QA Q&A

Edited by Dr. Yael K. Heher

Improving quality and safety in an evolving practice

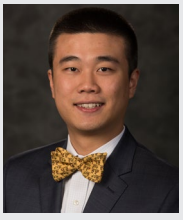
Using the Model for Improvement and Plan-Do-Study-Act to Effect SMART Change and Advance Quality

DEAR QA Q&A,
As the medical director of a laboratory, my team and I are always looking for ways to improve the quality of our clinical services in a cost-efficient manner. We have identified several opportunities to improve operations and reduce patient safety risk, and we are interested to know how various quality improvement (QI) tools such as Six Sigma or Plan-Do-Study-Act (PDSA) might help us. None of us, however, have any formal training in the tools, and we have no budget to hire consultants. We also were recently told by hospital education leadership that our laboratory is not fulfilling the mandatory Accreditation Council for Graduate Medical Education (ACGME) QI[1] project for our pathology training program. Can you help us with a low-cost, high-yield, and easy-to-use QI tool for our practice and for our trainees?

Dear reader,
There is no single "best" framework for QI activities and each has advantages and disadvantages. The Six Sigma model reduces performance variation using a custom data-driven approach, but can be complex.[2] Lean manufacturing QI concepts stress the importance of removing waste and improving productivity in daily workflows.[3,4] Total Quality Management focuses on a commitment to quality and process at all levels of the organization.[5] For laboratories such as yours, and for trainees with little QI knowledge who are looking for a simple tool that is easily deployed and does not require industrial engineering expertise, we recommend the PDSA cycle, also known as the Model for Improvement. PDSA cycles can help your team put QI ideas into practice immediately. If your laboratory has an accredited cytopathology training program, involving trainees in QI projects will have the added benefit of fulfilling new ACGME QI regulatory requirements and allow the next generation of pathologists to acquire critical leadership skills.

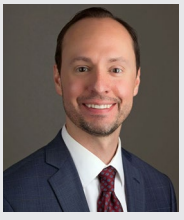
What Is a PDSA Cycle?

The PDSA cycle is a 4-stage, repeating process that evolved from the work of American statistician Edward W. Deming. His goal was to use the scientific method to improve business processes.[6] Each letter of "P-D-S-A" stands for a critical phase in the cycle: "Plan, Do, Study, Act." The cycle begins with developing a plan to test an improvement idea (Plan), followed by a small-scale experiment and data collection (Do). The team then observes and learns from the results (Study), and decides whether or not to roll out changes or make modifications by initiating a new cycle of improvement (Act) (fig. 1).



Yigu Chen, MPH, PMP

Yigu Chen, MPH, PMP, is a quality and process improvement specialist in the Department of Pathology at Beth Israel Deaconess Medical Center. He has a keen interest in propelling value-driven improvements in patient safety and health care quality. He oversees quality and operations data analytics, leads root cause analyses of adverse events, and facilitates improvement initiatives in the laboratory and across laboratory-related services.



Paul A. VanderLaan, MD, PhD

Paul A. VanderLaan serves as the Director of Cytopathology and the Director of Thoracic Pathology at the Beth Israel Deaconess Medical Center and is an Associate Professor of Pathology at Harvard Medical School, both in Boston, Massachusetts. He has widely published in the fields of cytopathology and pulmonary pathology, sits on the editorial boards of multiple medical journals, and consistently has an eye out for optimizing specimen processing and ongoing quality improvement measures in the cytopathology laboratory.

Yael K. Heher, MD, MPH

Yael K. Heher, MD, MPH, is an anatomic pathologist and the Director of Quality and Safety (Anatomic Pathology/Clinical Pathology) in the Department of Pathology at the Beth Israel Deaconess Medical Center and Harvard Medical School in Boston, Massachusetts. Her main focus is the role of quality improvement and patient safety in pathology, including performance and metric assessment, adverse event management, transparency, effective change, and leadership.

To achieve incremental progress, the model was designed to quickly and efficiently pilot new ideas in a structured way using data and iterative cycles. This experimental learning process ensures that reliable conclusions are drawn regarding the effectiveness of each intervention.[7]

The PDSA cycle has been applied widely in health care because of its simplicity and practicality. It has been endorsed by the Institute for Healthcare Improvement.[8] PDSA is flexible and can be used for nearly any QI challenge in the laboratory, from reducing the administrative workload through a redesign of the accessioning process to lowering the risk of patient mix-ups by implementing a paperless signout workflow.

