IMPROVING CARDIOVASCULAR HEALTHCARE

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

INTRODUCTION:

Why is Quality Improvement in Cardiovascular Care Important?

1. The current state of cardiovascular disease is not where it should be.

Data collected by a variety of organizations - including the Centers for Disease Control and Prevention, American Heart Association / American Stroke Association, and the Institute for Healthcare Improvement - regarding the current state of heart disease and stroke suggest there is significant room for improvement.

Some key statistics about cardiovascular disease are:

- About **630,000 people** die of heart disease in the United States every year – that's **1 in every 4 deaths**, making it the leading cause of death by disease in the US.[1]
- Heart disease is the leading cause of death for both men and women. **More than half** of the deaths due to heart disease in 2015 were in men.[1]
- In the United States, someone has a heart attack **every 40 seconds**. Each minute, more than one person in the United States dies from a heart disease-related event.[2]
- Heart disease is the leading cause of death for people of most ethnicities in the United States, including African Americans, Hispanics, and Whites. For American Indians or Alaska Natives and Asians or Pacific Islanders, heart disease is second only to cancer.[3]
- Coronary Heart Disease (CHD) is the most common type of heart disease, killing over **366,000 people** annually.[1]
- Every year about **720,000 Americans** have a heart attack for the first time. Another 335,000 happen in people who have already had a heart attack.[4]
- Heart disease costs the United States about **$200 billion** each year.[1] This total includes the cost of health care services, medications, and lost productivity.[1]

Cardiovascular disease is also a large health issue in South Dakota.

- Heart disease was the leading cause of death from 1994-2016, with the exception of 2010-2011 when cancer was the leading cause. In 2017 it was the second leading cause of death. In 2017, heart disease accounted for **1,708 deaths or 21.4% of deaths**.[5]
- Stroke was the sixth leading cause of death in 2017, accounting for **410 or 5.1% of deaths**. Since 2006, stroke fluctuated between the fourth and sixth leading cause of death.[5]
- In 2010, the estimated annual cost of cardiovascular diseases, which included diseases of the heart, stroke and an estimate of hypertension costs as well, was **$981 million** in South Dakota. This estimate will continue to increase as the population in SD continues to age.[6]

2. By improving outcomes, we can reduce total cost of care.

As a leading cause of death and disease burden, cardiovascular disease is a major contributor to health care spending nationally. However, with improvements in prevention and treatment the total cost of care related to cardiovascular disease has actually decreased.[7]

3. There are established scientific, evidence-based best practice guidelines and pathways as well as scientific based educational offerings.

The American College of Cardiology, American Heart Association and the American Association of Family Practice are well-regarded resources.[8,9,10]

REFERENCES

[1] *Centers for Disease Control and Prevention. Underlying Cause of Death 1999-2013. Retrieved from CDC WONDER Online Database:* https://wonder.cdc.gov/ucd-icd10.html

Note: Data are from the Multiple Cause of Death Files, 1999-2013, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

[2] *Heron M. Deaths: Leading causes for 2014.* National vital statistics reports. *2016;65(5). Retrieved from* https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_05.pdf

[3] *Centers for Disease Control and Prevention. Deaths, percent of total deaths, and death rates for the 15 leading causes of death in 10-year age groups, by race and sex: United States, 2013.*

[4] *Benjamin EJ, Virani SSJ, Callaway CW, et al. Heart disease and stroke statistics—2018 update: a report from the American Heart Association. Circulation. 2018;137(12):e67-492. DOI: 10.1161/CIR.0000000000000558*

[5] *South Dakota Department of Health. Vital Statistics 2015.*

[6] *Centers for Disease Control and Prevention. Chronic Disease Cost Calculator Version 2. Retrieved from* https://snaped.fns.usda.gov/library/materials/chronic-disease-cost-calculator-version-2

[7] *Kamal R and Sawyer B. (2017). What do we know about cardiovascular disease spending and outcomes in the United States? Retrieved from* https://www.healthsystemtracker.org/chart-collection/know-cardiovascular-disease-spending-outcomes-united-states/#item-start

[8] *American Academy of Family Physicians. (2019). Cardiovascular Clinical Recommendations & Guidelines. Retrieved from* https://www.aafp.org/patient-care/browse/topics.tag-cardiovascular.html

[9] *American College of Cardiology. (2019). Tools and Practice Support. Retrieved from* https://www.acc.org/tools-and-practice-support/expert-consensus-decision-pathways

[10] *American College of Cardiology. (2019). Clinical Topics. Retrieved from* https://www.acc.org/clinical-topics

RESOURCES

The current state of heart disease and stroke.

Facts, studies, and findings of the current state of heart disease and stroke are listed below:

Heart Disease Facts

From the Centers for Disease Control and Prevention

https://www.cdc.gov/heartdisease/facts.htm

This page provides national data about heart disease and its risk factors.

The Burden of Cardiovascular Diseases Among US States, 1990-2016

A report from the Global Burden of Cardiovascular Diseases Collaboration

https://www.ncbi.nlm.nih.gov/pubmed/29641820

This publication in the Journal of American Medical Association – Cardiology concludes that large disparities in total burden of cardiovascular disease (CVD) persist between US states despite marked improvements in CVD burden. Differences in CVD burden are largely attributable to modifiable risk exposures.

Advocacy Fact Sheets

From the American Heart Association

https://www.heart.org/en/about-us/policy-research/advocacy-fact-sheets

This page contains a repository of fact sheets on a variety of cardiovascular and public health topics.

Heart Disease and Stroke Statistics At-a-Glance

From the American Heart Association

https://www.heart.org/en/about-us/heart-and-stroke-association-statistics

This resource provides key statistics about heart disease, stroke, other cardiovascular diseases, and their risk factors.

Heart Disease and Stroke Statistics—2018 Update

A report from the American Heart Association

https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000558

This publication in Circulation documents statistics related to heart disease, stroke, and the cardiovascular risk factors, including core health behaviors and health factors that contribute to cardiovascular health.

Reducing the cost of care and improving outcomes.

Resources, publications, and information about how to prevent cardiovascular disease are listed below:

Reducing the Risk of Heart Disease and Stroke: A Six-Step Guide for Employers

From the Centers for Disease Control and Prevention

https://www.cdc.gov/dhdsp/pubs/docs/six_step_guide.pdf

This guide explains how to reduce costs by investing in worksite health promotion and negotiating with health plans to cover preventive services. It also gives tips for getting started.

Successful Business Strategies to Prevent Heart Disease and Stroke: A Toolkit Guide for Creating Heart Healthy and Stroke Free Worksites

From the Centers for Disease Control and Prevention

https://www.cdc.gov/dhdsp/pubs/docs/toolkit.pdf

This toolkit provides information and materials to motivate employers to provide prevention health benefits and services for their employees and establish effective worksite programs to prevent heart disease and stroke.

Long-Term Outcomes of a Cardiovascular and Diabetes Risk-Reduction Program Initiated by a Self-Insured Employer

White, N.D., Skrabal, M.Z.,Lipari, L., Lenz, T.L., Skradski, J.J. (2018). Long-Term Outcomes of a Cardiovascular and Diabetes Risk-Reduction Program Initiated by a Self-Insured Employer. Am Health Drug Benefit,11(4):177-183.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6207306/

This study published in the journal American Health & Drug Benefits concludes that sustained participation in an employer-sponsored disease management program can lead to significant changes in employees' health, well-being, and health-related costs.

An Ounce of Prevention...The Value of Prevention for Cardiovascular Disease

From the American Heart Association and American Stroke Association

https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_474332.pdf

This fact sheet provides information to support the case for specific system and environmental changes that promote cardiovascular health.

Heart Health in the Workplace

Paul, P.E., et al (2016). The Art of Health Promotion – ideas for improving health outcomes. American Journal of Health Promotion, 30(7):563-582.

http://journals.sagepub.com/doi/pdf/10.1177/0890117116668866

This issue of The Art of Health Promotion (from the American Journal of Health Promotion) describes "Life's Simple 7" and the American Heart Association's plan to work with workplaces to improve heart health.

