PART I

USING DATA FOR IMPROVEMENT
This book is about using data to improve health care and this chapter, a summary of *The Improvement Guide*, describes approaches and methods used to make improvements. It provides a backdrop, setting the stage for understanding and contextualizing the rest of the book. This chapter will:

- Describe the Model for Improvement
- Illustrate use of the Plan, Do, Study, Act Cycle for testing and implementing changes
- Introduce graphical methods to learn from data
- Describe a typical health care improvement project
- Enumerate the methods and tools used to support improvement

How do you make improvements? Historically people have used a trial-and-error approach to improving all aspects of their lives. Typically an idea for an improvement (a change) comes to someone. These ideas are often reactions to problems or difficulties that we all face in life and in our work. So we make the change and then see whether the situation improves. Sometimes we also check to see if anyone complains or if something else stops working because of the change that we made. Because of its sporadic track record on real, sustainable improvement, this natural trial-and-error approach has often been criticized as “jumping to solutions” without sufficient study.

As a response to this criticism, some improvement specialists have turned to extensive study of the problem before a change or trial is attempted. Sometimes this approach leads to a better track record on making sustained improvements, but more often it can lead to never actually making changes. The person with the problem gets bogged down in the study, “paralysis by analysis” sets in, or other problems begin to take priority. Many health care professionals are trained in research methods with strict protocols, rigid data requirements, and large sample sizes. When they begin work on improvement projects, they naturally bring this training to the project. How do we obtain a balance between the trial-and-error approach and extensive study that may never lead to action? How do we find the balance between the goals of formal clinical research and the natural learning and improvement from daily work in health care?

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This chapter presents a **Model for Improvement**\(^3\) that attempts to provide that balance. The model provides a framework for developing, testing, and implementing changes that lead to improvement. The model can be applied to improving aspects of one’s personal endeavors, as well as the improvement of processes, products, and services in health care organizations. The model attempts to balance the desire and rewards from taking action with the wisdom of careful study before taking action. The use of data in this book will frequently be connected to an individual or an improvement team that is using the Model for Improvement to guide their learning and execution.

**FUNDAMENTAL QUESTIONS FOR IMPROVEMENT**

The Model for Improvement is based on three fundamental questions:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What change can we make that will result in improvement?

The model is also based on a “cycle” for learning and improvement. Variants of this improvement cycle have been called the Shewhart Cycle, Deming Cycle, and PDSA Cycle. The cycle promotes a trial-and-learning approach to improvement efforts. The cycle is used for learning, to develop changes, to test changes, and to implement changes. Figure 1.1 contains a diagram of the basic form of the model.

Why are we promoting the use of this particular approach to improvement? Our experience with the Model for Improvement since its development in the 1980s shows that it:

- Is useful for both process and product improvement
- Is applicable to all types of organizations

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\(^3\)Ibid.
IMPROVEMENT METHODOLOGY

- Is applicable to all groups and levels in an organization
- Facilitates the use of teamwork to make improvements
- Provides a framework for the application of statistical tools and methods
- Encourages planning to be based on theory
- Emphasizes and encourages the iterative learning process
- Provides a way to empower people in the organization to take action

This framework is compared to other frameworks used in quality improvement (such as Six Sigma’s DMAIC) in Appendix C of *The Improvement Guide.* The use of the Model for Improvement begins with trying to answer the three basic questions.

What Are We Trying to Accomplish?

Before starting to develop any activities, or test or implement changes, participants and other stakeholders in the improvement effort need to agree on *what is to be accomplished.* The use of a well-written **aim statement** can be an effective tool for answering the first question in the Model for Improvement. If there is not a common understanding between people who are depending on the aim statement for guidance, then individuals will naturally try to fill the void of understanding with their personal view of what is to be accomplished. These well-intentioned efforts usually lead to misunderstandings—during team meetings and other activities—that will not achieve the intended accomplishments, ultimately resulting in wasted time, resources, and frustration for everyone involved. The written aim can be a formal document (sometimes called a charter) from a hospital’s strategic planning process or it can be a statement written on the whiteboard by a group of nurses and physicians brainstorming more effective care of their patients.

Why take the time to develop an aim statement for an improvement effort? A statement of the aim:

- Provides leaders a mechanism to think through all aspects of the proposed effort
- Aids in selection of the team to make the improvements
- Reduces variation in activities from the original purpose
- Helps in the selection of particular processes or products for study
- Empowers individuals to make changes in health care systems
- Clarifies the magnitude of improvement expected from this project
- Defines the time frame for the improvement work

Individuals or teams can complete improvement efforts. In many health care organizations, teams composed of two to seven people are given assignments to make improvements. The members of the team should be selected from those who are knowledgeable about the processes or services that are likely to be studied, or who have a stake in their performance. A well-thought-out aim statement will aid in the selection of team members.

Without a clear aim statement, it will be easy for a team to become sidetracked and work in areas that are only of minor relevance to the original purpose of the improvement activities. The team will also struggle with the appropriate scope of the activities. The aim statement will help the team focus its efforts and reduce unwanted variations from the original purpose.

