A widely used framework for improvement, which its developers, Associates in Process Improvement, called a Model for Improvement, is based on the PDSA (plan, do, study, act) cycle and three fundamental questions: 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? This model reflects a focus on change—on developing, testing, and implementing specific, identifiable changes. In an interview with Steven Berman in February 1997, Thomas Nolan, PhD, a statistician, improvement consultant, and co-author of The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (San Francisco: Jossey-Bass, 1996), discusses methods and issues in improvement and change. Dr. Nolan can be reached at Associates in Process Improvement, 1110 Bonifant Street, Suite 420, Silver Spring, MD 20910; phone 301/589-7981; fax 301/589-0154; e-mail apiwash@ix.netcom.com.

When you refer to the 'science of improvement,’ what do you include in that science?

The science includes methods to develop, test, and implement changes that result in improvement with respect to a set of defined criteria. The knowledge that underlies these methods include an appreciation of how people and processes interact in a system, standards for the design of effective tests, and principles for the collection and analysis of data.

You did not mention any tools such as flowcharts that are commonly associated with quality improvement.

Flowcharts and other tools can be helpful, but they can be overemphasized to the point that it appears using them is the aim. If a physician were asked to describe what was included in the science of medicine, one would not expect ‘stethoscope,’ for example, to be part of the description.

You focus on ‘specific, identifiable changes,’ as apart from ‘broad or vague organizational or cultural change; but don’t you need an overall climate that facilitates making and testing changes?

It is desirable to reliably produce improvements in a variety of settings. The organizational climate in a trucking company is very different from that in a law firm. The culture in a teaching hospital is often differ-
ent from that in a community hospital. Each organization needs to improve to stay competitive and accomplish its mission. We must develop methods that are robust to different organizational cultures. However, I will admit that it is very difficult to make substantial improvement if one or more of the following ingredients are missing: a spirit of cooperation to achieve a common aim, the intention and will to make changes, and an investment of time and other resources.

How does your approach of testing change compare to the use of randomized trials with controls, which is the standard for medical research?

All the authors have been involved in the design of research studies or other complex experiments. We discuss some of these designs in the book. However, it is neither feasible nor desirable to conduct a randomized controlled trial every time we make a change to a process of care. This is not an invitation to be careless in the design of tests. As a practical supplement to randomization and the use of blind controls, we advocate the use of sequential, small-scale tests, graphical display of data to facilitate understanding of the sources of variation, and measures plotted over time to estimate the impact of change.

You and your colleagues advocate a trial-and-learning method of testing change on a small scale before making very broad changes. Doesn't the recent health care insurance legislation mandating limited, experimental use of medical spending accounts show that perhaps we have learned something, after the massive, overnight introduction of DRGs (diagnosis-related groups) in the early 1980s or of the failed Clinton health care reform initiative?

The example you cite is encouraging, but I see little evidence that the federal government is inclined to test changes routinely on a small scale. To be fair, methods for testing changes in a politically charged environment under media scrutiny are not well developed. This is an important area for research.

But it often seems that people want the changes they implement to be dramatic and large scale. How do you get them to be patient and learn to live with sequential small-scale tests of change?

Your question contains elements of some of the misunderstandings that many people have when they hear the phrase 'sequential small-scale tests of change.' My colleagues and I aim to increase the impact of improvements and the pace at which they are made.

'Small scale' refers to the size of the test or the current scope of the implementation. The change being tested could be very innovative and a significant departure from current practice. Testing a change on a small scale actually speeds up the pace and increases the impact of improvement for a variety of reasons. For example, people are less resistant to a test than to a large-scale implementation; fewer people will be involved in a small-scale test, which means less logistics to be planned. Problems with the change can be identified and corrected early on.

Why is it important to conduct tests of change under a wide range of conditions, as you suggest?

Making a change to improve a system involves a prediction that the change will be beneficial in the long run. Yet conditions in the future will be different from the conditions of the test. Circumstances will arise that were unforeseen or not present at the time of the test. It is difficult if not impossible to accurately predict all the impacts of a change. The recent recognition that air bags may be harmful for young children or very short adults sitting in the front seat of a car is an example of a change that is an improvement only under certain conditions. If a change remains an improvement over a wide range of conditions, the degree of belief in its worth is increased.

Can you cite an example of where a test of a change worked initially but not later—and how varying the conditions for the tests might have helped?

