Options for Large-scale Spread of Simple, High-impact Interventions

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Abbreviations

ADE	Adverse drug event
AMTSL	Active management of the third stage of labor
HCI	Health Care Improvement Project
HIV	Human immunodeficiency virus
IHI	Institute for Healthcare Improvement
IHS	Iowa Health System
IOM	Institute of Medicine
NICU	Neonatal intensive care unit
NKE	Nurse Knowledge Exchange
PDSA	Plan, Do, Study, Act Cycle
PMTCT	Prevention of mother-to-child transmission of HIV
QAP	Quality Assurance Project
URC	University Research Co., LLC
US	United States
USAID	United States Agency for International Development
WHO	World Health Organization

Executive Summary

The Surgical Safety Checklist has the potential to save untold lives worldwide and to prevent even more surgical harm. Such success, however, will rest on effective implementation, which in turn will require adoption by many thousands of surgical practitioners, working in different cultures and contexts, many of them in remote, hard-to-reach areas.

The World Health Organization Patient Safety Programme and the Harvard School of Public Health commissioned the United States Agency for International Development's Health Care Improvement Project (HCI), managed by University Research Co., LLC (URC), to present its understanding of and experience with the effective adoption of simple, high-impact interventions, such as the surgical checklist. URC – through HCI and its predecessor project, the Quality Assurance Project – has over 20 years' experience in fostering the development and spread of such innovations. URC is joined in this effort by the Institute for Healthcare Improvement (IHI), which also has decades of experience in this field.

All too often in health care, evidence-based interventions that have been shown to produce superior results in certain locations do not spread to other sites. Therefore, practitioners of health care improvement have broadened their focus to not only develop superior models of care but also to take such models to larger scale by focusing on intentional spread, to more rapidly meet the needs of large numbers of patients. Such spread requires making changes in the organization of care delivery, policies, resources, and other factors that will influence the uptake of the superior model.

In planning to spread an evidence-based intervention, we must consider three key questions:

- What are we trying to spread?
- To whom do we want to spread it, and by when?
- How will we spread it?

The framework for spread requires a superior model or practice that has proven itself on a small scale through improved system results as well as a group of leaders committed to spreading this superior model. The model needs to be developed and packaged for optimal adoption by members of the social system in question.

It is important to understand the social system and its constituent parts, define the full scale of the intended spread efforts, identify the leaders within the social system, and define the channels of communication. It is imperative to identify and develop champions for change. The spread plan can then be organized such that the superior model will be broadly and successfully implemented in the social system.

For individual adoption, we must recognize that an individual's performance of a given behavior is primarily determined by his or her intention to perform that behavior. This intention is determined by his or her attitude toward the behavior and the influence of his or her social environment or subjective norm. Factors that influence the rate of spread include the relative advantage of the innovation over current practice, as perceived by the practitioner; compatibility with the practitioner's current beliefs and the context; simplicity; trialability, or the opportunity to test the innovation; and observability or the obviousness of the innovation and its results to the practitioner.

A key framework for improving health care quality addresses the integration of discipline-specific knowledge (the content of care) with the way in which care delivery processes are organized. Understanding local practices thus becomes critical in introducing an innovation.

Once such understanding is in place, testing and implementing changes can begin. A commonly used change model is the Model for Improvement, which asks three questions: What are we trying to accomplish? How will we know that the change is an improvement? What changes can we make that will result in improvement? This is followed by the Plan-Do-Study-Act Cycle for Learning and Improvement.

Having summarized the scientific basis for spread, the report offers several illustrative approaches for spread and lessons learned from applying them. The approaches include:

- Natural diffusion, which is the adoption of an idea or intervention by members of a social system in the absence of a formal dissemination effort.

- Executive mandates, which are orders or instructions.

- Extension agents, where mobile health care workers or community leaders spread ideas and best practices.

- Emergency mobilization, used in times of crisis, where plans, materials, and supplies are mobilized to respond quickly and efficiently.

- The affinity group, developed by Ascension Health, where two or three hospitals are recruited to develop a superior model for a priority care area. Once the innovation is developed and confirmed, a large conference-style meeting informs other sites in the system of its use.

- Collaborative, which brings together several teams from independent facilities for structured learning and exchange around shared aims, measures, and goals.

- Virtual collaborative, where participants meet virtually, via phone, WebEx, etc.

- Wave sequence, a systematic approach to rapidly spread to a large, nested system in which care is provided at multiple levels (tertiary, secondary, primary), often in a hierarchical structure.

- Campaigns, where a targeted social system connects with a shared, quantitative aim. This approach builds on a platform (evidence-based interventions to be spread), a simple measurement system, broad communications, and distributed field operations.

- Hybrid approaches, where combined elements from different approaches form a new approach.

Lessons learned from large-scale spread inform our understanding of the way forward for the spread of the surgical checklist and other simple, high-impact interventions. These lessons include:

- Recognize that impressive results from pilots will drive spread.

- Take the successful elements from the pilots and incorporate them in the spread strategy.

- Enable people in health systems to make changes in their work.

- Provide them with normative and regulatory resources, leadership, and other forms of support.

- Accumulate evidence of success.

- Foster shared learning for the development of better models in a shorter period. Energize staff by providing additional assistance to teams through site visits: Role modeling and leadership behaviors affect the functioning and hence success of the teams.

- Understand technology's role within the culture and current practice.

- Leverage existing networks and identify partners to supply crucial resources to ensure rapid growth at a low cost.

To determine which approach should be used to disseminate the surgical checklist, we recommend consideration of three processes. At the individual provider level, we need to know how to foster buy-in. This will involve examining providers' dissatisfaction with current practice and enabling system change. At the facility level, after individual adoption, whole-facility adoption will require connecting the facility's strategy and the priority. At the health system level, we must build on the inputs of the individual adoption phase and facility-level spread efforts. Leadership and connection with strategy become more prominent as does alignment between the system and the facilities within it. Additional factors that may influence adoption include policies, regulations, incentives, disincentives, and resources.

After considering whether to recommend a single, unified approach to disseminating checklists, the authors and reviewers agree that we not are in a position today to recommend one approach universally. Different approaches are appropriate, depending on the nature of the checklist and the systems in which it will be spread.

1. Introduction

This paper outlines what we know to be effective in the adoption and spread of high-impact interventions. The approaches described herein draw on the experience of the authors and reviewers in large-scale health care improvement work; other approaches successfully used in influencing behavior change and spread are also described. These approaches included "natural" spread (where an individual recommends an innovation to others) and the collaborative, wave sequence, and campaign approaches. These last three are the least familiar and most likely to be availed in the diffusion of the safety checklist, so they are presented in detail and with examples.

This report opens with the scientific and theoretical bases underpinning the spread of innovations. It goes on to describe key elements including leadership at the executive level, factors that influence spread, and understanding a social system and the interactions of its parts while learning to work within the appropriate communication channels.

The next section outlines effective spread approaches which rely first on the individual's adoption of the health care innovation and second on factors that may foster or hinder spread in the system. Previous large-scale spread experiences have shown that the appropriate approach depends on the innovation and the system surrounding it. The final section addresses the selection of an approach to spread, offering options depending on the innovation and surrounding system.

This paper is not intended to be an extensive review of the literature on this subject. It is written for the purpose of guiding the large-scale spread of health care checklists, as requested by the World Health Organization Patient Safety Programme and the Harvard School of Public Health. The first of these checklists is the Surgical Safety Checklist, an intervention to help surgical teams improve patient safety worldwide.

II. Background

The World Health Organization's Safe Surgery Saves Lives focuses on the fact that effective surgery is not only the result of skilled surgeons but of pre-operative care, the surgical operation, and post-operative management. Data suggest that at least half of all surgical complications are avoidable (Haynes et al. 2009). In industrialized countries, major complications are reported to occur in 3–16% of in-patient surgical procedures, and permanent disability or death in approximately 0.4–0.8%. A global movement to promote a system-wide approach to safer surgical care could save millions of lives worldwide (WHO 2008). The surgical checklist, developed by the Harvard Medical School, represents a high-impact, evidence-based intervention for the promotion of safe surgery.

The U.S. Institute of Medicine defines six aims for quality care (IOM 1999): safe, effective, patient centered, timely, efficient, and equitable care. The World Health Organization (WHO) is working with the assumption that every country can improve the safety of surgical care when hospitals use the Surgical Safety Checklist or a comparable intervention to ensure that the steps to promote safe surgery are accomplished in a systematic, timely fashion and within an established routine surveillance system that monitors surgical capacity, volume, and results (WHO 2008). The surgical checklist presents an opportunity to save lives as well as reduce complications, so WHO is taking steps toward its global implementation.

III. Spreading Evidence-based Interventions

All too often in health care, evidence-based interventions that have been shown to produce superior results in certain locations do not spread to other locations (McGlynn et al. 2003). This phenomenon does not seem to be limited to any particular setting (Nicholas and Heiby 1991): It is observed in both industrialized as well as developing country health systems, private and public systems, and at hospital and primary care levels. According to Mangham and Hanson of the London School of Hygiene and Tropical Medicine (2010), there are four pertinent issues in scaling up the coverage of health interventions: the costs of scaling up coverage; constraints to scaling up; equity and quality concerns; and key service delivery issues when scaling up.

Practitioners of health care improvement have broadened their focus to not only develop superior models of care but also to take such models to larger scale. The quest

for large-scale spread of evidence-based interventions started with a focus on how to influence the adoption at the individual level. The work of Everett Rogers in Diffusion of Innovations provided the foundation of our understanding of adoption by individuals in a social system. Rogers' theory acknowledges that, providing conditions are favorable, positive and effective ideas will spread due to their own good nature (Rogers 2003). However, it became apparent that whereas the theory of the diffusion of innovation focuses on the natural diffusion of ideas and practices between individuals, the needs in the field of health care improvement go beyond that. In this field, the need is to develop approaches for the intentional spread of models of better care to more rapidly meet the needs of patients. Such strategies invariably include adoption at the individual level along with adoption at the system level. Adoption at both levels often requires changes in the organization of care delivery, policies, resources, and other factors that will influence the large-scale spread of the superior model. The field has adapted and developed several successful approaches to spread, approaches that vary depending on the nature of the intervention and the scale and social system where it will be used.

IV. The Scientific Basis for Spread

Spread is defined as the science of taking a local improvement (e.g., an intervention, a redesign of a process or system) that has demonstrated better results than the current method and actively disseminating it across a system. In planning to spread an evidence-based intervention, it is important to first understand the history of the intervention in question, including such issues as the motivation of key stakeholders and the profile of the problem that the better practice seeks to solve. Then we must consider three key questions:

- What are we trying to spread?
- To whom do we want to spread it, and by when?
- How will we spread it?

What are we trying to spread?

In considering this question, we aim to understand the nature of the intervention and the optimal way to package it. Implementing some interventions requires systemic changes involving the interaction of many persons in

the care delivery process. Introducing others is more straightforward, in that they can be easily implemented within the existing care delivery systems or they require fewer persons to ensure their implementation. The nature of the intervention influences the likelihood of adoption and the choice of spread approach.

To whom do we want to spread it, and by when?

Here, we project the full scale desired of the effort in question and study the social system where we seek to disseminate the intervention. This includes considering the geography, number of facilities, number of health professionals, number of patients, etc. The timeline for reaching full scale will also influence the spread approach we will choose.

How will we spread it?

Here, we decide on a suitable spread approach in view of the nature of the intervention and the scale at which we want to spread it.

