when one of its own physicians suffered a medication error while undergoing treatment. This sentinel event spurred the leadership to action.

Regardless of its source or nature, the impetus had to be sustained within the organization to motivate and engage staff in ongoing change efforts. Senior leaders shaped their system's response to the impetus by setting organizational priorities and choosing the best strategy around which to rally the entire staff. They also engaged staff in change efforts by communicating about performance gaps, by holding staff accountable for improvement goals, and by actively participating in change-oriented activities.

Leadership

Leadership commitment to quality and change—beginning at the top of the organization but including all levels—was a critical element for organizational transformation. In Figure 1, leadership is shown in the upper left corner to reflect the importance of senior leadership promoting change down through the organization.

In our study systems, senior leadership drove change in two ways. First, senior leaders steered change through the organization's structures and processes to maintain urgency, set a consistent direction, reinforced expectations, and provided resources and accountability to support change. They set the path for other model elements and for the interactions among those elements in the larger organization. Second, to create the climate and momentum for dramatic improvement in patient care, leaders needed to demonstrate authentic passion for and commitment to quality. Many expended significant personal capital to inspire and motivate staff, often leading by example through personal involvement in QI efforts. At Site D, for instance, the CEO spoke of engendering an "edgy, impatient culture" around patient care quality. Although QI operations were led by a highly effective physician leader, the CEO remained personally involved, both as a champion for a clinical improvement team (despite not being a clinician) and as a member of the quality integrating committee. The CEO also worked actively behind the scenes to clarify expectations and to resolve problems.

Leadership involved more than the CEO. Engagement of the larger senior leadership team provided important linkages and facilitated cultural change throughout the organization. At Site F, the full senior leadership team (including the CEO) began each day with patient rounding in which team members asked patients and frontline staff specific questions about their experiences and then engaged in a debriefing session to resolve identified issues. Senior leaders also were required to serve as champions for improvement projects, with responsibility for linking the team to other senior managers who could help to resolve barriers.

Although leadership strategies began at the top of the organization, improvement was greater when middle and frontline managers were also committed to quality, being actively involved in supporting process redesign, and wholly aligned around the importance of QI. One strategy used in several systems was to include in improvement teams process owners who had operational responsibility for redesigned work processes. Their participation in the change process allowed them to successfully implement new work methods developed by the teams.

Improvement Initiatives

Targeted microsystem improvements were central to IHI's strategy in P2. Expanded-study sites also were committed to a strategy involving improvement initiatives, which are shown in the center of Figure 1 to signal their importance to transformation. Improvement initiatives contributed to transformation in at least three ways.

First, these initiatives, such as clinical redesign, improved operations. Those with sustained impact progressed beyond short-term improvement to build into routine work new practices that were visible, easier to perform, more reliable, and more efficient than old practices. Leaders in Site F, for example, found that improvement changes did not stick once special project resources were removed unless the system itself changed. In a surgical infection project, the site initially improved prophylactic antibiotic use through the use of guideline-based reminders and education but changed its approach after performance plateaued. To reach a zero-defect level, the site reengineered its practices to provide patients with antibiotics at a specific moment in the preoperative process signaled by explicit physical cues. As a result, the site attained consistently high performance without additional resources.

Second, improvement initiatives actively engaged staff across disciplines and hierarchical levels in problem solving around a concrete, meaningful, urgent problem. In the study systems, such engagement resulted in skill development, a newly honed sense of inquiry and problem solving, and more rigorous use of data. Equally important, engagement in problem solving generated a palpable sense of enthusiasm and accomplishment. As on person in Site F said,

> It was very rewarding to see how excited staff and physicians were about making these changes. It became a competition; it was fun and we celebrated successes, in part by posting the successes. . . It is part of the 'pull.' Doctors, respiratory therapists, etc. travel to all units and communicate 'what's doing' to other units. If it is good, people say 'why can't we have that?'

Third, successful initiatives built momentum for further change and improvement. They contributed to culture change when the clinical focus for improvement was aligned with the organizational mission and strategic direction, was an area needing improved performance, and had scientifically valid evidence on which to base redesigned practices. Projects included improving clinical care for patients with acute conditions, such as heart attack or stroke, and with chronic conditions, such as asthma. Such projects engaged clinical staff because of their unmistakable clinical importance and because of the momentum built by incremental, short-term gains.

