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Chapter 25

Quality Improvement: Small Changes That Can Make a Big Difference

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> Every system is perfectly designed to achieve exactly the results it gets.
>
> —*Paul Bataldin*

Introduction

Since April 2006, the federal Maternal and Child Health Bureau has provided support for all state-based Early Hearing Detection and Intervention (EHDI) programs for their implementation of quality improvement (QI) principles and strategies in an effort to reduce loss to follow-up (LTFU) in newborn hearing screening programs. Specifically, states have been using the QI methods outlined in the Model for Improvement (MFI) developed by Associates in Process Improvement (API, http://www.apiweb.org) and advocated for by the Institute for Healthcare Improvement (IHI, http://www.ihi.org). The MFI is a simple yet powerful tool for accelerating improvement and has been used in many healthcare, public health, and education organizations to improve

processes and outcomes. Many EHDI programs have successfully used the MFI to improve their processes and outcomes. To view a quick video of how the MFI can improve outcomes in healthcare, go to: https://www.youtube.com/watch?v=jq52ZjMzqyI&feature=youtube.

State EHDI programs have utilized the MFI to improve internal processes to accurately account for and report screening, diagnostic, and early intervention outcomes. Furthermore, state EHDI programs have utilized this model to support hospitals, audiologists, and intervention providers to improve the care they are providing to infants. Among other improvements, states that have fully embraced QI have been able to:

- *Increase* the number of homebirth babies who receive a hearing screening by 1 month.

National Center for Hearing Assessment and Management Utah State University™

- *Decrease* the number of false positives at screening.
- *Reduce* the amount of time between referral from screening to the initial diagnostic appointment.
- *Streamline* the process from confirmed loss to early intervention.

The goal of this chapter is to provide an overview of the MFI and how EHDI programs can use the MFI to ensure all deaf or hard-of-hearing (D/HH) babies get the care they need in a timely fashion.

MFI Overview

The essence of QI is using an iterative process to make systematic changes that yield improved outcomes for patients. Many organizations engage in aspects of QI without recognizing it. To fully realize the improvement an organization seeks, it is helpful to follow a systematic structure or model that helps to identify, implement, and measure change intended to improve a process or outcome.

According to the Health Resources and Services Administration (HRSA, 2016), a successful QI model always incorporates the following four key principles:

1   Works on systems and processes.

2   Focuses on patients.

3   Focuses on being part of the team.

4   Focuses on use of the data.

An In-Depth Look at the MFI

The MFI incorporates all four of these key principles and is driven by three fundamental questions (see *Figure 1*).

In the book, *The Improvement Guide: A Practical Approach to Enhancing*

Organizational Performance, the authors (Langley, Moen, Nolan, Nolan, & Norman, 2009) cite that any effort to improve something should result in an answer to these questions. The questions can be answered in any order. However, all three questions must be addressed when seeking improvement. The questions are combined with PDSA cycles to form the basis of the model. PDSA or Plan-Do-Check-Act (PDCA) cycles are central to most QI models but are often misused or misunderstood. To view a video that provides an overview of MFI, go to: http://www.ihi.org/education/WebTraining/OnDemand/ImprovementModelIntro/Pages/default.aspx

Just like all fields, QI has its own set of vernacular. Before delving deeper into MFI, it is helpful to understand some QI terminology (see *Table 1*).

Table 1
QI Terminology

Aims

A measureable statement of the expected results of the project. Aims can exist on multiple levels and cover the same concept as goals and objectives.

Measures

Numerical indicators of changes and can exist on both the process and outcome levels.

Strategies

Ideas a team has that may lead to improvement. They are sometimes referred to as activities or changes.

Plan-Do-Study-Act (PDSA) Cycles

Structured trials designed to test if a strategy results in improvement.

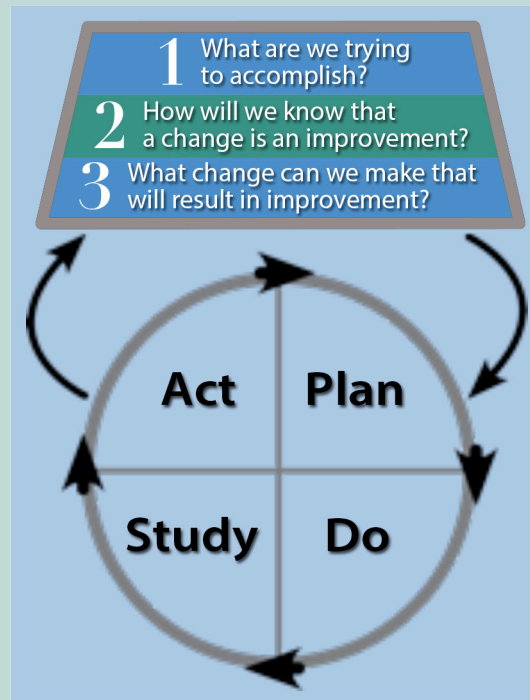### Run Chart

A line chart designed to show data over time.

