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An intraorganizational model for developing and spreading quality improvement innovations

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Background: Recent policy reforms encourage quality improvement (QI) innovations in primary care, but practitioners lack clear guidance regarding spread inside organizations.

Purpose: We designed this study to identify how large organizations can facilitate intraorganizational spread of QI innovations.

Methodology/Approach: We conducted ethnographic observation and interviews in a large, multispecialty, community-based medical group that implemented three QI innovations across 10 primary care sites using a new method for intraorganizational process development and spread. We compared quantitative outcomes achieved through the group's traditional versus new method, created a process model describing the steps in the new method, and identified barriers and facilitators at each step.

Findings: The medical group achieved substantial improvement using its new method of intraorganizational process development and spread of QI innovations: standard work for rooming and depression screening, vaccine error rates and order compliance, and Pap smear error rates. Our model details nine critical steps for successful intraorganizational process development (set priorities, assess the current state, develop the new process, and measure and refine) and spread (develop support, disseminate information, facilitate peer-to-peer training, reinforce, and learn and adapt). Our results highlight the importance of utilizing preexisting organizational structures such as

Key words: implementation, patient-centered medical home (PCMH), primary care, quality improvement, spread

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The authors have disclosed that they have no significant relationship with, or financial interest in, any commercial companies pertaining to this article.

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DOI: 10.1097/HMR.000000000000122

Health Care Manage Rev, 2016, 00(0), 00–00

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established communication channels, standardized roles, common workflows, formal authority, and performance measurement and feedback systems when developing and spreading QI processes inside an organization. In particular, we detail how formal process advocate positions in each site for each role can facilitate the spread of new processes.

Practice Implications: Successful intraorganizational spread is possible and sustainable. Developing and spreading new QI processes across sites inside an organization requires creating a shared understanding of the necessary process steps, considering the barriers that may arise at each step, and leveraging preexisting organizational structures to facilitate intraorganizational process development and spread.

After extensive focus on patient safety in hospitals, safety in ambulatory settings is now a chief concern (Gandhi & Lee, 2010; Singh & Graber, 2015; Wynia & Classen, 2011; Zuccotti & Sato, 2011). Growing interest stems from recognition of widespread error-prone processes (Bishop, Ryan, & Casalino, 2011; Schiff et al., 2013) and underdevelopment of safeguards, risk management support, and regulatory oversight in primary care (Phillips et al., 2004; Zuccotti & Sato, 2011). Policy reforms instituted to promulgate incentives for quality and safety improvement in primary care and at the intersection of ambulatory and inpatient care include most notably patient-centered medical homes (PCMHs; Rosenthal, 2008).

To achieve the promise of PCMHs to provide better coordinated, safer, more timely, and appropriate care for patients, ambulatory settings must redesign and improve care processes. As in complex health systems more generally, ambulatory safety has been stymied by the inability of health care organizations to spread promising innovations (Gandhi & Lee, 2010; Wynia & Classen, 2011).

This study aimed to contribute to knowledge about developing and spreading quality improvement (QI) innovations across sites inside large health care organizations. To do so, we compared one organization's traditional method of intraorganizational process development and spread—in which QI staff solicited improvement ideas from staff members from multiple disciplines, developed new processes based on them, and spread these processes through site level presentations and emails—to its new method—in which QI staff took staff, providers, and patients representing all disciplines from one practice site offline for 1–5 days to generate and refine improvement ideas and then spread the new processes using formal “process advocate” positions in each site for each role. We use comparative data on the traditional method (less successful) versus new method (more successful) to develop a conceptual model for intraorganizational process development and spread of QI innovations and to describe barriers and facilitators that influence each step.

Conceptual Framework

As in prior research, we define innovation as “novel behaviors, routines, and ways of working geared toward improving health outcomes, administrative efficiency, cost

effectiveness, or users' experience and that are implemented by planned and coordinated actions” (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004). To have significant impact on an organization, new processes must be developed and implemented locally and then spread more broadly. New process development refers to the method by which improvement teams carry out projects to analyze suboptimal processes and propose their redesign (Harrison et al., 2016). Spread is the process of facilitating the adoption of an innovation across multiple units, conditions, or types of patients (Parry, Carson-Stevens, Luff, McPherson, & Goldmann, 2013).

Considerable research consolidates lessons about innovation development, implementation, and spread. This research includes process models that specify the steps through which innovations are developed, implemented locally, and spread broadly; determinant frameworks that explain the factors that influence these processes; and evaluation frameworks for measuring new process development and spread efforts (Nilsen, 2015).