Alignment

Alignment, as defined in the Baldrige framework (Baldrige National Quality Program, 2005), refers to consistency of plans, processes, information, resource decisions, actions, results, and analysis to support key organization-wide goals. An important factor in successful organizational change, alignment is represented in Figure 1 as a vertical line to signify its role in moving work at all levels of the organization in a consistent direction.

The study systems used different methods to convey their messages to ensure consistent visions and purposes across the organization. The leadership at Site D, for example, identified 18 corporate strategies that defined the organization's direction and priorities. Staff members throughout the organization became familiar with these strategies and their meaning.

Effective alignment required not only shared understanding of purposes and goals but also deployment of resources to reinforce the behaviors, operations, and processes that supported organizational goals Study systems varied in how they accomplished this deployment, with several actively employing the Baldrige framework to create highly aligned priorities. In most systems, though, organizational priorities were translated into department goals for which managers were held accountable. Some systems carried alignment down to the front line of the organization. Site I, for instance, cascaded its organizational objectives to the front line through individual employee goals, with each employee expected to maintain a document containing position-specific goals that were measurable, time-dependent, and aligned with department and organizational goals. To illustrate, a nurse on a patient unit might have an individual goal of responding to patient call requests within *y* minutes to support the unit goal of improving patient satisfaction scores by *x*percent to support the organization's overall patient satisfaction goal.

Aligning goals down to the level of individual employees was challenging for most organizations. As one manager in Site F expressed it,

> We need to do a better job of connecting our front-line supervisors to our plan, connecting the dots. We are creating a web or a map so we can easily update each other on where we are relative to our 30-40 [quality and other strategic] initiatives.

Accountability was a key aspect of alignment, ensuring that behaviors, operations, and processes were, in fact, aligned to support organization-wide goals. All study systems used performance measures in some form to encourage alignment. In some cases, managers' performance evaluations and bonuses were tied to their performance on strategic quality measures and, in a few systems, these measures were a component of physician compensation.

Even so, most systems admitted that effective alignment and accountability were difficult to achieve. Site E managers acknowledged that a high-level goal not met in a fiscal

year was not likely to incur penalty or corrective action; instead, the goal simply was moved to the next year.

Integration

Integration across traditional organizational boundaries occurred at a later stage of transformation in our study systems. Consistent with the Baldrige framework, integration was needed to break down and bridge boundaries between individual components so that a system operated as a fully interconnected unit to support organization-wide goals (Baldrige National Quality Program, 2005). In Figure 1, integration is represented as a horizontal line to signify the importance of working across intra-organizational boundaries. In our model, integration is a multifaceted concept that applies to all organizational levels and is both an end state for a high-performing system and a strategy for transformation. As a strategy, integrating structures and processes can facilitate the spread of improved clinical practices across the organization.

All study systems worked to integrate clinical care to improve coordination and continuity of care. At the front line, extensive work on patient flow, case management, and electronic support systems (e.g., clinical reminders and registries) was aimed toward improving care for individual patients or populations. Several study systems developed comprehensive planned care models to integrate patient care processes across workgroups, microsystems, or the entire organization. Some systems used service lines to integrate providers and support staff to improve coordination of patient care. However, some service line structures also created new silos, integrating care within the lines but impeding integration across them.

Also at the front line, all systems facilitated care integration through multidisciplinary improvement teams that encouraged communication and problem solving across work units. However, by themselves, improvement teams ran up against the limits of traditional intra-organizational boundaries. Often teams could not obtain the commitment of resources or the cooperation from other departments needed to effect change. Without such collaboration, improvement efforts could not fully make the changes necessary to address sources of problems and to build improvement into the organization such that lasting change occurs. For example, some study systems working on medication errors were unable to acquire resources to implement new technologies, such as bar coding, which resulted in less than fully effective workarounds.

To move beyond the limits of a team's or service line's authority and resources, integration also was needed at the systems or organizational level in the form of structures and processes that involved managers with decision-making authority and responsibilities spanning the organization. However, integration at these high levels in our study sites appeared to be more difficult to achieve. As one manager in Site G expressed it,

> Getting people to talk to each other, breaking down silos, and getting people to work across units [is frustrating]. . . .Hospitals really do have silos and they are there for good reasons. What would be ideal is a tunnel that goes all the way across that would allow us to share each other's goals. You need a dynamism that takes people out of the structure and creates a new way of doing things.