Good aim statements are clear, concise, and results oriented. They should be aligned with the goals of the organization sponsoring the improvement to clarify why the work is being done. Teams make better progress when they have unambiguous, specific aims.

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4Ibid.
Setting numerical targets can further define the intent of the charter, create the will for change, and help focus measurements used in the improvement effort. Numerical goals can also be abused and lead to bad practices, so those providing a goal should convince the team that the goal is feasible by:

- Providing the level of support and resources that will be required to achieve the goals
- Observing other organizations that have made similar accomplishments
- Providing some basic ideas that could feasibly result in achieving the goals
- Demonstrating the benefit to the organization if the goals could be achieved

Other guidance given in the aim statement should include anything and everything to keep the team focused (strategies, resources, boundaries, patient populations, time and resource constraints, and so on). The following is an example of an aim statement for a team planning on improving care of asthma patients in a clinic:

**AIM STATEMENT**

During the next six months, the clinic’s practice will be redesigned to obtain a 30% increase in symptom-free days and a 50% reduction in the number of exacerbations reported for the pilot asthma population. At least 90% of patients with persistent asthma will be treated with maintenance anti-inflammatory medication and >80% of patients will have a completed written action plan.

**Guidance:** All patients with asthma (about 400 in population) of the Neighborhood Health Center will serve as the pilot population for this project. A registry of the asthma patients served by the center should be developed. The clinic should initially focus on patient self-management methods and delivery system design. All physicians in the center will participate.

This is an example of an aim statement for a hospital Emergency Department’s team formed to improve patient satisfaction in the ED:

**AIM STATEMENT**

Redesign Emergency Department processes to increase patient and family satisfaction with their experience in the ED by greater than 30% before June 2010.

**Guidance:** Focus on all aspects of the emergency department and related services. Emphasize improvements in physical comfort, coordination of care, management of the waiting time, and family involvement. The aim will be measured by the percentage of patients who say they would recommend the ED to a friend. The changes need to work with existing staffing levels.

**How Will We Know That a Change Is an Improvement?**

Although improvement is about making changes to processes and systems, measurement plays a key role in all improvement efforts. The purpose of measuring here is for learning, not for judgment or comparison. Project teams need measures to give them feedback that the changes they are making are having the desired impact. \(^5\)

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Some measures should focus at the project level (global measures) and be maintained throughout the project. For example, symptom-free days may be an appropriate global measure for a project improving asthma care. Other measures are done on an as-needed basis as part of PDSA Cycles for diagnosis and for assessment of the changes tested. For example, in an asthma project, the percent of patients using appropriate medications might be a useful Cycle measure.

The team in the ED department (aim statement given above) used the following as global measures for their improvement efforts:

- Percentage of patients saying they would recommend the facility to friends on the monthly patient satisfaction survey
- Percentage patients satisfied on specific questions concerning physical comfort, coordination of care, and, family involvement
- Average waiting time for patients visiting the ED

For specific PDSA Cycles, the team planned to use other measures to evaluate the impact of the changes they would test. The Cycle measures would include interviews with providers, staff, and patients affected by tests, and more specific time measures to understand waiting times.

Because improvements are made over time, in order to facilitate learning and communication, measures should be displayed on run charts or Shewhart charts, which are the major focus of the rest of this book. The time-ordered charts of a set of global measures will provide the primary way to assess the impact of each project team’s work. Rather than just doing a before-and-after assessment, feedback from the measures is consistent and ongoing throughout the project. This approach gives teams the opportunity to work on data collection problems and to communicate their progress every month of the project. Key changes made to care systems can be annotated on the charts to begin analysis of the impact of the changes.

What Changes Can We Make That Will Result in Improvement?

Sometimes when confronted with this third question of the Model for Improvement, the answer is obvious. The knowledge to support a specific change has existed for some time, but the conditions, resources, or inclination did not exist to make the change happen. Other times a change that will result in improvement is not known or not apparent. As changes are not readily available, people have a tendency to resort to some common and often ineffective ways of developing change, such as using more of the same (more people, more money, more time, more exhortations, more inspection, more controls, and so forth) or trying to develop the one perfect change.

Developing a change that will help accomplish the project aim usually requires making a fundamental change to the system. In developing changes, it is useful to think about two types of change:

- Changes that are needed to keep the system performing at current levels (first-order change)
- Changes that are needed to improve the system or create a new system (second-order change)
Making first-order changes when they are needed is an important activity, but it should not be confused with implementing second-order changes that prevent problems from occurring. Most improvement efforts require second-order changes because they:

- Require design or redesign of some aspect of the system
- Are necessary for improving a system that does not have many problems
- Fundamentally alter how the system works and what people do in the system
- Often result in improvement of several measures simultaneously
- Have an impact that is felt far into the future

A second-order change can be made by redesigning part of the current system or by designing an entirely new one. Eliminating part or all of the system may be a second-order change. The important notion is not the size of the change but the impact of the change. Big improvements can often be realized by making small changes directed at the right places in the system.