In order to spread effectively and efficiently one needs to consider the full extent of the spread up front- at the point when the prototype is being developed. The subsequent sections will review important factors to consider when developing the prototype and understanding the social system in which it will be spread. These factors fall into two groups:

Understanding the social system:

- Framework for spread
- Individual adoption/ behavior change
- Positive deviance
- Factors that influence the rate of spread
- Clear definition of the content of spread

Development of the prototype:

- Integrating content into process design
- Testing and implementing change
- Executing for system-level results

A. Framework for Spread

The starting point for any spread effort is a superior model or practice that has proven itself on a small scale through improved system results, combined with a

group of leaders committed to spreading this superior model (Figure 1). The model needs to be developed and packaged for adoption by members of its social system (e.g., a hospital or district). The leadership includes both executive sponsorship and day-to-day leadership. Executive sponsorship is a crucial component to accountability and encouragement for spread (Massoud et al. 2006).

It is important to understand the social system and its constituent parts, define the full scale of the intended spread efforts, identify the leaders within the social system, and define the channels of communication. It is imperative to identify and develop champions for change. The spread plan can then be organized such that the superior model will be implemented in the social system. Other key elements of the strategy include measurement and knowledge management systems to support the

spread effort. Also important is the existence of successful sites that will serve as a source of ideas to be spread and will show evidence of desired outcomes. In the case of the surgical checklist, the pilot sites provide the evidence, but focusing on demonstrating results with hospitals at a similar socio-economic level may encourage spread in similar regions. A spread effort is successful when the new ideas or practices become the way an organization does business. In order for spread to take hold, individual adoption and behavior change are necessary.

B. Individual Adoption and Behavior Change

There are multiple behavior change theories and models. The Theory of Reasoned Action/ Planned Behavior and the Social Learning/ Social Cognitive Theory can be viewed in light of improvement. The former states that an individual's performance of a given behavior is

Figure 1: Framework for spread
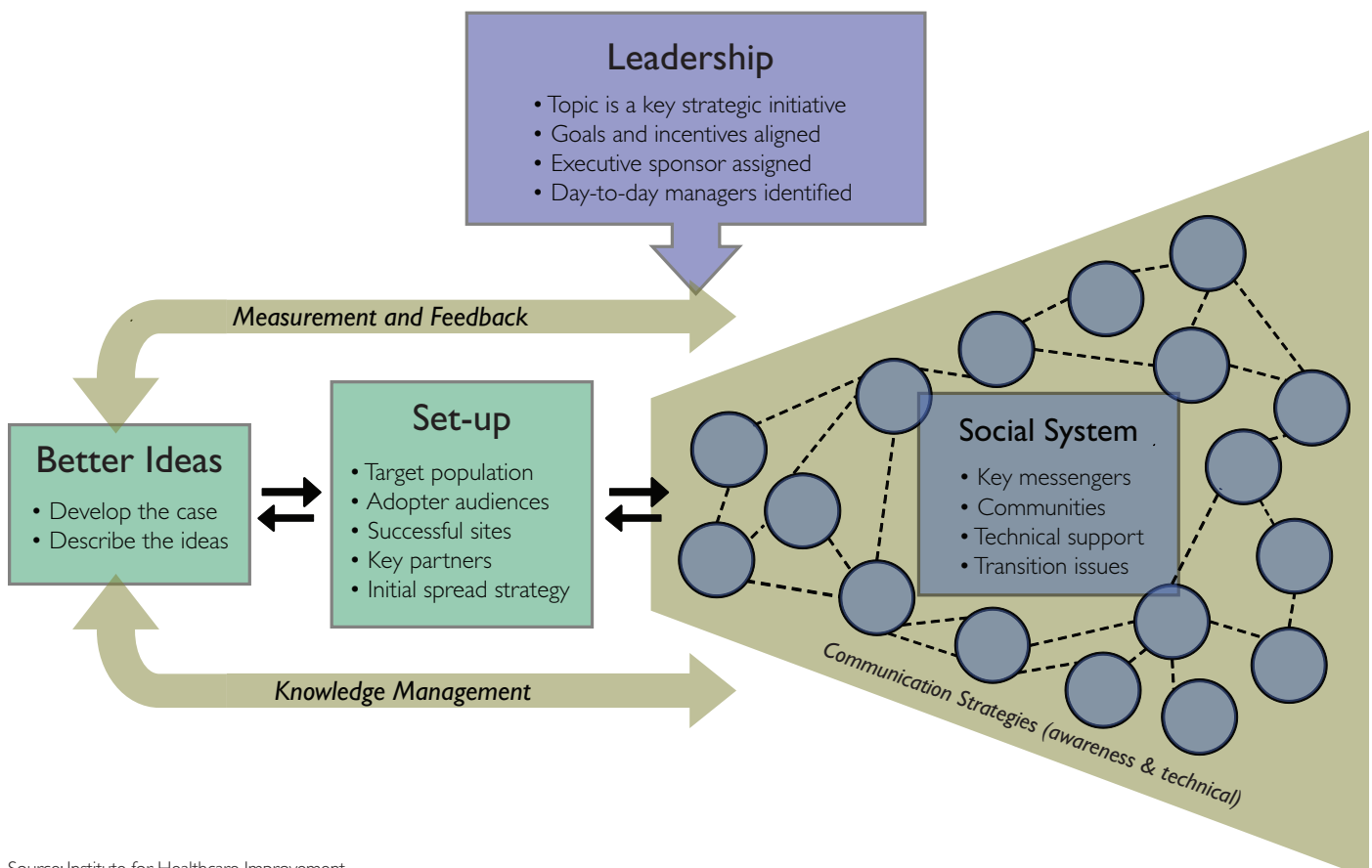
Source: Institute for Healthcare Improvement

primarily determined by his or her intention to perform that behavior. This intention is determined by his or her attitude toward the behavior and the influence of his or her social environment or subjective norm (for example, what he/she perceives what other the people will think he/she should do to comply with social norms). Perceived behavioral control over the opportunities, resources, and skills necessary to perform a behavior is believed to be a critical aspect of behavior change processes. In short, if those in the medical profession have become accustomed to a system that is imperfect and those within the system accept it as so, then no one will look to new ways to improve it.

Why would someone want to adopt a change? For an individual, the decision to make a change starts with dissatisfaction with an existing practice or outcome. If the individual is content with what exists, no motive exists to embark on change. Knowledge of a better alternative, or at least a belief that it may exist, can create an inner tension for change. In many situations, change agents promoting better practices may need to start by creating discontent with the existing situation and the inner tension for change. Factors that can influence someone to act on this tension include the individual's confidence in his/her ability to make that change, environmental factors promoting or hindering such change, and the presence or absence of support mechanisms for making the change. For a health professional, knowing that complications associated with surgical procedures can be avoided is a powerful motivation to seek a better alternative. Factors that can influence the health professional to act on this tension include the personal ability to implement the change within the work environment, such as confidence in one's ability to implement the evidence-based intervention – the surgical checklist – in his/her own work. Other factors include the presence of professional and managerial support for making the change.

Health professionals typically enter the care professions with a desire to help others and make a positive impact on the lives of their patients. They hope to provide a valuable service and contribute positively to individuals and society. However, they are often in situations where they encounter system breakdowns, lack of supplies, inadequate staff to meet the needs, and other challenges that make their jobs difficult and frustrating. Over time, these

professionals may become de-motivated and complacent with the outcomes of faulty systems. We have often seen these situations in the early stages of embarking on health care improvement. Key to motivating such professionals is reinforcing the values that brought them into the health care profession and providing the necessary support in embarking on the superior alternative. Once they are onboard with the change effort, uptake is rapid.

C. Positive Deviance

Positive deviance describes the phenomenon where individual behavior departs-in honorable ways—from group norms. (Spreitzer and Sonenshein 2004). It involves discovering outstanding achievements that stand out from the peer group. Once great results are identified, it is important to understand the factors that led to the positive deviance, because understanding what a particular site was able to accomplish can help others implement changes and achieve similar results.

For example, in an effort to improve care in cardiothoracic surgery, the Institute for Healthcare Improvement (IHI) convened an expert panel of high performers in both quality and cost reduction to understand how they achieved such impressive results. One hospital with some of the best outcomes and lowest expenditures reported that it had learned to reduce costs by performing surgery in developing countries. Each year the hospital sent a team to a resource-constrained setting to help perform cardiothoracic surgeries. In these settings, the doctors operated in circumstances different than their home hospitals, often lacking some materials they were accustomed to using. Working in these challenging environments helped the surgeons uncover what was not essential to providing great care. Once they learned what could be eliminated without compromising the quality of care, they returned to their hospitals and shared their new understanding relative to surgical efficiency and cost cutting. Over time, they were increasingly able to achieve high levels of care at lower cost.

Being deliberate about uncovering positive deviance in spread methods for an intervention is necessary for success. In 2002 the Quality Assurance Project was asked to work with the Ministry of Health in Rwanda to decrease the transmission of the HIV virus from mother to child (PMTCT services). All sites providing the service,

including those doing well, were invited to participate in a collaborative improvement effort and share their good results with the rest of the teams in order to identify positive deviance and increase the up-take of effective PMTCT practices.

## D. Factors that Influence the Rate of Spread

Diffusion is the process by which an innovation is communicated through certain channels over time among the members of a social system (Rogers 2003). The rate of diffusion is influenced by the attributes of the innovation:

- *Relative advantage*: To what extent is the innovation better than the existing practice at addressing the needs perceived by the potential adopter?

- *Compatibility*: How closely do the innovation and its source appear to align with the existing belief systems and contextual circumstances of the potential adopter?

- *Simplicity*: How simple and understandable is the innovation to the potential adopter?

- *Trialability*: To what extent does the potential adopter have an opportunity to test the innovation under a variety of conditions before committing to it?

- *Observability*: How visible is the impact of the new from the viewpoint of the potential adopter?

All of these factors will have to be taken into consideration for the worldwide adoption of the surgical checklist. As it has already been piloted and widely adopted in eight countries and within different contexts in each of these countries, the checklist should have a high rate of diffusion.

Diffusion theory posits that, when presented with change, people fall into one of the following categories: innovators, early adopters, early majority, late majority, and laggards (see Figure 2). Part of effectively advocating for a behavior change innovation is to understand that adopting will take time as people in each category become comfortable with the innovation. Additionally, targeting potential early adopters who represent the opinion leaders in the social system is critical in accelerating diffusion across the social

Figure 2: Diffusion of innovations and the categories of adopters
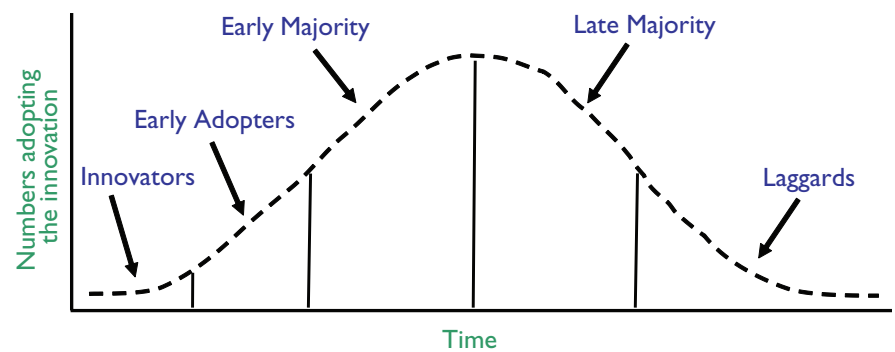
Source: Everett Rogers, *Diffusion of Innovations*

system. These opinion leaders attract the early majority, who are followed by the late majority.

This theory counters the commonly held belief that consensus must be reached among the members of a social system before spread can occur.

In addition to the diffusion theory's description of categories of adopters, we have also observed that an individual may be in different categories depending on the innovation. We have also seen that a single individual with respect to the same innovation may move over time from one category to another. Therefore, we view the Rogers categorization as a snapshot of a particular innovation in a given social system rather than a static condition.