Plan-Do-Study-Act (PDSA, popularized by Edward Deming as Plan-Do-Check-Act) is perhaps the iconic model for new process development and local implementation, providing a structure for the iterative application of scientific methods for testing small changes to improve quality in systems (Taylor et al., 2014). In simple terms, enacting a PDSA cycle requires planning a process including establishing criteria upon which to measure its achievement, doing or executing the plan, studying actual compared to expected result, and acting on the findings by adopting successful changes and repeating the process with iterative cycles. LEAN is another model for new process development and local implementation in which LEAN experts coach teams composed of frontline staff to use LEAN concepts and tools such as value stream mapping to analyze and redesign workflows to reduce waste (Harrison et al., 2016).

The Institute for Healthcare Improvement's “Framework for Spread” provides one example of a process model for spread across multiple units, conditions, or types of patients (Nolan, Schalll, & Kaluzny, 2007). It is organized around three phases: determining organizational readiness, developing an initial plan, and executing and refining it. The AIDED model is another process model addressing elements of both development and spread (Bradley et al.,

2012; Curry et al., 2013; Pérez-Escamilla, Curry, Minhas, Taylor, & Bradley, 2012). It draws on successful examples, the extant literature, and biological sciences to suggest that spreading health innovations requires being “AIDED” through five fundamental steps: assess the landscape, innovate to fit user receptivity, develop support, engage user groups, and devolve efforts for spreading innovation.

While these models elaborate approaches for new process development and spread, other models provide determinant frameworks that identify a variety of factors that may influence the diffusion and spread of innovations (Greenhalgh et al., 2004; Rogers, 1962; Simmons, Fajans, & Ghiron, 2007; Yamey, 2011), including features of the innovation, implementation leaders and process, potential adopters, and environment in which spread occurs (Bradley et al., 2012; Damschroder et al., 2009; Kaplan, Provost, Froehle, & Margolis, 2012; Kitson et al., 2008; Milat, Bauman, & Redman, 2015; Nolan et al., 2007; Parker, Wubbenhorst, Young, Desai, & Charns, 1999; Pronovost, Berenholtz, & Needham, 2008). In their book on spread, Sutton and Rao (2014) distill numerous lessons derived from multiple industries: Spread requires trade-offs between cloning an original model and encouraging local variation, stoking emotions as well as providing a rational argument to provoke action, “relentless restlessness” in pursuit of constant innovation, muddling through inevitable messiness that comes with spread, and cascading new practices through individuals and their social networks.

Research suggests that rigorous evaluation and monitoring of defined goals and milestones promote spread effectiveness. One example of an evaluation framework for implementation is PARIHS (Promoting Action on Research Implementation in Health Services; Kitson et al., 2008), which was designed as a practical and conceptual heuristic for researchers and practitioners to measure elements of evidence and context and then determine approaches to facilitation.

Although plentiful, most prior research addresses spread of evidence-based practices across organizations, rather than the development and spread of QI innovations inside an organization with multiple sites. Prior frameworks have also been criticized for providing only “limited ‘how-to’ support,” for being “too generic to provide sufficient detail for guiding an implementation process,” and for not identifying or systematically structuring information about barriers and facilitators (Nilsen, 2015). Indeed, in their comprehensive review of innovation spread in service organizations, Greenhalgh and colleagues (2004) call for multimethod, detailed, process-oriented research that illuminates the features that account for program success in a specific context. This article addresses these gaps by codifying one organization’s improvement journey based on ethnographic, interview, and clinical evaluation data. The result is the intraorganizational process development and spread of QI innovations model. Like the PDSA, Framework for Spread, and AIDED models, it is a process

model—one that is designed to guide both development and spread of new practices (PDSA and Framework for Spread address one but not the other) inside an organization rather than to scale up innovations across countries (as in AIDED). The distinguishing characteristic of our model is that it provides a detailed guide for facilitating new process development and spread across sites within an organization.

Methods

We used multiple methods to understand how a large, multispecialty, community-based medical group, the North Shore Physicians Group (NSPG), implemented a new method for process development and spread across 10 primary care practice sites. Specifically, we combined an ethnographic approach and interviews with key informants with quantitative outcomes comparing the organization’s use of their new method of process development and spread, which was informed by Virginia Mason and Hartford Medical Group approaches, versus their traditional method for two QI innovations related to standard work for rooming and depression screening, and vaccine error rates and order compliance. We also compared the organization’s use of no method versus their new method of new process development and spread for a third QI innovation related to Pap smear error rates. Since September 2013, NSPG has used this new method of development and spread to implement 15 workflow process innovations. We chose to focus on these three processes because they each have the potential to eliminate errors and patient harm because of missed diagnosis, vaccine errors, and mislabeled or unlabeled specimens.