A hospital was attempting to reduce its medication errors. To decrease errors of omission, standard times for administering medications were tested on one unit. The test was very successful. Hospital administration decreed that standard administration times would be used on all units.
Patients in the unit on which the test was performed were there for a relatively long time and their medication orders were not changed very often. The change actually produced more errors on units in which patients had short lengths of stay and frequent changes of medication orders. A test including a unit of both types would have uncovered this situation.

**How can you overcome this resistance to a wide range of conditions?**

Increase the capability of the organization to design effective tests and carry them out quickly. In the above example, the administration was frustrated with the slow pace of change. They believed that the additional tests were not worth the wait.

**What do you think accounts for the tendency of health care organizations to introduce large-scale initiatives such as reengineering or clinical pathways with little or no small-scale testing?**

Most of these initiatives addressed a need or targeted a weakness in available methods. Some were useful, but they were not integrated into an overall approach. Each was thought to be the answer, replacing rather than supplementing what came before. No such approach has yet been found. In our book we integrate many of these methods into a system of improvement.

**Perhaps the most agonizing, and probably the most widely publicized, quality problem in health care is the error or mistake—such as the removal of the healthy kidney or the tenfold increase in dosage of a cancer drug. So what do we do? Is it the people? the systems? Can health care delivery be made mistake-proof?**

It is the systems that are operated by people. Progress can be made. Principles from human factors engineering and other disciplines concerned with system design should be integrated into delivery systems. Some tenfold dosage errors result from mistaking $5.0$ for $50$. Following standards for prescribing medications that forbid the use of zeros after the decimal—$5.$ rather than $5.0$—is an example of an improvement.

**As you may know, last year The Joint Commission Journal on Quality Improvement ran a four-part series of articles by Gene Nelson, Paul Batalden, and others, on ‘Improving Health Care.’ In the last article, they acknowledge their intellectual debt to you and your colleagues for methods for ‘testing change’—such as change concepts, which can spin off into specific ideas for changes that lead to improvement. Can you explain what change concepts are?**

Usually a specific, customized change is required to obtain improvement in a particular set of circumstances. Thus, the variety of changes is limitless. However, we have found that these changes are developed from a relatively small number of concepts. Our list of change concepts contains some of the most effective concepts including smooth the flow of work, do tasks in parallel, develop contingency plans, synchronize to a common point in time, standardize procedures, and use pull systems. (See Sidebar 1, pp 220–221, for examples of change concepts and applications.)

**How can an individual or a team use these concepts?**

The change concepts provoke new ideas for an individual or a team. One or more of the change concepts could be selected from the list and then the team could explore how the concept might apply to the situation under study. Usually change concepts that seem to apply to the situation are chosen, but I have seen a random selection of concepts be effective.

The list and description of the change concepts can also be used as a means to teach people about the types of changes that are consistent with knowledge of systems.

**Tom, how did you become interested in improvement and change?**

As a statistician, I have always been interested in designing tests and analyzing data, which are important methods for improvement. My association with W. Edwards Deming in the 1980s deepened my appreciation for the depth and breadth of the science of improvement and its vast potential.

**I understand that you co-chaired the Institute for Healthcare Improvement’s (IHI’s)**
Sidebar 1. Examples of Change Concepts and Their Applications

The Improvement Guide lists 70 change concepts (in 9 categories) and provides examples of their application in health care and other industries. A new set of health care examples for some of the change concepts follows.

1. Use separate processes. Given the specifics of the situation, a system can be redesigned to use multiple processes. Rather than a one-size-fits-all large or complex process, multiple versions of the process are available. Each version is tuned to the needs of different customers or users.

Example: To make their hospital safer for patients, nurses and pharmacists cooperate to design a separate process for storage and handling of lethal drugs such as potassium. The lethal drugs are stored in a central location controlled by the pharmacy except on units where they are used frequently for urgent needs.

2. Find and remove bottlenecks. A bottleneck or constraint is that part of the system that restricts the throughput of the system. Potential constraints in a health care system include people of various disciplines, equipment, and rooms. Removal of the bottleneck or mitigation of its impact can increase a system’s capacity.