A deliberate focus on integration often occurred after an organization had learned to do redesign work and to address alignment. Many study systems used quality management steering committees to address cross-organizational issues in high-priority QI efforts, but only a few moved beyond integration around improvement projects to build integration into the way they worked by using standard or newly invented management structures. Site D, for instance, redesigned its horizontal management structures to create multidisciplinary groups responsible for care processes defined by patients' experiences (e.g., inpatient, outpatient, and emergency care teams). In addition, an integration committee staffed by senior leaders, including the CEO, addressed redundancy, conflicts, and the spread of best practices across groups. Site D saw these structures as transitional, recognizing inconsistencies with other structures in the medical center.

A Dynamic Model: Interaction and Iteration

The five critical elements of the model did not operate in isolation. Rather, they occurred in and through the context of complex and dynamic health care organizations. Substantial systemic change required interaction of the key elements with one another and with the rest of the organization, as illustrated in Figure 1. Our model shows the interconnections among elements that support transformational change, as called for in the *Quality Chasm* (IOM, 2001).

To illustrate the importance of these interactions, we found that improvement initiatives were unlikely to be sustained or spread across the organization if they were not linked to the organization's management structure and work processes. Structures and processes to create alignment and integration were critical to establishing those links. When an improvement initiative was aligned with the organization's priorities and strategic direction, senior managers were more likely to provide the needed infrastructure resources (e.g., staff time, funds, and data systems) and to hold staff accountable for

making necessary changes. Alignment also increased the likelihood that specific redesign would build momentum for further change as staff understood how their roles in achieving project objectives contributed to larger organizational goals. Integration facilitated redesign efforts by ensuring that all parts of the organization affected by redesign engaged in the redesign process, by fostering implementation through shared lines of communication and authority, and by resolving conflicting priorities and needs when multiple improvement projects affected common systems. This fundamentally changed how work was done throughout the organization, an important building block of sustainability.

Alignment and integration also interacted with each other. For example, Site D integrated its horizontal management structures around care processes and defined key priorities that cut across the horizontal management groups. To create alignment, each horizontal group was expected to address for each key priority how the group would contribute to meeting organizational goals and would collaborate with other groups. In our view, study systems that addressed alignment and integration at this level of the organization had a more advanced understanding of the need for consistency and interconnectedness throughout the organization. Even so, these organizations had not perfected an integrative approach. Although Site D had been developing its approach for almost 2 years, it still believed that it was a work in progress. The evolving integration structures sometimes conflicted or were redundant with traditional structures that remained in place. Patient safety, for instance, was a priority addressed by the horizontal integrating groups, but there was tension with the Patient Safety Committee's plans.

To achieve transformation, the five elements not only interacted with each other but also drove change through the organization's mission, culture, infrastructure, and operations. For example, some improvement initiatives interacted with the organizational infrastructure, such as information technology. Thus, infrastructure development ensured that organizational resources were in place to support improvement initiatives, but improvement projects also led to infrastructure enhancements. For example, in Site B, the medication reconciliation project stimulated the development of an online, interactive tool for patient use, and in Site G, work on patient flow triggered the design of an automated bed availability board to facilitate patient movement from the emergency department (ED) to the floor.

Improvement initiatives also interacted with other care processes, stimulating the spread of change across the organization and its incorporation into regular practices. Site F's first project involved work with county ambulance staff to improve triage of acute myocardial infarction (AMI) patients entering the hospital ED. These changes stimulated the broader redesign of ED processes for acute myocardial infarction patients, which led, in turn, to redesigned processes for patients coming to the ED with other conditions.

In addition to being interactive, organizational transformation was iterative. Individual improvements fed into one another and occurred over time. Making one system improvement often set the stage for others or uncovered new problems or opportunities requiring attention.

Conclusions

Based on interviews and discussions with 12 health care systems actively working to transform their organizations, we identified five elements that appear to be critical to successful organizational change to improve patient care. Other factors, such as effective communication, contribute to and are necessary for successful change, but the five identified elements were most prominent in driving the study systems toward transformation.

