

A Step-by-Step Guide to Understanding and Conducting Quality Improvement Initiatives in Orthopaedic Surgery

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Abstract

Numerous frameworks have been developed as methods to address complex quality improvement (QI) problems. We aim to provide orthopaedic surgeons with a foundational understanding of QI in order to facilitate their engagement in QI initiatives. We begin by providing a broad overview of QI terms and frameworks and then present a step-by-step guide for conducting QI initiatives using a popular, intuitive, and practical method: Lean (A3). We accompany our descriptions with links to publicly accessible short QI videos developed by the Stanford Medicine Center for Improvement. Additionally, we list key educational resources offered by the American Academy of Orthopaedic Surgeons (AAOS) and the Pediatric Orthopaedic Society of North America (POSNA) as well as provide information on a recently published textbook devoted to QI and patient safety in orthopaedic surgery.

Introduction

In recent years, pay-for-performance initiatives and accreditation standards have placed greater pressure on orthopaedic surgeons to improve the quality of services they provide.^{1,2} In addition, many orthopaedic surgeons feel a moral impetus to improve patient care. As such, developing an understanding of quality improvement

(QI) methods has become increasingly important for orthopaedic surgeons.

Numerous frameworks have been developed as methods to address complex QI problems.^{1,3} Some of the most popular frameworks include the (1) Lean

(A3) method from the automotive manufacturing industry, (2) Six Sigma method from the device manufacturing industry, (3) Agile method from the software development industry, and (4) Institute for Healthcare Improvement (IHI) from the healthcare sector.^{3,4} Although these frameworks can be useful for guiding QI efforts, understanding each one in detail can be daunting for orthopaedic surgeons who are new to the field.

We aim to provide orthopaedic surgeons with a foundational understanding of QI in order to facilitate their engagement in QI initiatives. We begin by providing a broad overview of QI terms and frameworks and then present a step-by-step guide for conducting QI initiatives using a popular, intuitive, and practical method: Lean (A3). We accompany our descriptions with links to publicly accessible short QI videos developed by the Stanford Medicine Center for Improvement. Additionally, we list key educational resources offered by the American Academy of Orthopaedic Surgeons (AAOS) and the Pediatric Orthopaedic Society of North America (POSNA) as well as provide information on a recently published textbook devoted to QI and patient safety in orthopaedic surgery.

Defining Key Concepts

One of the major barriers orthopaedic surgeons may experience when attempting to conduct QI initiatives is understanding the terminology used in QI literature. The terminology can be confusing due to the difficulty of universally defining “quality” and the widespread use of interchangeable terms in the field.⁵

Quality

In industry, quality describes products or services that meet or exceed expectations.⁵ A commonly accepted definition of quality in the healthcare sector has been proposed by the Institute of Medicine, who defined high-quality healthcare as being safe, timely, effective, efficient, equitable, and patient-centered (Figure 1).^{6,7}



Figure 1. Six Domains of Health Care Quality: Institute of Medicine. Figure developed from the Agency for Healthcare Research and Quality. Six Domains of Health Care Quality. Published 2018. <https://www.ahrq.gov/talkingquality/measures/six-domains.html>.

Quality Control, Quality Assurance, and Quality Improvement

Quality control, quality assurance, and quality improvement are a few of the most commonly used terms in QI literature. While they are occasionally used interchangeably, we will use the term quality control as being product/service-focused, quality assurance as being process-focused, and quality improvement as being system-focused. Each of the aforementioned concepts builds on the previous one in a sequential manner (Figure 2).⁸ Quality control involves evaluating a *final product or service* against quality standards, while quality assurance involves evaluating the *processes* involved in producing a product or service. Quality improvement incorporates both and involves conducting *system-level* evaluations to proactively identify opportunities for improvement, implementing interventions to address shortcomings, and assessing and refining the very standards used to define quality.



Figure 2. Differentiating Quality Control, Quality Assurance, and Quality Improvement. Figure adapted from the American Society for Quality. *Quality Assurance & Quality Control*. Published 2018. <https://asq.org/quality-resources/quality-assurance-vs-control>.

QI Initiatives Versus Traditional Clinical Research Studies

QI initiatives tend to differ from traditional clinical research studies (such as clinical trials) in several aspects (Table 1). QI initiatives aim to improve existing practices by testing multiple interventions at once.⁹ By contrast, traditional clinical research studies tend to test a focused, single intervention to generate new knowledge.⁹ QI initiatives, unlike clinical research studies, do not fall under Institutional Review Board (IRB) purview, as they

usually pose minimal risk to participants.¹⁰ QI initiatives often have an evolving hypothesis rather than a fixed one. Additionally, unlike traditional clinical research studies that separate participants into two or more intervention groups, QI initiatives test several interventions over time with an entire group of participants; thus, their analysis methods and presentation of results differ.⁹ While run charts (described in greater detail later) are often utilized for QI initiatives, traditional clinical research studies typically present the results of differences between groups, with associated p-values and confidence intervals. In addition, their intended audiences differ: QI initiatives generally receive the most interest from the organization in which they were conducted, whereas traditional clinical research studies may be of broader interest due to their new scientific knowledge.⁹ Finally, findings from QI initiatives can often be implemented relatively quickly, whereas traditional clinical research studies can take much longer.

QI Tools and Frameworks

Overview

Numerous tools and frameworks have been developed to guide people interested in conducting QI initiatives, such as those outlined in Table 2.¹

Although there are differences between QI tools/frameworks, any tool/framework can be utilized based on surgeon familiarity.⁴ Each of these tools/frameworks

Table 1. Quality Improvement Initiatives Versus Traditional Clinical Research Studies

	Quality Improvement Initiatives	Traditional Clinical Research Studies
Aim	Improve existing practices	Generate new knowledge
Intervention	Multiple interventions	Focused, single intervention
Hypothesis	Evolving hypothesis	Fixed hypothesis
Presentation of Findings	Run charts	Between-group differences with p-values & confidence intervals
Target Audience	Organizations	Broader scientific community
Timeframe	Relatively quick	Lengthy

Figure adapted from Reinhardt AC, Ray LN. *Differentiating Quality Improvement From Research*. *Appl Nurs Res*. 2003;16(1):2-8. doi:10.1053/apnr.2003.50000.

Table 2. Summary of Key Quality Improvement Tools and Frameworks

Key Quality Improvement Tools and Frameworks	Description
Clinical Practice Guidelines	Formal guidelines for diagnosis or management of a clinical situation that are usually generated in an evidence-based manner.
Appropriate Use Criteria	Guidelines developed based on the collective judgment of experts on the appropriateness of various diagnostic testing and treatment options in specific clinical scenarios.
Care Pathways (Clinical pathways, Care map)	A formal pathway that outlines how care for a specific condition is to be delivered throughout the entire episode of care.
Plan-Do-Check-Act (PDCA) Cycles Plan-Do-Study-Act (PDSA) Cycles	A four-step, iterative, continuous improvement cycle that envisions what the process should look like (“plan”), implements the plan (“do”), records the results (“check” / “study”), and adjusts the process based on the results (“act”).
Lean Method	A multidisciplinary, team-based process for improving value and flow in the provision of services, developed by the Toyota Motor Company.
Six Sigma	A process improvement strategy introduced by the Motorola Company that focuses on (1) decreasing the rate that defects (errors) occur and (2) reducing variation in the production process.
Lean Six Sigma	An amalgamation of the principles of Lean (eliminating waste and improving workflow) and Six Sigma (decreasing the rate of errors and reducing process variation).
Root Cause Analysis	A formalized approach to evaluating the cause(s) of an adverse event.

Table condensed and reproduced from Pinney SJ, Page AE, Jevsevar DS, Bozic KJ. Current Concept Review: Quality and Process Improvement In Orthopedics. *Orthop Res Rev.* 2015;8:1-11. doi: 10.2147/ORR.S92216.

have specific features that can be beneficial for quality improvement and may, in certain situations, be used in tandem. For example, the Lean (A3) method integrates root cause analyses and Plan-Do-Check-Act (PDCA) cycles, which are also utilized in IHI methodology.¹¹ The explanations in Table 2 clarify some of the benefits of each.¹

Lean (A3) Method

The Lean (A3) method focuses on trimming down processes to eliminate anything that does not add value (“waste”), thereby making the process “lean.” Henry Ford, founder of the Ford Motor Company, revolutionized this model through his introduction of “flow production” in the automotive industry. He arranged fabrication equipment in sequence and

assembled components on an assembly line, resulting in dramatic reductions in production time and costs.¹² The framework was further refined during the 1960s, when the Toyota Motor Company developed a management system based on its principles.¹² The Lean (A3) method has since been applied in sectors, including healthcare.¹² The term “A3” relates to an international-size piece of paper, which can be used to illustrate the entire QI process (Figure 3).^{11,13} When all aspects of the QI process are depicted on a single page, everyone involved in the initiative gains a unified perspective.¹¹ An A3 displays each step of the QI process from the top left corner to the bottom right corner, starting with developing a problem statement and ending with a sustainment plan if interventions (“countermeasures”) are found to be successful.