1 *What are we trying to accomplish?* Develop a specific, time-limited, and measurable aim statement.

2 *How will we know that a change is an improvement?* Identify process and outcome measures to track improvement and determine if an organization is making progress toward its aim.

3 *What change can we make that will result in improvement?* Consider what strategies an organization can test to move toward their aim. As organizations work to answer this third question, ideas are trialed utilizing Plan-Do-Study-Act (PDSA) cycles. This approach is used to rapidly test the change by planning the change, trying the change, observing the results of the change, and then acting on what is learned from the cycle in planning next steps. Initially, PDSA cycles start on a very small scale, and once confidence in the strategy is established, the change is expanded. The goal of a PDSA cycle is to identify a change that will eventually be scaled up so that all patients experience this new process.

Figure 1
Model for Improvement

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

Act | Plan
Study | Do

> Before an organization can begin an improvement effort, it is essential that it bring together a group of stakeholders that can provide unique perspectives to the outcomes and processes of the organization.

What are we trying to accomplish?

Before an organization can begin an improvement effort, it is essential that it bring together a group of stakeholders that can provide unique perspectives to the outcomes and processes of the organization. This group of stakeholders must take an in-depth look at the current system to identify where needs and gaps lay. This review may include any qualitative and quantitative data that provides insight into the organization's system. Once the group identifies an area of need, they collectively develop what is known as an "aim statement." What an organization is trying to accomplish is succinctly described in an aim statement and provides the needed direction to guide an improvement project. An aim statement should include:

- *What.* What is an organization seeking to accomplish?
- *For whom.* Who is the target population?

- *By when.* What is the timeline or deadline for accomplishing this improvement?
- *How much.* What is the measurable change or improvement an organization seeks to accomplish. "How much" must include specific measurable outcomes.

Aims are at the heart of all improvement projects. Though aims do not spell out how improvement will be accomplished, they do provide a measurable end. State EHDI programs may have multiple aims.

"Which road do I take?" she asked.
"Where do you want to go?" responded the Cheshire cat.
"I don't know." Alice answered.
"Then," said the cat, "it doesn't matter."

Family of Measures

Outcome. The ultimate result intending to be impacted or improved.

Process. Drive the outcome and help assess if steps in the system are performing as expected.

Balance. Determine if changes designed to improve one part of the system is causing new problems—an unintended consequence.

For example, a state may have an aim to reduce LTFU at diagnosis; then several sub-aims that will ultimately help them reach the larger aim. Some examples of an aim and subaims in EHDI are shown in *Table 2*.

EHDI improvement efforts need to focus on outcomes where progress can be seen within a 6- to 18-month timeframe. Though reducing LTFU is the ultimate outcome, those numbers are constantly shifting until the data is submitted to the Centers for Disease Control and Prevention (CDC). Also, by the time the CDC numbers are submitted, the babies can be up to 2 years old.

How will we know that a change is an improvement?

As described above, an organization has now identified the gap between their current system and where they want to go, which is described in their aim statement. While QI is not solely focused on data and measurement, without it, it is impossible to assess improvement.

To assess whether an organization is making improvement toward accomplishing their aim, they should develop a small package of measures often referred to as a *family of measures*. This select set of measures should include outcome and process measures but may

also include balance measures. A balance measure helps improvement teams to identify if there is an unintended impact or outcome of the improvement efforts. For more information about measures, go to: http://www.ihi.org/education/IHIOpenSchool/resources/Pages/AudioandVideo/Whiteboard15.aspx.

Categories of measurement. Organizations are accustomed to collecting data at some level. If the organization receives grant funding, the data it collects is primarily geared toward accountability or evaluation. If an organization conducts research and publishes results, the data it collects revolves around supporting the research. Data for improvement differs from data from evaluation and research. Solberg, Mosser, and McDonald (1997) outline the distinction between the three different categories of measurement (see *Table 3*):

- *Improvement.* Focus on improving outcomes and processes in a system.
- *Accountability/Evaluation.* Focus on providing results to external parties. This data can include outcome measures but often focuses on aggregate data for populations, such as LTFU. Don't provide insight to how the system could be changed in order to improve the outcome.
- *Research.* Focus on seeking new knowledge—often long-term, elaborate design, and costly.