Best practice guidelines.

These resources are regularly updated as more is learned about best practices for managing cardiovascular disease:

Best Practices Guide for CVD Prevention

From the Centers for Disease Control and Prevention

https://www.cdc.gov/dhdsp/pubs/docs/Best_Practices_Guide_intro_508.pdf

This guide highlights effective strategies for widespread control of hypertension and hyperlipidemia, focusing on health care systems interventions and community programs linked to clinical services.

Guidelines and Clinical Documents

From the American College of Cardiology

https://www.acc.org/guidelines

This page contains a repository of guidelines on a variety of cardiovascular topics.

Focus on Quality

From the American Heart Association

http://www.heart.org/en/professional/quality-improvement

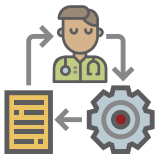
This page has sets of guidelines for creating programs to improve care related to several cardiovascular conditions.

Heart Risk Calculator

From Ahead Research, Inc.

http://www.cvriskcalculator.com

This online calculator calculates 10-year risk of heart disease or stroke using the Atherosclerotic Cardiovascular Disease (ASCVD) algorithm.



OVERVIEW OF QUALITY IMPROVEMENT

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

INTRODUCTION:

What is Quality Improvement?

Quality improvement, or QI (also known as continuous quality improvement, quality management), **is an organizational approach to managing and improving the systems that support the work of an organization.** It focuses on creating system-level changes so that the organization's work meets or exceeds the needs and expectations of everyone who depends on that work.

Process and system thinking is critical to QI. All work of any kind is regarded as a process; a series of related activities or tasks aimed at producing a particular outcome. Everything that we do in health care involves processes, whether they are the defined steps in making an appointment or the multiple steps in managing the more complex needs of a person with cardiovascular disease.

QI is all about continuous improvement, a never-ending quest to improve processes by identifying root causes of problems. Process improvement involves making gradual improvements in everyday processes to reduce variation and redundancies, improve quality of services, and increase customer satisfaction.

What is the Difference Between QI and QA?

There is often confusion about the difference between Quality Improvement (QI) and Quality Assurance (QA).

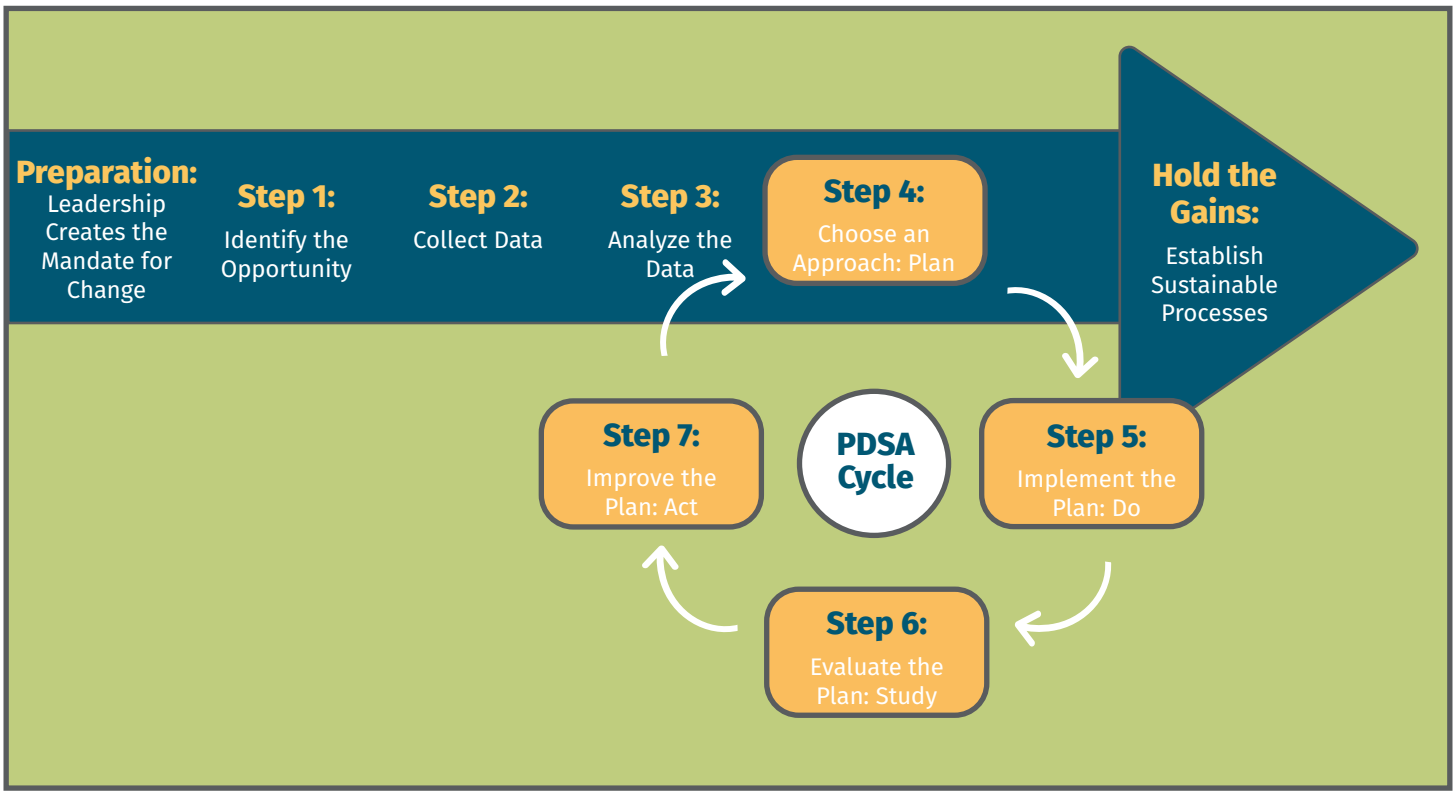
Here are some distinguishing factors:

Quality Improvement	Quality Assurance
Proactive, thinking about ongoing processes in place and how to make measurable improvements.	Reactive, going back to check on how things had been done.
Signals the organization's desire to operate in a culture of always improving.	Often results from regulation.
Deliberately involves staff at all levels.	Managers typically take the lead.
Ongoing effort.	Done on a periodic, scheduled basis.
Works to exceed expectations - always setting the bar higher.	Operates on a pass/fail basis - either something was done correctly or not.

The Quality Improvement Approach

In this Toolkit, we will describe the Quality Improvement Approach using the following steps, also shown in the figure:

- **Preparation:** Leadership Creates the Mandate for Change
- **Step 1:** Identify the Opportunity
- **Step 2:** Collect Data
- **Step 3:** Analyze the Data
- **Step 4:** Choose an Approach -- Plan
- **Step 5:** Implement the Plan -- Do
- **Step 6:** Evaluate the Plan – Study
- **Step 7:** Improve the Plan – Act
- **Hold the Gains:** Establish Sustainable Processes



RESOURCES

QI has its own terminology and a set of defining principles.

Key QI principles and some definitions are provided in the following resources:

Basics of Quality Improvement

From the American Academy of Family Practice

https://www.aafp.org/practice-management/improvement/basics.html

This page describes the basics of QI, including benefits, key concepts, and frameworks.

What is quality improvement and how can it transform healthcare?

Batalden, P.B. & Davidoff F. (2007). What is quality improvement and how can it transform healthcare. Qual Saf Health Care, 16(1):2–3.

doi: https://qualitysafety.bmj.com/content/qhc/16/1/2.full.pdf

This editorial published in *Quality and Safety in Health Care* defines QI and describes tools and methods for implementing it.

Practice Facilitation Handbook Module 4. Approaches to Quality Improvement

From the Agency for Healthcare Research and Quality

https://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/mod4.html

This module gives an overview of the 14 Deming principles, which focus on underlying processes as the primary source of error and variation, and describes a model for process improvement.