TITLE	Quality Improvement Team Sponsor: _____ Communicator: _____ Team leader: _____ Team members: _____ Last Updated: _____																										
Background: Problem Statement What is the problem? To whom does it matter? Why should it be prioritized?	Interventions: Key Drivers & Countermeasures <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="background-color: #4a7ebb; color: white; padding: 5px;">Key Drivers</th> <th style="background-color: #4a7ebb; color: white; padding: 5px;">Countermeasures</th> </tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> </table>	Key Drivers	Countermeasures																								
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Figure 3. Sample A3 Template.

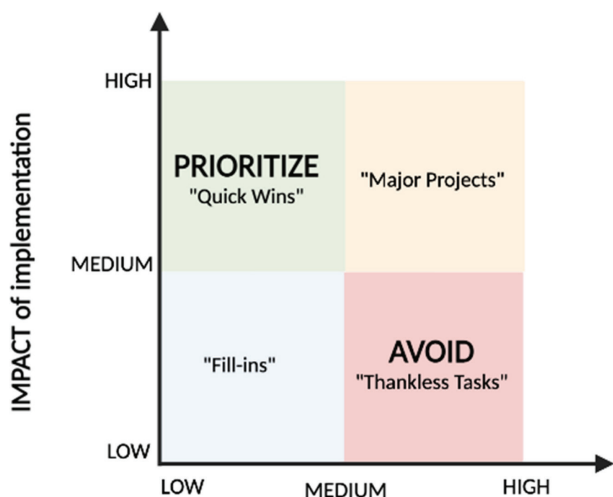
Step-by-Step Guide to Conducting QI Initiatives Using the Lean (A3) Method

Step 1: Identify an Area for Improvement

Several methods exist for orthopaedic surgeons to identify areas for improving quality. Among the methods are: (1) anecdotal clinical experiences (e.g., those presented at morbidity and mortality [M&M] conferences and discovered through Root Cause Analyses), (2) key performance indicators tracked by orthopaedic departments (e.g., surgical cases, referral volume, and clinic wait times), (3) preliminary outcome data (e.g., suboptimal outcomes derived from electronic medical records), and (4) institutional outcomes compared with national benchmarks

(e.g., outcomes compared with those recommended by the National Surgical Quality Improvement Program).¹⁴

Once problems have been identified, it is essential to prioritize those that require the most urgent attention. Thus, high-impact or high-value initiatives should be selected. To determine the level of impact or value, it can be helpful to create an Impact-Effort Matrix and/or Value-Risk Matrix (Figures 4 and 5).^{14,15} In doing so, one can identify initiatives that are likely to have the greatest impact while simultaneously avoiding wasting resources on those that are likely to have a low impact (Impact-Effort Matrix) or likely to have the greatest value with the least risk (Value-Risk Matrix).^{14,15}



EFFORT required to implement

Figure 4. Impact-Effort Matrix. Figure adapted from the American Society for Quality. Impact Effort Matrix. <https://asq.org/quality-resources/impact-effort-matrix>.

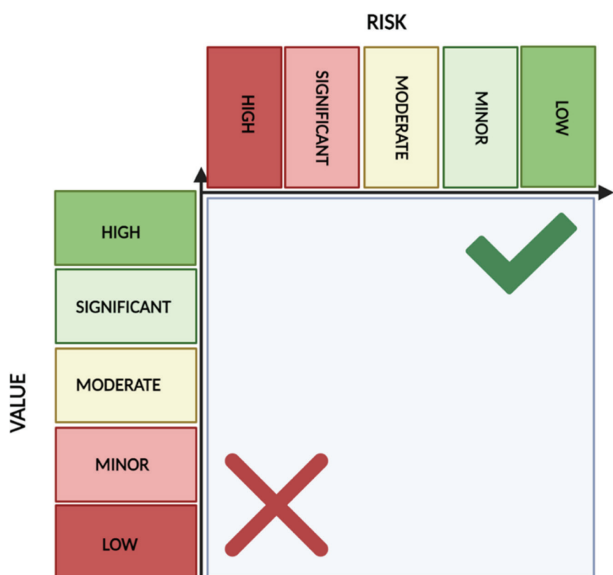


Figure 5. Value-Risk Matrix. Figure adapted from: Method Grid. Value – Risk/Complexity/ Effort – Matrix. <https://methodgrid.com/examples/value-matrix-risk-template-example/>.

Problem prioritization also requires (1) aligning with internal priorities (e.g., those proposed by the orthopaedic department) or external priorities (e.g., those proposed by hospital leadership or national regulatory systems) and (2) demonstrating financial viability

through cost assessments.¹⁴ It is especially important to consider overall hospital strategic quality priorities when performing this work as alignment with the larger organization often leads to increased resources and easier spread across the institution.

Step 2: Assembling a QI Team

Stanford Medicine Center for Improvement: QI Video Series

Building an Improvement Project Team: <https://youtu.be/BUnKeKMNSYM>

Once areas for QI have been identified, it is necessary to assemble a multidisciplinary team of motivated individuals to form a QI team.^{2,16} In some institutions, a group of QI leaders exist that orthopaedic surgeons can join. In other instances, orthopaedic surgeons may need to create a unique team to address areas for improvement. The QI team should include (1) a sponsor, (2) a leader, (3) a communicator, (4) multidisciplinary team members, and be included on the A3 (Figures 6 and 7).^{2,16} It is important for the leader to be fully committed to achieving the QI goals and have cultural authority to lead the team. It is also helpful for team members to be involved in direct clinical care and have representation from the various elements of the patient's episode of care.

It is important for teams to define clear roles and norms from the beginning to decrease the amount of time spent in less productive stages of group development.¹⁶ As teams work through a QI initiative, they often go through four stages of development: forming, storming, norming, and performing (Figure 8).^{16–18} In the first stage, forming, team members orient themselves, establish ground rules, and demonstrate a respectful and positive attitude.^{16,17} As the team progresses, conflicts may begin to arise between members, which leads to the storming stage.^{16,17} During the norming stage, members learn how to collaborate and develop cohesiveness despite their differences.^{16,17} In the final stage, team members begin to appreciate each other's strengths and

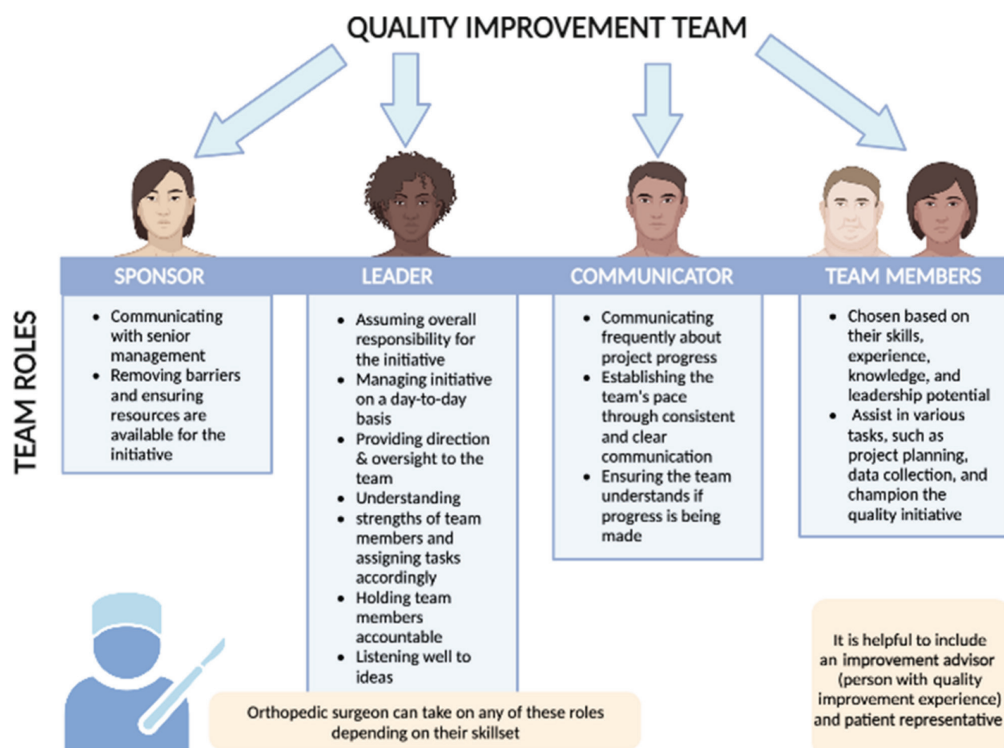


Figure 6. Roles of QI Team. Figure adapted from (1) Wolfstadt JI, Ward SE, Kim S, Bell CM. Improving Care in orthopaedics: How to incorporate quality improvement techniques into surgical practice. *The Journal of Bone and Joint Surgery*. 2018;100(20):1791-1799. doi:10.2106/JBJS.18.00225 and (2) Stanford Medicine Center for Improvement. Building an Improvement Project Team. Published 2021. <https://youtu.be/BUUnKeKMNSYM>.

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Figure 7. Documenting QI Team Members on A3.