Table 2
Examples of an Aim and Subaims in EHDI

State Aim 1
By March 2017, XYZ EHDI program will reduce LTFU at diagnosis by 15%.

Subaim 1.1	Subaim 1.2
By June 2016, reduce the number of "no show" appointments at ABC and XYZ and audiology clinics by 20%.	By July 2016, reduce the refer rate at the seven highest referring hospitals in the state by at least 5%.

Table 3
Distinction between the Three Different Categories of Measurement

Measurement	Improvement	Accountability/ Evaluation	Research
Aim	Improve care	Compare, reassure, spur change	New knowledge
Methods Test Observable	Yes	Evaluate current performance	Test blind or controlled
Bias	Accept stable bias	Adjust data to reduce bias	Design to eliminate
Sample Size	Just enough data; small, sequential samples	Report 100%	Just in case data
Hypothesis Flexible	Yes, revised as learn and test	No hypothesis	Fixed hypothesis
How to Determine Improvement	Run or Shewhart charts	No focus on change	Hypothesis, statistical tests: F-test, t-test, chi square, p value
Testing Strategy	Small, sequential tests	No tests	One large test
Data Confidential	Data used only by those involved in improvement	No subjects; data is for public	Subjects protected

Springboarding off the aim statement examples provided in the previous section, a family of measures might look like *Table 4.*

IHI and API provide a few guidelines for teams to consider while developing a measurement strategy:

- The outcome measure should be reflected in the aim statement.
- Track data over time.
- Identify measures that can be tracked frequently, preferably at least monthly.
- Set aside time to review the data, preferably at least monthly.
- The measures should be responsive to change and able to detect improvement in a short time period.

- Don't track too many process measures and lose sight of the outcome.
- Make data collection reasonable/ practical. If it won't be used, don't collect it.
- Create a data collection plan (what data will be collected, how will the data be collected, who will collect the data, and when and where will the data be collected).

Learning from data. Data for QI is solely for learning and helps an organization determine if the changes that are being tested are impacting the aim. A family of measures enables an organization to make data-based decisions, seek meaningful improvement, and maximize resources.

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Table 4
Family of Measures

Aim	Outcome	Process	Balance
Aim 1: Reduce LTFU	*Numerator:* # of babies considered LTFU *Denominator:* # of babies who referred	*Numerator:* # of babies unknown *Denominator:* # of babies who referred *Numerator:* # of babies contacted but unresponsive *Denominator:* # of babies who referred *Numerator:* # of babies unable to contact *Denominator:* # of babies who referred	*Numerator:* # of babies whose parents refuse *Denominator:* # of babies who referred
Subaim 1.1: No show	*Numerator:* # of babies who attend appt *Denominator:* # of babies scheduled	*Numerator:* # of families reached over the phone *Denominator:* # of families called	*Numerator:* # of cancellations *Denominator:* # of babies scheduled
Subaim 1.2: Refer rate	*Numerator:* # of babies who referred *Denominator:* # of babies scheduled	*Numerator:* # of screeners who score 90% or better on the screening checklist *Denominator:* # of screeners evaluated by the checklist	*<1% refer rate*

> Without having a clear direction of where an organization is trying to go and defined measures to determine how it will know if it gets there, how it gets there will not matter.

Learning in an improvement project often comes from identifying themes or patterns in the data. Patterns are easier to detect when the data is plotted over time. The data can show improvement or help to display an opportunity for improvement. Additionally, understanding variation helps people learn from the pattern. A simple way to plot data over time is by displaying the data through a run chart, which is easy to construct using Excel or statistical processing software (e.g., QI Charts, Chart Runner, QI Macros). A run chart displays variation of the data and highlights the impact changes have on the data (gains, maintenance, and loss). For more information about using run charts to understand variation, go to http://www.ihi.org/education/WebTraining/OnDemand/Run_ControlCharts/Pages/default.aspx

In *Figure 2*, the first run chart displays improvement a team has made over time, the second shows maintenance of improvement, and the third demonstrates how a run chart can detect losing the gains of improvement. Without the utilization of a run chart for the visual display of data, identifying these trends over time is incredibly difficult.

What change can we make that will result in improvement?

The aims and measures provide the scaffolding of the QI work, and the changes provide the flesh. Without having a clear direction of where an organization is trying to go and defined measures to determine how it will know if it gets there, how it gets there will not matter.