Second-order changes can be developed by critical thinking about the current system, learning from approaches in other organizations, using new technology, applying creative thinking methods, or by using concepts that have worked in other improvement situations. For complex projects, it is often useful to first develop a concept design and then follow with PDSA Cycles to test changes to support the concept.

THE PDSA CYCLE FOR IMPROVEMENT

To help individuals and teams test, adapt, and implement changes, the Model for Improvement uses the Plan, Do, Study, Act Cycle (PDSA) as the framework for an efficient trial-and-learning methodology. The cycle begins with a plan and ends with action taken based on the learning gained from the Plan, Do, and Study phases of the cycle. The four steps in the cycle consist of planning the details of the study, test, or implementation and making predictions about the outcomes (Plan), conducting the plan and collecting data (Do), comparing the predictions to the data collected (Study), and taking action based on the new knowledge (Act). Figure 1.2 describes the activities for each step of the PDSA Cycle.

Knowledge is built by an iterative process of developing a theory, making predictions based on the theory, testing the predictions with data, improving the theory based on the results, making predictions based on the revised theory, and so forth. Tests of change are designed to answer questions that come from a combination of theory about the subject matter and conclusions from analysis of data from past studies. When designing studies for testing a change, the planned tests should match this sequential nature of building knowledge.

Each PDSA Cycle is designed to answer specific questions related to the team’s aim. Each cycle should build on the current knowledge about the changes being considered and answer specific questions required to implement the change into standard practice. Numerous small-scale cycles accumulate into large effects through synergy. Figure 1.3 illustrates this process.

In a typical improvement effort, most PDSA Cycles are designed to test and adapt changes. Developing a good plan is critical for an effective, successful test cycle. The plan

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begins with a statement of the specific objective of the cycle. **Cycles to test a change** will have varying objectives depending on the current degree of belief about the change. Some typical objectives of a PDSA test are:

- Increasing degree of belief that the change will result in an improvement
- Deciding which of several proposed specific changes will lead to the desired improvement
- Evaluating how much improvement we can expect if we make the change
- Deciding how to adapt the proposed change to the actual environment of interest
The objective of the cycle described at the beginning of the plan step will clarify the specific focus of testing the change. After agreeing on the objective, the team should state the specific questions to be answered in the cycle. These questions provide the format for describing the team’s predictions about the change(s) that will be tested in the cycle. The predictions should be worded in such a way that the results of the tests conducted in the cycle can be compared to the predictions. Thus, stating the predictions will have an impact on the data collection plan of the cycle.

Next, the team develops a plan for the test. The plan should include:

- Who will schedule and conduct the test?
- Exactly what changes will be made?
- Where will the test be conducted?
- When will the test be done?
- What data will be collected to answer the questions in the cycle?

Some hints for planning useful cycles for testing changes include:

- Think a couple of cycles ahead of the initial test (future tests, implementation).
- Scale down the size and decrease the time required for the initial test.
- Do not try to achieve buy-in or consensus for the test; recruit volunteers for the test.
- Use temporary supports to make the change feasible during the test.
- Be innovative to make the test feasible.

In the Do step of the cycle, the test is performed and the data collected is analyzed. The information obtained during this step should prepare for the Study step. What if the test of a change is not successful? There are a number of possible reasons:

1. The change was not properly executed.
2. The support processes required to make the change successful were not adequate.
3. The change was implemented successfully but the results were not favorable.

Information should be obtained during the Do step to clearly differentiate which of these situations occurred.

The third step of the PDSA Cycle for testing, Study, brings together the predictions made in the Plan step and the results of the test conducted in the Do step. Comparing the results of the data analysis with the predictions made for the specific questions asked during the planning step creates this synthesis. This point is where learning occurs and where the degree of belief about the change can be increased. If the results of the test match the predictions, our degree of belief about our knowledge is increased. If the predictions do not match the data, we have an opportunity to advance our knowledge through understanding why the prediction was not accurate.

In the Act step of the PDSA Cycle for testing a change, the project team must decide on the next course of action:

- Is further testing needed to increase our degree of belief about the change?
- Do alternative changes need to be tested?
- Do we need to learn about other implications (such as costs) of the change?
IMPROVEMENT METHODOLOGY

- Are we ready to implement the change on a full-scale basis?
- Do we need to modify the proposed change or develop an alternative change?
- Should we drop consideration of the proposed change?

The decision on course of action will lead to developing the next PDSA Cycle. The use of multiple cycles allows knowledge to increase as we progress from testing to implementing a change, thus minimizing risk and consequences of any failures. As degree of belief that the change will be successful is increased, the scale of the test can be increased. Based on the results of a test, a change or some part of the change could be implemented as is, the change could be modified and retested, or it could be abandoned.

**Cycles for implementing a change** differ from test cycles in a number of ways:

- Support processes need to be developed to support the change as it is implemented.
- Failures are not expected when the change is implemented.
- Increased resistance to the change can be expected as it affects more people.
- Cycles for implementing a change take longer than test cycles.

Figure 1.4 summarizes the use of the PDSA Cycle to test and implement changes.