In this installment of QA Q&A focusing on the Model for Improvement, we will use a simple and common example of how PDSA cycles can improve cytology report signout turnaround time (TAT).

Case Example: Gynecologic Cytopathology TAT Project

The timeliness of finalized pathology results is a critical aspect of quality management for gynecological cytology specimens. For gynecological cases, our laboratory struggles with meeting a target of signing out final reports within 5 working days from specimen collection. Clinicians also have expressed concerns regarding unpredictable variations in TAT performance, with rates ranging from 30% to 60% of cases signed out within 5 days. Here, we will adopt a PDSA approach to improve TAT.

Stage 1: Plan

Planning is the first and foremost step in a PDSA cycle and sufficient time and resources must be allocated to this stage. Thorough and careful design helps to prevent wasted PDSA cycles and also determines the final quality and success of the QI project.

Assemble an engaged multidisciplinary team: "Who needs to be part of this change?"

Identifying and recruiting team members with subject matter knowledge of the problem or opportunity for improvement is a critical first step. Making sustainable improvements requires a collaborative team effort. A multidisciplinary team brings in different expertise and perspectives that are critical to effective change. This helps to break down workflow siloes and facilitates outsidethebox thinking for improvement ideas. Frontline employees should be included because they are closest to the work and understand vital details regarding the specific challenges at hand. Engaging frontline staff also can be beneficial for later stages of the PDSA cycle when change management is required. The pilot implementation ("Do") phase will be more successful if frontline staff are engaged in early planning (fig. 2).

For this project, we assembled a QI team composed of the cytology laboratory medical director, local operational leadership (cytology supervisor), and frontline employees (cytotechnologists and laboratory assistants).

Define your problem and goals: "What are we trying to accomplish?"

Before generating improvement ideas, a concise problem statement with clear goals must be delineated.[3] This step helps the PDSA team to stay focused on problems without overextending their scope and set specific, achievable, and time-bound targets.

The definition of goals is critical, and we recommend using the validated "SMART" method[9]:

- **S**pecific: The goal should target a specific area of improvement or answer a specific need.
- **M**easurable: The goal must be quantifiable, or at least allow for measurable progress.
- **A**ttainable: The goal should be realistic, based on available resources and existing constraints.
- **R**elevant: The goal should align with quality, safety, efficiency, or business objectives to be considered worthwhile.
- **T**ime-bound: The goal must have a deadline or defined end date.

An example using SMART goals would be "Within 6 months, we plan to improve gynecologic cytology specimen TAT to a target of 75% of cases finalized within 5 days of specimen collection." An example without SMART goals would be "We plan to improve gynecologic cytology specimen TAT, which has been a key problem and source of complaints by treating clinicians."
Using SMART goals builds in feasibility. For example, the SMART system would prevent one from pursuing a project that requires that a new hospital information technology system be purchased. The SMART system ensures that goals are relevant and quantifiable, with specific timelines specified up front.

Define your measurements: "What will we measure to demonstrate that we have achieved our goals?"

The effectiveness of your intervention can be assessed only if you collect data.[3] There are 3 different types of measurements in PDSA cycles that might be appropriate. Outcome measures are measures that can demonstrate sustainable improvement in the final goal. An example would be "For this project, we will monitor the total number of accessioned gynecological cytology cases every week, and the number of cases that are signed out within 5 working days from specimen collection date, to determine the percentage of cases falling within our QI target." Process measures are measures associated with an individual improvement idea. They enable the team to understand whether the change itself has been carried out as planned. An example would be "Using our project as an example, we identified that a large number of gynecological specimens are not logged into