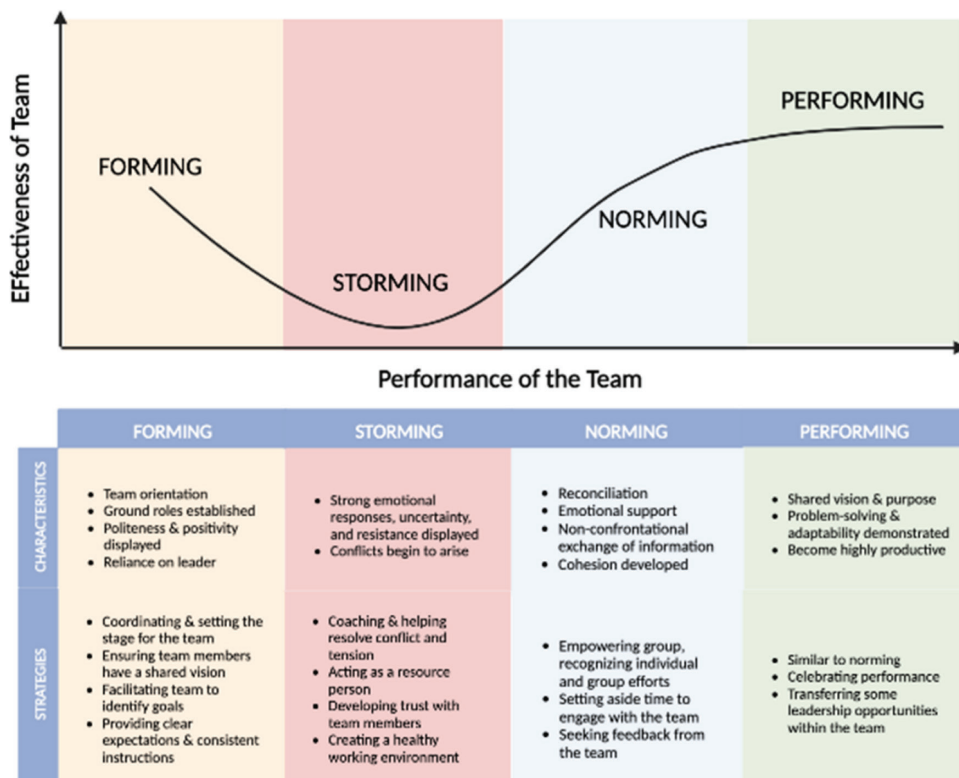


Figure 8. Tuckman's Model of Group Development. Figure adapted from (1) Tuckman BW. Developmental sequence in small groups. *Psychol Bull.* 1965;63:384-399. doi:10.1037/h0022100 and (2) Manges K, Scott-Cawiezell J, Ward MM. Maximizing Team Performance: The Critical Role of the Nurse Leader. *Nursing Forum.* 2017;52(1):21-29. doi:10.1111/nuf.12161.

share a clear vision and purpose, which leads to high productivity.^{16,17}

Step 3: Developing a Problem Statement

Stanford Medicine Center for Improvement: QI Video Series

Writing a Problem Statement: <https://youtu.be/rweAtunTny0>

Team members may have divergent perspectives on a problem; therefore, defining the problem to be addressed—as a team—will be the first step to developing a problem statement.¹¹ Teams should aim to have a one-to-two sentence statement that explains (1) what the problem is, (2) to whom the problem matters, and (3) why the problem should be prioritized over others.¹⁹

In order to develop good problem statements, teams must (1) first recognize that more time should be spent analyzing the problem than thinking about its solution, (2) understand that stakeholders often care less about the problem itself and more about *why* it needs to be solved, (3) align the problem statement with internal or external organizational priorities, (4) ensure the problem statement is clear and concise, and does not include goals or countermeasures.^{19,20} After agreeing on the problem statement, teams can write it on their A3 (Figure 9). The problem statement may evolve over time as teams gain a deeper understanding of the problem.^{19,20}

We use a recent orthopaedic QI initiative focused on reducing opioid use in pediatric patients with supracondylar humerus fractures as a case example for conducting QI initiatives.²¹ Figure 10 presents a hypothetical problem statement for this QI initiative.

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Figure 9. Documenting Problem Statement on A3.

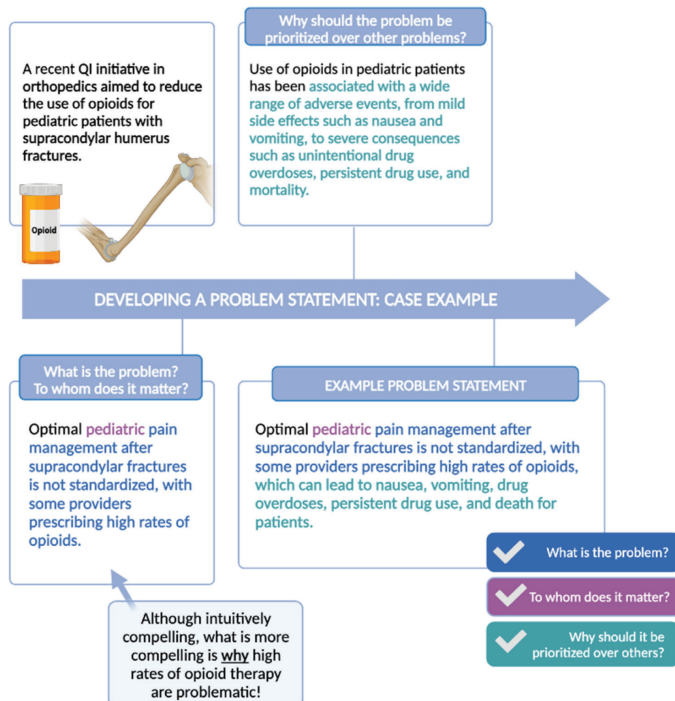


Figure 10. Developing a Problem Statement: Case Example. Hypothetical problem statement developed for Winslow L, Holstine J, Samora JB. Samora. *Jt Comm J Qual Patient Saf.* 2020;46(10):581-587. doi:10.1016/j.jcjq.2020.06.010.

Step 4: Conducting a Current State Analysis

Stanford Medicine Center for Improvement: QI Video Series

Current State Analysis: <https://youtu.be/NloUtDFTAdQ>

QI teams should conduct a current state analysis to (1) document the current state of the problem and (2) develop a clear understanding of the processes that influence it.²⁰

It is crucial for teams to understand that real improvements can only be achieved by observing current conditions.¹¹ *Genchi genbutsu shugi* is Toyota Motor Company's term for this principle, which emphasizes the importance of observing what is actually happening at the place where work is being performed.¹¹ There are three main stages of conducting current state analyses: (1) observing the current state, (2) identifying waste in a process, and (3) building a process map.²²

(1) Observing the current state: Multiple members of the QI team should observe the problematic process in its entirety several times to obtain a better understanding of its current state, often referred to as “going to *gemba*” (the place where work is being performed).^{3,22}

(2) Identifying waste in a process: QI team members should discuss waste in the process after witnessing its current state.²² The acronym “TIMWOODS” can help team members identify waste areas within the following eight categories: Transport, Inventory, Motion, Waiting, Overprocessing, Overproduction, Defects, and Skills (Figure 11).^{22,23}

(3) Building a process map: Once a thorough understanding of the current state has been obtained, QI team members can create a process map together.²² A process map is a visual representation of the steps involved in a process; it is used to identify opportunities for improvement and future development.² When trying to map out an entire process, it may seem overwhelming. Some recommendations to guide developing process maps include (1) keeping the map as simple and linear as possible while still accurately reflecting the existing

process, (2) starting with the book ends of the process map (i.e., the very first and last steps), (3) creating a box for each step of the process, (4) using verbs to describe each step; (5) only mapping out steps that usually occur (i.e., more than 80% of the time); (6) only including the steps that the QI team observe, and (7) involving people who perform the work at hand (“front-line workers”), as they have the best knowledge of the process and its challenges.²² We offer a hypothetical process map for a case example in Figure 12.²¹ Upon completion, teams can write their current state analysis on their A3 (Figure 13).