Five Deming Principles That Help Healthcare Process Improvement

From Health Catalyst

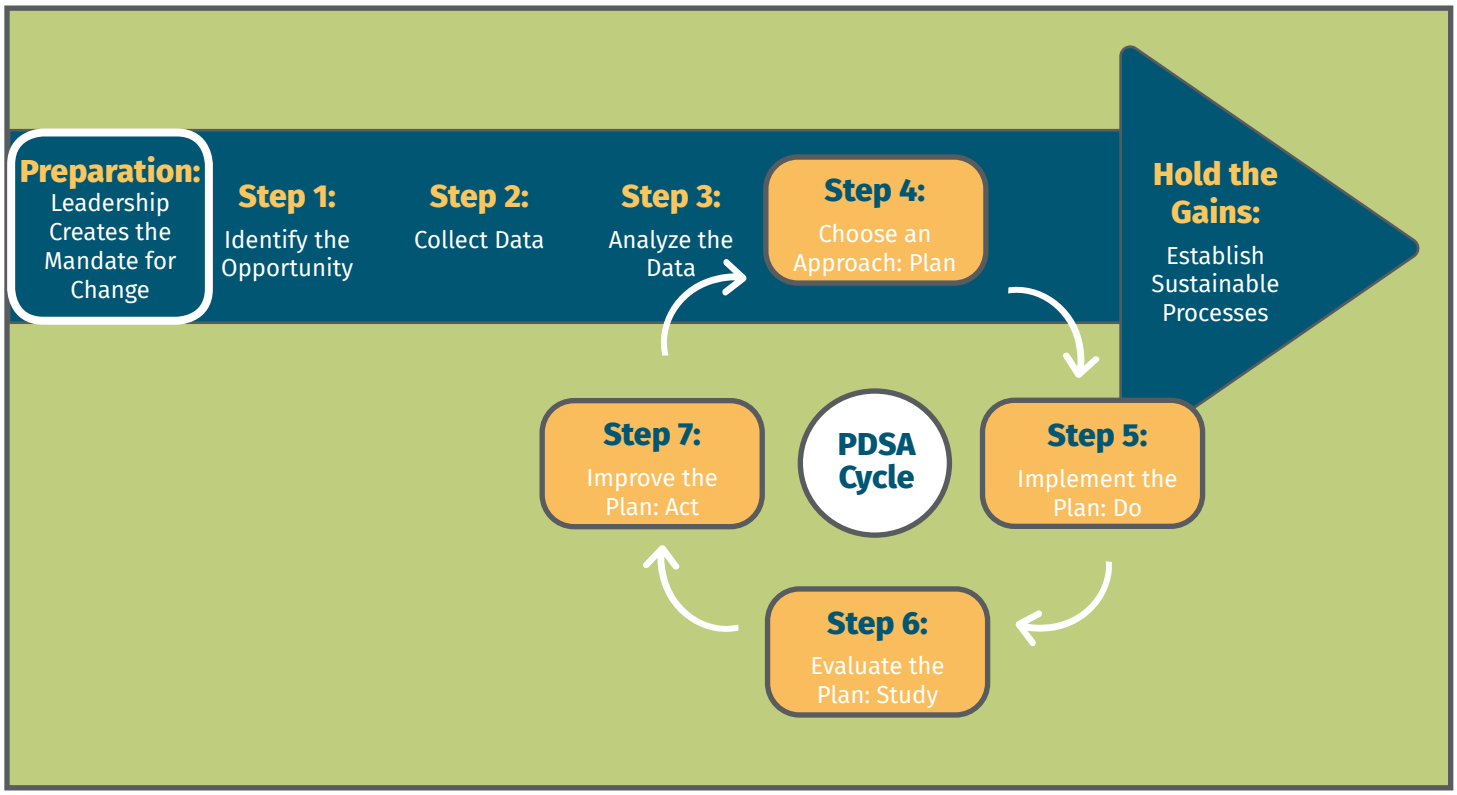
Article: *https://www.healthcatalyst.com/insights/5-Deming-Principles-For-Healthcare-Process-Improvement*
Infographic: *https://downloads.healthcatalyst.com/wp-content/uploads/2014/03/Five-Deming-Principles-help-process-improvement.png*

This page and infographic describe how five of the fourteen Deming principles apply to healthcare process improvement.

PREPARATION: LEADERSHIP CREATES THE MANDATE FOR CHANGE

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

The purpose of this section is to help you decide whether you and your organization should take a lead in cardiovascular care quality improvement efforts, and outline your tasks in leading this QI effort.

"Active and committed leadership is the most important determinant of success in making lasting improvements to patient care."

The Institute for Healthcare Improvement (IHI) emphasizes the importance of leadership creating a foundational infrastructure for quality improvement as fundamental to the way an organization does its work. They have identified Five Core Drivers for successful Quality Improvement Infrastructure, as described on the following page.[1]

Foundation	1. **Develop infrastructure:** *Creating the structures to support quality* 2. **Create a culture that enables and activates people:** *Creating the activities and environment that support people to act*
Continuous Practice	3. **Plan:** *Understand and design to meet the customer need* 4. **Improve:** *Creating breakthroughs in improvement* 5. **Sustain:** *Assuring predictable and reliable process*

An activated and committed leadership that creates and articulates a mandate for change is essential for the success and sustainability of quality improvement to the care delivery system. A leader has the authority in an organization to make changes and delegate the resources needed to implement and sustain those changes. Without leadership commitment, progress toward the desired state will diminish and likely results will not be sustained even if they do occur.

Virtually any organization could assume a leadership role in cardiovascular care improvement if they have long term commitment, clear improvement goals, dedicated resources (staffing, budget, time, etc.), and provider interest and buy-in.

Clinic and organizational leaders (those with the authority to change policy or redirect resources) lay the groundwork by:

- Making cardiovascular care improvements a system-wide priority
- Establishing or adopting cardiovascular care guidelines supported by all clinicians
- Ensuring that a multidisciplinary improvement team is convened
- Defining the team's mission and improvement aim
- Identifying a clinic leader to act as the project sponsor and liaison to management on behalf of the QI team. If there is a quality improvement infrastructure already in place, someone engaged with that process who also has an interest in cardiovascular health would be a possible choice.

Ongoing leadership commitment and support is essential for the success of any QI effort. Leadership will determine readiness of the organization to take on a QI project.

Role of the Project Sponsor

The unique role of the Project Sponsor will be to:

Create and maintain a supportive environment for change:

- Demonstrate the need for improvement
- Create an expectation for change
- Establish incentives (or remove disincentives) for improving cardiovascular care
- Help to identify and remove barriers to improvement

Prepare your organization for its leadership role:

- Establish cardiovascular care improvement as a very high priority for your organization
- Define your organization's cardiovascular quality improvement plans
- Seek additional partners as needed to leverage scarce resources and extend reach
- Provide the opportunity for education of staff in the basic principles and techniques of QI
- Identify a team within your organization to implement the QI process and set expectations for roles
- Monitor and evaluate your organization's progress

Spread successful improvement strategies:

- Maintain regular, effective communication to keep stakeholders informed, engaged, and committed to the improvement efforts.

- Share experiences and successes
- Spread the improvement program to other sites and to the care of other chronic conditions

Facilitate continuous improvement in the clinics/sites:

- Promote your organization's long-term role in facilitating cardiovascular improvements
- Help clinics/sites create a culture of continuous improvement
- Offer recognition and rewards to stimulate continued commitment to improvement

QI Team Membership

One of the Project Sponsor's tasks is to identify a Team Leader and a Clinical Leader to implement the QI process. They will be responsible for preparing for and conducting each meeting, ensuring accountabilities are defined, and ensuring progress is happening and communicated. They will also be responsible for identifying a Team Facilitator and team members for the QI Workgroup.

The number of QI Team members should be defined by the process and what pieces of the process need to be represented. Generally, having 8-10 people on the QI Team is manageable.