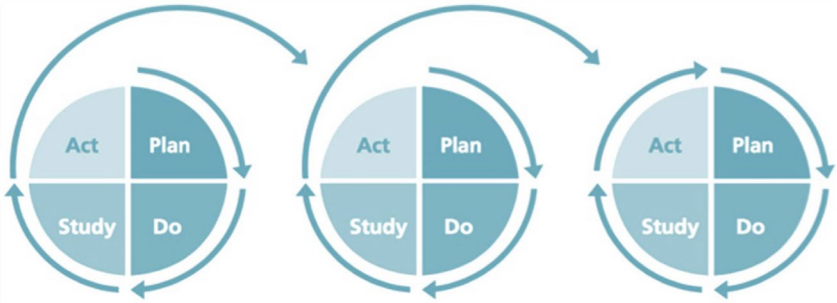


FIGURE 1. Plan-Do-Study-Act is a 4-stage, repeating process focused on quality and process improvement that can be implemented for all types of laboratory (lab) processes. Adapted from Davies A, Offer M. Using sequential Plan-Do-Study-Act cycles to facilitate implementation of a morbidity and mortality review process. *Future Healthc J*. 2019;6(suppl 2):79.

our laboratory information system on the day the specimen is received. We believe that a reduction in waiting time for accessioning will improve TAT. Therefore, we will measure percentages of same-day login before and after the change." Process measurements help you to understand your improvement effort and decipher, if the PDSA cycle fails to demonstrate the change you expected, whether poor adherence to the implementation plan contributed to the failure. Sometimes, changes to laboratory processes cause unexpected consequences in other areas of the laboratory. Balancing measures are used to assess these potentially negative impacts. An example would be "We are concerned that our PDSA study might result in gynecologic specimens receiving extra priority at the expense of other services. We will monitor turnaround performance for non-gynecological cases while our PDSA project is in place, to determine if these cases were affected by the change." (fig. 3).

Develop improvement ideas: "What changes can we make to our workflow or system that will result in improvement?"

Although the PDSA framework encourages bold and simple ideas, the key principle of PDSA cycles is to test a feasible idea rapidly on a small scale and discover whether it leads to incremental improvement.[3] Therefore, large, system-wide projects should be divided into small tasks and tested using multiple PDSA cycles before they are implemented globally.

Root cause analysis is a technique that can be used to identify effective improvement ideas. Root cause analysis exposes the underlying causes of a complex problem, and therefore can help to improve the efficiency of deploying PDSA cycles. Your hospital's quality department may have an individual trained in root cause analysis available to help you with this technique. An example would be "After completing detailed process mapping and root cause analysis, we identified 2 targets for improvement. The first is a capacity bottleneck in accessioning gynecological specimens, which we addressed by increasing the amount of by laboratory assistants available to log in specimens by 0.25 FTE (PDSA cycle 1). The second challenge is the performance variation among cytotechnologists and cytopathologists. We aimed to minimize variation by collecting TAT data regarding individual cytotechnologists (PDSA cycle 2) and cytopathologists (PDSA cycle 3), and providing them with confidential, personalized feedback.

Create an execution plan

At this step, summarize what you have learned from the first 4 steps and develop detailed action steps in a spreadsheet or table. You should use a spreadsheet to assign tasks to each individual member, set timelines, allocate resources, and track the status of PDSA execution. Your action plan should answer the following questions:

- Who is responsible for this task?
- What needs to be done?
- When is this task due?
- Where will the pilot take place?
- What data need to be collected?

Timeline	Role / Task	Medical Director	Cytology lab supervisor	Cytotechnologist representative	Lab assistant representative	Quality Analyst
Week 1, day 1	1. Kick-off meeting	x	x	x	x	x
Week 1, day 5	2.1 Define project scope	x	x	x	x	x
	2.2 Set goals	x				
	2.3 Brainstorm improvement ideas	x	x	x	x	x
	2.4 Design measurements		x			x
Week 2, day 1	3. Start baseline data collection		x		x	x
Week 3, day 5	4.1 Follow-up meeting to plan for pilot tests	x	x	x	x	x
	4.2 Review 1st week baseline data	x	x			x

FIGURE 2. Responsibility assignment matrix. Critical when conducting quality improvement work is clarity around who is responsible for every task, plus accountability for task completion on a timeline. FTE indicatesfull time equivalent (employee position); PDSA, Plan-Do-Study-Act; TAT, turnaround time.