Step 5: Developing SMART Goals(s)

Stanford Medicine Center for Improvement: QI Video Series

SMART Goals and Measures: <https://youtu.be/nS4HnMk8tCo>

By knowing the problem and its current state, QI teams can begin developing a goal for their QI initiative.²⁴ In addition to keeping people motivated, it can help them stay on track towards a common endpoint. We recommend that teams

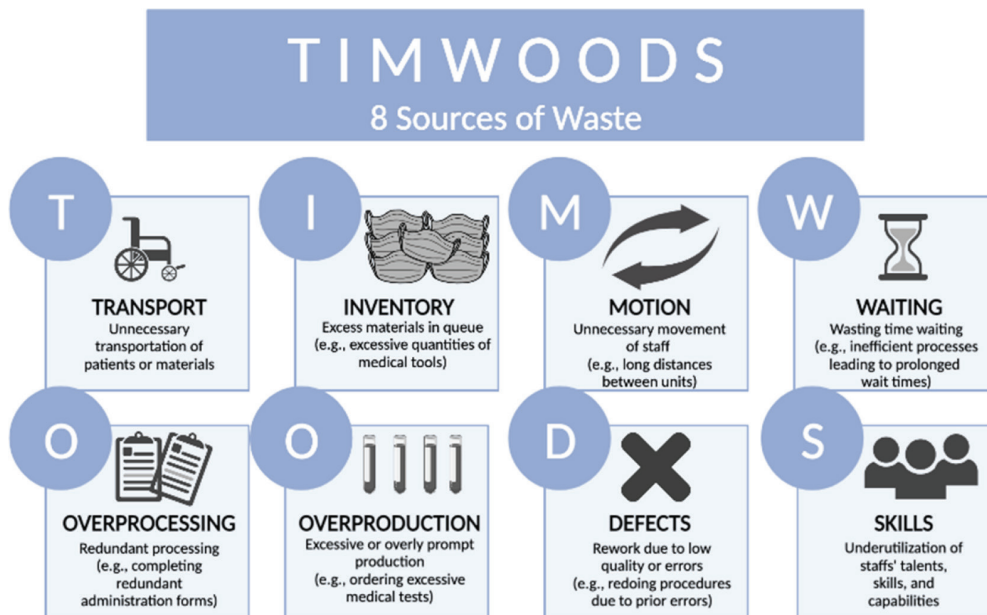


Figure 11. TIMWOODS: Eight Sources of Waste. Figure developed based on Hines P, Nick R. The seven value stream mapping tools. *Int J Oper Prod.* 1997;17:46-64.

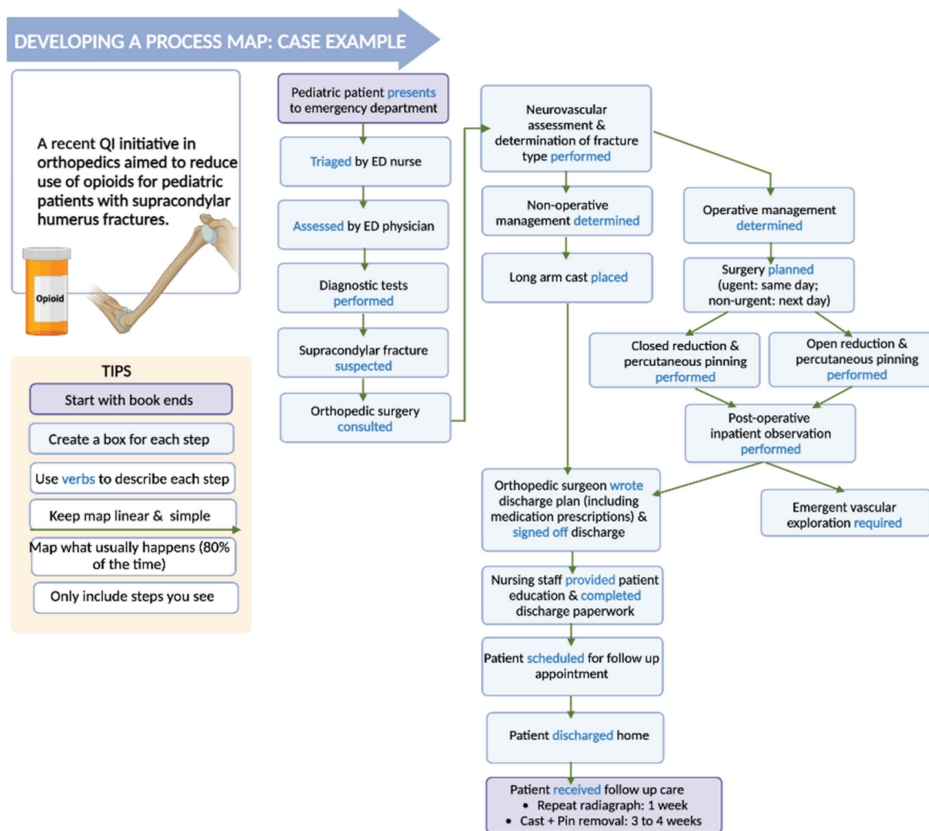


Figure 12. Developing a Process Map: Case Example. Hypothetical process map developed for Winslow L, Holstine J, Samora JB. Reducing the Use of Opioids for Pediatric Patients with Supracondylar Humerus Fractures. *Jt Comm J Qual Patient Saf.* 2020;46(10):581-587. doi:10.1016/j.jcjq.2020.06.010.

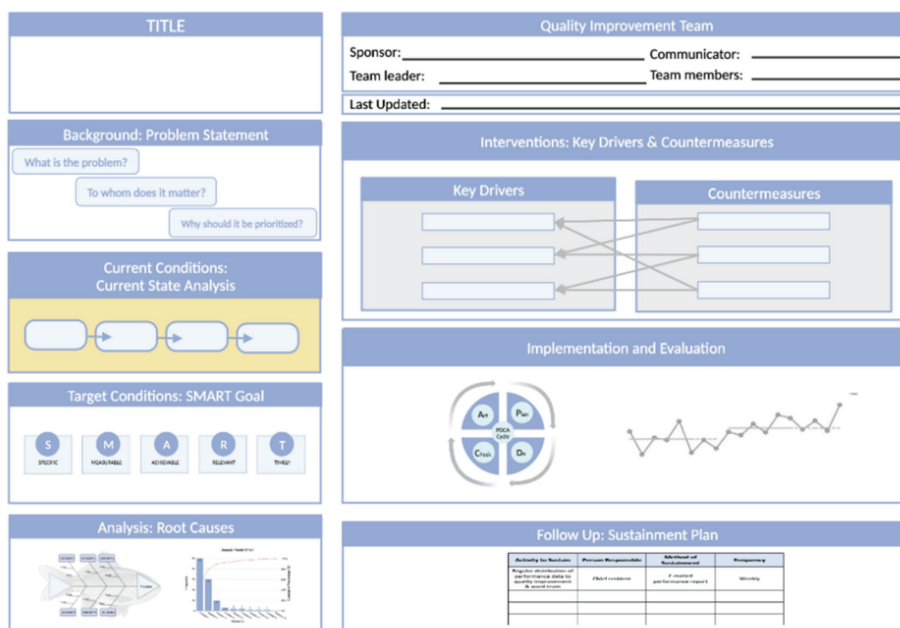


Figure 13. Documenting Current State Analysis on A3.

develop “SMART” goals (also known as aims per IHI standards²⁵), which are specific, measurable, achievable, relevant, and timely.³ In Figure 14, each component of a SMART goal is defined with a case example.²¹ To demonstrate the significance of a goal, surgeons may find it useful to identify why they chose to pursue it (e.g., based on existing literature or prior performance levels). Once a SMART goal is developed, teams can document it on their A3 (Figure 15).

Step 6: Identifying Root Causes

Stanford Medicine Center for Improvement: QI Video Series
Identifying Root Causes: https://youtu.be/0rnjQfLvlm4
Prioritizing the Vital Few: https://youtu.be/ZUjppgU1mnU

Teams should identify the “root causes” contributing to their problem. Root causes are high-level factors that ultimately cause a problem. While it is tempting to address a problem based on “gestalt,” teams should rather work systematically to determine what elements are leading to the problem.^{11,26} The final step, exploring the root causes, requires identifying *all* possible root causes and then specifically identifying *principal* root causes (Figure 16).²⁶

Identifying all Possible Root Causes

In the first stage, QI team members can work to identify *any* root cause that could be contributing to the problem.²⁶ Teams can use a variety of techniques to brainstorm, including the “five whys” or “fishbone diagram”.^{2,3,26} Five whys is an interrogative technique for exploring the cause-and-effect relationship between