Ethnographic Observation and Interviews

Our approach combined ethnographic observation and interviews. One author (K.C.K.), a sociologist and trained ethnographer with extensive experience observing medical staff interactions, conducted a 20-month ethnographic field study. She observed headquarters staff, site managers, clinical staff, and patient service representatives at NSPG’s 10 primary care practice sites from 5 months before the first of these three processes was implemented using the new method to 15 months afterwards. These data are part of a larger research project on the implementation of innovations in primary care.

The ethnographer spent 70 days (1–3 hours per day) shadowing NSPG staff in their daily work and in meetings and events related to the development and spread of new processes. The occurrence and timing of events were recorded chronologically during the course of each day in the form of field notes. To complement observational data, the ethnographer conducted fifty-six 20- to 30-minute semistructured interviews with Site Medical Directors, Site Managers, providers, medical assistants (MAs) and patient

service coordinators (PSRs) (at least four at each of the 10 practice sites), and central administrators. Interview responses were typed in real time.

The ethnographer asked questions to understand how respondents experienced the implementation of the traditional versus new method of process development and spread and what they saw as barriers to and facilitators of the new method. The ethnographer analyzed the data by engaging in multiple readings of the field and interview notes and coding based on themes emerging from the data (performed in ATLAS.ti qualitative software) regarding work activities and regarding facilitators and barriers to developing and spreading processes using the new method. When formal data collection had finished, she presented her analysis for review by NSPG staff members to ensure that these interpretations represented their experiences.

Quantitative Process Outcomes

For each of the three new processes, we identified and monitored quantitative process outcomes over time. We evaluated the significance of an improvement in outcomes using the new method versus traditional method of spread with a standard one-tailed z test.

We evaluated spread of the standard rooming process in 2013 and 2014 by conducting two types of review: process audits and retrospective chart review. First, we audited adherence to standard work, including depression screening, in the summer of 2013, after the use of the traditional method of spread, and in 2014, after the use of the new method of spread. An auditor posed as a patient and tracked each completed step of the rooming process. Retrospective chart reviews of depression screening documentation involved two reviewers who examined the patient flow sheet for evidence of the Patient Health Questionnaire two-question screen (PHQ-2). For each primary care physician and nurse practitioner, we randomly selected one full day in June 2013 and June 2014 and calculated the percentage of patients seen that day who had been screened for depression, excluding patients under 18 and no-shows from the denominator.

We used two measures to assess the spread of a new vaccine administration process: self-reported immunization errors and retrospective chart review. NSPG tracks immunization errors if a patient receives an incorrect vaccine, additional doses, incorrect dosage, expired vaccine, or incorrect vaccine administration. We measured vaccine error rates by comparing error rates during the use of the traditional method (October 2012 to June 2014, 21 months) to error rates during the use of the new method (July 2014 to August 2015, 14 months). To measure vaccine order compliance, we performed a retrospective chart review for vaccine order compliance in November 2013, after the use of the traditional method of spread, and in December 2014,

after the use of the new method of spread. We reviewed charts for a signed provider order for the vaccine for up to 3 patients per provider, 9–23 patients per practice in November 2013, and 15–35 patients per practice in December 2014, which estimates suggested would suffice for revealing significant differences.

In contrast to the two previous examples where NSPG spread a new process using the traditional method and then the new method, there was no standardized process for Pap smear labeling a priori. We measured labeling error rates by comparing error rates reported by the laboratory completing the test during the use of no method (October 2012 to April 2014, 18 months) to error rates during the use of the new method (May 2014 to August 2015, 16 months). Examples of Pap smear labeling errors include unlabeled specimen sent to the lab, label on the specimen did not match the patient information on the accompanying requisition, label on the specimen was for the incorrect patient, and transcription errors on the label including incorrect date of birth.

Findings

Results From Quantitative Analysis of Process Changes

Table 1 details that, regarding standard rooming, 64% of rooming steps were completed in 2013 with the traditional method compared to 80% of rooming steps completed in 2014 with the new method, a 16 percentage point increase (z score = 7.42, $p < .01$). There was also an increase in depression screening with the use of the new method, with a mean improvement of 20 percentage points from 2013 to 2014 (z score = 9.2, $p < .01$). Regarding vaccine administration, 60% of the charts included physician orders for vaccines in 2013 with the traditional method compared to 96% in 2014 with the new method, a 36 percentage point increase (z score = 8.81, $p < .01$). There was also a decrease of vaccine error rate with the use of the new method, with a mean decrease of 0.03 percentage points (z score = -1.65 , $p < .05$). Regarding Pap smear labeling, there was a decrease in Pap smear labeling errors with the use of the new method versus no method of intraorganizational process development and spread. There was a Pap smear labeling error rate of 0.83% before implementing the new process compared to a 0.18% error rate after implementing the process using the new method, a decrease in 0.65 percentage points (z score = -3.81 , $p < .01$).