Regardless of the number of members, the QI Team should include the following roles:[2]

Leadership Team Members

- **Project Sponsor** – Someone with executive authority who can provide liaison with other areas of the organization, serve as a link to senior management and the strategic aims of the organization, provide resources and overcome barriers on behalf of the team, and provide accountability for the team members. The Sponsor is not a day-to-day participant in team meetings and testing, but should review the team's progress on a regular basis. The Project Sponsor is a member of the QI Leadership Team.
- **Clinical Leader** – This is the person who will champion the work among other providers. This person has knowledge of the identified process, is well-respected among his/her colleagues, and is a team player. The Institute for Healthcare Improvement (IHI) states this should be someone "with enough authority in the organization to test and implement a change that has been suggested and to deal with issues that arise. The team's Clinical Leader understands both the clinical implications of proposed changes and the consequences such a change might trigger in other parts of the system."

TIP: The Project Sponsor, Clinical Leader, and Team Leader comprise the QI Leadership Team.

It is important for the Sponsor to remain informed of the progress and to be available for assisting with challenges and barriers the team encounters. To do this, most Team Leaders and Clinical Leaders will schedule regular meetings with the Sponsor. The Clinical Leader and Team Leader are the connection between the organizational leadership and the full QI Team.

- **Team Leader**– This is the day-to-day leader and driver of the project, who will assure that tests of change are implemented and will oversee data collection. It is important that this person understands not only the details of the system, but also the various effects of making change(s) in the system. This person also needs to be able to work effectively with the Clinical Leader and other physician champion(s).

Other QI Team Members

- **Technical Expert** – This is someone who is very familiar with the content and the process that the workgroup will be tasked with improving. There may be several Technical Experts if the process involves many steps. Consider anyone involved with the process you are trying to improve. Team members might be nurses, pharmacists, and other clinical personnel, but also consider including any staff such as information technology (IT), reception, scheduling, laboratory technicians, or others who may be able to offer some insight to improvements that could be made.

- **Team Facilitator** – An expert on improvement methods can provide support by helping the team determine what to measure, assisting in design of simple, effective measurement tools, and providing guidance on collection, interpretation, and display of data. While some content experts may also have experience with facilitating QI project workgroups, having a Team Facilitator who is not also a content expert will allow all content experts to focus on the discussion and not be concerned with documenting the discussion, keeping everyone on task and on time.
- **Adhoc Members** – You may consider some people to be Adhoc Members who will participate only as their area of expertise is needed. Anyone who is considered an Adhoc Member should always be kept in the loop on all communications and progress. As you progress, you may find there are some people missing that should be at the table. Bring them up to speed prior to their first meeting so as to not hold the whole group up during a meeting. This is work that should be delegated to the Team Leader and Clinical Leader; they can keep the Sponsor informed of any changes in team membership.

The "Kick-off"

Purpose

Prior to beginning the QI process, hold a kick-off event to emphasize the need for action. This kick-off event will set the stage for the task ahead. The kick-off celebration will also help to build excitement and engage leadership in taking the first steps in the QI process.

Objectives

- Hold a festive event to announce the charge of the team
- Engage leadership in demonstrating full support of the QI effort
- Motivate the team and enlist their full commitment to the process
- Educate the team about the current state and why change is needed

Preparation

- Planners will likely be the appointed Team Leader plus the Sponsor
- Invite the selected team even if they have not fully committed. The kick-off can be used to help get that commitment and build excitement around the work.
- Prepare a brief summary and purpose of the initiative and the group's mission as it is currently understood, for the benefit of any guests as well as for those who will be part of the team
- Present the QI process that will be used
- Present a high level timeline with milestones if known at this time
- Recruit and schedule guest speakers as desired and prepare a presentation outline for each
- Make it **FUN**!

REFERENCES

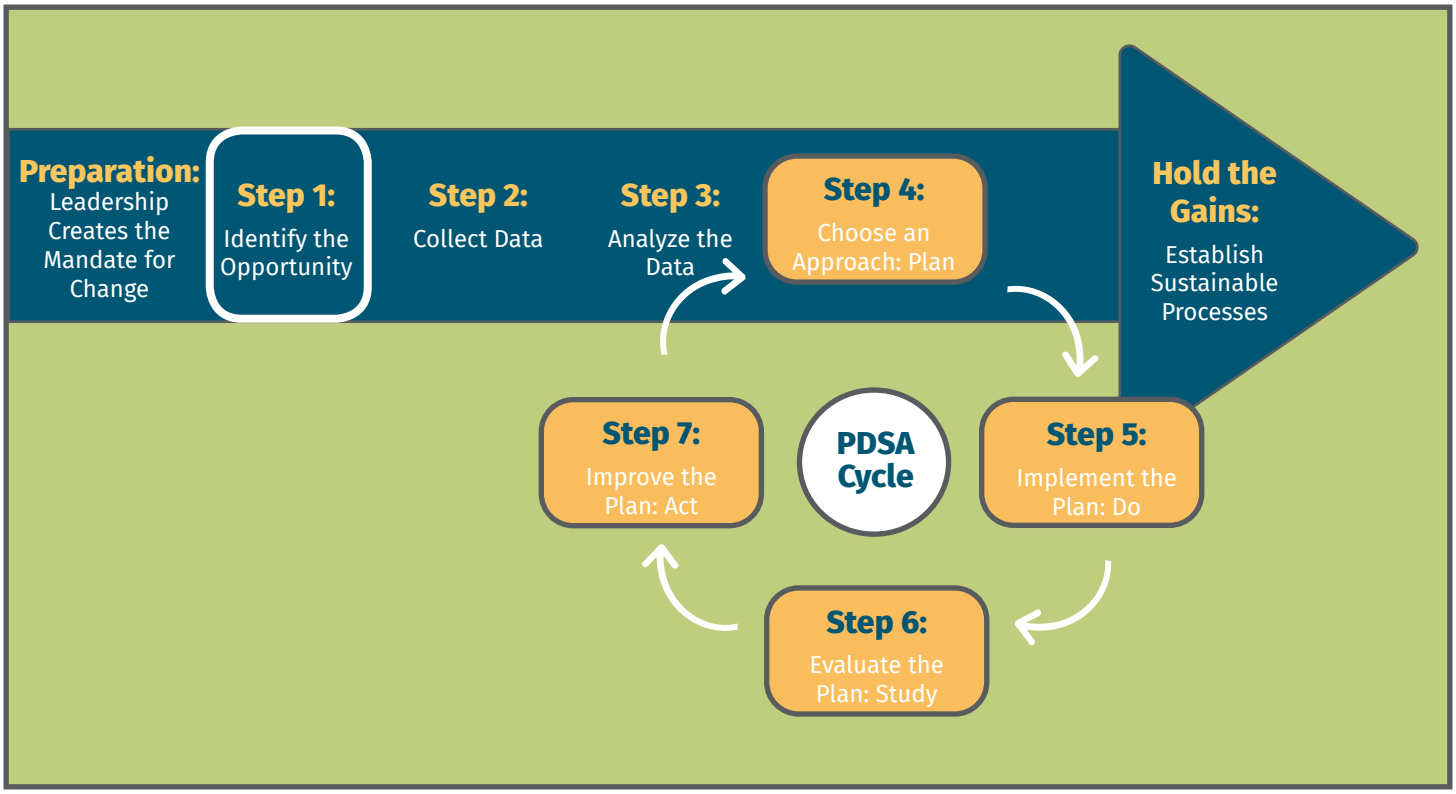
[1] *McGrath P, Shippy AA, Williams DM. Leading quality across a system. Healthcare Executive. 2018 Nov;33(6):66-68. Retrieved from* http://www.ihi.org/resources/Pages/Publications/Leading-Quality-Across-a-System-CQO.aspx

[2] *Institute for Healthcare Improvement. Science of Improvement: Forming the Team. 2019. Retrieved from* http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementFormingtheTeam.aspx

STEP 1: IDENTIFY THE OPPORTUNITY

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

Identifying the opportunity will allow the team to gain a clear and common understanding of the destination. This is the first step of a seven-step quality improvement model for improving cardiovascular care.