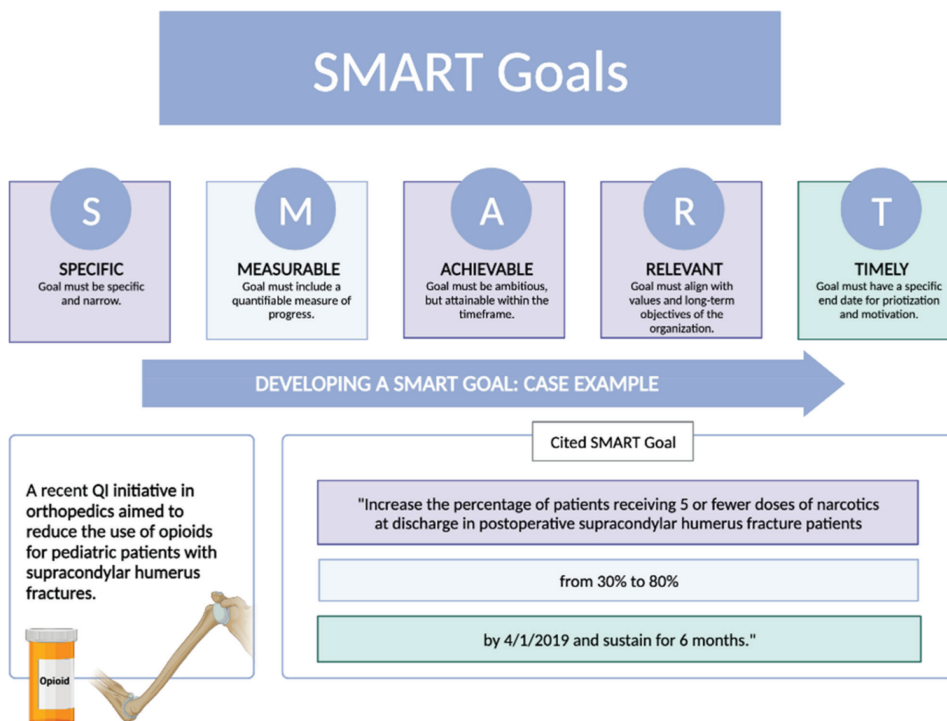


Figure 14. Developing a SMART Goal/Aim: Explanation & Case Example. Figure developed based on (1) Doran GT. There's a S.M.A.R.T. way to write management's goals and objectives. *Management Review*. 1981;70(11):35-36 and (2) Stanford Medicine Center for Improvement. SMART goals and measures. Published 2021. <https://youtu.be/nS4HnMk8tCo>. Goal extracted from: Winslow L, Holstine J, Samora JB. Reducing the Use of Opioids for Pediatric Patients with Supracondylar Humerus Fractures. *Jt Comm J Qual Patient Saf*. 2020;46(10):581-587. doi:10.1016/j.jcjq.2020.06.010.

TITLE

Sponsor: _____ Communicator: _____

Team leader: _____ Team members: _____

Last Updated: _____

Background: Problem Statement

What is the problem?

To whom does it matter?

Why should it be prioritized?

Current Conditions: Current State Analysis

Target Conditions: SMART Goal

S SPECIFIC

M MEASURABLE

A ACHIEVABLE

R RELEVANT

T TIME?

Analysis: Root Causes

Quality Improvement Team

Interventions: Key Drivers & Countermeasures

Key Drivers

Countermeasures

Implementation and Evaluation

Follow Up: Sustainment Plan

Activity for Monitor	Person Responsible	Method of Measurement	Frequency
Regular observation of quality improvement efforts at Special Events	Chief cook/chef	If needed, performance report	Weekly

Figure 15. Documenting SMART Goal on A3.

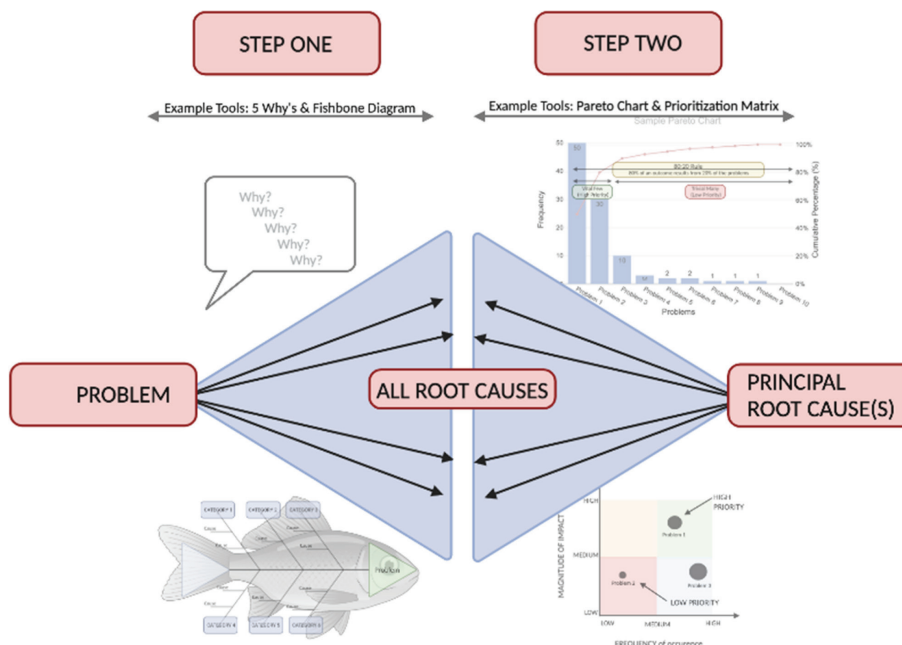


Figure 16. Identifying Root Causes. Figure adapted from Hopkins J. A3 Project Management: Improving clinical care, research, and education. Presented at Stanford Leadership Development Program; 2020.

root causes and problems. It involves repeatedly asking “why” (around five times, though this number varies) until the root causes of a problem are identified; it involves determining systemic issues rather than blaming

individuals.³ Fishbone diagrams (also known as Ishikawa diagrams or cause-and-effect diagrams) are visuals created to illustrate the causal relationship between root causes and problems by examining possible root causes

in different categories, such as the *four Ms* (methods, manpower, materials, and machinery) or *four Ps* (policies, procedures, people, and plant) (Figure 17).^{5,27}

Identifying Principal Root Cause(s)

QI team members must narrow their focus on the root causes that are the most important. “Pareto charts” and

“prioritization matrices” can be utilized to define the key causes.^{3,26} In a Pareto chart, root causes are listed on the X-axis and their frequency in causing quality problems are listed on the Y-axis (Figure 18).³ The Pareto principle states that 80 percent of performance outcomes are the result of 20 percent of the root causes.³ In QI initiatives, it is recommended to

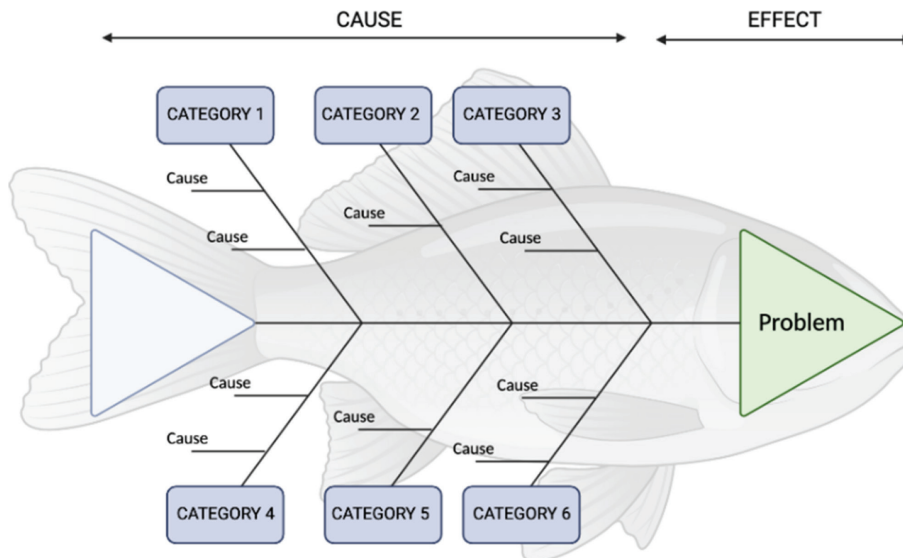


Figure 17. Fishbone Diagram / Ishikawa Diagram / Cause-and-Effect Diagram. Figure adapted from Ishikawa K. *Guide to Quality Control*. Asian Productivity Organization; 1976.

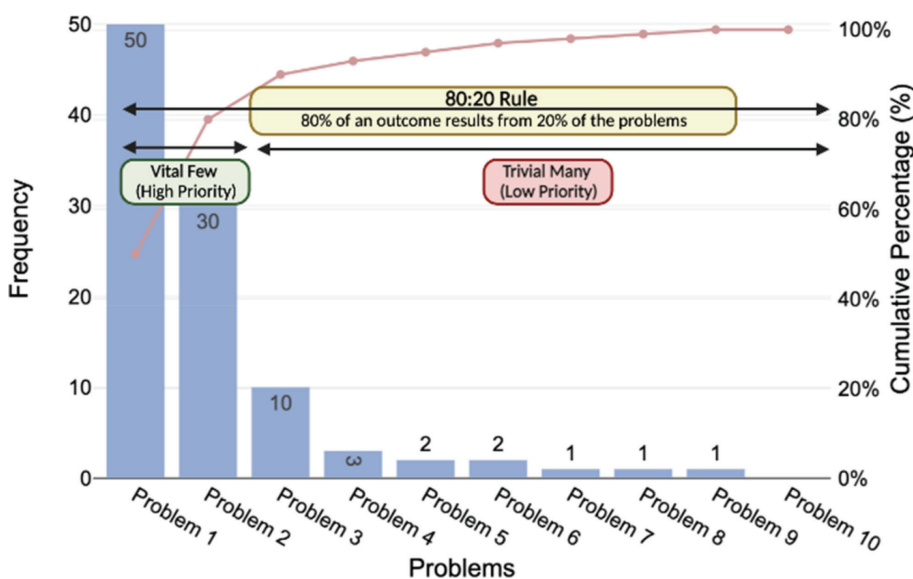


Figure 18. Pareto Chart. Figure adapted from Spath P. *Introduction to Healthcare Quality Management*. 3rd ed. Health Administration Press; 2009.