Figure 2
Run Charts

Improvement Over Time   **Maintenance of Improvement**   **Losing Gains of Improvement**
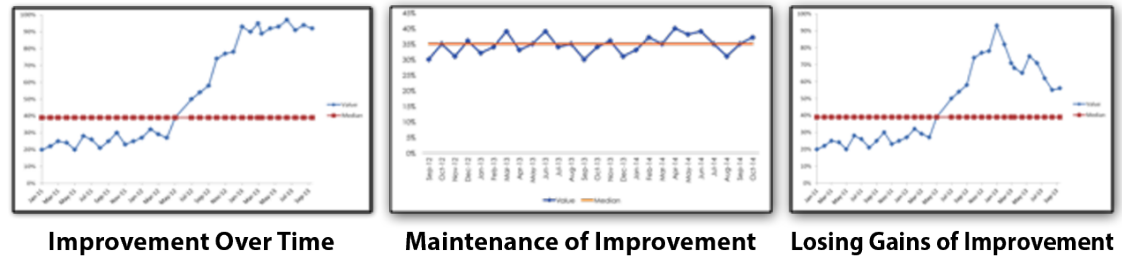
> All improvement requires change, but not all change will result in improvement.

To answer the question of "What change can we make that will result in improvement" requires the team to develop changes to test. The ability to develop, test, and implement changes is essential for any individual, group, or organization that wants to continuously improve. Changes are often referred to as strategies or change ideas and are in essence ideas the team wants to try in order to reach the aim and improve the system. Brainstorming and testing strategies is often the more exciting and one of the easier parts of QI and the area that teams prematurely delve into.
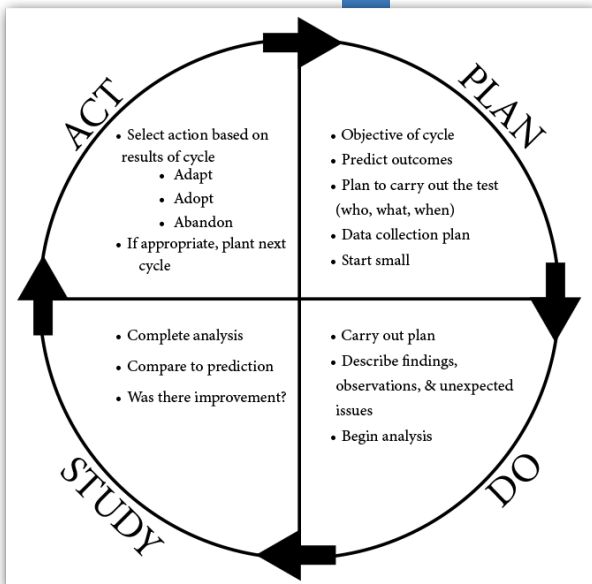
Theory of change. If a team wants to make a fundamental change—a change that redesigns the current system—it must create a theory of why the change they want to test will improve the system. Stating this theory or prediction helps a team design tests to validate or adapt the strategies from the results of the tests.

Tests of change. Once the three fundamental QI questions are answered, PDSA cycles can be used to turn change ideas into action and connect back the aim and measures. Initially, PDSA cycles are implemented on a very small scale (e.g., one audiologist, three babies, one day). Once confidence is gained that the strategy is resulting in improvement, the PDSA is incrementally expanded.

PDSA cycles are all about learning what improves the system and what does not. The cycles are iterative and use both deductive and inductive learning. Deductive learning takes place when there is a theory or prediction tested; then the organization inductively learns from observations of the test. The gap between observation and prediction are studied; then the theory is updated. Change ideas are at the core of improvement, but how these changes are tested is what makes the MFI unique. Using PDSA cycles effectively does require some effort, but teams find value in working through the process and appreciate not having to allocate large amounts of time and resources into an idea that has not yet proven to be effective. For an overview of PDSA cycles, go to: http://www.ihi.org/education/IHIOpenSchool/resources/Pages/Activities/WilliamsLearnPDSA.aspx. Organizations can develop their own way to track their PDSA cycles, but many find PDSA worksheets a useful tool. These worksheets are available on the IHI website at: http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx

There are a few additional pieces of information about PDSA cycles worth noting:

- Not all changes are appropriate for PDSA cycles. For example, if a team is working to improve the process of referrals from audiologists to early intervention providers, but doing so requires a memorandum of understanding (MOU), the MOU either is created and signed or not. It cannot

ACT
- Select action based on results of cycle
  - Adapt
  - Adopt
  - Abandon
- If appropriate, plant next cycle

PLAN
- Objective of cycle
- Predict outcomes
- Plan to carry out the test (who, what, when)
- Data collection plan
- Start small

STUDY
- Complete analysis
- Compare to prediction
- Was there improvement?