"As with the start of any journey, you need to know where you want to go."

This step can be frustrating to those who like to dive right in and start fixing things, but the work in this step is critical. Without it there is no common foundation or baseline. Everyone could end up going in different directions with cross-purposes in mind. They will gain no sense of accomplishment without an endpoint or specific goal in mind.

Objectives

- Describe the current process of cardiovascular care in your organization
- Define the charge of the QI Team
- Introduce team members and establish roles and responsibilities
- Seek consensus on the opportunity statement

Preparation for Team Work

Much of the work described in this and subsequent steps will be accomplished in team meetings.

Clarify roles and responsibilities

- The QI Leadership Team (Project Sponsor, Clinical Leader, and Team Leader) needs to establish how they will work together, including roles and responsibilities, frequency of meetings, communication methods, etc.
- The QI Leadership Team should meet to clarify roles and responsibilities in directing team activities and in communicating with the leadership.
- The Project Sponsor, as part of the QI Leadership Team, should help develop a clear understanding of the QI Team's charge by outlining their purpose with: a goal statement; the need for improvement; and the improvement objectives or specific aim.
- See **Appendix A** for tips on team and meeting management, communication and decision-making techniques.

Determine the current state compared to benchmarks

- National benchmarks relevant to cardiovascular disease will provide guidance as to what is considered a best practice and can be used to help you determine an appropriate goal compared to where you currently are.
- This may require some initial data collection to determine the current state of cardiovascular care in your organization.
- See **Appendix B** for more on SMART goals and setting Aim of the improvement effort.

Prioritize the opportunities

- There may be multiple "opportunities," in which case the QI Team will need to prioritize them and make a decision about where to begin.
- Taking them all on at once may be too much and undermine your success. You can always come back to the others once you have completed your top priority.
- This should be part of the initial work of the group and the decision may require a shift in who is at the table.

Structure the meeting process

- Decide on Step 1 meeting date, create the first meeting's agenda, and contact all team members.
- Instruct team members to bring their calendars to schedule future meetings.
- Effectiveness of the team depends upon the level of trust in each other and in the QI process. Trust is facilitated by having a structured meeting process, making all decisions by consensus, and having clarity of purpose and individual responsibility.
- At the first team meeting, make introductions, outline each person's role on the team, and describe why each member was asked to participate.
- The rest of Step 1 should serve to clarify the team's purpose and goals.

Set the agenda

- Send the agenda out to all invited members of the QI Team with information regarding location of meeting and/or log-in information for virtual meetings.
- See **Appendix C** for a sample meeting agenda.

Overview of Suggested Activities

1. Introduce team members and roles, review agenda, and set ground rules
2. Describe the Aim statement and reach consensus
3. Create a flowchart of the current process
4. Discuss next steps

Suggested First Meeting Activity Details

1. Introduce team members and roles, review agenda, and set ground rules

- Assign a recorder/scribe and a timekeeper for the meeting. Team members may choose to rotate these tasks from one meeting to the next.
- Review the agenda and describe the purpose and objectives of Step 1.
- Make introductions and outline team member roles. It is important that everyone knows who is in the room and why they have been invited to participate.
- Describe the team's reason for existence and what they are expected to accomplish.
- Set meeting ground rules and determine how you will make decisions as a group. This is an important task at the beginning so that everyone understands the expectations. See **Appendix A** and the Resources section for more information.

2. Describe the Aim statement and seek consensus

- This is a critical step and it is important to take the time to clearly define your Aim statement.
- In developing your Aim statement you should consider these three questions:
  - **What are we trying to accomplish?**
  - **How will we know that a change is an improvement?**
  - **What change can we make that will result in improvement?**
- It will be important that the Aim is measurable with a defined time frame. It is also important to identify how it will be measured and how you will know when you have achieved it. Consider using the SMART goal format when developing an aim statement. See **Appendix B** for more information.

TIP: The Institute of Healthcare Improvement (IHI) uses a model developed by the Associates for Process Improvement (API):

http://www.apiweb.org.

While IHI and API both emphasize the importance of this step, they agree that it is not critical to get it perfect right away, or even to go in the order they are listed here.

- Your final Aim statement should be based on data, so the Aim statement may change as you learn more about the process. It will be important to continually check in with the team and with the Project Sponsor to obtain consensus on any changes that are made. **Use the data as part of your justification for the change.**

3. Create a flowchart of the current process

- An important part of your initial data collection is to understand how the current process is at the beginning so that you can start to identify areas that need improvement. To do this your team will need to create a high level flowchart describing the current process regarding your selected area of improvement.
- Review flow-charting instructions as needed. Someone will need to facilitate this process. It does not have to be the Team Leader or the Team Facilitator. Be sure you have identified someone who is comfortable with this process and can get the team through the task efficiently and effectively.
- Your initial Aim statement will help you hone in on the process you will be flowcharting. Keep in mind, you may uncover some things that will lead you to rethink your Aim. Be careful to not get frustrated. This is all part of the process and helps you ensure you are not focused on the wrong things.
- If flowcharting is a new skill for your team, provide some basic instruction and be sure to walk them through the process with clear direction. You can send this information to your team prior to the meeting so they will come more prepared for the task.
- See **Appendix D** and the Resources section for more information on how to create a flowchart.

4. Discuss next steps

- Seek Sponsor approval if any revisions have been made to the Aim statement and/or your overall mission.
- Review the meeting record and task assignments/accountabilities. Be sure accountabilities are documented in the record along with timelines.
- Assign all team members to check the accuracy of the flowchart by consulting with other clinic/organizational staff who are part of the process. Don't forget about people such as receptionists, schedulers, lab technicians, and others who may not be a part of your team. You may find that for some processes it might be quite valuable to have people in these roles on your team.
- Evaluate the meeting and make changes to improve meeting process as needed.
- Set a tentative agenda and date/time/location for the next meeting.

RESOURCES

Quality Measures

From the American Academy of Family Physicians

https://www.aafp.org/practice-management/improvement/measures.html

This page defines quality measures, gives examples of common measures, discusses how to decide what to measure, what constitutes a quality measure, and benchmarking.

Writing Smart Objectives

From the Centers for Disease Control and Prevention

https://www.cdc.gov/healthyyouth/evaluation/pdf/brief3b.pdf

This Evaluation Brief describes how to write SMART objectives and provides a SMART objectives checklist and sample objectives.

The Essential Guide to Writing SMART Goals

From Smartsheet

https://www.smartsheet.com/blog/essential-guide-writing-smart-goals

This article describes what a SMART goal is, provides advice on how to craft them, and offers a template to help guide the process of writing SMART goals.

Quality Improvement Tools for Decision Making

From the Public Health Foundation

http://www.phf.org/programs/QItools/Pages/Quality_Improvement_Decision_Making_Tools.aspx

This webpage provides several decision-making models and tools.

What is a Process Flowchart?

From the American Society for Quality

http://asq.org/learn-about-quality/process-analysis-tools/overview/flowchart.html

This site explains what a flowchart is, when to use it, and how to create one. It also provides example flowcharts and a flowchart template.

Flow Charting

From the American College of Cardiology

https://cvquality.acc.org/docs/default-source/qi-toolkit/14e_flow-charting_12-10-13new.pdf?sfvrsn=e5468fbf_2

This document provides an overview of how to create a flowchart.

Flowchart

From the Agency for Healthcare Research and Quality (AHRQ)

https://healthit.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/flowchart

This document provides an overview of how to use a flowchart as well as several examples of flowcharts for many general healthcare system processes such a “common office visit” or “post-lab visit” and others.