Results From Qualitative Analysis of Process Changes

The model for process improvement that we detail here includes two sequential stages: (a) intraorganizational

Table 1

Outcomes for traditional versus new method of intraorganizational process development and spread

	Traditional method	New method	Difference in percentage points ^a
Adherence to standard work for rooming ^b	64% (n = 630)	80% (n = 1,029)	16%***
Depression screening rates	15% (n = 806)	35% (n = 744)	20%***
Vaccine order compliance	60% (n = 169)	96% (n = 222)	36%***
Vaccine error rates	0.06% (n = 27,125)	0.03% (n = 24,611)	-0.03%**
Pap smear error rates	0.83% (n = 4,554)	0.18% (n = 3,288)	-0.65%***

p < .05. *p < .01.

^aAll outcomes compare performance achieved with traditional versus new method of intraorganizational process development and spread except Pap smear error rates, which compare performance achieved with no method versus the new method of process development and spread.

^bEstimations for both the traditional and new method are made based on data for 7 of 10 sites, because three sites were not measured in 2013 under the traditional method. If we include these three sites in the new method calculation, adherence to standard work under the new method is 80%, n = 1,470, p < .01. Difference in sample size for traditional and new method is due to difference in number of people audited per site. Fewer people per site were audited in 2013 to assess the traditional method than in 2014 to assess the new method.

process development and (b) intraorganizational spread (Figure 1). Table 2 details the steps of the model of intraorganizational development and spread and the key barriers and facilitators associated with each step.

Intraorganizational new process development. The steps in intraorganizational new process development include setting priorities, assessing the current state and identifying opportunities for improvement, developing the new process, and measuring and refining the new process. In some ways, the new process development stage of our model is similar to other process models of development such as the PDSA model. However, our model for new process development takes into account the needs and expertise of the entire organization rather than that of a local team. In addition, we identify the facilitators and barriers associated with doing this at each step.

In “Setting Priorities,” executive leaders assess not only local objectives but also the broader environmental context including factors such as external pressures on the organization from payors, new clinical evidence, and PCMH/accountable care organization (ACO) requirements as well as organizational priorities beyond QI. By including an assessment of the environmental context, our model ensures that new workflows will meet not only the needs of local teams but also the needs of the broader organization. Perhaps because setting priorities takes into account the needs of the broader organization, one barrier to this step is that prioritized new processes do not always match the top priorities for providers and staff at local sites. They reported feeling overloaded and wanted more input into the setting of priorities. We found that a key facilitator of setting priorities was joint prioritization of improvement work with other organizational initiatives in which providers and staff members at the local sites were being asked to participate.

In “Assess Current State,” Improvement Specialists not only perform sophisticated analyses with LEAN tools such

as value stream mapping and takt time but also take into account the voice of the customer. By including an assessment of the voice of the customer, our model ensures that new workflows will meet the needs of local teams and the broader organization. The sophisticated analyses used in assessing the current state require gathering data about waste and defects through direct observation of staff doing their day-to-day work. One barrier to this step is that, even if the organization has a culture of improvement, there is still a hierarchy in primary care. Lower-level staff expressed concern about being observed. Having someone do this observation

Figure 1

Intraorganizational model of process development and spread

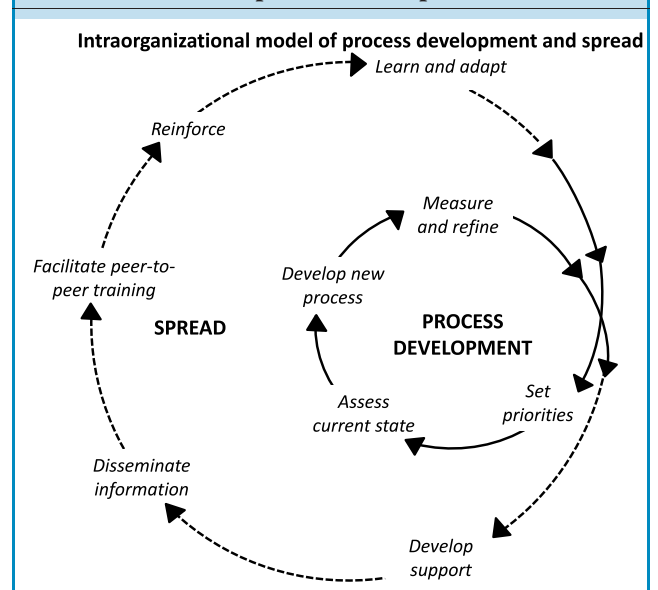


Table 2

Intraorganizational model of process development and spread: Steps, barriers, and facilitators