focus on the 20 percent of root causes affecting 80 percent of performance (the “vital few”), and not on the many other potential root causes (the “trivial many”).³ Teams can vote (based on expert knowledge) or collect prospective data to determine

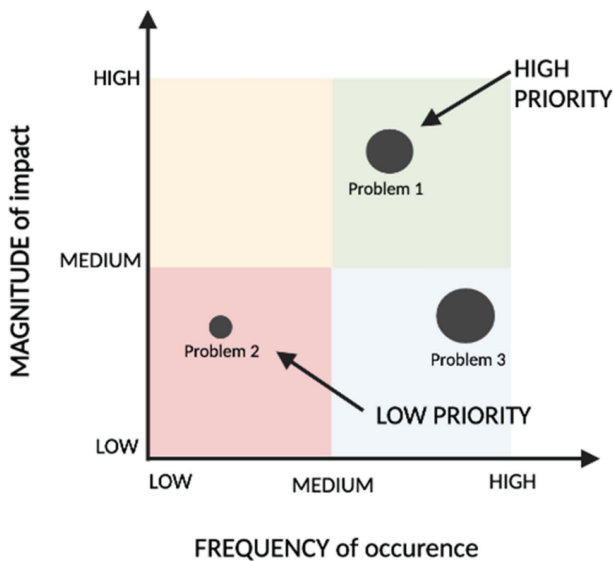


Figure 19. Prioritization Matrix. Figure adapted from Stanford Medicine Center for Improvement. Prioritizing the Vital Few. Published 2021. <https://youtu.be/ZUjppgU1mnU>.

the frequency with which root causes contribute to a problem.^{2,26}

A prioritization matrix (Figure 19) is an alternative to a Pareto chart that is more qualitative and takes into account the frequency of a root cause’s occurrence (X-axis), its magnitude of impact (Y-axis), and its ability to be controlled (circle size).²⁶ When using this method, teams discuss the frequency, magnitude, and controllability of each root cause and prioritize those which are frequent, of high impact, and able to be controlled.²⁶ Once this stage is complete, teams can update their A3 (Figure 20).

Step 7: Identifying Key Drivers

Stanford Medicine Center for Improvement: QI Video Series

Developing Key Drivers: <https://youtu.be/-O3LcvJOmP4>

Team members must then identify the “drivers” to target. “Drivers” are conditions that must be present in order for interventions to be effective.^{14,20} The process of identifying key drivers can be divided into two stages: drafting and refining.²⁸

TITLE 		Quality Improvement Team Sponsor: _____ Communicator: _____ Team leader: _____ Team members: _____ Last Updated: _____																	
Background: Problem Statement What is the problem? To whom does it matter? Why should it be prioritized?		Interventions: Key Drivers & Countermeasures <table border="1"> <tr> <th>Key Drivers</th> <th>Countermeasures</th> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </table>		Key Drivers	Countermeasures														
Key Drivers	Countermeasures																		
Current Conditions: Current State Analysis 		Implementation and Evaluation 																	
Target Conditions: SMART Goal S: _____ M: _____ A: _____ R: _____ T: _____ SPECIFIC MEASURABLE ACHIEVABLE RELEVANT TIMELY		 																	
Analysis: Root Causes 		Follow Up: Sustainment Plan <table border="1"> <tr> <th>Activity for Sustaining</th> <th>Person Responsible</th> <th>Method of Sustaining</th> <th>Frequency</th> </tr> <tr> <td>Regular distribution of performance data to quality improvement team & other leaders</td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </table>		Activity for Sustaining	Person Responsible	Method of Sustaining	Frequency	Regular distribution of performance data to quality improvement team & other leaders											
Activity for Sustaining	Person Responsible	Method of Sustaining	Frequency																
Regular distribution of performance data to quality improvement team & other leaders																			

Figure 20. Documenting Root Causes on A3.

Drafting

A useful way for QI teams to draft root causes is for them to first evaluate the root cause analysis to examine factors that contribute to the problem.²⁸ For example, a root cause of inappropriate opioid prescriptions postoperatively may be the prescribing physician's lack of awareness of effective alternatives (e.g., acetaminophen). Drivers may be considered to be the inverse of root causes, that is, conditions that must exist in order for a problem not to occur. In this case, it may be provider awareness and education.

Refining

Teams refine the drivers further to ensure that they are patient-centered and acceptable to both the team and the leadership and then document them (Figure 21).²⁸ We provide a case example of identifying drivers in Figure 22.²¹

Step 8: Developing Countermeasures

Having a thorough understanding of the problem being addressed, its root causes, and the key drivers allows QI teams to develop countermeasures. A countermeasure (or intervention) is a specific action taken to address one or more of the drivers. The best countermeasures are those that address more than one driver.¹¹ Lean (A3) thinking typically uses the term “countermeasures” instead of “solutions”, because it acknowledges that any apparent “solution” will create new problems, thus serving as a temporary solution until better ones can be identified.¹¹

As a first step, QI teams should brainstorm multiple countermeasures as advocating for only one countermeasure is seldom supported by sufficient facts or consensus.¹¹ Additionally, several stakeholders should be consulted while developing countermeasures, which increases the likelihood of gaining buy-in, and lay the groundwork for successful implementation.¹¹ QI team members can collaborate to focus in on a smaller number of measures.

Figure 21. Documenting Key Drivers on A3.

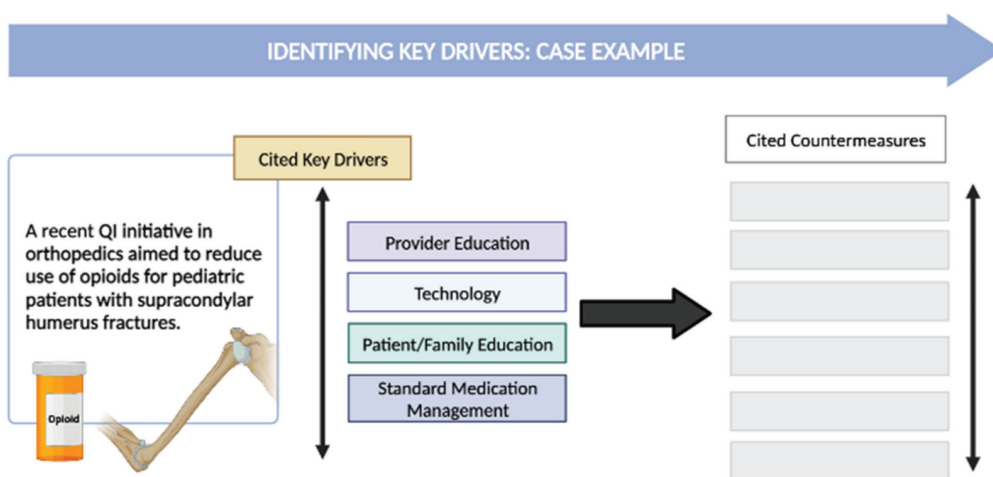


Figure 22. Identifying Key Drivers: Case Example. Key drivers extracted from: Winslow L, Holstine J, Samora JB. Reducing the Use of Opioids for Pediatric Patients with Supracondylar Humerus Fractures. *Jt Comm J Qual Patient Saf.* 2020;46(10):581-587. doi:10.1016/j.jcjq.2020.06.010.

Examples of countermeasures used in orthopedic QI initiatives include (1) implementing checklists, clinical pathways, or clinical practice guidelines to standardize processes, (2) simplifying clinical processes, (e.g., through automation), and (3) implementing educational interventions.² Countermeasures that eliminate the greatest amount of waste as well as enhance effectiveness and efficiency at the same time should be the focus. Additionally, it is critical that they do not require large amounts of additional work from teams, since these often fail due to difficulties obtaining compliance from front-line workers. Each countermeasure should be linked to the root cause(s) they address (Figure 23). A case example of developing countermeasures is illustrated in Figure 24.²¹

Step 9: Implementing and Evaluating Countermeasures

Stanford Medicine Center for Improvement: QI Video Series
Testing Changes: https://youtu.be/cLlNi3WzPxU
Building and Using Run Charts: https://youtu.be/qwrleR5QgPM

TITLE Background: Problem Statement What is the problem? To whom does it matter? Why should it be prioritized? Current Conditions: Current State Analysis Target Conditions: SMART Goal S M A R T SPECIFIC MEASURABLE ACHIEVABLE RELEVANT TIMELY Analysis: Root Causes	Quality Improvement Team Sponsor: _____ Communicator: _____ Team leader: _____ Team members: _____ Last Updated: _____ Interventions: Key Drivers & Countermeasures Key Drivers Countermeasures Implementation and Evaluation Follow Up: Sustainment Plan
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Figure 23. Documenting Countermeasures on A3.