2018 ACC/AHA Clinical Performance and Quality Measures for Cardiac Rehabilitation

A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures

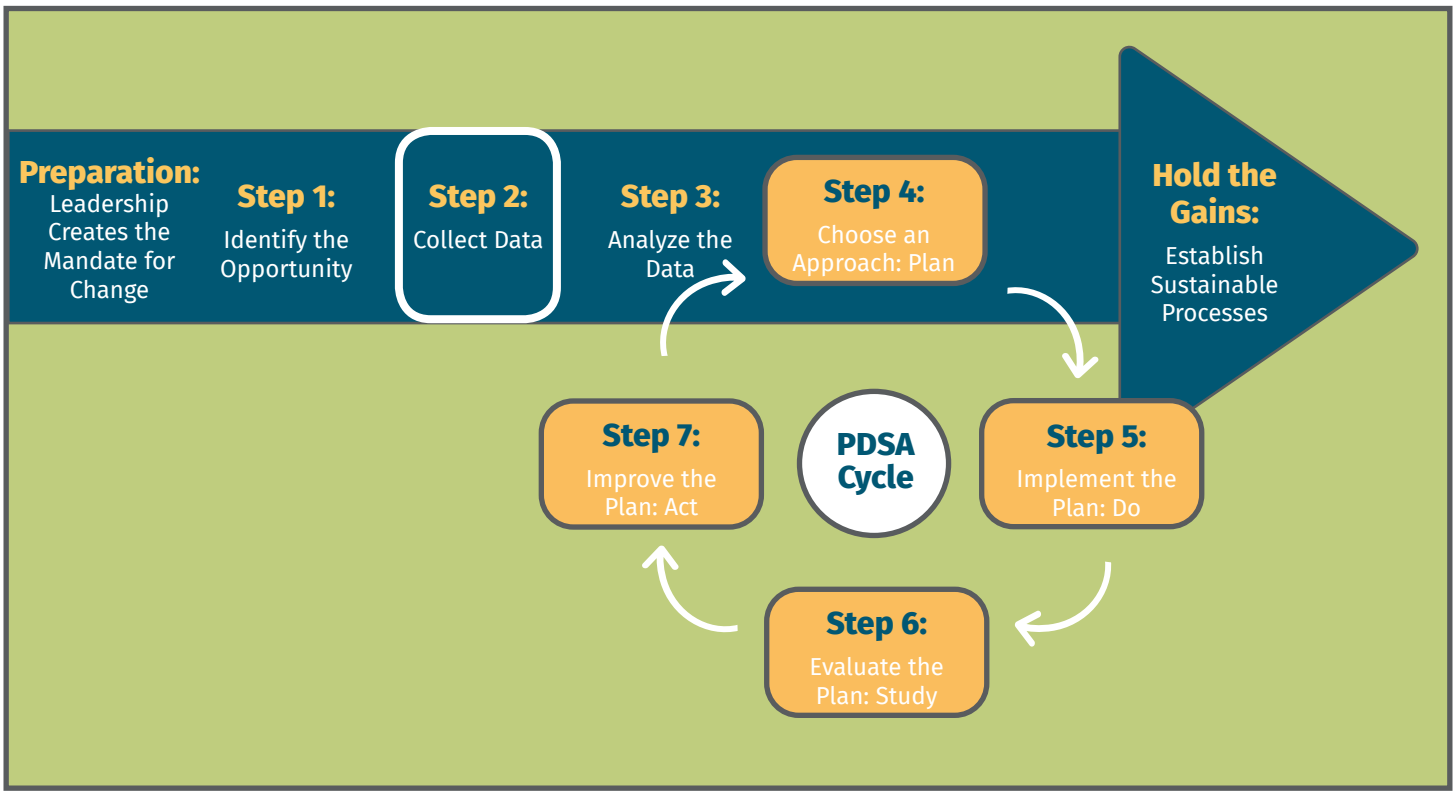
https://www.ahajournals.org/doi/10.1161/HCQ.0000000000000037

This report developed by the ACC/AHA provides practitioners and institutions that deliver cardiovascular services with tools to measure the quality of care provided and identify opportunities for improvement.

STEP 2: COLLECT DATA

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

One of the strengths of QI is that it is based on facts and data. Some data will be needed to gain an understanding of the issues with the current care system that are impeding optimal cardiovascular care. This step will provide the team with a foundation on which to proceed. It will also supply comparative data for evaluating the benefits of any changes the team makes.

Well-planned and careful data collection results in:

- A common framework for understanding and analyzing a system
- Data that is convincing to others when the team recommends changes
- A sound basis for decisions
- Methods that will tell the team whether improvements have occurred
- Skills to collect data for monitoring and making further improvements

In Step 2, the team will learn how well the system flowcharted in Step 1 actually performs in meeting cardiovascular care within the scope of your improvement effort.

Step 2 is intended to be an informal information gathering, not an extensive study. Teams that collect more data than necessary run the risk of getting bogged down by their experience (or lack of experience in data collection). Mountains of data do not necessarily provide any more information than a simpler approach may provide.

Some people will come into this step with a preconceived notion of what the root cause of a problem is. The data they collect should either support their hunch or provide a different explanation in an objective manner.

Step 2 is not just about gathering information but also serves to help develop "systems thinking." This is an important step in QI but is often a difficult concept for even highly focused professionals to grasp.

Creating a data collection plan and actually collecting data can be a lengthy process, especially if you haven't done it before. You will likely need multiple team meetings and/or offline work to accomplish this step.

As a part of each meeting, you'll want to make sure to:

- Discuss next steps
- Review the meeting record and task assignments
- Evaluate the meeting and make changes to improve the meeting process where indicated
- Set a tentative agenda for your next meeting

Objectives

- Identify what information the team will need to know to improve cardiovascular care and what data will supply that information
- Set clear data collection objectives. For each objective, identify:
  - **The most appropriate data collection approach**
  - **A representative sample of the population identified**
  - **The most appropriate data collection tools**
- Design and test ways of gathering the data
- Develop a detailed work plan and initiate data collection
- Document your data collection and analysis processes - this task is often neglected, but can be very useful for later reference

Preparation for Team Work

- Convene the Team Leader, Sponsor, Clinical Leader and/or a clinical information expert to identify a list of available data sources and to determine how best to identify the patients who will be within the scope of the improvement effort (i.e.: adults between 18-65 with known cardiovascular disease as defined by..., or all adults 18-65 with diagnosed heart failure).
- Compile a selection of data collection tools for the team's review and discussion.
- Plan for a way to display the high level flow chart of the current process for easy viewing and reference.
- Review the flowchart of the current process that was outlined in Step 1.
- Review the Suggested Activities (below) and prepare to present to the team.

Overview of Suggested Activities

1. Review the Step 1 meeting records and provide an overview of Step 2
2. Determine your data collection objectives
3. Identify an appropriate collection methodology and likely data sources for each objective
4. Gather, modify, or create data collection tools to fit the methodology
5. Assemble a data collection plan
6. Plan for how you will pilot test the data collection methodology
7. Collect the data and monitor the collection process

Suggested Activity Details

During the QI Team meetings...

1. Review the Step 1 meeting records and provide an overview of Step 2

- Review the Step 1 meeting records, including the final versions of the opportunity and mission statements, with the team.
- Describe the purpose and objectives of Step 2.

2. Determine your data collection objectives

- Most teams collect too much information, wasting precious time and resources. Specific data collection objectives should help the team focus on only what minimum information is needed to be believable among the team.
- Start the process of forming general, overall data collection objectives by focusing on the following three questions:
  - **Does the current system/process meet everyone's needs and expectations?**

    For instance, clinicians and health plans want to know that each patient is receiving guideline care, cardiovascular risk factors are reduced, and people with cardiovascular risk or disease practice good self-care. Patients want their interactions with the care system to be efficient and caring, know that they can receive help with developing good self-care skills, and make the changes that will give them the best possible quality of life.