E. Understanding the Social System

It is very important to understand the social system in which we want to spread an innovation (Rogers 2003). This means accounting for contextual factors (like local resources, infrastructure, and skills), and it also means understanding local norms around adoption decisions. Rogers differentiated four types of adoption decisions: optional, where a member of a social system is free to decide whether to adopt or not; collective, where the adoption decision is made by consensus among the members of the social system; authority, where the adoption decision is made by a few members of the social system who have the authority and power to decide on behalf of the system; and contingent, where the individual decision to adopt is contingent on another adoption decision, such as by the authority.

F. Integrating Content into Process Design

A key framework for improving health care quality addresses the integration of discipline-specific knowledge, otherwise referred to as the "content of care," with the way in which care delivery processes are organized (Figure 3). To the extent that it is possible to 1) implement an evidence-based intervention within the existing care delivery processes or 2) redesign the care delivery processes in order to enable the implementation of the intervention, we will be successful at achieving the desired improvements. This framework applies equally in the development of the superior model and its subsequent spread. Processes, though often looking similar on the surface, differ greatly based on the setting. The ability to fine-tune and adjust the way in which an intervention is implemented at the local level is key to its success (Batalden and Stoltz 1993; Massoud et al. 2001). For example, Box 1 on page 11 describes integration of active management of the third stage of labor (AMTSL) in Niger. AMTSL is the content of the care, whereas the method of pre-filling a syringe with oxytocin and placing it on an icepack is part of the process of care that enables AMTSL to be carried out effectively in the Niger setting.

In planning a spread effort, it is important to differentiate between the core elements of the intervention – the components that cannot be changed without compromising the intervention – and those that represent variations around that core, which exist primarily to enable the implementation of the core elements.

Looking at Figure 14 on page 15, the "Neuron" was an example and tool for tracking information, versus the core process of the hand off and exchange of information. Variations around the hand off methods, be it the Neuron or written documents, still accomplish the goal—increased effective hand-offs between nurses at shift changes.

G. Testing and Implementing Change

In order to make improvements and spread them, changes to care delivery processes must be tested before they are introduced. A commonly used change model is the Model for Improvement, depicted in Figure 4, which consists of three questions: What are we trying to accomplish? How will we know that the change is an improvement? What changes can we make that will result in improvement? This is followed by the Shewhart Cycle for Learning and Improvement, otherwise known as the Plan-Do-Study-Act (PDSA) Cycle (Langley et al. 1996; Massoud et al. 2001).

For example, when a team clarifies what it wants to accomplish and develops measures to monitor progress toward accomplishing the aim, it conducts a series of PDSA cycles, each following a pattern:

- Plan: The team considers and plans a change, who will be involved, and where and when the change will be tested.

- Do: The team conducts a test on a small scale and documents results, including anything unexpected.

- Study: The team analyzes the results and summarizes what they have learned.

- Act: The team decides on next steps. If the test was successful, the team may introduce it at a larger scale; if not successful, they may decide to discard it or adapt the change to make it work more successfully.

In redesigning a process, it is important to ensure that it operates in a reliable fashion (Nolan et al. 2004). Reliability is defined as the inverse of the defect rate. Reliable process design considers the levels of reliability and the types of changes that can yield them. A defect rate of one or two out of 10 opportunities is expressed as 10^{-1} level of reliability. Most health care processes operate in this range. A defect

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Figure 3: Quality improvement: Integrating the content and processes of care
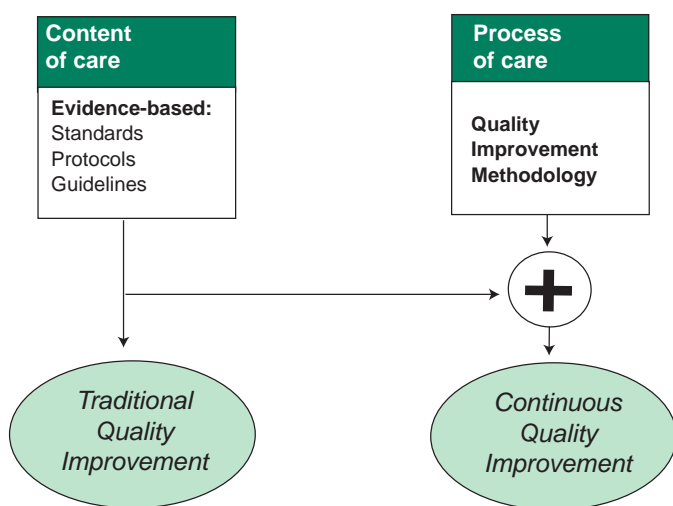
Source: Batalden and Stolz (1993)

rate of five or less per 100 opportunities is called a 10^{-2} level of reliability, and a defect rate of five or less per 1000 opportunities is called a 10^{-3} level of reliability, and so on. Defect rates of more than two out of 10 opportunities characterize chaotic processes. Designing care processes with a high degree of reliability requires: 1) standardization according to best known practices in order to achieve

Figure 4: The Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What changes can we make that will result in improvement?

Act Plan

Study Do
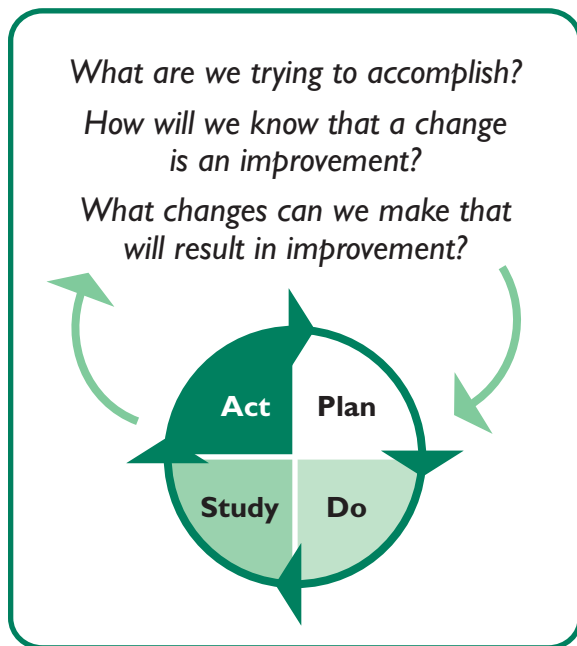
Source: Associates in Process Improvement

initial levels of reliability, usually at the 10^{-1} level of reliability; 2) analysis of failures and testing/ implementation changes capable of achieving higher levels of reliability; and 3) redesigning processes to enable the achievement of higher levels of reliability.

For example, in the implementation of the ventilator bundle, education and feedback led to improvement at the 10^{-1} level of reliability, which is characteristic of these types of changes. Improvements at higher levels of reliability required process redesigns integrating follow-up on compliance with the ventilator bundle at daily medical rounds and hourly respiratory therapist rounds. The latter types of changes are characteristic for 10^{-2} levels of reliability and yielded the higher levels of improvement shown in Figure 5.

H. Executing for System-level Results

The goal of effective health care is a healthy patient. This requires a series of decisions and actions at multiple levels that can impact the final outcome. In designing system-level interventions, outcomes should be identified and steps and processes developed to reach the desired result.

For example, in Niger the United States Agency for International Development (USAID) Health Care Improvement Project addressed the outcome of maternal mortality. As postpartum hemorrhage is a major contributor to such mortality, it was chosen as the

Figure 5: Implementing the ventilator bundle

Education as a 10^{-1} concept

Baseline

Feedback on compliance as a 10^{-1} concept

Integrate daily goals with Multidisciplinary Rounds to identify defects as a 10^{-2} change concept (step 1)

Redundancy in the form of a check by repiratory therapist built into 1 hour scheduled vent checks as a 10^{-2} change concept (step 2)

Ventilator bundle

Percentage of patients

Week
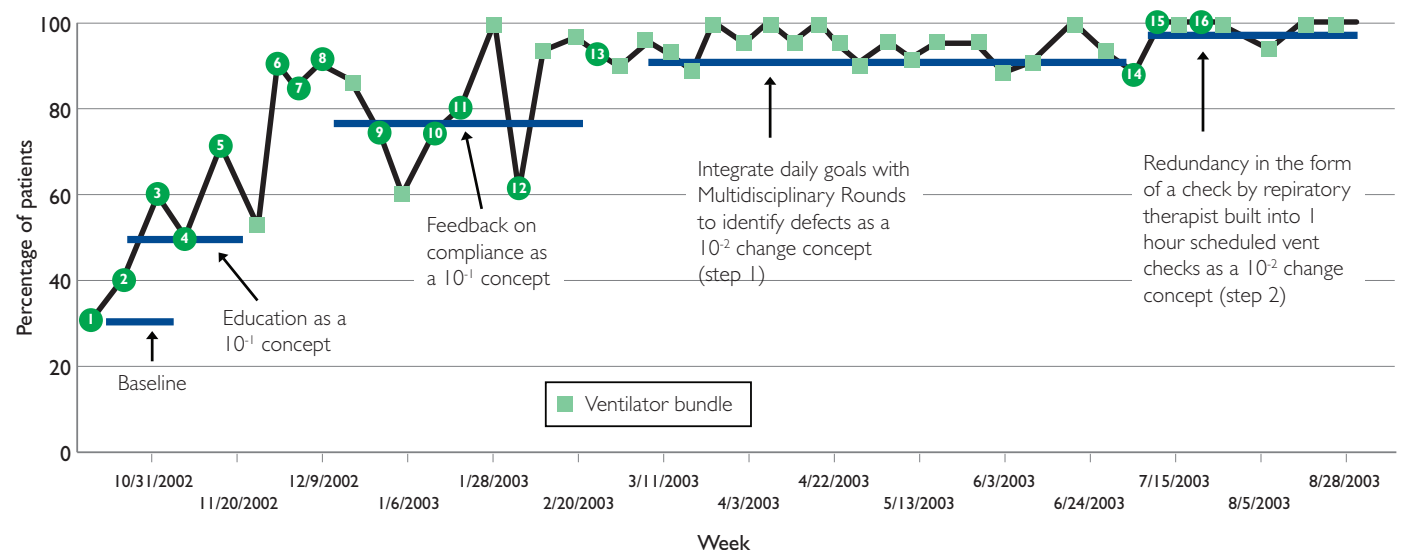
Source: Institute for Healthcare Improvement

initial intervention point. Once postpartum hemorrhage interventions were showing improvement, eclampsia and postpartum infection were addressed. Health care improvement champions decided how the interventions should be prioritized and sequenced. Sequencing – rather than incorporating a full change package of all the possible, promising interventions – was vital: Sequencing revealed to care providers how to improve care relative to each complication.

In the case of postpartum hemorrhage, changes were made by training nurse-midwives, making pre-filled syringes of Oxytocin available, and ensuring the drug stayed cool.

To ensure system-level results, we break the process into parts; identify and prioritize which parts to begin with; and then as effects are noticed and parts of the process are completed, add to the process with the next steps. Figure 6 illustrates how PDSA cycles ran in numerous areas ("ramps") toward improved care and that they overlapped in time to approach better health outcomes.

V. Approaches for Large-scale Spread

There are many possible ways to spread an effective practice. The following is by no means a comprehensive list, but rather an illustrative one to show the variety.

Figure 6: Running multiple PDSA cycles to improve care towards a single aim

A. Natural Diffusion Approach

This is the adoption of an idea or intervention by members of a social system in the absence of a formal dissemination effort (Rogers 2003). This process happens without external assistance and at unpredictable rates.

B. Executive Mandates

These are orders or instructions, which usually take place in hierarchical systems. Where social norms allow, these mandates can drive change quite rapidly.