Prior to implementing countermeasures, the QI team must identify the measures that will be used to assess whether the countermeasures have had an impact. In most cases, three to eight measures are sufficient. Measures can be grouped into three general categories: process measures, outcome measures, and balancing measures (Table 3).^{2,14}

Following the identification of the measures, countermeasures can be tested in an iterative, test-fail manner.²⁹ A method of iterative testing is the Plan-Do-Check-Act cycle (PDCA cycle, also known as the Deming Cycle or Deming Wheel, Figure 25).³⁰ As the driving force behind the A3 process, PDCA cycles serve as the engine that determines when countermeasures will be implemented and what is and is not working in the QI process.¹¹

As part of the “plan” phase, teams define specific objectives, formulate hypotheses, and develop test plans.¹¹ In the “do” phase, teams implement the test plan and collect data.¹¹ Teams then analyze the data and summarize the results during the “check” phase.¹¹ At the end of the process, they adapt, adopt, or abandon

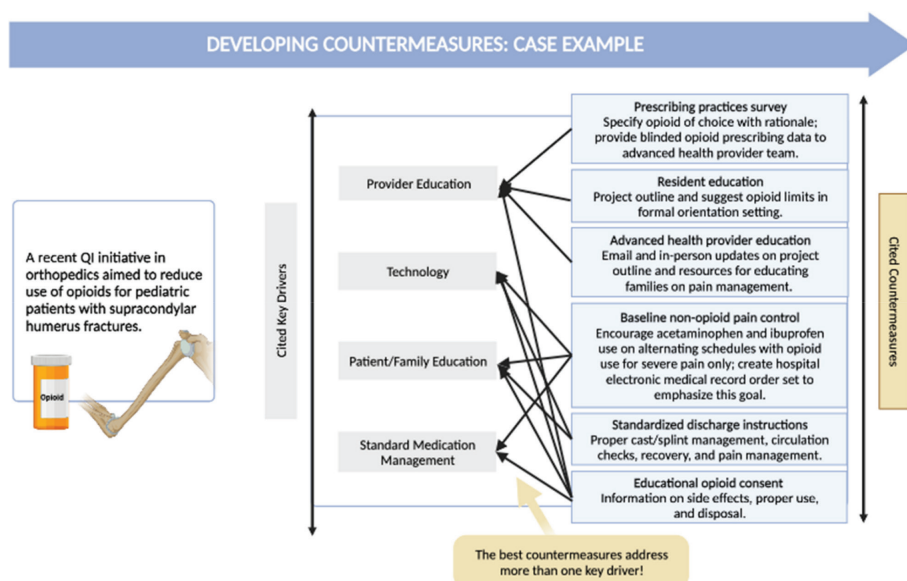


Figure 24. Developing Countermeasures: Case Example. Countermeasures extracted from Winslow L, Holstine J, Samora JB. Reducing the Use of Opioids for Pediatric Patients with Supracondylar Humerus Fractures. *Jt Comm J Qual Patient Saf.* 2020;46(10):581-587. doi:10.1016/j.jcjq.2020.06.010.

Table 3. Types of Outcome Measures

	Process Measure	Outcome Measure	Balancing Measure
Definition	Measures activity and performance change post-countermeasure(s) implementation.	Measures the direct impact of implementing countermeasure(s) on patients' health.	Measures the potential unintended consequences or adverse effects from intervention(s).
Case example in QI initiative focused on reducing opioid use in pediatric patients with supracondylar humerus fractures	Proportion of patients prescribed five or fewer opioids at discharge (cited by paper)	Proportion of opioid-related adverse events at 1-month follow-up (hypothetical)	Proportion of prescription fills or refills from the facility within 14 days after discharge to identify inadequate initial opioid prescriptions (cited by paper)

Example measures extracted from Winslow L, Holstine J, Samora JB. Reducing the Use of Opioids for Pediatric Patients with Supracondylar Humerus Fractures. *Jt Comm J Qual Patient Saf.* 2020;46(10):581-587. doi:10.1016/j.jcjq.2020.06.010.

their original plan in the “act” phase and prepare for the next cycle.¹¹ Team members should begin with small tests of the countermeasures or to test them within a small group; this allows for the countermeasures to be refined through cascading PDCAs.³ After the process becomes efficient, it can be rolled out to a wider audience and spread throughout the organization. In large centres with large geographical reach, this

can be difficult; therefore, helpful recommendations include prioritizing key countermeasures according to institutional quality goals to ensure that end users do not feel overburdened, communicating countermeasures through a variety of channels, demonstrating the effectiveness and efficiency of countermeasures, and rewarding success rather than punishing failure in improving quality.

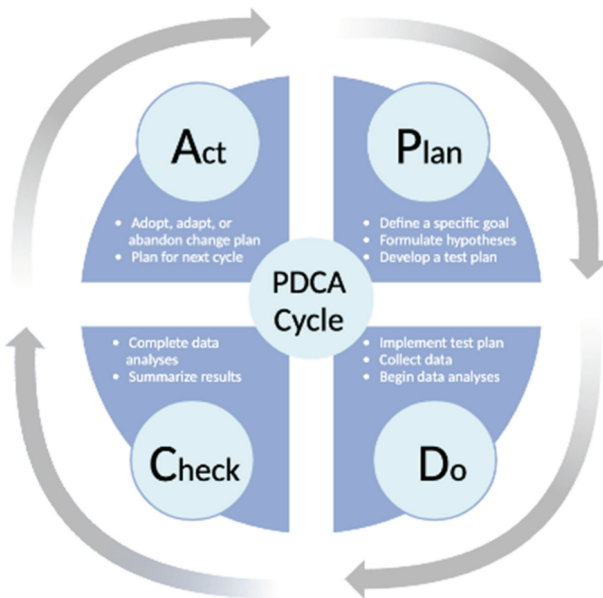


Figure 25. Plan-Do-Check-Act (PDCA) Cycle / Plan-Do-Study-Act (PDSA) Cycle. Figure adapted from (1) Deming W. *Out of the Crisis*, 1986. Massachusetts Institute of Technology Center for Advanced Engineering Study; 1991. and (2) Shook J. *Managing to Learn: Using the A3 Management Process to Solve Problems, Gain Agreement, Mentor, and Lead*. Lean Enterprise Institute, Inc; 2008.

When QI teams obtain their data, they must present it in a manner that is transparent and easy to understand. Run charts are common methods to display data from QI initiatives, as they help determine if improvement has been achieved and sustained.² The Stanford Medicine Center for Improvement offers instructions for building a run chart on Excel, summarized in Figure 26.³¹ It is also imperative that all data be formatted correctly (e.g., outcome data formatted as a number or percentage, rather than as general text on Excel) as well as including a title, axis labels, and annotations.³¹ A case example of a run chart for a QI initiative is shown in Figure 27.²¹ As PDCA cycles and run charts are completed, teams can update their A3 (Figure 28).

Step 10: Crafting a Sustainment Plan

Stanford Medicine Center for Improvement: QI Video Series

Sustaining the Gains: <https://youtu.be/gb5YZwzp0qU>

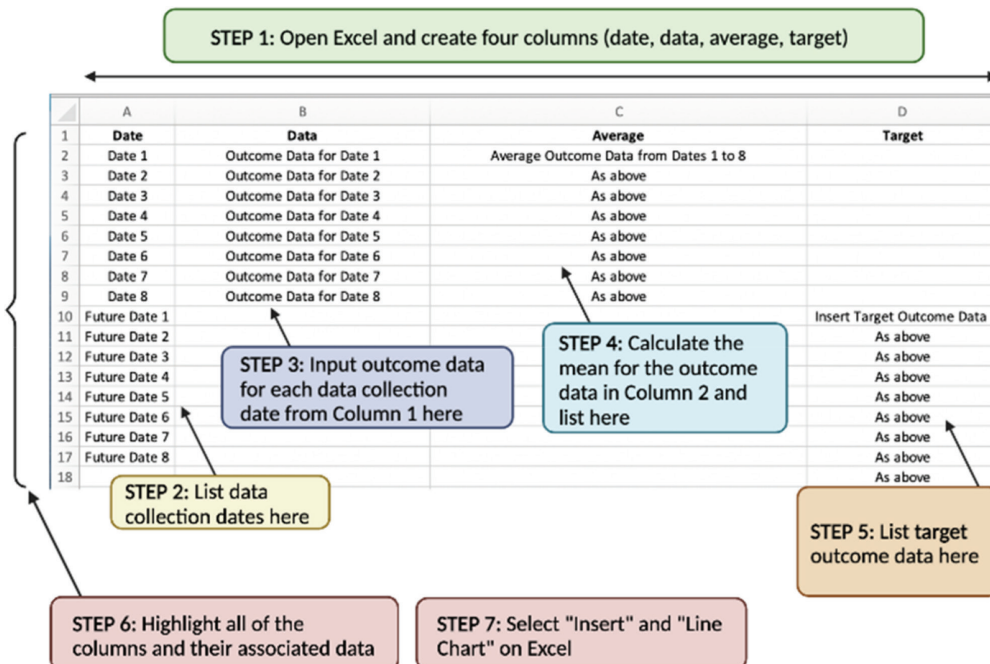


Figure 26. Creating a Run Chart in Excel. Figure developed from Stanford Medicine Center for Improvement. *Building and Using Run Charts*. Published 2021. <https://youtu.be/qwrleR5QgPM>.