Process step	Activities	Key barrier	Key facilitator
Development			
Set priorities	<p>Understand environmental context</p> <ul style="list-style-type: none"> – External pressures (payors, new evidence, PCMH/ACO) – Organizational priorities <p>Gather needs of users in each role</p> <ul style="list-style-type: none"> – Provider needs – Staff needs (“rock in the shoe”) – Patient needs (access, quality, safety) 	<p>Site leadership wants more input into priorities</p> <p>Site Medical Director: “It ends up feeling like the decision has been made, and here is how it’s going to be, and now go and do this. We are being told to take time out of time to see patients...we want more input into the priorities.”</p>	<p>Joint prioritization of quality initiatives and other organizational initiatives</p> <p>Site Manager: “We’ve got the process improvement people telling us things and the operations people telling us things...It’s helpful to have a calendar that puts everything together in one place so there aren’t too many requests at once.”</p>
Assess current state	<p>Assess existing workflow</p> <ul style="list-style-type: none"> – Direct observation – Use of LEAN tools (e.g., value stream map) – Analysis of defect rates – Analysis of the voice of the customer <p>Set targets for workflow improvement</p>	<p>Staff fear of evaluation</p> <p>Medical Assistant: “When they did the new process for standard rooming, they timed us and followed us so they could do things like spaghetti maps. It’s uncomfortable and tough to have someone following you around when you are trying to work... You have people watching every move you make, and you worry, ‘Am I doing something wrong?’”</p>	<p>Observations done by a trusted staff member</p> <p>Improvement Specialist: “[Improvement Specialist] started out working as a float [PSR] in many of the sites before he moved to our office. Because many of the staff know him personally, they trust him, and feel comfortable when he is the one following them around with a stopwatch.”</p>
Develop new process	<p>Gather new workflow ideas</p> <ul style="list-style-type: none"> – Gather ideas from the people who do the work – Solicit information from the field on current standard workflows in other organizations <p>Engage in offline workflow process improvement</p> <ul style="list-style-type: none"> – Pull staff from each role involved in the workflow offline for an RPIW or Kaizen event <p>Carry out workflow change on a small scale</p> <ul style="list-style-type: none"> – Execute the planned change on a small scale – Document problems and unexpected observations 	<p>Local site staffing shortfall during event</p> <p>Site Manager: “It’s a lot of pressure on the other staff when you do a RPIW. In our last RPIW, providers, PSRs, MAs, and I were pulled offline for an entire week.”</p>	<p>Participation by outside expert</p> <p>Improvement Specialist: “It’s helpful to have an outsider participate in the event who has some relevant experience from elsewhere. For our Pap smear labeling Kaizen event, we invited an MA from one of women’s health practices because that practice does a lot of Paps and has already done a lot of thinking about their process...That was also one less person we needed to pull offline from the practice.”</p>
Measure and refine	<p>Study</p> <ul style="list-style-type: none"> – Analyze data and compare data to targets at 30, 60, 90 days <p>Act</p> <ul style="list-style-type: none"> – Continue PDSAs to refine process over 30 days in one practice <p>Document</p> <ul style="list-style-type: none"> – Create materials to document new standard workflow. At 90 days, if process is stable, it is ready to spread 	<p>Difficult to cut off failed ideas immediately</p> <p>Site Medical Director: “For the new patient intake RPIW, we figured out relatively soon that the medical records weren’t very useful but we felt like we had to keep tracking them down because we were trying to hit that measure. So that felt a little too formal.”</p>	<p>Close communication between improvement specialists and site level process owners</p> <p>Site Manager: “We were meeting on a regular basis with [Improvement Specialist], and she helped us decide when we could cut parts of the process that weren’t working.”</p>

(continues)

Table 2**Intraorganizational model of process development and spread: Steps, barriers, and facilitators, Continued**