**Tools and Methods to Support the Model for Improvement**

The Model for Improvement with its cycle for learning and improvement provides the structure and road map for accomplishing improvement of health care processes. In many improvement efforts, that is all that is required. Other times, teams get stuck looking for an idea or trying to understand the problems in the current process. Over the past fifty years, the quality improvement profession has developed methods and tools to assist with the improvement process, which are described in Table 1.1. Many of the tools commonly used in improvement projects are shown in Table 1.2.

**FIGURE 1.4 PDSA Cycles from Testing to Implementation**

7Langley et al., *The Improvement Guide*, Appendix C.
When thinking about these tools, it is important to keep a perspective on the improvement initiative. If the aim can be accomplished without the use of any of the tools, then they do not need to be used. They exist to provide additional insight when solutions are not obvious. In this book, the tools most closely associated with statistical process control (Shewhart charts, run charts, frequency plots, Pareto charts, and scatter plots) will be emphasized.

### Designing PDSA Cycles for Testing Changes

The art of effective use of the Model for Improvement is the design of useful PDSA Cycles to test changes. Three basic principles of testing a change will help increase the rate of learning about changes:

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### Table 1.1 Overview of Methods for Improvement

<table>
<thead>
<tr>
<th>Category</th>
<th>Method</th>
<th>Typical Use of Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viewing Systems and Processes</td>
<td>Dynamic Programming</td>
<td>Map relationships with mathematical equations and then simulate performance.</td>
</tr>
<tr>
<td>Gathering Information</td>
<td>Surveys</td>
<td>Obtain information from people.</td>
</tr>
<tr>
<td></td>
<td>Benchmarking</td>
<td>Obtain information on performance and approaches from other organizations.</td>
</tr>
<tr>
<td></td>
<td>Creativity Methods</td>
<td>Develop new ideas and fresh thinking.</td>
</tr>
<tr>
<td>Organizing Information</td>
<td>Quality Function Deployment (QFD)</td>
<td>Communicate customer needs and requirements through the design and production processes.</td>
</tr>
<tr>
<td></td>
<td>Failure Mode and Effects Analysis (FMEA)</td>
<td>Used by process and product designers to identify and address potential failures.</td>
</tr>
<tr>
<td></td>
<td>Problem Solving</td>
<td>A collection of concepts and tools (is/is not, five why’s, stratification) to address the special case of improvement where a problem has been identified.</td>
</tr>
<tr>
<td>Understanding Variation</td>
<td>Statistical Process Control</td>
<td>A philosophy and a set of methods for improvement with its foundation in the theory of variation. SPC incorporates the concepts of an analytic study, process thinking, prevention, stratification, stability, capability, and prediction.</td>
</tr>
<tr>
<td></td>
<td>Measurement System Analysis</td>
<td>Procedures to understand the impact of bias and precision of the measurement process on variation in data.</td>
</tr>
<tr>
<td></td>
<td>Statistical Methods</td>
<td>Graphical and numerical procedures to help understand and quantify patterns of variation in data.</td>
</tr>
<tr>
<td>Understanding Relationships</td>
<td>Planned Experimentation</td>
<td>Design studies to evaluate cause-and-effect relationships and test changes.</td>
</tr>
<tr>
<td>Project Management</td>
<td>PDSA Cycle</td>
<td>Method for organizing learning, testing, and implementing during an improvement project.</td>
</tr>
</tbody>
</table>

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8Langley, J. et al., *The Improvement Guide.*
<table>
<thead>
<tr>
<th>Category</th>
<th>Tool</th>
<th>Typical Use of Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Linkage of Processes</td>
<td>Develop a picture of a system composed of processes linked together.</td>
</tr>
<tr>
<td></td>
<td>Causal Loop Diagrams</td>
<td>Identify reinforcing and balancing processes.</td>
</tr>
<tr>
<td>Gathering Information</td>
<td>Form for Collecting Data</td>
<td>Plan and organize a data collection effort.</td>
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<td></td>
<td>Operational Definitions</td>
<td>Provide communicable meaning to a concept by specifying how the concept will be applied within a particular set of circumstances.</td>
</tr>
<tr>
<td>Organizing Information</td>
<td>Affinity Diagram</td>
<td>Organize and summarize qualitative information.</td>
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<tr>
<td></td>
<td>Force Field Analysis</td>
<td>Summarize forces supporting and hindering change.</td>
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<tr>
<td></td>
<td>Cause and Effect Diagram</td>
<td>Collect and organize current knowledge about potential causes of problems or variation.</td>
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<tr>
<td></td>
<td>Matrix Diagram</td>
<td>Arrange information to understand relationships and make decisions.</td>
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<tr>
<td></td>
<td>Tree Diagram</td>
<td>Visualize the structure of a problem, plan, or any other opportunity of interest.</td>
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<tr>
<td></td>
<td>Interrelationship Diagram</td>
<td>Identify and communicate logical and sequential connections between components of a problem.</td>
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<tr>
<td></td>
<td>Radar Chart</td>
<td>Evaluate alternatives or compare against targets with three or more variables or characteristics.</td>
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<tr>
<td></td>
<td>Driver Diagram</td>
<td>Display the theory for improvement in an improvement project.</td>
</tr>
<tr>
<td>Understanding Variation</td>
<td>Run Chart</td>
<td>Study variation in data over time; understand the impact of changes on measures.</td>
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<tr>
<td></td>
<td>Pareto Chart</td>
<td>Focus on areas of improvement with greatest impact.</td>
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<tr>
<td></td>
<td>Frequency Plot</td>
<td>Understand location, spread, shape, and patterns of data.</td>
</tr>
<tr>
<td></td>
<td>Shewhart Chart</td>
<td>Distinguish between special and common causes of variation.</td>
</tr>
<tr>
<td>Understanding Relationships</td>
<td>Two-Way Table</td>
<td>Understand cause-and-effect for qualitative variables</td>
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<tr>
<td></td>
<td>Scatter Plot</td>
<td>Analyze the associations or relationship between two variables; test for possible cause-and-effect.</td>
</tr>
<tr>
<td>Project Management</td>
<td>Gantt Chart</td>
<td>Organize the project tasks over time with key milestones identified.</td>
</tr>
<tr>
<td></td>
<td>PERT Chart</td>
<td>Display the sequential relationships of the project tasks and determine the critical path.</td>
</tr>
<tr>
<td></td>
<td>Work Breakdown Structure</td>
<td>Develop a hierarchical relationship between the tasks on a project.</td>
</tr>
</tbody>
</table>
● Initially test on a small scale and build knowledge sequentially.
● Collect data over time.
● Include a wide range of conditions in tests in latter cycles.