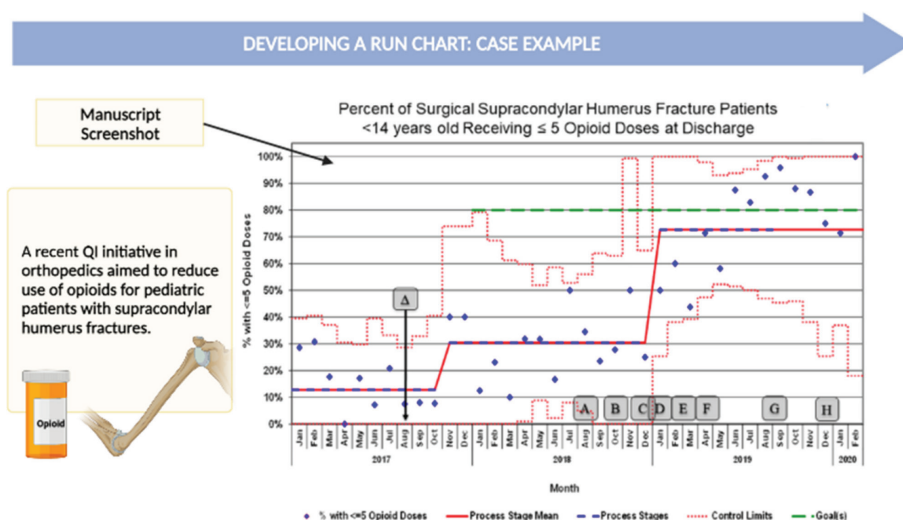


Figure 2: This p-chart demonstrates the outcome measure of the percentage of surgical SCH fracture patients receiving five or fewer doses of opioid at discharge. Since July 2019 we have had several months meeting our goal of 80%. Intervention labels are defined in Table 1. SCH, supracondylar humerus.

Figure 27. Presenting Project Impact via Run Charts: Case Example. Run chart extracted from Winslow L, Holstine J, Samora JB. Reducing the Use of Opioids for Pediatric Patients with Supracondylar Humerus Fractures. *Jt Comm J Qual Patient Saf.* 2020;46(10):581-587. doi:10.1016/j.jcjq.2020.06.010.

TITLE 		Quality Improvement Team Sponsor: _____ Communicator: _____ Team leader: _____ Team members: _____ Last Updated: _____									
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Current Conditions: Current State Analysis 		Implementation and Evaluation 									
Target Conditions: SMART Goal S: SPECIFIC M: MEASURABLE A: achievable R: RELEVANT T: TIMELY		Follow Up: Sustainment Plan <table border="1"> <thead> <tr> <th>Activity to Sustain</th> <th>Person Responsible</th> <th>Method of Measurement</th> <th>Frequency</th> </tr> </thead> <tbody> <tr> <td>Regular distribution of performance data to quality improvement & clinical teams</td> <td>Quality Improvement</td> <td>Monthly performance reports</td> <td>Monthly</td> </tr> </tbody> </table>		Activity to Sustain	Person Responsible	Method of Measurement	Frequency	Regular distribution of performance data to quality improvement & clinical teams	Quality Improvement	Monthly performance reports	Monthly
Activity to Sustain	Person Responsible	Method of Measurement	Frequency								
Regular distribution of performance data to quality improvement & clinical teams	Quality Improvement	Monthly performance reports	Monthly								
Analysis: Root Causes 											

Figure 28. Documenting Implementation and Evaluation on A3.

Upon finding that a QI initiative is improving outcomes, sustainment plans must be developed to ensure long-term success. A sustainment plan should (1) clearly state the activities that require continued support, (2) identify a designated person to oversee each sustainment activity, and (3) describe a method for assessing sustainment

for each activity, including its format and frequency of measurement (Figure 29).^{20,32} It is important that QI teams include their sustainment plans at the bottom of their A3s (Figure 30) and provide a summary of pertinent information regarding maintaining the initiative, including any new systems that have been put in place.³²

Activity to Sustain	Person Responsible	Method of Sustainment	Frequency
Regular distribution of performance data to quality improvement & ward team	Chief resident	E-mailed performance report	Weekly

Figure 29. Developing a Sustainment Plan. Figure adapted from Stanford Medicine Center for Improvement. Sustaining the Goals. Published 2021. <https://youtu.be/gb5YZwzp0qU>.

TITLE

Background: Problem Statement

Current Conditions: Current State Analysis

Target Conditions: SMART Goal

Analysis: Root Causes

Quality Improvement Team

Interventions: Key Drivers & Countermeasures

Implementation and Evaluation

Follow Up: Sustainment Plan

Figure 30. Documenting Sustainment Plan on A3.

Of note, it is essential that any team member responsible for sustaining the initiative is informed about it *well* before the QI work is complete. Teams can optimize the changes of sustaining success by sharing updates on the initiative regularly and ensuring the novel operating systems in place are supported by leadership.³²

Challenges to Implementing QI Initiatives

The practical challenges of implementing and carrying out a QI initiative in healthcare can be considerable. The QI process is often foreign to most healthcare workers

who may have become comfortable with the status quo. Two common challenges include (1) the practical reality of teams in healthcare and (2) existing traditional processes that are based on a fundamentally flawed organizational foundation.

The Challenge of Teams

Healthcare “teams” are often not formed in accordance with patients’ episodes of care, but rather in accordance with traditional silos (e.g., surgery, nursing, physical therapy, case management, and administration). QI

Table 4. Recent QI Initiatives in Orthopaedic Surgery

Caruso TJ, Trivedi S, Chadwick W, Gaskari S, Wang E, Marquez J, Lagasse S, Bailey M, Shea K. A quality improvement project to reduce combination acetaminophen-opioid prescriptions to pediatric orthopedic patients. <i>Pediatr Qual Saf</i> . 2020;5(3):e291.
Jones K, Engler L, Fonte E, Farid I, Bigham MT. Opioid reduction through postoperative pain management in pediatric orthopedic surgery. <i>Pediatrics</i> . 2021;148(6):e2020001487.
Rowan MR, Balch Samora J. A quality improvement initiative to reduce cast transitions in a pediatric hospital. <i>J Pediatr Orthop B</i> . 2021;30(4):405-409.
Schommer J, Allen S, Scholz N, Reams M, Bohn D. Evaluation of quality improvement methods for altering opioid prescribing behavior in hand surgery. <i>J Bone Joint Surg Am</i> . 2020;102(9):804-810.
Shapiro LM, Dinh MP, Fox PM, Richard MJ, Eppler SL, Kamal RN. Barriers and facilitators of outcome collection during hand surgery outreach: A quality improvement Study. <i>Hand (N Y)</i> . 2021 Apr 1:15589447211003183.

initiatives that are oriented around improving team function need to first ensure that they actually have the correct “team” in place and that all participants in the process have a similar definition of that team. There may be numerous barriers to achieving QI results when QI leaders believe they are dealing with a unified team, when in fact there are several teams intersecting the process.

Flawed Foundational Processes

Many processes in healthcare are based on tradition, and the way that hospitals and healthcare systems have evolved has often served to reinforce some of these processes. If a QI intervention is focused on a problem that directly or indirectly stems from a fundamentally flawed process, it may be necessary to completely redesign the process from scratch. This is often something that will meet with widespread resistance but may be the only way to achieve the goals of the QI initiative. “Design thinking” is a QI strategy that is iterative and challenges traditional assumptions about how a process should be organized. It may be used to augment the A3 process when the care delivery process needs to be redesigned, not merely improved in an incremental manner.

Recent QI Initiatives in Orthopaedic Surgery

Examples of recently published QI initiatives in orthopaedic surgery are presented in Table 4, which may

serve as a guide for orthopaedic surgeons interested in conducting initiatives.

Overview

Orthopaedic surgeons who are committed to improving clinical care for their patients will benefit from a basic understanding of QI principles and techniques. This will allow them to recognize gaps in clinical care and develop effective strategies to address them. We have provided an overview of QI terminology and frameworks as well as a step-by-step guide for conducting QI initiatives using the Lean (A3) method. In order to enhance understanding, we reference published examples of QI initiatives in orthopaedic surgery as well as cite publicly accessible supplemental videos on QI offered by the Stanford Medicine Center for Improvement.

Additional Links

- Stanford Medicine Center for Improvement: [QI Video Series](#)
- Stanford Medicine Radiology Improvement: [Team Education \(RITE\): QI Video Series](#)
- Samora JB, Shea KG, eds. [Quality Improvement and Patient Safety in Orthopaedic Surgery](#). Springer International Publishing; 2022. doi:10.1007/978-3-031-07105-8

- AAOS Educational Video: [Quality Improvement and Patient Safety in Orthopaedics: An Introduction](#)
- AAOS Educational Video: [Quality Improvement Principles and Models](#)
- POSNAcademy: [Introduction to QSVI: Principles and Practical Applications to Your Practice](#)
- POSNAcademy: [QSVI Webinar: Quality Improvement Principles in Practice](#)
- POSNAcademy: [Aligning Organization Quality Priorities: A Guide to Development of the Pediatric Orthopaedic Quality Score Card](#)

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Disclaimer

The authors have no conflicts of interest to report.

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