DO
- Carry out plan
- Describe findings, observations, & unexpected issues
- Begin analysis

be tested on a small scale, because it is a task not a test. That stated, most change ideas could be tested via PDSA cycles.

- Although the primary purpose of PDSA cycles is to test changes, the cycles can help an organization learn more about their current system. For example, a team may have the theory that some babies are mistakenly put into LTFU categories due to incorrect closure codes. They may review cases in a PDSA cycle format to understand if this theory is in fact correct and use the results to help them brainstorm potential strategies to test to improve the process.

- Most strategies have to be tested through multiple PDSA cycles. Many organizations ask, "When can we stop doing PDSA cycles and fully implement a strategy?" The answer is not as straightforward as some may like. The authors of *The Improvement Guide* . . . suggest a strategy can move from testing to implementation only when there is enough confidence that the strategy is leading to improvement.

- Test several change strategies before determining what is most effective. Thirty-fifty percent of strategies will not result in improvement, so an organization must test multiple strategies to achieve the improvement they seek.

- For a change to have impact, there has to be a shift from the current system. Sometimes the shift can be disruptive, so it is important to consider those who are involved in the change as well as those who will benefit from the results of the change.

> For a change to have impact, there has to be a shift from the current system. Sometimes the shift can be disruptive, so it is important to consider those who are involved in the change as well as those who will benefit from the results of the change.

Taking the example aim of reducing "no shows" in an audiology clinic, the clinic staff may want to test the strategy of appointment reminder phone calls. Their PDSA cycles may look like *Table 5*.

Table 5
Example of PDSA Cycles

PDSA	Cycle 1	Cycle 2	Cycle 3	Cycle 4
Plan	Call for the next three babies scheduled. Call families during the day.	Call for the next three babies scheduled. If families don't answer in the day, repeat call after 5:00 p.m.	Call for the next 10 babies scheduled. If families don't answer in the day, repeat call after 5:00 p.m. If not clear if number is the right family, call alternative phone number listed in baby's chart.	Repeat plan for Cycle 3 with next 20 babies.
Do	Did multiple phone calls in day; too time consuming.	Work schedule did not easily allow for after-hours work. Also, suspect first phone number listed isn't best.	Fairly time consuming, but results were worth it.	Nothing new noted.
Study	1 of 3 babies showed.	2 of 3 babies showed.	7 of 10 babies showed.	16 of 20 babies showed.
Act	Adapt test again, but call at night.	Adapt test again, but allow scheduler to come in late and stay late. Also, use second phone number listed if first is unsuccessful.	Adopt—scale up.	Scale up or implement.

> The MFI is a simple yet powerful tool to support EHDI programs in improving their processes and outcomes.

At this point, depending on the percentage of improvement over baseline, the team may decide to implement reminder phone calls for all babies scheduled for a diagnostic evaluation, or they may decide to try additional cycles that expand the scale.

Generic change ideas. There are an infinite number of possible change strategies. If a team is having difficulty brainstorming strategies to test, it may be helpful to consider strategies that have lead to improvement in other EHDI programs, utilized in other public health programs, reviewed through literature, or presented at conferences. For more information on change concepts, go to: http://www.ihi.org/resources/Pages/Changes/UsingChangeConceptsforImprovement.aspx.

API has developed 10 primary concepts of change that can also be used as a springboard for a brainstorming session (see *Table 6*).

Conclusion

The MFI is a simple yet powerful tool to support EHDI programs in improving their processes and outcomes. EHDI programs have been utilizing this model for several years and can link it to improved processes and outcomes for the early detection of D/HH children. Staying focused on each of the three questions in the MFI and using the iterative process of testing through PDSA cycles holds the greatest potential for improvement.

Table 6
API Primary Concepts of Change

Eliminate Waste

Screening machine-uploading results directly to EHDI-IS instead of manually.

Improve Workflow

Obtain EI consent for release of information.

Optimize Inventory

Securing an accurate PCP contact before discharge.

Change the Work Environment

Flexible work hours for staff to contact families in evening hours or weekends.

Enhance the Producer/Customer Relationship

A parent of a deaf child does follow-up with families.

Manage Time

Make rescreen appointment before discharge.

Manage Variation

One hospital staff sends reports to state EHDI to decrease variation.

Design Systems to Avoid Mistakes

Make changes in data system that alert the audiologist to submit a report.

Focus on a Product/Service

Working with a hospital to upload hearing results more frequently.

References

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