Stage 2: Do

The major tasks in this stage are: 1) measure baseline data; 2) pilot the improvement ideas; and 3) observe and collect follow-up data. It is critical to collect baseline data prior to implementing any changes. Such data not only confirm the need for the QI initiative but also allow you to evaluate the effectiveness of your intervention(s) through comparison of preimplementation and postimplementation results. In addition to gathering quantitative data, you should consider collecting qualitative feedback by observing processes and interviewing participants. As you watch what happens during the experiment period, you will be able to document how the people involved react to the changes, problems raised, and/or unexpected effects. Qualitative feedback can help you adjust existing plans and can lead to new improvement ideas.

Stage 3: Study

Visualize data

Once the hard work of implementing pilot changes and measuring their impact is complete, you may have hundreds or thousands of data points. How to best analyze these data and draw meaningful conclusions is the key at this stage. Instead of poring over numerical spreadsheets and summary reports, consider visualizing the data using charts and graphics. Typically, this is a more efficient way to evaluate outcomes. Run charts display observed data over time and are the most frequently used graphic in QI. Run charts make trends or patterns over a specified period of time easy to identify. Comparisons between different PDSA cycles make it easy to recognize effective change.[10,11] Other data visualization techniques such as control charts for detecting process stability and reliability and Pareto charts for identifying most frequent defects also can be adopted depending on the type of data you collect.[12] An example follows. In the top run chart, the percentage of cases signed out within 5 days was plotted against the week. The PDSA cycles were indicated using text and different background shading. In the bottom run chart, the percentage of cases accessioned on the day they were received is plotted by week.

Evaluate the results

The effectiveness of the interventions can be determined by comparing test results with the goals we drafted in stage 1. We may find that the change has been very successful, but it also is common to find that the results failed to meet expectations. The purpose is not to judge the PDSA cycle by assigning a binary "pass" or "fail." In many cases in which the results did not attain preset goals, the change still might achieve some improvements when compared with the baseline. The process of evaluating the results is more about identifying trends or patterns and learning