C. Extension Agents Approach

This approach uses mobile health care workers or community leaders to spread ideas and best practices. It has been successfully used in the agricultural sector in the U.S. (Rogers 2003) as well as in many health sectors worldwide. Coaching and supportive supervision practices, successfully used in many countries, are essentially extension agent models.

D. Emergency Mobilization Approach

In times of crisis, such as after a natural disaster, plans, materials, and supplies can be mobilized rapidly to respond to the disaster quickly and efficiently. This approach is usually difficult to maintain for a prolonged period.

E. Affinity Group Approach

This approach was successfully developed by Ascension Health, a system of more than 70 acute care hospitals in the United States. Ascension Health set eight priorities, based upon 50 consecutive death chart reviews at each hospital, to make it the safest system in the country. In the planning phase, alpha sites were selected to develop and test a superior model for each priority area. The sites were selected upon several

Figure 7: Increase in deaths averted (lives saved) compared to baseline, Ascension Health, FY2005–third quarter FY2010

Ascension Health's five-year goal, set in 2003, was to reduce mortality by 900 lives by 2008.
In three quarters of FY2010 alone, 3,852 lives were saved. To date, over 16,514 lives have been saved

Source: Ascension Health

Figure 8: Observed mortality rate and case mix index at Ascension Health, FY2004–third quarter FY2010

First nine months of FY10 risk-adjusted results–1,085 fewer deaths compared to baseline
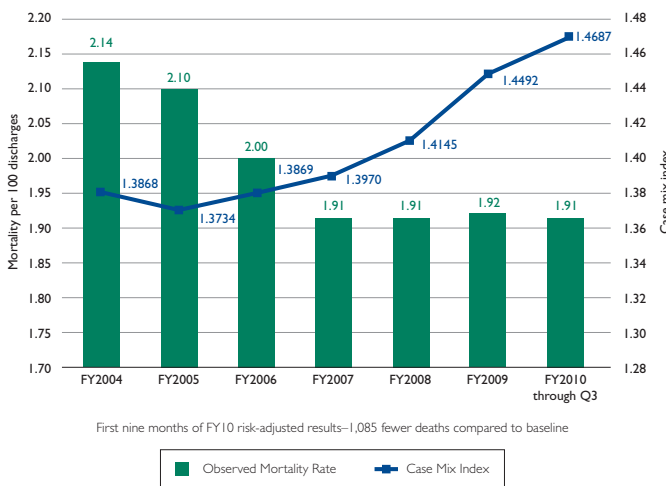
Source: Ascension Health

factors, but most importantly the strength of the local leadership's will to lead change on behalf of the system. It was predicted that alpha to beta spread might take 12-18 months, but the early successful alpha results simulated "viral" spread. Within a matter of months, many hospitals adopted successful practices to emulate similar results. Once the superior models were developed and the

results confirmed the improvements, the other hospitals were invited to a large clinical leadership forum where key stakeholders from each hospital system adopted system metrics and definitions for each priority area. The other hospitals took the learning from the initial sites and adopted it to fit their own settings. Six years later, as seen in system mortality performan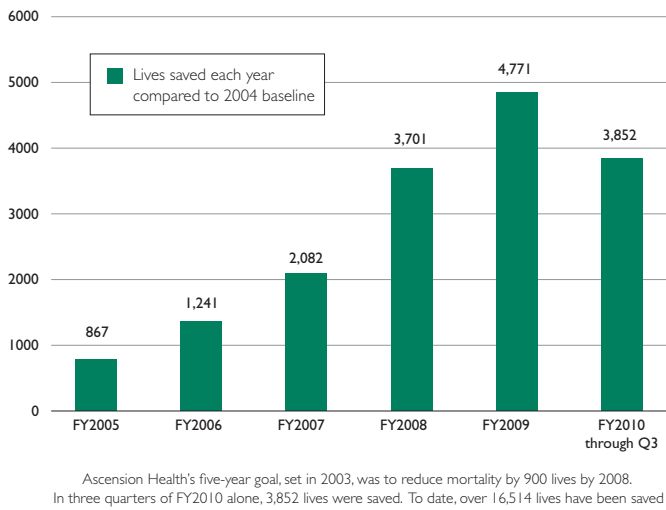ce data in Figures 7 and 8, results have been sustained in all priority areas, and improvement continues with high reliability as a framework for remaining events.

F.   Collaborative Approach

The collaborative approach was developed by IHI and is known as the IHI Breakthrough Series Collaborative (BTS). A major advantage of collaborative improvement is the peer-to-peer learning that takes place between teams as they are exchanging their improvement experiences. This motivates and energizes teams—creating healthy competition. It also enables the rapid testing of multiple changes simultaneously.

An improvement collaborative brings together multiple teams, usually at least 20–50, from numerous, independent facilities, for structured learning and exchange (using a variety of media) around shared aims, measures, and goals (IHI 2003; Fraser 2008). A collaborative typically lasts 9–18 months. Because a collaborative involves many sites, in itself it represents a spread approach. Additionally, collaborative improvement has been adapted in many other ways to enable spread (USAID Health Care Improvement Project 2008; Franco et al. 2009). For example, often following the initial collaborative (usually called a "demonstration" or "phase I" collaborative), a follow-on spread collaborative (often referred to as a "phase II" collaborative) is undertaken to spread the superior model developed in the phase I collaborative to other sites. In other instances, the collaborative continues to add on teams from new sites. These new sites quickly build on the work of their peers from the initial sites.

The collaborative approach is applicable when the nature of the intervention is systemic and cross-functional, and where shared learning in implementation is an advantage. It is as applicable when the organizational structure is dispersed and not connected as it is for facilities within a system. The social system is often created or enhanced during a collaborative. Importantly, the collaborative

Figure 9: The Improvement Collaborative Model
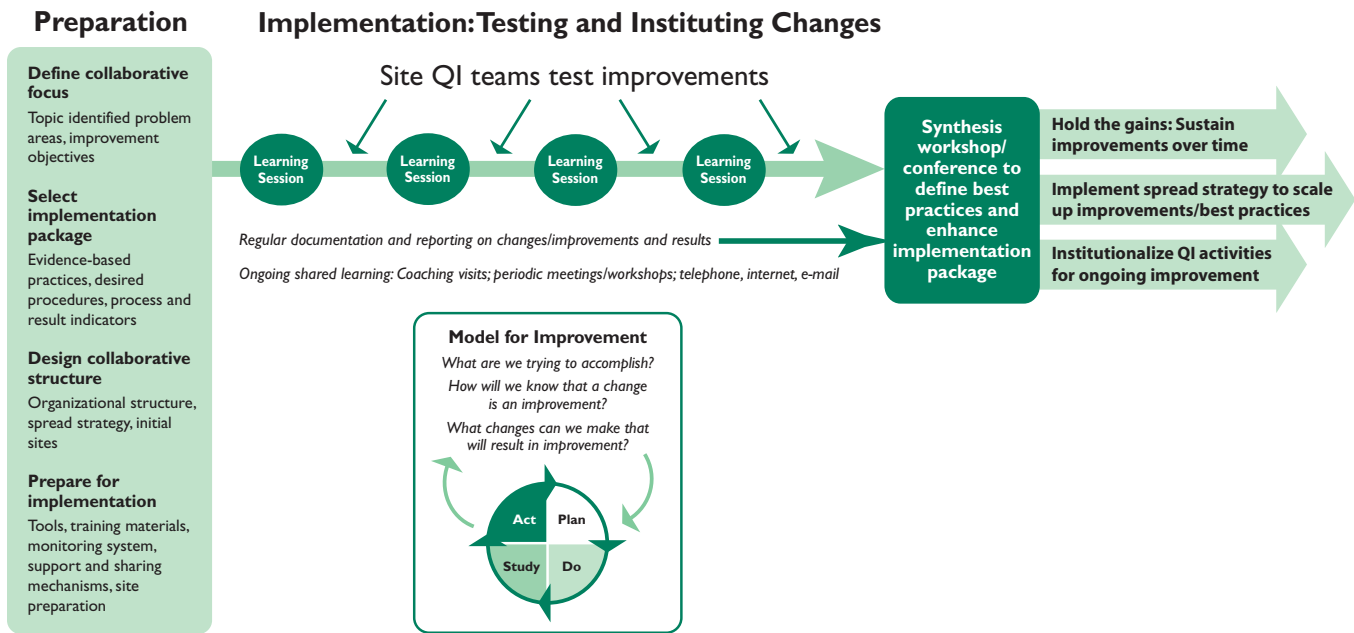
Source: USAID Health Care Improvement Project (2008). Adapted from the IHI Breakthrough Series Model (IHI 2003).

approach is applicable when one can reach the target population all at once. It does require face-to-face meetings. The USAID Health Care Improvement Project's adaptation of the IHI Breakthrough Series model is in Figure 9.

Box 1 shows the results of national level spread in Niger of active management of the third stage of labor, a bundle of three interventions. A collaborative implemented in Niger by the Quality Assurance Project achieved 10-2 level of reliability with a corresponding drop in postpartum hemorrhage.

Box 2 describes the spread experience of an improvement collaborative implemented in Rwanda by the Quality Assurance Project (QAP).

G. Virtual Collaborative

In a virtual collaborative participants don't meet in person, only virtually, via tools such as phone, web conferencing, and video conferencing. This approach is used when the intervention requires collaborative learning, but restraints preclude meeting in person, necessitating other communication means. Common barriers include time restraints, geography, and prohibitive cost. The ideal size

of a virtual collaborative is 40–100 participants. During a virtual collaborative, it is crucial for everyone involved to be able to access information and changes simultaneously.

The process for a virtual collaborative includes developing an aim statement, a change package, meetings, and – as in a standard collaborative – testing changes, returning to the group, and reporting on the impact of those changes. Creating an electronic mailing list of collaborative team members is useful to encourage communication, distribute information, and foster commitment to virtual meetings and sharing.

H. Wave Sequence Approach

Wave sequence (or "multiplicative") spread is a systematic approach to rapidly spread multi-level interventions (i.e., interventions that cross tertiary, secondary, and primary care settings and might even branch into the community). This approach builds on the collaborative improvement approach and emphasizes developing champions from within the system to carry out the subsequent spread. As shown Figure 10, a slice of the system representing the different levels of care in each administrative division is

Box 1: Successful implementation of AMTSL in Niger

A collaborative was launched in 2006 under the USAID Quality Assurance Project, HCI's predecessor, with the goal of successful implementation of the active management of the third stage of labor (AMTSL) in Niger. The AMTSL bundle has three elements: intravenous Oxytocin at the third stage of labor, controlled cord traction, and external uterine massage.

As seen in the figure below, upon beginning the work, few instances showed complete use of the AMTSL bundle. Challenges in implementing AMTSL included the difficulty of accessing Oxytocin, which was kept in a locked refrigerator (it is thermally unstable) at night; women arriving at the health center after delivery; and time restraints in tending to the woman's and newborn's other needs.

Teams thought through the process of how to make the best practice of AMTSL available with a realistic knowledge of the resources available. One change was pre-filling a syringe with Oxytocin and keeping it chilled on an ice pack or in a cooler to have available without need of the pharmacist. With this change in process, it is then available at the third stage of labor for administration at any time.

The graph shows that the percentage of compliance in implementing all three steps of AMTSL increased with this intervention, overcoming a major challenge in providing quality care at the time of delivery.