Process step	Activities	Key barrier	Key facilitator
Spread Develop support	<p>Build support and address resistance inside the organization using formal positions and communication channels</p> <ul style="list-style-type: none"> – Cultivate support among staff members holding formal leadership positions by presenting at the monthly meeting of Site Medical Directors – Facilitate knowledge sharing and technology transfer by presenting at the monthly meeting of Site Managers – Provide organization-wide training to continue to build culture of change 	<p>Lack of direct communication to providers</p> <p>Doctor: “I learn about new standard work within day to day work. So, the other day, a patient needed a vaccine, and the MA said, ‘There is a new process that I learned about.’ It would be helpful if, when something new was rolled out, I was alerted a little more directly about it...It would be good to get an FYI: why we are doing it and here is what all of the MAs will be doing.”</p>	<p>Well-attended site level provider meetings</p> <p>Doctor: “Buy-in at the beginning is very strong point for us. We’ve got a monthly meeting, and it’s well attended...They take us through the presentation (explaining how the new process has been developed and tested). When it’s presented that way, we know that we’ve had an intact team try it ahead of time. When I worked at a different site, if something was thrown at me, I had no idea if it had already been tried.”</p>
Disseminate information	<p>Introduce the new process to lead users using formal process advocate positions and formal communication channels</p> <ul style="list-style-type: none"> – Appoint an MA and a PSR process advocate for each site – “Train the trainers” by presenting to process advocates at the monthly MA/PSR Council Meeting – Translate the new standard work for the process advocates by developing a computer-based learning module 	<p>Confusing standard work documents</p> <p>Site Manager: “The standard work they write out—I know it’s a simplified tool and is supposed to be straightforward—but a lot of staff will read through it, will go back and question it multiple times, and still won’t understand it...For standard rooming, there are 32 steps and it is kind of all over the place compared to how you will really room somebody. It’s not laid out in the best way.”</p>	<p>Simplification of standard work training materials</p> <p>Improvement Specialist: “We simplified the training documents and standardized the Healthstream module to include the “why,” the opportunities for improvement, the process flow, the key improvements, results, and lessons learned.</p>
Facilitate peer-to-peer training	<p>Appoint process advocates from each site to spread the innovation to their peers in the same formal position at their site</p> <ul style="list-style-type: none"> – Site Manager meets with site process advocates to discuss new standard work – Process advocates train peers in the same position at their site – Improvement Specialists distribute computer-based learning module to all employees via Healthstream to translate the new standard work – Improvement Specialists round out to any sites that are having difficulty to provide troubleshooting help 	<p>No protected time to train</p> <p>PSR Process Advocate: “The problem I have is finding the time to sit with each person. I am supposed to sit with them, give them a little lesson. Even if everyone has watched the Healthstream, I can’t be taking phone calls and also going around to check in with people. When I leave my desk, someone has to cover.”</p>	<p>Site manager support for training</p> <p>PSR Process Advocate: “[Site Manager] has been very supportive of it and helping me find the time. After the last PSR Council meeting, I spoke to [Site Manager] and she carved out an hour Tuesday–Friday from 2–3 pm. She put that aside for me to be off of the phone to train [the other PSRs at my practice site].”</p>

(continues)

Table 2

Intraorganizational model of process development and spread: Steps, barriers, and facilitators, Continued

Process step	Activities	Key barrier	Key facilitator
Reinforce	Reinforce use of new workflows <ul style="list-style-type: none"> – Process advocates perform competency checks of peers at their sites at 30–60–90 days – Improvement Specialists round out to all sites to audit adherence to new standard workflow 	Overload Site Manager: “[The MAs and PSRs] are under pressure to get a lot done, and it’s coming fast and furious. It’s really hard to find the time to understand and do all of the new standard work.”	Site manager redistribution of existing work Site Medical Director: “MAs and PSRs take the brunt of the changes. They need to know that some of their work will be redistributed, if necessary. The Site Manager does continuous ongoing work redistribution as we introduce new standard work. We do our best to level load.”
Learn and adapt	Solicit feedback and adapt new processes <ul style="list-style-type: none"> – Improvement Specialists discuss spread of new standard workflows and solicit feedback at monthly meetings of the MA/PSR Council, the Site Medical Directors, the Site Managers, the Headquarters Staff Members, and the Quality Council – Top managers solicit feedback during Senior Rounding to the sites 	Perceived rigidity of standard work Doctor: “The sense is that it’s done. We can’t say, ‘Can we change it?’ No. It is coming down from above as opposed to a collaborative approach. We get our orders and are under pressure to make sure certain things are rolled out in a certain way.”	Strong relationship between site managers and improvement specialists Site Manager: “Because I’m involved with Quality Council, most of the time, I can answer whatever questions [the providers or staff] have. And if I have a question I can always email [Head of QI]...In terms of the details of the process, you can say to whoever developed it, ‘We’re only doing 80% of it because of this reason.’ And that’s fine. Or, I’ll say, ‘I’m running into this and I think we can handle it this way.’”

Note. PCMH = patient-centered medical home; RPIW = Rapid Process Improvement Workshop; MA = medical assistant; PSR = patient service coordinator.

who was known to and trusted by staff at the practice site helped Improvement Specialists to assess the current state.

In “Develop New Process,” the Rapid Process Improvement Workshop or Kaizen Event team not only carries out workflow change on a small scale and engages in offline workflow process improvement but also solicits new ideas from people throughout the organization and from outside organizations. By including this broader gathering of new workflow ideas, our model ensures that those developing new workflows will use the existing expertise within the broader organization and within the industry. One of the key barriers to offline process improvement is that it creates a shortfall of staff during offline process improvement events. A key facilitator for this step was developing an annual calendar for process improvement events and utilizing NSPG

float staff for the sites during the process improvement events. A second facilitator was including outside experts or staff representatives from other sites at the events. This both ameliorated the staffing shortfall at the focal site and allowed for participation by a staff member who had specific expertise in the process being improved.