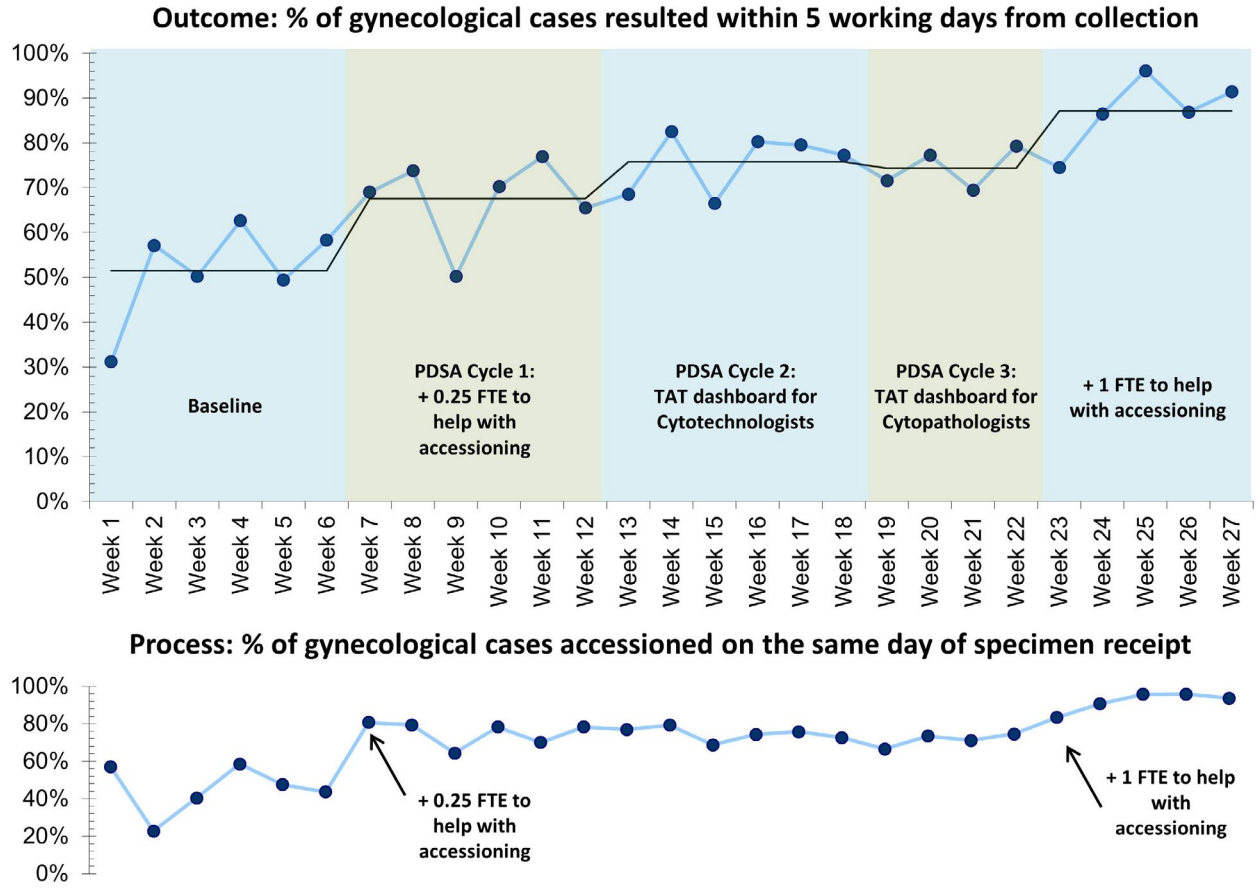


FIGURE 3. Run charts display turnaround time results over multiple Plan-Do-Study-Act (PDSA) cycles.

TABLE 1. PDSA Stages

Stages	Steps	Key Points	Cytopathology Case Study
Plan	Build a team	• Multidisciplinary • Frontline engagement	• Cytology laboratory medical director • Cytology supervisor • Cytotechnologists • Laboratory assistants • Quality improvement analyst/data analyst
	Define scope and set goals	SMART rules • Specific: Target a specific area of improvement or answer a specific need • Measurable: Quantifiable or allow for measurable progress • Attainable: Realistic goals based on available resources and existing constraints • Relevant: The goal should align with quality, safety, efficiency, or business objectives to be considered worthwhile • Time-bound: The goal must have a deadline or defined end date	Using SMART rules: • Within 6 mo, we plan to improve gynecologic cytology specimen turnaround time to a target of 75% of cases finalized within 5 d of specimen collection. Without SMART rules: • We plan to improve the gynecologic cytology specimen turnaround time, which has been a key problem and source of complaints by treating clinicians
	Design measurements	Type of measurements • Outcome: Measurements demonstrate change has led to sustainable improvement in the final goal • Process: Specific measurements to evaluate the implementation of an improvement idea • Balancing: Measurements to monitor unexpected consequences	• Outcome: Weekly percentage of gynecological cytology cases that are signed out within 5 working d from specimen collection date • Process: Daily percentage of gynecological specimens that are logged into LIS on the same d • Balancing: Average turnaround time in d for nongynecological cases
	Develop improvement ideas	• Target root causes using a "Root Cause Analysis" form if possible • Simple and incremental	• Re-deploy laboratory assistant (0.25 FTE) to help with logging in specimens (PDSA cycle 1) • Reduce performance variations among cytotechnologists by providing timely data-driven feedback (PDSA cycle 2) • Reduce performance variations among cytopathologists by providing timely, data-driven feedback (PDSA cycle 3)
	Create an action plan	• Who, what, when, where, and what data • Assignment matrix	See Figure 1
Do	Collect quantitative data	• Must collect baseline data at the start	• Data from 6 wks prior to implementing any improvements served as baseline data
	Gather qualitative feedback	• Observe and interview	• Document what frontline laboratory assistants think about the task adjustment and how cytotechnologists/cytopathologists react to the new mechanism of turnaround time performance feedback
Study	Visualize raw data	• Run chart displays observed data in a time sequence to identify trends and patterns	See Figure 2
	Evaluate results	• Not a binary assessment • Focus on patterns, trends, and lessons learned	See Figure 2 • PDSA 1: Adding 0.25 FTE to specimen accessioning area increased the overall signout turnaround time success rate from 51% to 69% • PDSA 2: Providing cytotechnologists with timely performance feedback eliminated some variations and improved the overall signout turnaround time success rate to 78% • PDSA 3: Signout turnaround time success rate did not change after implementing feedback mechanism to cytopathologists
Act	Adopt and scale-up	• Continuous improvement via iterative cycles	• Reallocated a surgical pathology laboratory assistant (1 FTE) to cytology laboratory after we observed positive results from cycle 1 • Incorporated performance feedback mechanism for cytotechnologist into a standard practice in our laboratory
	Modify and retest	• Analyze discrepancies and find correctable root causes	
	Present data to laboratory personnel	• Presenting data not only will lead to greater acceptance of the changes you are recommending, but will increase familiarity with QI in general and PDSA specifically in the laboratory and will lead to new ideas and projects	
	Drop and start a new change	• Failures are normal	• No improvement identified in PDSA cycle 3; intervention to provide performance feedback to cytopathologists was discontinued and a new PDSA cycle was initiated focusing on resident/fellow preview time for abnormal cases prior to signout by the cytopathologist

