Quality by Design

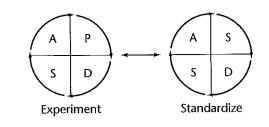
What Is the SDSA Cycle?

Whereas the focus of the PDSA cycle is experimentation, the focus of the SDSA cycle is *standardization*. The idea behind this is simple and powerful. You run experiments (PDSA tests of change) until you reach your measured aim. Then, once you are able to achieve the desired level of performance, you want to maintain these gains by continuing to do the right things the right way. This calls for the adoption of a standard method and its continued use until the time comes to make new improvements.

The SDSA (standardize-do-study-act) cycle is the approach you take once you have successfully done one or more PDSA cycles and have enough experience and measured outcomes to determine that you have reached your original aim. The purpose of using the SDSA approach is to hold the gains that were made using PDSA cycles and to standardize the process in daily work.

Once you have reached the point where you should switch from the PDSA cycle to the SDSA cycle, that is not the end of the story. As new technologies arrive, and as your microsystem gains additional process practice and insight, you may need to move from SDSA back to PDSA again, to learn additional information and to test new ideas and processes. This back-and-forth process—between experimentation and standardizing—will result in higher levels of efficiency and an ability to hold your gains. Never think that once a process is in the SDSA cycle it will stay constant. Ongoing review and evaluation will tell you whether the best-known practice is in place and may reveal that you need to move back to PDSA, as shown in Figure 14.5.

FIGURE 14.5. THE BACK-AND-FORTH RELATIONSHIP OF PDSA AND SDSA.



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The Model for Improvement

What Is Involved in Each of the Four Steps of Standardize, Do, Study, and Act?

The first SDSA step is to standardize. Standardized tasks are fundamental for continuous improvement and employee empowerment. Through repeatedly performing a task in a standardized manner, people gain new knowledge and insights for further improvement activities.

Liker (2004) has reminded us that American industrialist Henry Ford, pioneer of the assembly-line production method, once stated, "Today's standardization . . . is the necessary foundation on which tomorrow's improvement will be based. If you think of 'standardization' as the best you know today, but which is to be improved tomorrow-you get somewhere. But if you think of standards as confining, then progress stops" (p. 141). In a similar vein Brent James, a vice president for medical research and executive direction at Intermountain Health Center, Salt Lake City, Utah, often suggests it's more important to do something the same way than to do it the right way, because if you do it the same way you can learn from the results and then discover the best way (personal communication to E. C. Nelson, 1995).

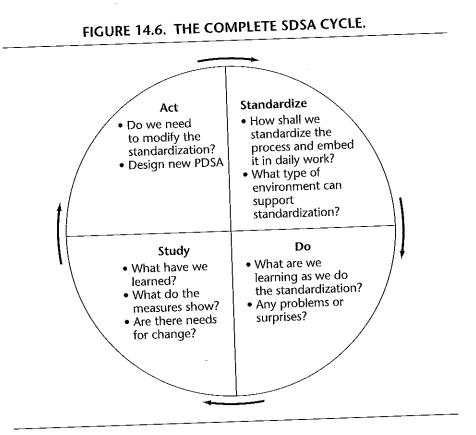
This is the important assumption that supports SDSA thinking: it couples standardization with learning. It is through standardizing and stabilizing the process that learning and deeper insight occurs and processes and outcomes can be continuously improved.

The standardize phase in the SDSA cycle starts with determining how the current best process will be standardized in your daily work (Figure 14.6). A good first step toward standardization is to make a deployment flowchart to show who should do what and in what order. Also consider how you can shape the environment to help the process unfold reliably and consistently. Think about new habits your microsystem has adopted successfully. What helped it to maintain them? How will new employees be oriented to them? This can help you and your team gain insight into how to successfully maintain this new improvement, by making the new standard method a habit.

What are you learning in the *do* phase about the standardization within daily work? As you perform the new standardized process, what helps to ensure that it is done in a standardized way? What inhibits it from being done consistently?

As you *study* the standard process, what measures let you know whether the process is being done consistently? How many times does the process not get completed in a standard way? When you talk with those involved in the new process, what can you learn about the reasons the process is or is not consistent? Based on the lessons from the field, are there signs that SDSA should move back to PDSA? What are the indications for change?