Finally, in “Measure and Refine,” Improvement Specialists and site level process owners use not only rapid cycle improvement but also data analysis in a structured way at 30, 60, and 90 days. A key barrier in this step is the formality of the 30-, 60-, 90-day remeasurement requirement. Time and energy were sometimes wasted because the formal requirement made it difficult to change parts of the new process that were immediately seen to be ineffective. A facilitator for this step was for Improvement Specialists and

site level process owners to be in close communication so that they could flexibly adapt the parts of the process that were clearly ineffective when brought into the real world setting of the clinic.

Intraorganizational spread. The steps in intraorganizational spread include developing support, disseminating information, facilitating peer-to-peer training of staff, reinforcing, and learning and adapting. In some ways, the spread stage of our model is similar to other process models of spread such as the AIDED model. However, because our model is designed to be used for spreading new processes across sites inside an organization, it uses preexisting organizational structures such as established communication channels, standardized roles, common workflows, formal authority, and performance measurement and feedback systems.

In “Develop Support,” Improvement Specialists and site level process owners build support and address resistance using preexisting, formal positions and communication channels. The key activities associated with developing support include cultivating support of Site Medical Directors and Site Managers at their scheduled monthly meetings. One barrier to developing support is that the timeline for introducing new processes does not always map onto the preexisting structure of scheduled meetings for organizational leaders. This sometimes resulted in Site Medical Directors and Site Managers feeling that they did not have enough time between learning about a new process at a monthly meeting and rolling out that process at their sites. In addition, the use of MA and PSR process advocates as a key means of spread sometimes resulted in providers at the sites not hearing about a new process until they were midsession and their MA or PSR informed them of it. Key facilitators for this step were creating timelines for rollout that took into account the preexisting meeting schedule for organizational leaders and introducing new processes at well-attended site level provider meetings.

In “Disseminate Information,” process owners introduce the new process into lead users’ daily routines by appointing lead users to formal positions with responsibility for spread (who we call “process advocates”). Within an organization, there are already shared norms and common daily workflows for organization members in particular roles, so there is less of a need for translation and integration activities directed at lead users than has been shown in other models of spread such as the AIDED model. Instead, the key activities associated with this step are to formally appoint process advocates for each site, train them at a monthly process advocate meeting, and develop a computer-based learning module to help process advocates incorporate the new process into their existing workflows. One barrier to disseminating information is that MA and PSR process advocates may not fully understand the new process after it is introduced to them. Process advocates sometimes found the new standard work documents to be confusing. Dissem-

inating information was facilitated by simplifying the training materials to highlight each step by role and by incorporating lessons learned into computer-based learning modules.

In “Facilitate Peer-to-Peer Training,” process managers spread the new process using a peer network composed of organization members who share their same organizational role and using the authority of Site Managers who manage the day-to-day work of the process advocates and the target users. The key activities in this step involve ensuring that the Site Managers give the process advocates protected time to train their peers and give the target users protected time to complete the computer-based learning module. It is also key that the Improvement Specialists provide troubleshooting help to Site Managers and users who need it. A key barrier to facilitating peer-to-peer training is overloaded process advocates; process advocates need to have time to help staff struggling with particular aspects of a new process. A key facilitator of peer-to-peer training was gaining the buy-in of the Site Manager so that he or she took the time upfront to talk to the process advocates and understand the process in-depth in order to help make any necessary modifications before the process advocates started their training.

Our model includes two final steps—“Reinforce” and “Learn and Adapt” across the organization. Because, within an organization, there are structures such as formal performance management processes and formal communication structures, our model uses these to reinforce the new process in an ongoing way, to solicit feedback to continue to adapt the new process to user needs across the organization, and to drive further improvement. The key activities in this step include process advocates performing competency checks of their peers, and Improvement Specialists auditing adherence to new processes and soliciting feedback within the preexisting communication structures of monthly staff meetings. One of the barriers to learning and adapting new processes is that some staff may perceive that the new processes are set in stone and that Improvement Specialists are not amenable to feedback. A key facilitator was a strong relationship between the Site Manager and the Improvement Specialists; this empowered the Site Manager to make changes to standard work and to explain to the Improvement Specialists why they were doing so. In turn, this gave staff confidence that they could suggest modifications to their Site Manager.