Abbreviations: FTE, full time equivalent (employee) ; LIS, laboratory information system; PDSA, Plan-Do-Study-Act; QI, quality improvement; SMART, **S**pecific (the goal should target a specific area of improvement or answer a specific need), **M**easurable (the goal must be quantifiable or at least allow for measurable progress), **A**ttainable (the goal should be realistic based on available resources and existing constraints), **R**elevant (the goal should align with quality, safety, efficiency, or business objectives to be considered worthwhile), and **T**ime-bound (the goal must have a deadline or defined end date).

from what worked and what did not. An example would be "In PDSA cycle 1, we found that by reallocating existing human resources (0.25 FTE) to the accessioning station in the afternoon, our weekly average success rate of meeting the TAT target improved from 51% to 69%. In PDSA cycle 2, we deployed weekly TAT reports in a dashboard that gave each cytotechnologist timely performance feedback. This helped to further boost our success rate to an average of 78%. In PDSA cycle 3, we implemented a similar dashboard turnaround report for pathologists to address variability in TAT among pathologists. PDSA cycle 3 did not result in any further improvements in TAT."

Stage 4: Act

Based on reflection regarding the results, future actions can be summarized into the following 3 categories.[13]

Adopt and scale-up

When goals are achieved by the pilot implementation without causing unexpected problems, it may be appropriate to expand the program to a larger scale or spread it across your entire practice. At this stage, it also is important to consider plans to sustain the gains, or make even further improvements, through future PDSA cycles that contribute to "continuous improvement."

Modify and retest

If the original plan failed to achieve the desired results or caused new problems, analyze the discrepancies to try to understand why. It is at this stage that qualitative data, including discussion with the participants, can be useful. If the failures can be corrected, consider modifying the plan and retesting through a new PDSA cycle.

Drop and test a new change

It is very common to have a failed PDSA cycle in the improvement journey. If your team believes a different approach would be more successful, consider abandoning the current intervention and starting a new cycle with a different plan. An example would be "We adopted and scaled up the idea of increasing capacity at the accessioning station. We reallocated a surgical pathology laboratory assistant (1 FTE) to the cytology laboratory after we observed positive results from PDSA cycle 1. The intervention was continuously effective, with the average TAT success rate remaining higher than 85%. Performance feedback for the cytotechnologist also appeared to improve the TAT and now is standard practice in our laboratory. A similar feedback mechanism for cytopathologists helped to address performance variation. However, it did not appear to improve the overall laboratory gynecologic cytology signout TAT further." A summary of all PDSA cycle phases, key points, and corresponding details from the case study is provided in Table 1.

Conclusions

The PDSA cycle is a simple QI tool that requires few resources, can be deployed rapidly, and can lead to meaningful change. Thorough planning is critical to success. To be successful, one must be able to measure either the quality and safety outcome desired, critical process metrics, or both. Qualitative data are important to collect because they can be invaluable in generating new hypotheses for process improvement. Data analysis is best performed using run charts and other validated visual QI tools. If your PDSA intervention is effective, laboratory policies should be formalized to reflect QI changes and new workflows. To ensure success in QI endeavors, quality leadership should plan to present the data collected and PDSA project ideas to as many involved personnel as possible regardless of rank or title. By its nature, QI is innovative, iterative, and collaborative and therefore both successes and failures are expected as the process evolves. A successful QI project using PDSA can improve patient outcomes, laboratory efficiency, and morale and engagement among the laboratory team.

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