Active management of the third stage of labor reduces postpartum hemorrhage in Niger
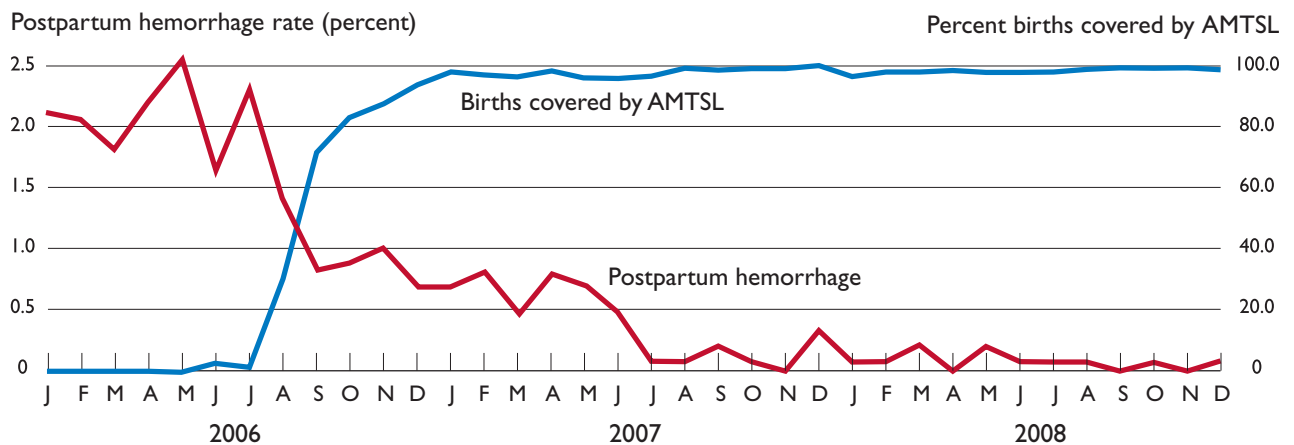
Box 2: Prevention of mother-to-child transmission of HIV in Rwanda

In 2002, the Quality Assurance Project ran an improvement collaborative in 40 sites to decrease the rate of mother-to-child transmission of HIV. At the time, women visited a health center for antenatal care upon determining their pregnancy. They were then tested for HIV, and spouses were encouraged to take the test as well to learn their HIV status. However, only 20% of spouses complied.

As part of the improvement process, health care providers worked in teams toward improvement aims. The aims were that every woman be tested, that the spouses of women who were HIV positive be tested, and that these women start therapeutic treatment to prevent mother-to-child transmission.

There was particular difficulty in getting spouses to agree to present to the health center for HIV testing. In one site, a nurse-midwife discussed with a patient how to encourage her partner to be tested. The patient reported that if they doctor would personally invite her husband to the clinic for testing, he would consider it. The nurse-midwife began sending letters from the doctors to these spouses, and it had a tremendous impact on the numbers of patients tested. Within a few weeks, the rates rose from around 20% of spouses tested to nearly 80%, simply due to the invitation letters. Another intervention was to have providers call spouses' cell phones and extend the invitation verbally, achieving similar results. Lastly, clinics were opened on Saturdays for testing, which also improved the spouse testing rates.

Percent of partners tested at Muhura Health Center PMTCT Program, Rwanda (Jan 2003–Jan 2005)
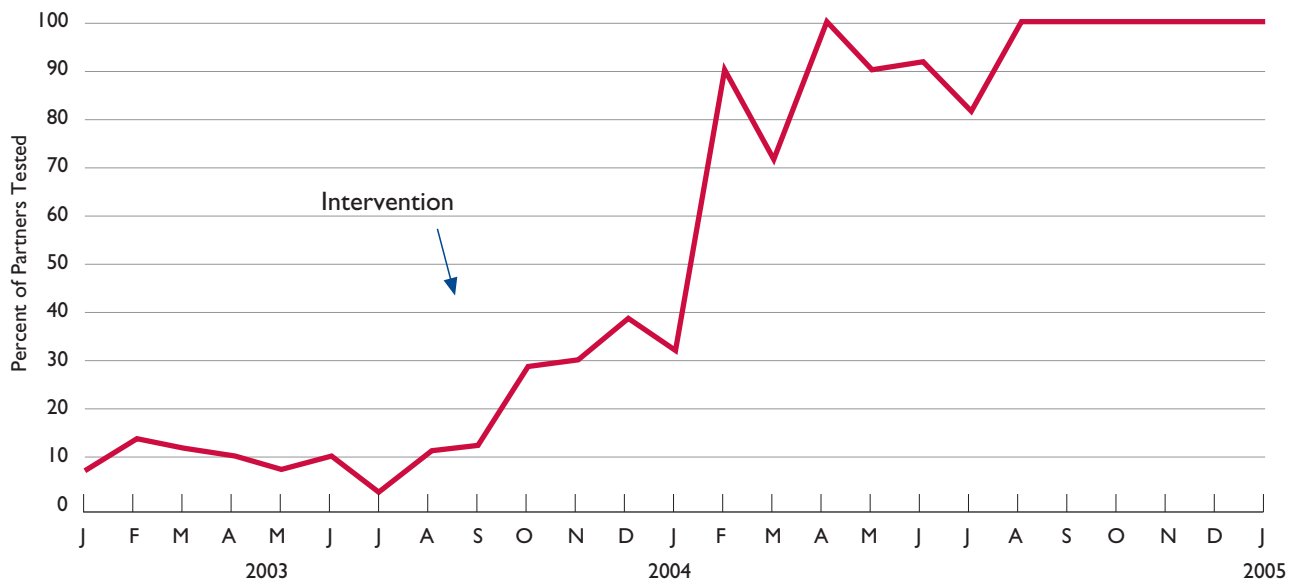
selected to participate in the phase I collaborative. Then champions from that collaborative are identified and equipped to conduct the phase II collaborative in their respective subdivisions (Berwick 2004; WHO 2004).

The wave sequence approach is applicable when the nature of the intervention is systemic and cross-functional and when shared learning during implementation is an advantage. It requires a nested organizational structure. The social system is enhanced during spread. It is applicable in situations where the full scale cannot be reached all at once. Therefore a phased approach is used as shown in Figure 10. Wave 1 would be a collaborative involving the green slices which are simultaneously being prepared to embark on Wave 2. Champions from Wave1 spread to the remainder of the slices in the system shown below in brown. In practice, this has shown itself to be very effective (see results in Figures 11-13) as well as efficient—utilizing people in the system as primary catalysts. It is particularly useful when there are constraints related to human resources or finances, as it utilizes the system's health workforce to implement the subsequent waves of spread. Working successfully in a slice of the system will also build confidence and skill for subsequent waves of activity.

Figure 10: Wave sequence spread
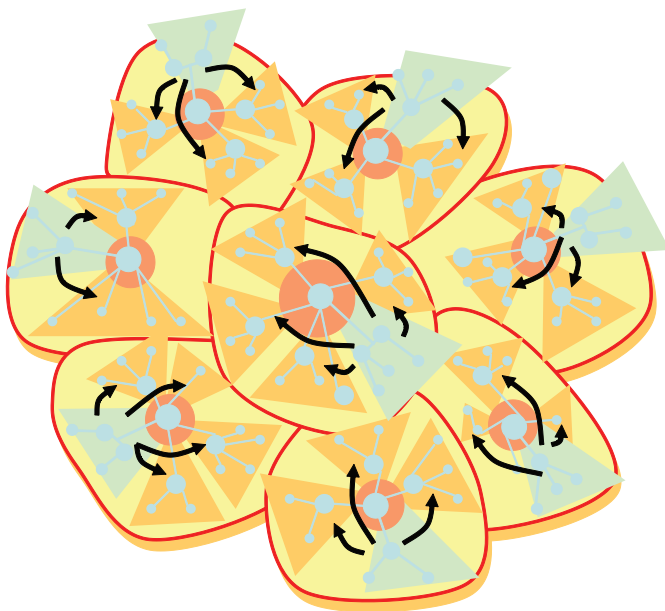
One of the first applications of the wave sequence approach improved care for neonates with respiratory distress syndrome in Tver Oblast in the Russian Federation. Tver Oblast had an infant mortality rate near 20,000/year at the time of the start of a QAP-supported collaborative in 1998. The leading cause of infant mortality was hyaline membrane disease (or respiratory distress syndrome), which occurs in the first week of life. Tver Oblast's high infant mortality rate was largely caused by respiratory distress syndrome.

The system of neonatal care was redesigned initially in five facilities. The redesign of care resulted in pooling resources to a central neonatal intensive care unit (NICU), practicing neonatal resuscitation when babies were delivered in hospitals and peripheral maternities, and establishing a transport mechanism to relocate mothers and babies to the NICU if necessary. The redesign necessitated the closure of poorly functioning peripheral NICUs, changing the policy (Directive #273) on transporting neonates younger than age 10 days, and reallocating resources to strengthen the central NICU and create the neonatal transport system.

Figures 11 and12 present data showing that both the rate of newborn complications such as hypothermia and mortality from respiratory distress among neonates in the first week of life declined appreciably. As a result of this redesign, the percentage of babies that died from respiratory distress syndrome dropped from an average of 50% to an average of 5%. Figure 13 shows that some seven years after the project intervention ended (2001), the results have been maintained and the improvement efforts deepened without project support.

Kaiser Permanente Experience

Kaiser Permanente developed and implemented another example of wave sequence spread: the Nurse Knowledge Exchange (NKE). NKE is a set of practices to solve the problem of handoffs at shift changes by hospital ward nurses. In 2005, Kaiser embarked on developing a way to spread any superior model in use to the remainder of their system. The reason for choosing NKE was that different nurses in each hospital or unit had their own way of organizing, retaining, and maintaining large amounts of complex information about patients. When shifts

Figure 11: Russia: Percentage of neonates arriving at the neonatal center with hypothermia, 1999–2001
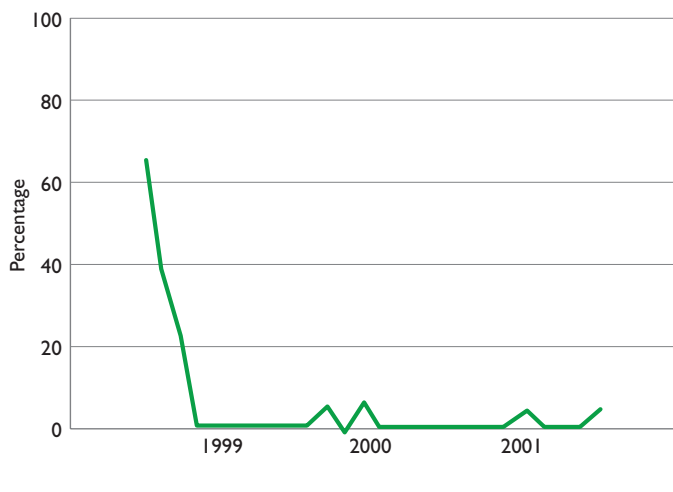
Figure 12: Russia: Neonates with respiratory distress who died in the first week of life, 2000–2002