Progress toward transformation was consistent with the model in all study systems, although the model was more evident in some systems than in others and no system had fully implemented all elements. The model fits across different types of health care organizations. Although the P2 initiative accelerated transformation efforts, the factors affecting the transformation in P2 systems were not systematically different from those in the expanded-study systems.

Our conclusion that the model reflects key factors associated with successful transformation is supported by preliminary findings from a survey of staff in eight study systems (seven P2 systems and one expanded-study system), to be reported in a separate article. The analyses show that systems with stronger presence of model elements also scored higher on survey items reflecting progress to transformation, including ratings of patient care quality in the organization and judgments regarding the impact of the organization's QI efforts on productivity/efficiency, patient outcomes, medical errors, and staff involvement in QI efforts.

Each of the five model elements is supported by a substantial literature. The principal contribution of this article is the finding that *all* five elements are needed for organizational transformation that substantially improves patient care. Transformation occurs when the five factors interact with each other over time and drive change through the larger organization. The article adds to the growing literature on multilevel theories of change and innovation (e.g., Poole & Van de Ven, 2004). For example, it extends the multilevel framework of Nelson et al. (2002), which focuses on clinical

microsystems as an essential building block of system transformation, by elaborating on the nature of the links between the microsystem and the larger organization. As another example, it extends the multilevel system redesign framework of Wang, Hyun, Harrison, Shortell, and Fraser (2006) by adding integration and alignment as important elements to direct and coordinate work across the multiple levels of the system.

One limitation of the study is the lack of a common set of clinical performance measures across systems that might serve as indicators of success in improving patient care. All P2 systems began with specific objectives, but the project content, goals, and metrics were site-specific and often changed over the life of P2. The evaluation would have benefited from shared clinical measures, but any such measures would not have equally reflected the priorities of participating systems and thus would not have evaluated them on a level playing field.

Another study limitation from some perspectives is that it focused on 12 leading systems that were committed to making major changes to improve patient care. By design, our evaluation tracked attempts at transformation under the most favorable conditions. However, we recognize that many health care systems are not at the same stage of organizational readiness for change. We did not study the processes by which an organization and its leadership decide to engage in transformation. Further research is needed in this regard to understand the motivation behind major system redesign and the capabilities necessary for the transformation journey.

Practice Implications

Transformation of health care systems is a complex and difficult undertaking. The P2 systems had the advantage of sharing ideas and working with IHI, but no system had a roadmap for achieving perfect care, and each learned as it went along. Their experiences, however, provide important lessons that can facilitate the process in other systems.

First, each model element as described earlier in the article offers direct practice implications for system managers seeking to change their systems to improve patient care.

Second, however, no single element is sufficient to achieve organizational transformation. For example, successful improvement projects can contribute importantly to improved quality, but improvement projects alone do not ensure sustainability of the improvements, including the spread of core values and expectations, the engagement of staff in delivering near-perfect care, and the skills and methods for achieving it. Managers should recognize that all model elements need to be part of organizational transformation and that the challenge is to maximize the likelihood that the elements and the organization will interact in complementary ways to maintain urgency to change and to move the organization forward. Full transformation may be attained only when multiple improvements are *spread* across the system and *sustained* over time.

Third, successful transformation takes time. All study systems acknowledged that transformation (and the attainment of near-perfect care) most likely unfolds over a decade or more. No study system became fully transformed in the sense that values and expectations for near-perfect care were completely shared or that organizational functions operated to achieve near-perfect care in all major care processes. Although many systems demonstrated considerable progress, they described transformation as a continuing journey with no fixed end point. They argued that changes and adaptations always are needed to stay abreast of the volatile health care environment and the discovery of new areas for improvement. Clearly, organizations embarking on this journey require persistence and constancy of purpose.

Although based on 4 years' experience in only 12 health care systems, the conceptual model nonetheless holds promise for guiding other organizations in their efforts to pursue fundamental system redesign for dramatically improving patient care. In the meantime, we continue to test and refine the model through further research, including a Veterans Affairs-funded project that assesses the implementation of model elements to support the use of evidence-based practices and a second RWJF-funded project to validate the model in other health care systems.

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