Following these principles will result in conducting tests where the effects observed can be clearly tied to the change of interest. Often, the simplest way to design a PDSA Cycle is to make the change and study run charts of the global measures and specific measures relevant to the cycle before and after the change. But even with run charts over a long period of time, it is always possible that some other cause that occurred near the same time that the change of interest was made could be responsible for the observed effects. Some other ways to increase the rigor of the test include:9

● Remove the change and see if the process returns to its initial levels. This can be repeated as many times as necessary (make the change, observe results over time, remove the change) until an adequate degree of belief is obtained.
● Adding some type of comparison group or control group to the study. The same measures would be made for the comparison group as for the environment where the change is made. A run chart for the control group can then be compared to the environment undergoing the change.
● Use the methods of planned experimentation to separate effects of changes of interest and background variables.

Planned experimentation10 is a collection of approaches and methods to help increase the rate of learning about improvements to systems, processes, and products. An experiment is a change to a process or product and an observation of the effect of that change on one or more measures of interest. The methods of planned experimentation are appropriate for understanding the important causes of variation in a process and evaluating multiple changes to the process. Using these methods, it is possible to design a single PDSA Cycle to evaluate multiple changes. Planned experimentation allows the determination of the individual (main effects) and combined effects (interactions) for the changes being evaluated.

The theory of applying planned experimentation to improvement activities was described by Deming.11 He differentiated studies designed to understand a fixed population (enumerative studies) from studies designed where the population of interest was in the future (analytic studies). Whereas enumerative studies are used to develop estimates of the population, the ability to predict future results is the focus of analytic studies. The approaches and methods in this book have their foundation in Deming’s analytic studies framework. Chapter Two provides further discussion of analytic studies.

Planning one large PDSA Cycle in a study to attempt to get all of the answers should almost always be avoided. Testing the change during full-scale implementation should be considered only when:

- The team has a high degree of belief that the change will result in improvement.
- The risk is small (losses from a failed test are not significant).
- The team cannot find a way to test the change on a small scale.

During the design of studies to test a change, those responsible for developing the change should continually be asking themselves how they could reduce the risks of the test and still gain some knowledge. The following are some ways to design a test on a small scale:

- Simulate the change (physical or computer simulation).
- Have others in the organization with knowledge of the change review and comment on it.
- Have members of the project team test the change before introducing it to others.
- Incorporate redundancy in the test; make the change side-by-side with the existing process.
- Conduct the test in one facility in the organization, or with one group of patients.
- Conduct the test over a short time period (one hour or one day).
- Test the change with a small group of volunteers.

One of the most common designs for a test of change is the “before and after test” (or pretest/posttest design). In this design for a test, a change is made and the circumstances after the change are compared to the circumstances before the change. The collection of data before the change provides the historical experience that is the basis of the comparison. When considering the design of a PDSA test, a run chart that includes multiple measurements before and after the change is made provides minimal complexity and excellent protection from misinterpreting the results of the test.

Figure 1.5 shows the results of such a before-and-after test. Data was collected on week 4, the change was made during week 7, and then data was collected again on week 11. The reduction in delay time from 8 hours to 3 hours was considered very significant for the process of interest. The bar chart in Figure 1.5 shows a summary of the test data.

Summarized in this way, does this test provide an adequate degree of belief that the change, when implemented, will lead to an improvement? Are there other feasible explanations of the reduction in delay time after the change was introduced?