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To *act*, consider what changes need to occur and be tested. Review the PDSA cycle and design a new pilot based on the knowledge you have obtained using the standard process. Once you have conducted the new PDSA cycle, be prepared to move back to SDSA after you have tested and refined the new improved process, and once again consider making a deployment flowchart to make the standard process clear to all.

What Tools Can Assist Your PDSA Cycle \leftrightarrow SDSA Implementation?

The PDSA \leftrightarrow SDSA worksheet shown in Figure A.15 in the Appendix is a helpful tool. It provides a map and reminders for conducting PDSA \leftrightarrow SDSA work. Many frontline teams use this worksheet to guide and record progress. (You can also find this worksheet at http://www.clinicalmicrosystem.org.)

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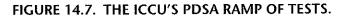
What Are Some Tips for Using the PDSA \leftrightarrow SDSA Method?

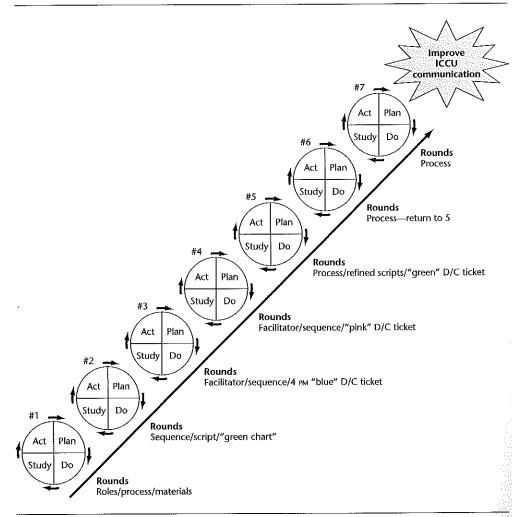
- · Always start with a specific aim statement.
- Answer the question, What are we trying to accomplish?
- The question, How will we know if this is an improvement? can only be answered with data.
- Small tests of change done in short periods of time accelerate learning and pave the way to rapid improvement. For example:
 - Start with six patients
 - Test for three shifts
 - Test for two days
 - Start with one to two providers
 - Sample every other patient or process
- Designate someone to *oversee* the test and be the ears, eyes, and support to those engaged in it.
- Offer participants the opportunity to debrief *frequently* during the pilot.
- Have fun with special food or materials during the pilot.
- Celebrate completion of the first pilot, to encourage staff to continue.
- Post results in your microsystem space for all to see.
- When going to SDSA, use a deployment flowchart to provide a clear picture of who does what and in what order.
- When doing SDSA, schedule regular reviews to reflect on the process, monitor results, and avoid *slippage*.
- Sustain the effort by having a clearly designated work process *owner* who leads the SDSA phase of the process change.
- Alert senior leaders to the fact that PDSA \leftrightarrow SDSA is being used to make improvement.

Case Studies

Intermediate Cardiac Care Unit (ICCU)

The ICCU lead improvement team members reviewed the model for improvement to become aware of the path ahead of them and to become more knowledgeable about the discipline of improvement. They believed this would support their becoming a community of scientists. Figure 14.7 shows how the ICCU team used multiple PDSA cycles within the improvement model to reach its aim of improved communication.





Note: D/C = discharge.

Plastic Surgery Section

Review of the improvement model by the section's interdisciplinary lead improvement team provided the structure and discipline of improvement. The team members were eager to have successful improvements, and the model gave them a path forward to follow and a way to measure progress. With all Quality by Design



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that the lead improvement team was learning about the processes to be improved, the improvement model provided a paced, disciplined way to move through improvement activities without being overwhelmed.

Review Questions

- 1. What is the model for improvement?
- 2. What is a PDSA cycle, and how does it differ from a SDSA cycle?
- 3. Can an improved process move between PDSA and SDSA cycles?
- 4. What are the key elements of each phase of PDSA and SDSA?
- 5. When does an improved process move from SDSA to PDSA?

Between Sessions Work

- 1. Review and discuss the model for improvement, to clarify the path forward for the lead improvement team.
- 2. Review the PDSA ↔ SDSA worksheet (Figure A.15) to gain insight into the next steps.

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