Discussion

Developing and spreading QI innovations inside organizations is critical to accomplishing better coordinated, safer, more timely, and appropriate care for patients. Innovation implementation and spread in ambulatory settings is particularly important in accomplishing the goals of reforms such as PCMHs in primary care and in addressing patient safety concerns in this relatively neglected setting. Although PCMHs have received considerable attention in the

literature (e.g., Jackson et al., 2013), approaches for developing and spreading innovations to improve them have not. Improving and spreading care processes inside ambulatory care organizations with multiple sites will not be easy. Our observations and interviews revealed that even ambulatory care practice sites that had engaged in LEAN transformation for many years encountered major challenges to new process development and spread.

Some of our findings are consistent with the results of earlier studies. For example, other process models of innovation implementation include steps related to both the development and spread. The PDSA model addresses process development and local implementation, and the AIDED model addresses development, local implementation, and spread (Bradley et al., 2012; Curry et al., 2013; Pérez-Escamilla et al., 2012). AIDED's first two steps—assess the landscape and innovate to fit user receptivity—are new process development steps. Their second three steps—develop support, engage user groups, and devolve efforts for spreading innovation—are spread steps. Also, like in other models of process development and spread, we found that the adoption of an innovation by individuals in an organization is more likely if key individuals in their social networks act as champions for the innovation (e.g., Markham, 1998; Meyer & Goes, 1988).

However, our model is unique in that it addresses process development and spread across sites within an organization. It also extends existing process models. Specifically, our model extends PDSA's process development model by encouraging broad environmental assessment to ensure that the new process meets the needs of the broader organization, sophisticated analysis, and systematic long-term follow-up components that increase the likelihood of implementing new workflows efficiently and effectively across an organization. Also, our model extends AIDED by addressing new process development and spread within an organization rather than within and across countries; process steps in our model leverage preexisting organizational structures, such as communication channels, standardized roles, common workflows, and performance measurement systems.

Our study also extends prior models in that, whereas other studies have shown the importance of innovation champions, our study provides empirical evidence of how to harness the energy of a particular kind of champion—process advocates—for the spread of new processes. Process advocates are working staff members in each practice site (e.g., MAs and patient service representatives) who are formally appointed to serve in this role, are trained in each new process, and offer one-on-one training to peers. We describe in detail the position of process advocates and how this position can be enabled and enhanced. Process advocates lead by example by always performing the new process, supporting colleagues' use of the new process by answering their questions, and relaying feedback to their managers regarding any implementation problems.

Yet, although formally appointed process advocates are a very effective mechanism for spreading new processes inside an organization, we found that there are several potential barriers to their use: lack of understanding of new processes on the part of process advocates, lack of protected time for process advocates to train their peers, and problems inherent in new processes that arise during training. We found facilitators to address each of these barriers to spread by process advocates, including simplification of standard work documents, support of site managers for protected time to train, and Improvement Specialist's help with troubleshooting new processes.

Our findings should be considered in light of limitations inherent in the study design. First, the study used a pre/post design, and without a control group, we cannot establish a cause-and-effect relationship between the use of the new method and the change in outcomes. Although we attribute the improvement entirely to the change of method, it is possible that some of the improvement could also be related to changes beyond the change of method, for example, if practices were being held to new levels of accountability either by regulators or payors. Second, the study of a single organization limits the generalizability of the findings. There was a high level of support for QI innovation in this organization, so this organization may have experienced fewer implementation problems than would other organizations. Finally, many of the facilitators of new process development and spread that were identified came from early adopter sites that may have experienced fewer barriers than late adopters.

Practice Implications

Despite these limitations, we believe that our findings provide important direction for managers about how to develop and spread new QI innovations across sites within large organizations. To meet the challenges required to do so effectively, we recommend that leaders develop a clear and shared understanding of the steps required for intra-organizational process development and spread of QI innovations. It is also important for managers to consider the barriers that are likely to arise at each step of the innovation implementation process and the facilitators that can be used to address these barriers. In implementing and spreading the innovation, managers should leverage available organizational structures to facilitate the integration of new processes into existing workflows and systems. We also recommend that organizations employ formally appointed process advocates in each site for each role to help spread new processes through coaching and leading by example.

Conclusion

Given the difficulty of developing and spreading QI innovations inside organizations, it is understandable that

organizations attempting to implement reforms to redesign primary care may fail to do it. Our research demonstrates, however, that successful spread inside organizations is possible and sustainable. Only by successfully spreading QI innovations can we achieve the promise of improved safety in ambulatory settings.

The Appendix comparing our intraorganizational model to the PDSA and AIDED models (Appendix A, Supplemental Digital Content 1, <http://links.lww.com/HCMR/A14>) can be viewed online.

Acknowledgment

The authors acknowledge financial support from the MIT Sloan School of Management.

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