The run chart at the bottom of Figure 1.5 (Case 1) shows one possible scenario that could have yielded the results observed in the test. The delay on week 4 is 8 hours and the delay on week 11 is 3 hours as described by the before-and-after bar chart. The run chart shows results for delay times for weeks 1 to 14 (three weeks before the change was made until three weeks after the second test observation was made) is shown. The run chart in Case 1 confirms the conclusion that the change did result in a meaningful improvement.
Figure 1.6 shows run charts for five other possible scenarios that offer alternative explanations of the test results. In each case a run chart of delay time for weeks 1 to 14 is shown. The test results for week 4 (delay time of 8) and week 11 (delay time of 3) are the same for all cases.

In Case 2 there is no obvious improvement after the change is made. The measures made during the test are typical results from a process that has a lot of week-to-week variation. The conclusion from study of the run chart is that the change did not have any obvious impact on the delay time.

In Case 3 it appears that the process has been steadily improving over the 14-week period. The rate of improvement did not change when the change was introduced. Although the delay time for the process has certainly improved, there is no evidence to show that the change made any contribution to the steady improvement in the process over the 14 weeks.

In Case 4 an initial improvement is observed after the change is made, but in the last three weeks the process seems to have returned to its prechange level of delay time. The results may be due to a “Hawthorne effect,” which is named after some tests on productivity conducted at the Western Electric Hawthorne plant in the 1920s. Whenever changes were made in the work environment, initial improvements were observed. But performance quickly returned to normal levels after workers became accustomed to the change. This effect is similar to a “placebo effect.” Because the workers are focused on
the process and paying particular attention to the measures of interest, observers see an initial improvement. Later, when focus on the change is lessened, the delay times revert to the original process levels.

In Case 5, an improvement in the process delay times has occurred, but it appears that the improvement occurred in week 5 before the change was made after week 7.
The improvement in delay time should be attributed to some other phenomenon, not the change of interest.

In Case 6 the process appears to be consistent, except for an unusual result that occurred in week 4 when the pretest results were obtained. The strange high result on week 4 made it appear that the more typical result on week 11 was an improvement. Once again, there is no evidence that the change contributed to any improvement. (Note: a visual analysis was used to interpret these run charts. Chapter Three will introduce some more formal analysis methods.)

From this example, it is obvious why the simple before-and-after test is often not rigorous enough to increase degree of belief about a change in an analytic study. This design should only be used when the change has had previous testing and has proven effective in a wide variety of environments. Then the test is being done to confirm performance in the specific environment of interest or to measure side effects of the change.

What can be done to increase the rigor of the before-and-after test in other situations? Often, the simplest alternative is to conduct the test over a longer time period, both before and after the change is made. Plotting the test results on a run charts like those shown in Figure 1.6 usually will provide convincing evidence of the effect of the change.

**Analysis of Data from PDSA Cycles**

The specific approach to analysis of data from a PDSA Cycle will differ depending on the design of the study that is conducted. Classical statistical methods based on hypothesis tests, confidence intervals, or probability analysis usually are not applicable because of the nature of the analytic studies in improvement work (described earlier in this chapter and discussed in more detail in Chapter Two). Knowledge of the subject matter is important in studying the results of tests of a change. The following elements will usually be part of the analysis of all tests of change:

1. Initially show all the data.
2. Plot the raw data in the order in which the tests were conducted. This is an important means of identifying the presence of trends and unusual results in the data.
3. Rearrange this plot to study other potential sources of variation that were included in the study design, but not directly related to change under study. Examples of such variables are patient categories (age, sex, comorbidities, and so on), hospital, operating room, clinic, physician, laboratories, and other environmental conditions.
4. Use graphical displays to assess how much of the variation in the data can be explained by the change(s) of interest. These displays might include using different symbols to identify the change or ordering the test results to highlight data before and after the change.
5. Summarize the results of the study with appropriate graphical displays.

The following example illustrates these approaches to analyzing the results of PDSA Cycles.

A health care organization was concerned about the long wait from diagnosis to treatment for certain types of cancer. A change in scheduling procedures was developed in an attempt to reduce the delays. The change was piloted for five weeks in one geographic area. Figure 1.7 shows an analysis of the data collected to evaluate the change. The three hospitals in the area reported the average wait time to treatment for cancer patients over an 11-week period. The change in scheduling was introduced after week 6 in each of the hospitals.

The first run chart (see Chapter Three for details on run charts) in Figure 1.7 shows the data from each hospital in time order. No unusual results or unexpected changes are obvious. There appeared to be a slight downward trend in the data after week 6.
The second run chart separates the data for each hospital. There are obvious differences in average waiting times from the three hospitals. From this graph, it appears that there was no change in Hospital A. After investigation, it was found that the new scheduling procedure was not properly implemented in Hospital A. But both Hospitals B and C had properly implemented the change.

The third graph in Figure 1.7 summarized the effects of the scheduling change in the three hospitals. Based on these results, the health care organization spread the
implementation of the scheduling change to the rest of their system, expecting about a 12- to 15-day improvement in the waiting time after the method was properly implemented.

This example illustrates the general approach to analyzing data from PDSA Cycles. A number of more sophisticated methods and tools for analyzing the data from Cycles will be described in the remaining chapters of this book.