Tver Oblast, Russian Federation
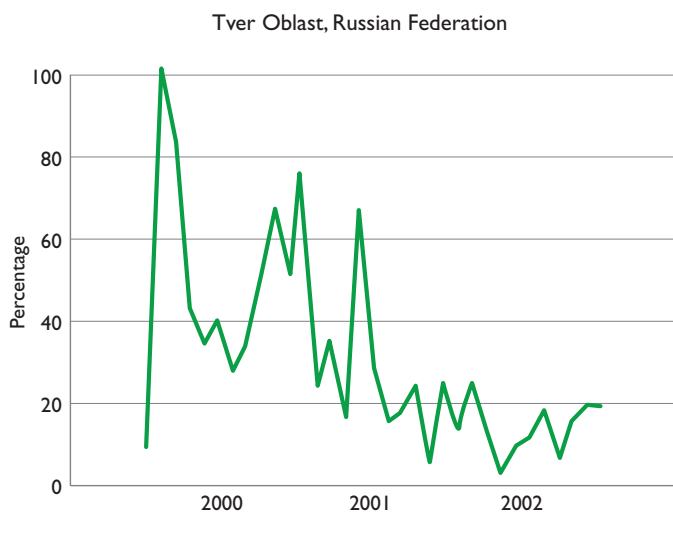
Figure 13: Russia: Declines in neonatal and infant mortality, Tver Oblast, 1998–2008
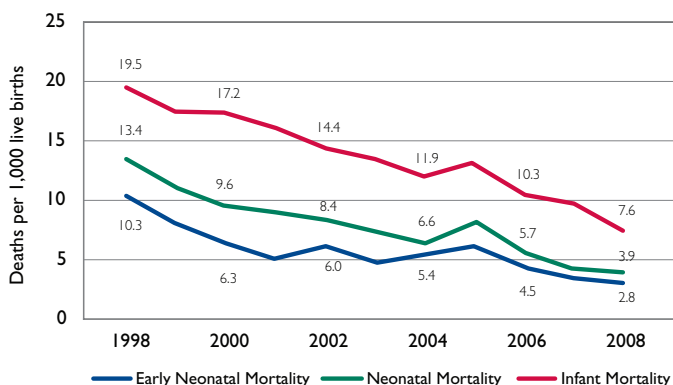
changed, handoffs were not necessarily well organized and often required follow-up by the next shift's nurses with doctors and patients. One issue was communication: What was needed was face-to-face handoffs with a structured reporting tool and engaging all members in the process, which is a common practice in aviation and other industries. Kaiser took this strategy and applied to the NKE. The communications aspects of the NKE change package, shown in Figure 14, are not unlike those of the surgical checklist. Kaiser spread NKE as a first example in testing their approach of approving care at Kaiser overall. This spread effort was structured by building will within hospitals and staff, which involved a shared vision involving nurse executives and regional and hospital levels and developing a communication plan (Schilling and McCarthy 2007).

The NKE was characterized as member/patient-centered, patient-safe, team-centered, efficient, and focused (focused on reporting just one nurse's patients). Through implementing the new system, Kaiser planned to improve patient and staff satisfaction and reduce harm incidents through improvements in communication. At the end of the pilot 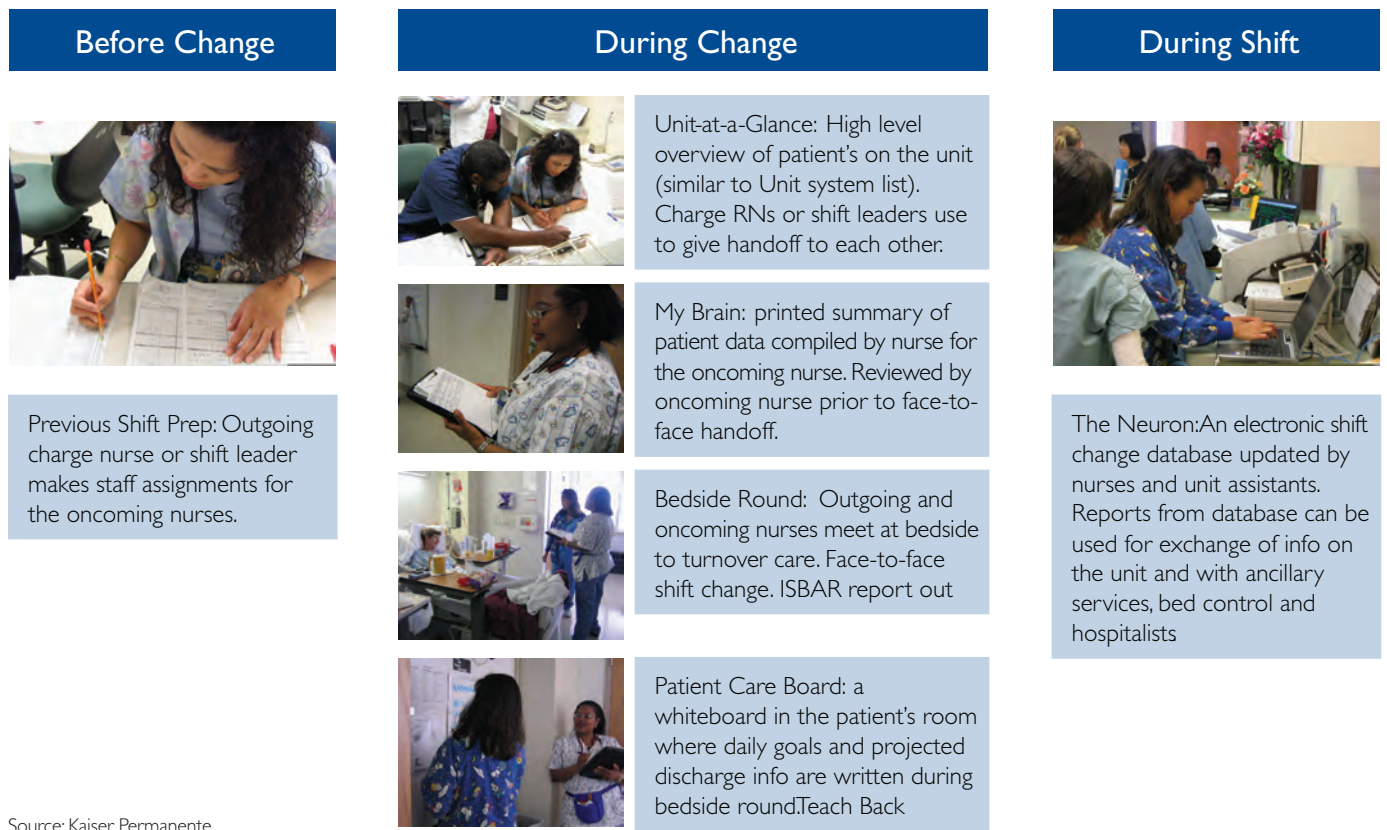period, the nurses and patients were very satisfied with the NKE. After the pilot, the nurse executives and senior executive leadership supported the use of the NKE for shift handoffs. At the time of beginning spread, national, regional, and hospital-level champions and support teams were formed to support the efforts. This involved one of the most important aspects of success of the spread: communication and support between the project leaders and the staff. Nurses became comfortable with the practice and communicated with the patients who gave positive feedback. Champions and pilot sites used story-telling to engage front-line staff and new sites to adopt the practice. This peer communication encouraged and empowered new adopters. Successful spread hospitals developed their own local spread collaborative, which was similar to the national system and structure and started with a kick-off and mass training events to introduce the system changes. These were followed up with local support. At the end of spread, the system had effectively incorporated all Kaiser facilities by empowering the staff, creating leadership, promoting the results of an effective pilot, and giving autonomy to each hospital to control its trainings.

Figure 14: The Nurse Knowledge Exchange at Kaiser Permanente

Before Change	During Change	During Shift
	Unit-at-a-Glance: High level overview of patient's on the unit (similar to Unit system list). Charge RNs or shift leaders use to give handoff to each other.	
Previous Shift Prep: Outgoing charge nurse or shift leader makes staff assignments for the oncoming nurses.	My Brain: printed summary of patient data compiled by nurse for the oncoming nurse. Reviewed by oncoming nurse prior to face-to-face handoff.	The Neuron: An electronic shift change database updated by nurses and unit assistants. Reports from database can be used for exchange of info on the unit and with ancillary services, bed control and hospitalists
	Bedside Round: Outgoing and oncoming nurses meet at bedside to turnover care. Face-to-face shift change. ISBAR report out	
	Patient Care Board: a whiteboard in the patient's room where daily goals and projected discharge info are written during bedside round. Teach Back	

Source: Kaiser Permanente

Figures 15 and 16 show some of the metrics used to show the results of the NKE as it was spread through the Kaiser System. Figure 15 shows the reduction in minutes between arrival of new nurses and completion of the handoff process, while Figure 16 shows improved outcomes (increase in the amount time between falls) following the adoption of NKE.

I. Campaign Approach

The campaign approach in health care has its origins in electoral campaigns. It offers a shared, quantitative aim that the targeted social system can connect with (McCannon; 2006). An example is the Institute for Healthcare Improvement's 100,000 Lives Campaign in the United States, promoted with the slogan "Some is not a number, soon is not a time – Save 100, 000 lives in the next 18 months."

A campaign approach builds on a platform (evidence-based interventions to be spread), a simple measurement system, broad communications, and distributed field operations. Interventions that are less complex, requiring less process redesign, lend themselves well to the campaign approach. This approach has been successfully used in several countries.

The campaign approach is applicable when the nature of the intervention(s) is easy to sell and straightforward and aligns with other national initiatives and connects with the public. A campaign has to have a galvanizing target. The organizational structure is often nodal – it works through "field offices" in smaller geopolitical areas (states, districts) or systems, and it identifies and uses mentor facilities to teach peers. It is a simple means to reach a large number if the intervention is suitable. Due to the galvanizing goal, it can be used to deliberately bring together alliances that

Figure 15: Metrics one month after going live

South Sacramento

Baldwin Park

Hawaii

■ Prototype
■ Baseline
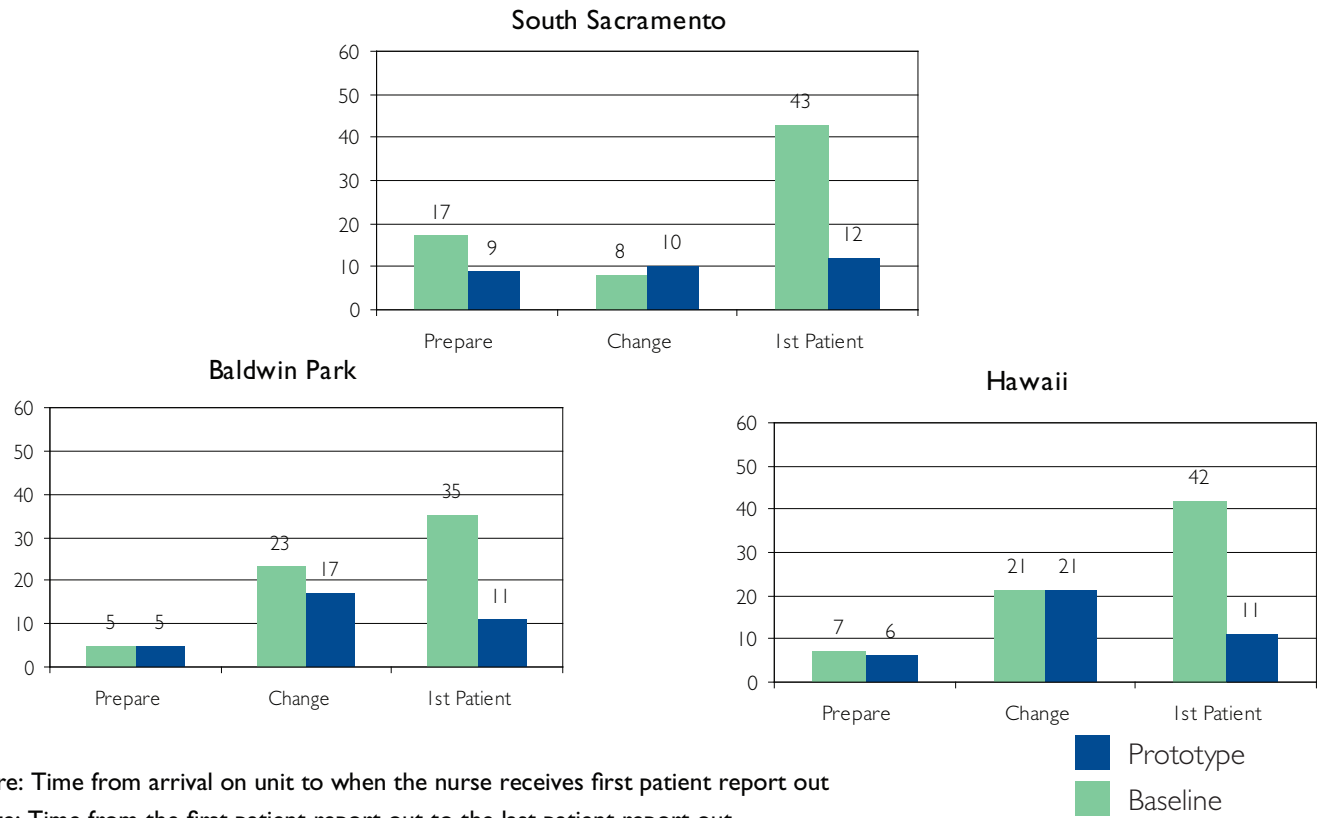
Prepare: Time from arrival on unit to when the nurse receives first patient report out