  - **What are the barriers and problems with the current system/process?**

    Besides learning how the current system/process is working, the team will need to know the reasons for any inadequacies in that system. The objectives here could include:

    1. Identify the main problems with the current system/process
    2. Determine where in the system/process the problems occur

  - **What are the attitudes toward potential change?**

    Change is always difficult. A team can collect data about their patients and care system/process problems, and develop an excellent plan for improvement, but find unexpected resistance when implementing the changes. To understand and prepare for people's reactions to change, consider collecting this information.
    Objectives here might include learning how clinicians and staff feel about:

    1. Using the EHR for creating a patient registry, using it as a database, or using it to gather other relevant patient information
    2. Using flowsheets or other formats within the EHR or other potential changes in documenting and tracking patient information, which may include best practice alerts
    3. Delegating part of the care process to other care team members

TIP: When collecting information about why problems occur, keep focus on the processes involved, not the people. Otherwise this step can be reduced to unproductive blaming and finger-pointing, causing fear and distrust that can undermine the team's efforts. Problems are typically due to faulty processes, not the people working within these faulty processes.

3. Identify an appropriate collection methodology and likely data sources for each objective

- The team will need to identify the best source of the information (from individuals, medical records, etc.) and the best method of obtaining the data.
- Common data sources and collection methods include:
    - **Existing information:**

      Billing information and lab data are often overlooked sources of useful information. However, it may not be accurate, current, readily available, or in a usable format. Have a team member investigate the availability and reliability of this type of patient data.

TIP: Keep your data collection short and simple. A handful of indicators may tell you what you need to know. Collecting data on everything will bog you down and may even jeopardize your improvement effort.

    - **Check sheets:**

      Data collection does not have to be high tech. A check sheet is a quick and easy way to capture repeated occurrences like the number of clinic visits in a week or the number of patients receiving a specific service. Data is entered simply by placing a tally mark for each occurrence in the appropriate category. Obviously, this will work best for a smaller number of occurrences. If you are working with a large group of patients, this will not likely be your best choice.

    - **Audit forms:**

      This is a more complex form capturing multiple items from single occurrences. Use this method when you want detailed information. An example is a chart audit form that collects data such as a patient's lipid profile, their blood pressure over time, and dates of service. If there is an EHR in place, this is the type of information that should be readily available, however, retrieval is highly dependent upon how it is entered into the EHR. Seeking assistance from someone well-connected with how the EHR works and how to retrieve data will be very helpful.

    - **Surveys:**

      A survey is a good method for collecting subjective information such as satisfaction, attitudes, beliefs, and behaviors. Surveys can also collect objective (i.e.: factual) information such as risk factors and descriptions of the population like age and gender – although age and gender could also be pulled from the EHR. If you are conducting a survey, aim for a response rate of at least 33% to ensure the results are believable. This is not a research study so ensuring statistical significance is not important. What is important is that the key stakeholders will believe the data reflects what is intended. Rather than aim for a specific percentage, ask key stakeholders what would be believable for them as a guide. Online survey platforms (e.g. Survey Monkey, Qualtrics, others) make it easy to conduct surveys by e-mail and still maintain anonymity unless the person responding wants to identify themselves. These platforms also provide simple data analysis (e.g. frequencies) and visualization (e.g. tables and graphs).

4. Gather, modify, or create data collection tools to fit the methodology

- Many tested and reliable data collection tools already exist for chart audits and patient or staff surveys. Chances are, these tools will serve your needs. Avoid revising or adapting validated tools, as you may compromise their reliability.
- If the tools you need do not already exist, the team will have to design them. Whether designing or adapting a data collection tool, keep it simple and easy to understand. If you have access to someone in your organization who is an expert in data collection, seek their input early on in the process.
- Make sure to draft instructions for the data collection processes. Writing instructions that mean the same to all users is difficult, so it is important to pretest the instructions by having a few people use it. It is important to do this before a broader pilot to ensure the instructions and the process is clear and well thought out.
- Writing out data collection instructions may also raise some issues. For instance, if you are doing a retrospective chart review, how far back in the chart do you audit? How do you verify a diagnosis? What deadline for return do you give a survey? Is an incomplete survey still usable? Issues like these often become apparent only when you actually begin collecting data. That is why it is important to pretest your entire data collection process.

5. Assemble a data collection plan

- The data collection plan will describe all the steps, assign responsibilities, identify the resources needed, and set timelines.
- Drawing up a detailed data collection work plan will help you track the team's progress and determine what resources you will need, how much time the data collecting will likely take, and who should be involved. A workplan will also document your process for future reference.
- Some of the factors to consider when completing a work plan include:
  - **Objectives (the specific questions the team wants answered)**
  - **Description of how the population was identified**
  - **The sample size and sampling strategy used and why**

    See Focus On: Selecting Your Sample *on next page*
  - **Description of the data collection tool(s) to be used**
  - **Instructions for the data collectors to follow**
  - **How the collection instrument and instructions will be tested**
  - **How the data will be analyzed and displayed**
  - **Who will perform each step**
  - **The timeline for each step**
- To plan for all of these factors, you may find it useful to flowchart your data collection process step-by-step.

6. Plan for how you will pilot test the data collection methodology

- Plan to test the methodology on a few individuals or samples to ensure that it can be done as you intended. You need only test the data collection approach on a few cases, but omitting this step can result in problems, if not complete failure.
- Things to look for when pilot testing include:
  - **Unclear meaning of questions**
  - **Variability or inconsistency in responses**
  - **Unexpected results**
  - **Difficulties in answering the questions or completing the forms**
  - **Excessive time or resources needed to complete the form or questionnaire**
  - **Poor fit to your data needs and objectives**
- Modify the methodology, tools, and even data collection objectives if necessary.
- Retest after making your alterations. If you find you cannot obtain the data you want, you may need to revise the data collection objectives.

Focus On: Selecting Your Sample

Considering your sample and sample size will need to be part of your workplan. Here are some suggestions for how to select your sample.

TIP: Keep it simple. A small random sample will tell you what you need to know.

Identify people meeting your criteria.

- There are several methods for identifying people with cardiovascular disease. Some methods are more accurate than others, but none are error-free.
- Select a slightly larger sample size than needed to accommodate the inevitable discards.
- If using the list for a survey, verify the diagnosis first. Patients can become alarmed when asked about their cardiovascular disease when they have not been told they have the disease.
- It is also imperative to follow HIPAA rules for contacting patients. For QI, it is generally not necessary to go through your Internal Review Board for approval, but some organizations may require it for QI as well as for research projects. It is important to check this out at the beginning of your process.
- Generally, any data collected for QI purposes will be de-identified and aggregated when it is reported so no personal information will be shared as part of the process. But you will want to identify people at the outset to ensure you are collecting data on people directly connected to your QI work.

Determine the sample size.

- A sample is a group to represent your target population. If selected randomly, a relatively small sample should be representative and yield the same results as if the entire population was studied.
- For the purpose of this data collection, the general rule of thumb for the optimum sample size is at least thirty –OR– five percent of your total population (whichever is lowest).

Select a random sample.

- The goal of sampling is to obtain a representation of the population. It is extremely important that the sample is random, which means that each case in the population has an equal chance to be in the sample.
- Random sampling helps avoid bias. Bias is defined as any influence or condition that distorts the data or interferes with generalizing from the sample to the population. This sampling strategy should ensure that each patient with cardiovascular disease has an equal chance of being selected to be in the sample.
- To select a random sample, pick from a list of patients (even one listed in some order such as alphabetically) by numbering each patient, then using a random number table to select the sample, or pull numbers from a hat.
- Check your sample to make sure it is indeed representative. For instance, look at the distribution by gender, age and type of cardiovascular disease to see if they are about the same proportions as the whole population.

7. Collect the data and monitor the collection process

- Put the work plan into action:
  - **Finalize the data collection objectives and approach based on the pilot test**
  - **Train everyone involved in the data collection**
  - **Monitor your progress as soon as the collecting begins**
  - **Address problems as soon as they arise**
  - **Avoid the urge to collect more data than the team truly needs**
  - **Document the data collection process so it can be repeated to collect comparative data following your improvements**

TIP: STEP 2 should not be a lengthy process, taking a few days to collect the data. Once data collection begins, monitor it closely and address all problems immediately. Look at the data being collected to verify that it is what you want and will meet your objectives. Also try to analyze the test data as you would the real thing (see Step 3).