CASE STUDY: IMPROVING CARE OF DIABETIC PATIENTS

This case study illustrates the approach and principles described in this chapter to use the Model for Improvement to guide an improvement project in a primary care health care clinic.

A team composed of an endocrinologist, two primary care physicians from the south clinic, a nurse manager, an information system specialist, and the director of the clinic was formed to redesign the office system of care for their diabetic patients. This work also served as a pilot for the care of other chronic diseases and for general preventive care. The concept design for their work was the Chronic Care Model. The team used the Model for Improvement as a road map for their work. During their first meeting, they attempted to answer the three questions of the Model for Improvement:

What are we trying to accomplish?
During the next 10 months, improve the care of patients with diabetes by redesigning the office practice using the Chronic Care Model. Pilot the system in the South Clinic with a population of about 200 diabetic patients so that:
- >80% of diabetic patients have set collaborative goals (self-management).
- The average HbA1c level for the diabetic population will be <8.0%.

How will we know that a change is an improvement?
1. The average HbA1c of the pilot population using a registry of patients with diabetes
2. Percentage of patients in the registry who have set collaborative goals
3. Additional measures of progress on the key changes

What changes can we make that will result in improvement?
The six components of the Chronic Care Model (Self-Management, Decision Support, Delivery System Design, Clinical Information System, Community Resources and Policies, and Organization of Health Care) provide the concept design for this improvement effort. The team will develop and test specific changes under each of these components.

The team made plans to begin reporting the data on the two key measures monthly. They decided to collect data from 20 randomly selected charts of diabetic patients who had visited the clinic for the previous three months to establish a baseline. After that, they would use the current registry of population of diabetic patients to develop the measures each month.

They then begin planning their first series of PDSA Cycles to test and implement the concept design. Table 1.3 describes their initial 14 cycles planned in four of the Chronic Care Model components.

### Table 1.3 Initial Team Plan for PDSA Cycles

<table>
<thead>
<tr>
<th>Concept</th>
<th>PDSA Cycle #</th>
<th>Description of PDSA Cycle</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Clinical Information System</td>
<td>A.1</td>
<td>Develop simple database in Access for diabetic patients. Download list of patients based on system codes for diabetics. Begin completing records during initial chart review.</td>
<td>Jones</td>
</tr>
<tr>
<td></td>
<td>A.2</td>
<td>Develop method to put laboratory and visit data directly into the database.</td>
<td>Jones</td>
</tr>
<tr>
<td></td>
<td>A.3</td>
<td>Test visit sheet printed from database with two physicians on the team.</td>
<td>Jones</td>
</tr>
<tr>
<td>B: Self-Management</td>
<td>B.1</td>
<td>Dr. Smith trial self-management goal setting process with five patients during next week.</td>
<td>Smith</td>
</tr>
<tr>
<td></td>
<td>B.2</td>
<td>Test incorporating the self-management process into the diabetic visit flow sheet.</td>
<td>Smith</td>
</tr>
<tr>
<td></td>
<td>B.3</td>
<td>Distribute information to diabetic patients on self-management.</td>
<td>Marshall</td>
</tr>
<tr>
<td></td>
<td>B.4</td>
<td>Develop 2-hour session to educate staff and prepare for broader rollout of collaborative goal setting.</td>
<td>Marshall</td>
</tr>
<tr>
<td></td>
<td>B.5</td>
<td>Schedule a documented encounter at least annually to promote patient identification of their appropriate self-management opportunities.</td>
<td>Rogers</td>
</tr>
<tr>
<td>C: Decision Support</td>
<td>C.1</td>
<td>Develop electronic prompts to communicate evidenced-based standards based on ADA guidelines.</td>
<td>Allen</td>
</tr>
<tr>
<td></td>
<td>C.2</td>
<td>Recently established monthly QA review as part of the faculty meeting.</td>
<td>Allen</td>
</tr>
<tr>
<td>D: Delivery System Design</td>
<td>D.1</td>
<td>Test with two patients a letter to inform diabetics of the redesign of the diabetic care system. Requested them to schedule an appointment if they have not visited in the last six months.</td>
<td>Rogers</td>
</tr>
<tr>
<td></td>
<td>D.2</td>
<td>Established a protocol for routine HbA1c measurements.</td>
<td>James</td>
</tr>
<tr>
<td></td>
<td>D.3</td>
<td>Test a system for blood pressure documentation and tracking with protocols for identification and drug management.</td>
<td>James</td>
</tr>
<tr>
<td></td>
<td>D.4</td>
<td>Develop an intervention program that advocates regular foot exams for all diabetics and protective foot care behaviors for diabetics with high-risk feet.</td>
<td>James</td>
</tr>
</tbody>
</table>

Exhibit 1.1 shows example of the documentation for one of the first PDSA Cycles completed. The team met over lunch every Friday during the next two months to work on the plan and study of the PDSA Cycles.

(continued)
EXHIBIT 1.1 DOCUMENTATION FOR INITIAL SELF-MANAGEMENT PDSA CYCLE

PDSA Cycle B.1 Self-management

Objective: Begin to understand the issues involved in implementing self-management practices with all diabetic patients.