Example: An emergency department found that delays were occurring because no exam rooms were available in which to see patients. The management of the department redesigned the space to provide a place within the treatment area for patients to wait for the results of tests after they had been examined by a doctor. This action removed the exam room as the constraint in the system, increasing throughput and making better use of physicians’ time.

3. Smooth the flow of work. Habit, tradition, or changes in demand cause workloads to vary significantly throughout the day or week. The labor and other resources needed to handle these peaks in demand are often wasted at other times. Costs can be reduced by looking for ways to smooth the work flow over time.

Example: A hospital pharmacy delivered all the IV (intravenous) medications for the day at a certain time in the morning. A team of nurses and pharmacists redesigned the system so that IVs were prepared and delivered multiple times during the day. This resulted in a 30% reduction in the number of IVs prepared, in part because it was easier to respond to changes in medication orders.

Breakthrough Series Collaborative on Reducing Delays and Waiting Times—a project involving 23 health care organizations attempting to significantly reduce delays in their systems. What have you learned about improvement and change from that project?

The project, which I led in cooperation with Marie Schall from IHI, was quite successful. Reductions of 50% or more in delays or waiting times were achieved by many of the organizations. Others obtained more modest results. Many of the methods in our book, such as the use of change concepts, testing changes on a small scale, and the use of measures plotted over time, proved to be useful in this setting (see Sidebar 2, p 222, for an example).

However, the experience taught me a lot about what leaders must do to manage the myriad change efforts in their organizations. The approach that Marie and I used entailed helping people set clear and focused aims, using simple measurement systems to track the progress of multiple projects, encouraging action, and helping people see the larger system context of their work.

Methods for senior leaders to effectively manage numerous large-scale improvement efforts may be one of the most important outcomes that result from the IHI Breakthrough Series.

And what have you learned about collaboration?

People and organizations will cooperate willingly given an environment that is conducive to doing so. Even organizations that competed with one another in local markets exchanged ideas for improvement. Delays are inherently part of poorly designed systems, and cooperation between departments and professions was necessary to reduce them.

Finally, with all the concern about cost cutting, is there still room for improvement?

Cost cutting, if obtained by redesign of the system of care, is a form of improvement. Market pressures dictate that investment must be made in cost-cutting efforts. If this work is combined with other efforts to improve quality, better value for customers will result.
4. Standardize. The use of standards or a standard process has a negative connotation to many people. However, an appropriate amount of standardization can provide a foundation on which to improve quality and cost. Effective standardization focuses only on the parts of the system for which reduced variation would affect costs or quality.

Example: A large hospital found that the admission and discharge criteria for its intensive care unit (ICU) were not used. More than 30% of the patients in the ICU did not meet the criteria. After some minor revisions in the criteria, the physicians and hospital staff agreed to a standard process concerning the admission and discharge of patients to the unit. The percentage of patients not meeting the criteria dropped from more than 30% to less than 5% and remained at that rate.

5. Use pull systems. In a pull system of service, the timely transition of work from one step in the process to another is the primary responsibility of the subsequent (that is, downstream) process—for example, the ICU orchestrating the transfer of the patient from the emergency department. This is in contrast to most traditional "push systems," in which the transition of work is the responsibility of the upstream (that is, prior) process—for example, the emergency department (ED) trying to "push" patients into the ICU.

Example: A health system aimed to reduce the number of repeat visits to the emergency department for acute asthma. Many of the patients were not managing their asthma with the help of a primary care doctor. The ED and several primary care practices cooperated to set up a pull system to get the patients to the primary care doctor after an ED visit. The primary care practices reserved certain dates and times for visits for asthma problems and authorized the ED to fill them. These appointments could then be given directly to the patients during their ED visits. This pull system and other changes resulted in better management of this chronic disease and in fewer return visits to the ED.

6. Synchronize to a point in time. Production of products and services often involves multiple processes operating simultaneously that are timed relative to each other—the surgeon comes to the operating room after the preparation and induction processes have been completed. To reduce variation, the processes are synchronized to a point in time—the surgeon enters the operating room at a specified time.