Change: Time from the first patient report out to the last patient report out

1st Patient: Time it takes from arrival on unit until the nurse physically see their first patient

Source: Kaiser Permanente

Figure 16: Outcome metric: Pilot site, December 2002-March 2006

Days Between Falls - 4W SoSAC

NKE Implemented

♦ Post-Implementation
■ Pre-Implementation
— Linear (Pre-Implementation)
— Linear (Post-Implementation)
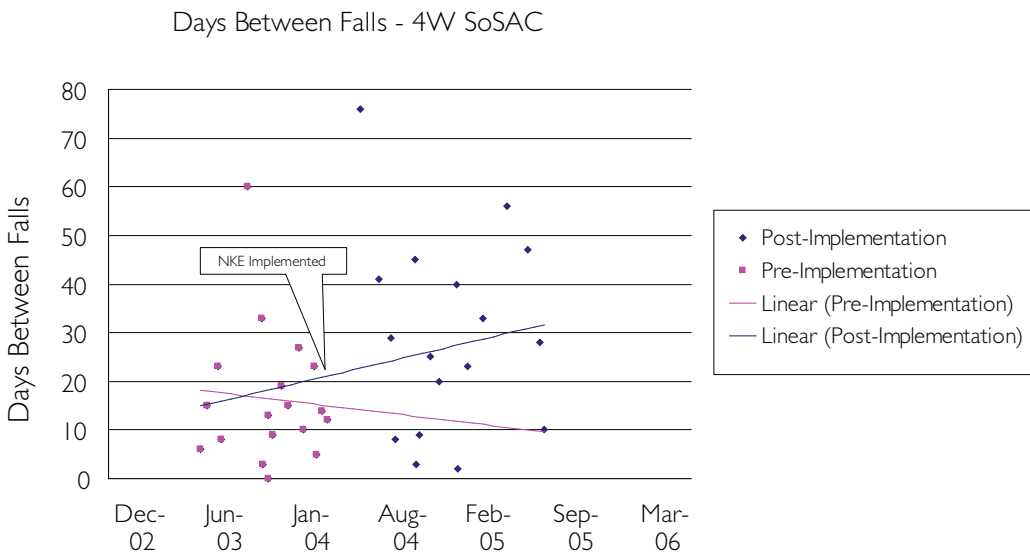
Source: Kaiser Permanente

may not naturally work together. For example, applying a campaign strategy to vaccinations incorporates health systems, schools, and local government to achieve a societal and public health goal. In the case of the surgical checklist, a campaign approach could bring together the ministry of health in countries and the health systems that work within it.

Figures 17 and 18 show the 100,000 Lives Campaign map and field operations structure. The campaign enrolled in excess of 3000 American hospitals and estimated that participants avoided over 100,000 deaths within 18 months, in part through the introduction of six evidence-based interventions that the campaign recommended. It has since been replicated in several countries.

J. Hybrid Approaches

Many successful spread efforts have combined elements from different approaches into new hybrid-type approaches. These approaches feature ideas and applications from more than one spread approach that are adapted to meet the needs of the spread effort at hand. An example of a hybrid approach is that at Iowa

Figure 17: 100,000 Lives Campaign map
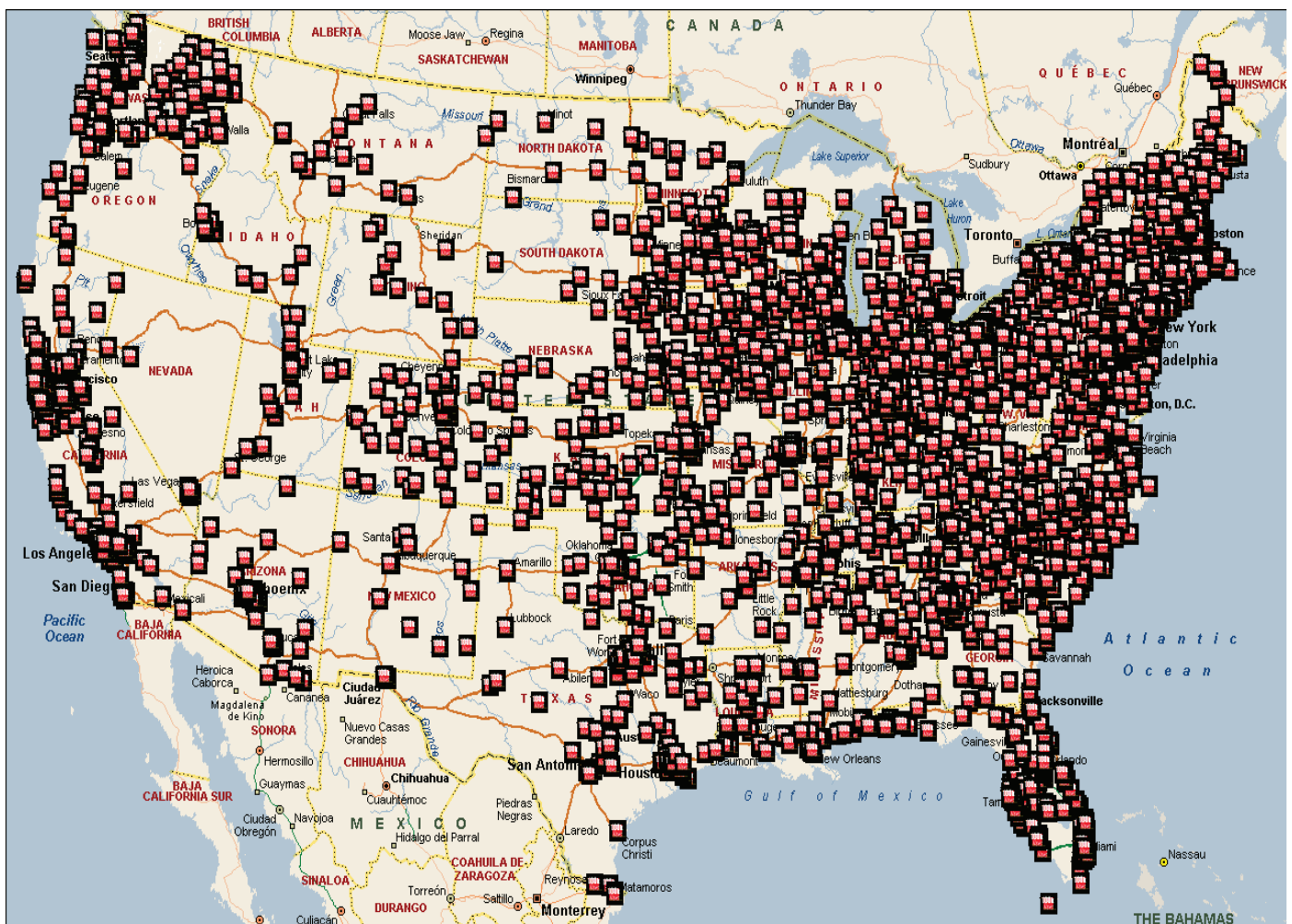
Source: Institute for Healthcare Improvement

Figure 18: 100,000 Lives Campaign field operations structure

Ongoing communication

FACILITIES (3000-plus)

Mentor Hospitals

NODES (approx. 75)
* Each Node Chairs
1 Local Network

IHI and Campaign Leadership

Implementation (with roles for each stakeholder in hospital and use of existing spread strategies)

Local recruitment and support of a smaller network through communication/collaboratives
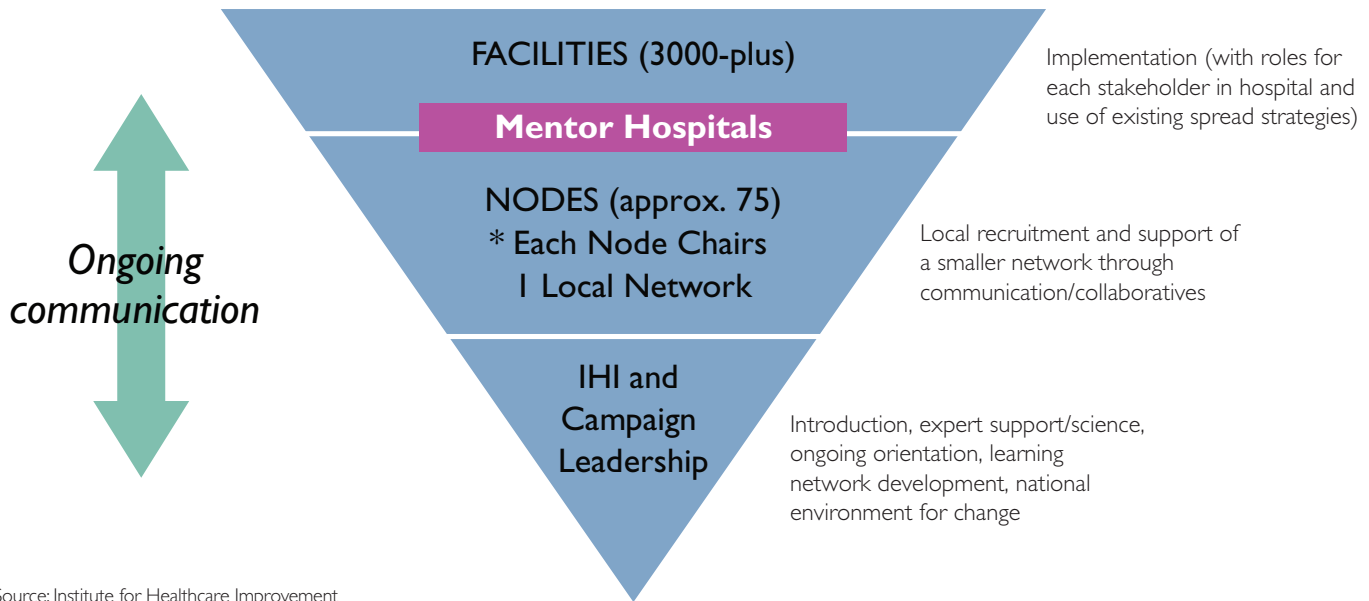
Introduction, expert support/science, ongoing orientation, learning network development, national environment for change

Source: Institute for Healthcare Improvement

Health System (IHS), which set out to spread a number of safety practices – including Unit Briefings, Executive Walk Rounds, and Medication Reconciliation – from one hospital to the remaining 10 hospitals in IHS. The objective was to reduce adverse drug events (ADEs) within two years. Critical to the success of this improvement was deliberately targeting a change in the organization's culture. IHS developed its own spread approach, which combined elements of having a full-scale plan at the outset, including a system-level strategic aim, a system-wide patient safety implementation team, prototype slices at different levels of the system of care, and two initial pilots followed by an internal collaborative for the remaining 10 hospitals. Several leadership and deployment structures and interactions were set up as an integral part of the spread effort. Figure 19 shows the system-wide results achieved in 2001-2003.