Plan

Question: Can the providers incorporate self-management methods into the visit of a diabetic patient? Will patients accept self-management?

Predictions: There will be some initial problems with overrunning appointments, but visit can be adjusted to accommodate. Most patients will be receptive to collaborative goal setting.

Plan for test: Develop interviewing tool. Dr. Smith will trial self-management goal setting process with five patients during next week.

Data collection: Ms. Rogers reviews Dr. Smith’s notes from visit. Receptionist interviews patients on their reaction to offer of self-management. Dr. Smith summarizes his perceptions of the process after completing with five patients.

Do: Dr. Smith offered collaborative goal setting with five patients during a two-day period. One patient was not interested in participating. Script was modified after visit with second patient.

FIGURE 1.8 Run Charts of Key Measures for Diabetes Improvement Project
Study: Three of the five patients left the visit with an agreed goal to be accomplished during the next month. Four of the five patients were appreciative of the opportunity and one patient was delighted with his involvement in setting a goal. Dr. Smith has some other ideas to modify the interviewing tool and for better incorporating the methods into the visit by modifying the visit flow sheet.

Act: Dr. Smith will continue to use the revised interviewing tool with all diabetic patients. Dr. James will try with one patient next week.

The team had an offsite meeting two months later to review progress on the project and make additional plans. They reviewed their aim and the run charts (Figure 1.8) of their two global measures related to the aim. They reviewed their progress on each of the components of the care model. For the next three months, they decided to concentrate on delivery system design and patient self-management. Table 1.4 shows some of the PDSA Cycles planned for continued testing and implementation of the changes.

### Table 1.4 Some Additional Plans for PDSA Cycles

<table>
<thead>
<tr>
<th>Concept</th>
<th>PDSA Cycle #</th>
<th>Description of PDSA Cycle</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Clinical Information System</td>
<td>A.5</td>
<td>Test use of registry for follow-up phone calls by office staff, office initiated scheduling of visits with diabetics needing routine screening, and a reminder system for office-initiated patient notification of annual foot exams.</td>
<td>Jones</td>
</tr>
<tr>
<td>B: Self-Management</td>
<td>B.11</td>
<td>Update patient education material for use in clinic. Monitor patient satisfaction with education material and improved where appropriate.</td>
<td>Smith</td>
</tr>
<tr>
<td></td>
<td>B.12</td>
<td>Worked with HMOs to make it possible for all patients to receive education regardless of health plan coverage.</td>
<td>Marshall</td>
</tr>
<tr>
<td></td>
<td>B.13</td>
<td>Develop the concept of a clinical educator to lead self-management with providers, staff, and patients for all chronic diseases.</td>
<td>Marshall</td>
</tr>
<tr>
<td>C: Decision Support</td>
<td>C.8</td>
<td>Develop a set of decision support information (ASA, general guidelines to specialists, diabetes medication information and dietary recommendations) and made available in every examination room.</td>
<td>Allen</td>
</tr>
<tr>
<td></td>
<td>C.9</td>
<td>Begin offering smoking cessation courses and document patient response to the offer.</td>
<td>Allen</td>
</tr>
<tr>
<td></td>
<td>C.10</td>
<td>Test an annual meeting for the entire care team to assess their working relationships and make the appropriate improvements to maximize cooperation and the application of the best clinical expertise.</td>
<td>Allen</td>
</tr>
<tr>
<td>D: Delivery System Design</td>
<td>D.7</td>
<td>Develop prewritten prescriptions for glucometers and medical shoes to aid in the wording requirements for Medicare reimbursement.</td>
<td>James</td>
</tr>
</tbody>
</table>

(continued)
The team continued testing, adapting, and then implementing specific ideas for each of the components of the Chronic Care Model. They reviewed their progress with the organization’s senior leaders in the fifth month of the project. Their measures (Figure 1.8) confirmed the progress of the team. The senior leaders offered to get involved in the Community Resources and Policies and the Organization of Health Care components of the care model. The team held a second meeting with their senior leaders after the ninth month of the project. They had accomplished their self-management goal and predicted accomplishment of the clinical outcome measure with the next two months. Plans were begun to spread this work with diabetic patients to other chronic diseases.

SUMMARY

This chapter introduced the Model for Improvement as a road map for execution of an improvement project. The important connection of the use of data with the model was emphasized:

1. To answer: How do we know that a change is an improvement?
2. To provide for learning in PDSA cycles.

The rest of the book will assume the Model for Improvement as the backdrop for the tools and methods used to learn from data. A listing of the methods and tools used in improvement work was included in Tables 1.1 and 1.2.

The case studies in Chapter Thirteen illustrate the use of the Model for Improvement as a framework for the improvement project. Most of the case studies are focused on a portion of the project that emphasizes the use of data for learning on the project. Case Study F on readmissions presents the three questions of the model and describes three PDSA cycles on the project.

KEY TERMS

Aim statement
Implement changes
Model for Improvement
Plan, Do, Study, Act Cycle (PDSA)

Run chart
Shewhart charts
Test and adapt changes