Example: A surgery department defined the start of a case as incision time. All processes leading up to the start of the case were then designed to be completed at a time consistent with the designated incision time. This change and other changes resulted in more than a 50% reduction in delays of the start of cases throughout the day.
Sidebar 2. Case Study: Reduction of Inappropriate Intensive Care and Transitional Care Utilization

Connie Sixta, Vice President, Operations, York Hospital, York, Pennsylvania

**Background:** York Hospital, York, Pennsylvania, is a 558-bed community teaching hospital in the York Health System. From 1993 to 1995 the hospital experienced an increasing demand for both intensive care unit (ICU) and transitional care unit (TCU; step down) beds. Even though a construction project in 1994 increased the number of both kinds of beds, the demand continued to exceed the capacity. Administration, nursing, and physicians suspected inappropriate utilization of ICU and TCU beds as the cause of our insufficient bed capacity. The high inappropriate utilization of beds was costly and a source of delay in transfer of patients from the emergency department. An improvement effort to reduce the inappropriate utilization was launched as part of a larger initiative to reduce delays of transfer of patients throughout the hospital. This initiative was accomplished as part of participation in the Institute for Healthcare Improvement's (Boston) collaborative effort on Reducing Waits and Delays.

**Aim:** Significantly reduce the number of patients in ICU and TCU who did not meet the admission criteria.

**Cycle 1:**
- We had a hunch that if we used a physician-friendly, nurse-managed process of daily evaluation of patients according to well-defined criteria for occupancy in the unit, we could achieve appropriate utilization of the ICU and TCU beds. We charged the critical care committee with revision of the admission and discharge criteria for the units. Once the criteria were revised and appropriate approval was obtained, we planned to test the criteria on a small scale using one medical-surgical ICU. The test involved the use of the criteria as part of a daily collaborative evaluation of each patient by the appropriate physician and staff registered nurse (RN).
- We chose this unit for the first test primarily because we had a staff RN with excellent credibility and communication skills who was willing to manage the test. The RN champion taught the admission and discharge criteria and the use of the related monitoring tool to the RNs in the selected ICU. The RNs in turn familiarized the attending physicians on a one-to-one basis with the revised admission and discharge criteria. The RN and physician applied the criteria to each patient being considered for admission. If the patient did not meet the criteria, he or she was transferred from the unit.
- Baseline data, obtained for the four-week period between June 1 and June 30, 1995, showed that 16 (>35%) of the 45 patients in the medical-surgical ICU did not meet the admission criteria. Results within four weeks of the implementation of the new process showed that 6 (<12%) of the 53 patients in the medical-surgical unit did not meet the criteria.

**Cycle 2:**
- The success of cycle 1 generated interest in the remaining ICUs and TCUs. We then began to implement cycle 2, which essentially was a repeat of cycle 1, in each of those units. By January 1996, our results showed that 2 (<3%) of the 262 patients in all the ICUs and TCUs did not meet the admission criteria. We had achieved our aim.

**Cycle 3:**
- In fall 1996 we completed cycle 3, which was a test to determine whether we could retain the gains that were obtained nine months earlier. In June 1996 we again found that <3% (6 of 288) patients in the ICUs and TCUs did not meet the admission criteria, indicating that we had maintained our results during the intervening time—supporting evidence that our original changes made a lasting impact (see Figure 1, above).

**Conclusion:** Use of appropriate admission and discharge criteria enabled us to reduce our occupancy rates in the ICUs and TCUs. Moreover, the lower occupancy rate contributed to a significant decrease in the delay of transfer of patients to the ICU and TCU beds from the emergency department.
Description of chart: This chart shows a bar chart with annotations for each cycle. The annotations appear as an arrow pointing halfway between each month period for cycles 1 and 2 and directly at the bar for cycle 3.

## Reduction of Inappropriate Utilization of the Intensive Care Units (ICUs)

<table>
<thead>
<tr>
<th>Percentage of Cases Not Meeting Criteria</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>37</td>
<td>Jun-95</td>
</tr>
<tr>
<td></td>
<td>Cycle 1 (one ICU)</td>
</tr>
<tr>
<td>12</td>
<td>Aug</td>
</tr>
<tr>
<td></td>
<td>Cycle 2 (all ICUs)</td>
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<tr>
<td>10</td>
<td>Sep</td>
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<td>8</td>
<td>Oct</td>
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<td>9</td>
<td>Nov</td>
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<td>10</td>
<td>Dec</td>
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<tr>
<td>3</td>
<td>Jan-96</td>
</tr>
<tr>
<td></td>
<td>Cycle 3 (hold the gains)</td>
</tr>
<tr>
<td>3</td>
<td>Oct</td>
</tr>
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