Hybrid approaches are applicable when the nature of the intervention(s) is complex, requires cultural change, and spans more than one microsystem. In the IHS case, it required creating an organizational structure to bring together parts of a system that otherwise function as independent entities. The social system was strengthened and a system-wide, multi-disciplinary team was formed
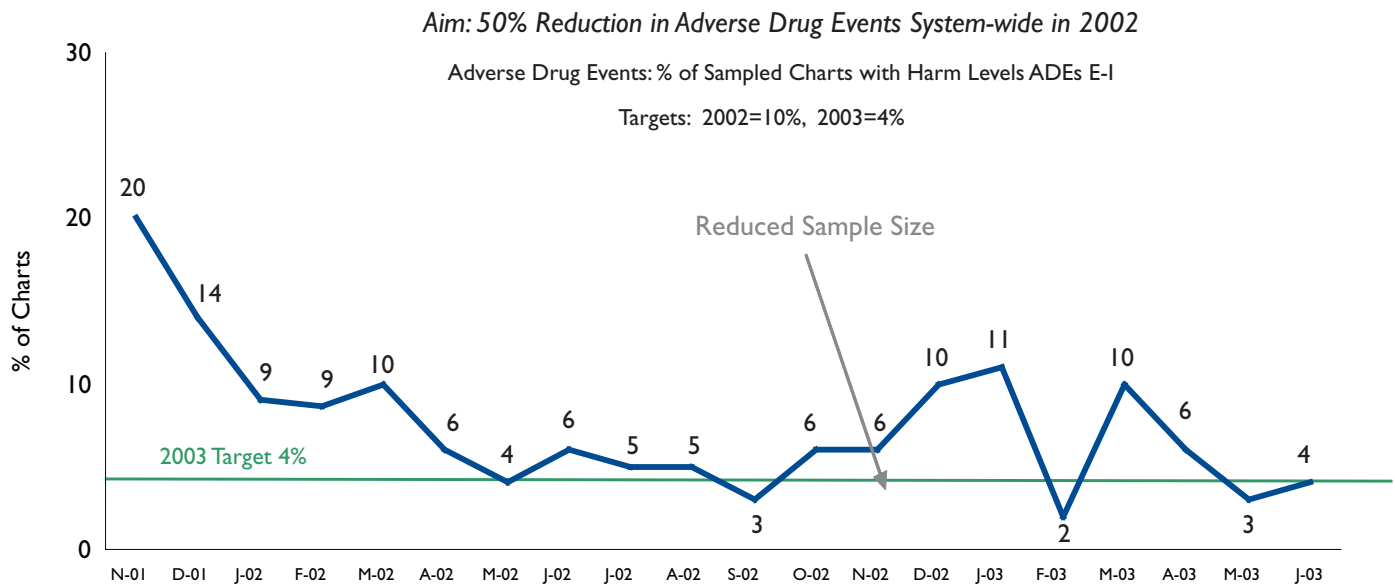
to influence local colleagues. Not all target sites could be reached at once, given the nature of the changes.

K. Lessons Learned from Large-scale Spread

Experience with several spread efforts has contributed to our current understanding of large-scale spread. Key learning from these efforts includes:

- Recognize that good improvement results that are "spread-worthy" and that were obtained in the demonstration phase are the key drivers for large-scale spread.

- Take the successful elements from the pilot phase and incorporate them in the spread strategy. If more core elements can be standardized in the planning phase, this will increases the likelihood of success, provided allowance is made for certain modifications to components of the intervention, appropriate to the local context.

- Enable targeted adopters in health systems to make changes in their own work: Equip them with systems thinking and a change model, such as the PDSA Cycle.

- Provide them with normative and regulatory resources, leadership, and other forms of support.

Figure 19: Iowa Health System: Percentage of sampled charts with harm-level adverse drug events, November 2001–June 2003

Aim: 50% Reduction in Adverse Drug Events System-wide in 2002

Adverse Drug Events: % of Sampled Charts with Harm Levels ADEs E-I

Targets: 2002=10%, 2003=4%

- Accumulate evidence of success of productive outcomes for constituents as the intervention is expanding. Share this to continue to motivate old and new teams.

- Ensure shared, structured learning, which occurs in the collaborative improvement approach (even in the demonstration phase): Such learning enables the development of better models in a shorter period. Energize staff by providing additional assistance to teams through site visits: Role modeling and leadership behaviors affect the functioning and hence success of the teams.

- Understand the role of technology within the culture and practices. Time and again, we see people respond creatively to constraints, when given license to do so, reinforcing the adage, "Necessity is the mother of invention."

- Leverage existing networks and identify partners to supply crucial resources to ensure rapid growth at a low cost.

- Emphasize the importance of well-managed logistics in coordinating the spread process; inattention to detail can stop an initiative in its tracks.

- Use many levers to stimulate change, applying positive incentives (e.g., recognition and rewards) and negative consequences (transparency, chastising) at different times.

In going to scale, thinking through and organizing the scale-up effort has proven to be critical: projects must begin with the full scale in mind. Defining the full scale before embarking on the demonstration enables the creation of superior models that are scalable to the required levels. It also allows for the design of optimal spread plans. In doing so, it is important to look for any nested systems that could be leveraged and to consider creating any form of "system-ness" around the units that will go to full scale. If we can go full scale all at once, there is no reason to delay the spread process. If not, then a wave sequence approach is an alternative.

Another major learning regards the important role of the champions who develop the prototypes in leading the scale-up. The homophily effect, a preference for ties to peers or similar colleagues, has over and again shown its advantage. Creating positive peer pressure for change is key. As spread efforts require multiple factors

to come together successfully, attention to logistics is also paramount. However, much of that happens at the local level, so devolving control and trusting local adaptation is critical to success. As spread efforts and success are directly related to leadership, it is vital to develop leaders within the system and at various management levels. Just as there may be constraint factors in going to scale, such as the availability of human resources, there are often favorable scale-up factors such as facilities, equipment, and systems (e.g., the Tver neonatal redesign) that can serve multiples of patients and sites once developed as part of the prototype.

Other factors to consider include the information system needs. It is better to integrate demonstrative phase data into the standard health information system since it will be needed and less complicated during the scale-up phase. Similarly, communications in the spread phase are better if integrated within the usual communication mechanisms for that system. The oversight of the scale-up should also be integrated within the administrative structures of the system.

An emerging learning is that of the increased rate of spread in the spread phase compared with the demonstration phase. Over the course of HCI, we are seeing this pattern constantly and believe it is attributable to having results from the initial demonstration sites and the homophily between the spread agents and the peers to whom they are spreading in a number of wave sequence spreads. Two examples are worth highlighting:

- The results of the national level spread in Niger of AMTSL, a bundle of three interventions, described in Box 1: It achieved 10^{-2} level of reliability with a corresponding drop in postpartum hemorrhage.

- The higher rate of adoption of active management of the third stage of labor after seeing initial results from peers in three groups of hospitals in Ecuador, shown in Figure 20 below.

The phenomenon of more rapid improvement by later groups has been observed in multiple countries and is related to the homophily of the spread agents when champions from the demonstration phase are used as spread agents in the consequent phases.

Figure 20: Ecuador: Percentage of deliveries where AMTSL was implemented in accordance with standards

Three groups of hospitals (started 2003-2004, n=55; 2005, n=21; 2007, n=10) . Total 86 hospitals reporting 2003-2009.
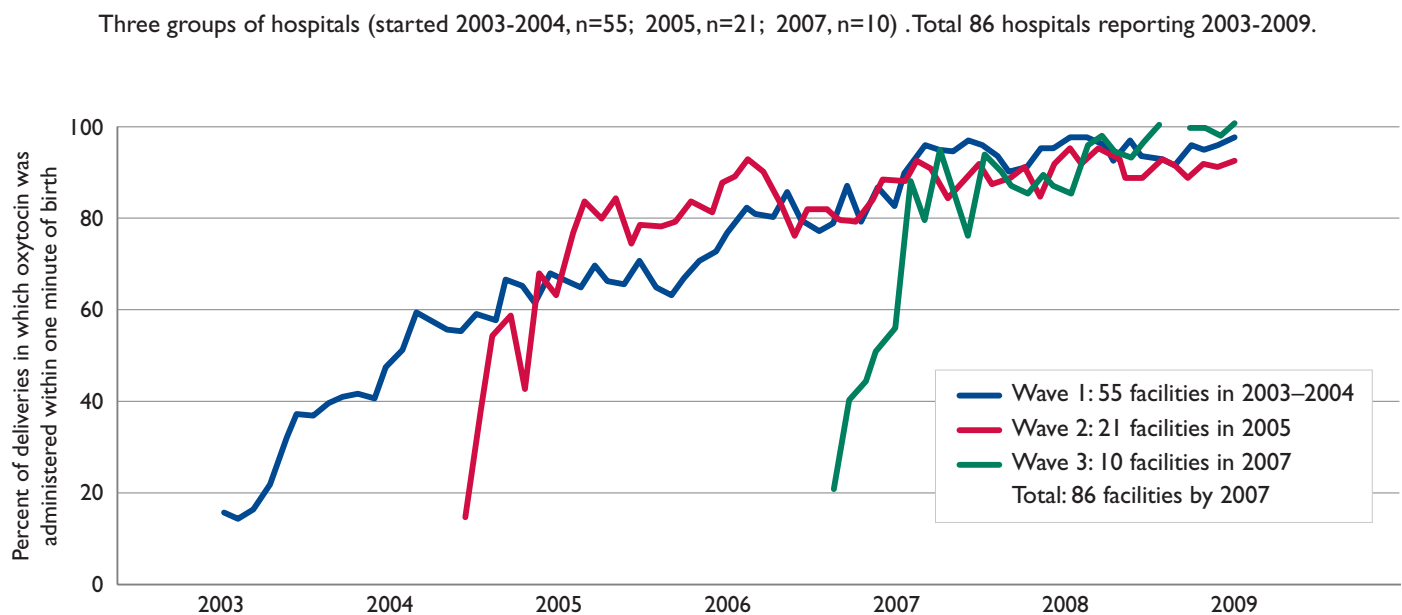
VI. Which Approach Should Be Used to Disseminate Checklists?

In the arena of patient safety, the surgical checklist tool can be combined with a health system goal to reduce the incidence of surgically related complications and deaths. Within a large public or private hospital system, consisting of 25 organizations, for instance, the collaborative methodology might make sense. Spread in multiple facilities that are connected includes building on the inputs of the individual adoption phase and facility-level spread efforts. Under this circumstance, two or three pilot units in representative facilities will pilot the checklist, testing it under a variety of conditions, after which facilities could come together, face to face, to learn from their peers and adapt the checklist to their own setting. Clear executive sponsorship and measurement of reliability with which the checklist is introduced will be crucial, and, with a resource constraint around geography, funding or travel, the same organization might choose to manage the same collaborative activity virtually or apply an extension agent model where an expert practitioner travels from site to site, introducing the intervention, collecting innovations and helping to solve emergent problems.

By contrast, spreading the checklist across an entire resource-constrained nation will require different methods; with an intervention as streamlined as the surgical checklist, it might make sense to take a so-called broad and deep approach- working intensively with a small group on advanced methods and extremely reliable results while using the campaign method to build will and awareness and initiate first tests of the new practice. If leaders seek to introduce the checklist across care settings (i.e., inpatient and outpatient) then the wave sequence approach might be powerful.

In no case is there a "correct" approach; constant adjustment and adaptation will be required to account for evolving beliefs, needs, resources and skills in the system. With whatever strategy is elected, the scale- up efforts will be as successful as the enthusiasm and commitment of those working within the system, as well as the clarity of the design. The simplicity and efficacy of the surgical checklist should lead to rapid uptake and contribute to making surgery safer worldwide—one step at a time.

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