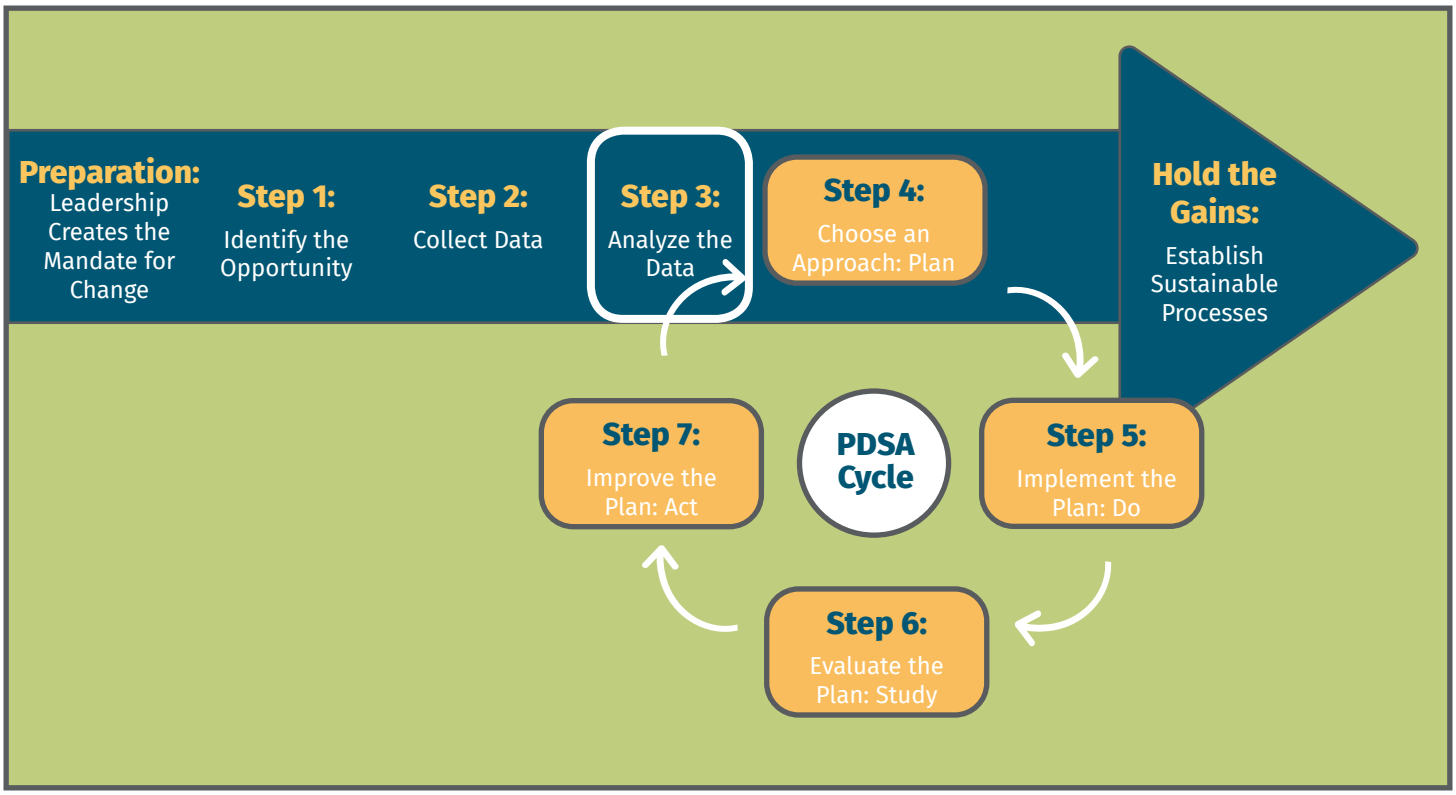
ACCELERATED QI OPTION

The purpose of Steps 2 and 3 is to answer the question "How will we know if a change is an improvement?" The only information absolutely essential to the team is how well you are currently providing the care specified in your guidelines and Aim statement. Therefore, you can limit Step 2 to a chart audit that will give you the baseline data you need to target improvements and to measure how well the improvements actually improved care.

STEP 3: ANALYZE THE DATA

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

By itself, data can be fairly meaningless. Some organization and translation is usually needed to transform the data into useful information. By translating the data collected into useful information, the team will be able to make key observations about the process they are focusing on and determine the root causes. This is what is meant by data analysis.

Data analysis is like making a diagnosis based on lab test results, symptoms, family history and other patient data. The lab data enables the provider to diagnose the underlying illness causing the patient's symptoms. Likewise, identifying root causes will allow you to direct your improvement efforts at the underlying "disease" (i.e.: the causes of the problems) rather than simply treating the symptoms.

Analyzing and presenting the data can be a lengthy process, especially if you haven't done it before. As with Step 2, Step 3 may require multiple meetings and work between meetings to accomplish this step. The team should be prepared for that.

As a part of each meeting, you'll want to make sure to:

- Discuss next steps
- Review the meeting record and task assignments

- Evaluate the meeting and make changes to improve the meeting process where indicated
- Set a tentative agenda for your next meeting

Objectives

- Transform the data into usable information by organizing and displaying it clearly and simply
- List key observations from the data collected
- Identify all the root causes of process problems
- Communicate the findings in order to build understanding and support for future changes

Preparation for Team Work

- Gather all the data in one place
- Review the data collection objectives
- Display your high-level flow chart so all can easily view it

Overview of Suggested Activities

1. Review the raw data to determine its integrity and whether objectives are met
2. Summarize the data
3. Determine the best way to display the data
4. Make key observations about problems you observe with the current process
5. Determine root causes of each of the key observations
6. Review your high level flow chart to see where in the process the root cause of problems occur
7. Communicate the team's conclusions

Suggested Activity Details

During the QI Team meetings...

1. Review the raw data to determine its integrity and whether objectives are met

- Gather the data in one place, and inspect the results while asking:
  - Were there any problems encountered with the data collection which may have distorted the results?
  - Was the desired sample size actually attained?
  - Were any questions on the forms left blank?
  - If a survey was conducted, what was the response rate? If less than 25%, the results may be biased.
  - If a sample was used, was it representative of the population (i.e.: randomly selected)?
- Discard any items having obvious collection problems, biases, incompleteness or implausible results. Look for answers to any questions about the data, interviewing the data collectors if necessary.
- If significant problems occurred with the data collection process, you may have to revise your approach and collect more data.
- Determine whether the data meets your objectives.

TIP: Piloting, evaluating and revising your process in Step 2 will help mitigate some of these issues before you do your full data collection.

2. Summarize the data

- If you did use a survey/questionnaire and used a program such as Survey Monkey, much of the analysis can be done within the program. If not, you will need to do some basic analysis.

- Begin by developing a score sheet based on the questions in your collection tool. This can be a blank copy of the data collection form used to tally the responses or data entry screen for an electronic data base. Tally any numeric (quantitative) data onto a blank collection form or score sheet and perform any calculations of percentage scores or rates. Microsoft Excel and other similar software work well for this and also allow you to display your data graphically as well.

    1. See **Appendix E** for a sample Excel dashboard template

- Tally any numeric (quantitative) data onto a blank collection form or score sheet and perform any calculations of percentage scores or rates.

    2. ***See* Focus On: Calculating Rates, *below***

- Double-check your calculations. If possible, have a second person or group of people check all calculations for errors, even if done electronically.
- Summarize the qualitative data, such as open-ended survey questions. Type out all the responses to each qualitative question together on one document. Create categories for possible answers and try to group responses within these categories. Summarizing (and analyzing) qualitative data is always subjective and can be frustrating. First ensure the data has sufficient value to warrant this effort.

Focus On: Calculating Rates

Calculate the percentage scores (also called rates) for each possible answer to each question.

This is done by:

1. **Determining the total number of eligible responses for each individual question (discard those responses that are incomplete or problematic). This will be your denominator, or N for the question.**
    - For example, if 50 surveys were returned (this is your sample size), but only 47 respondents chose to answer question #4, the denominator (N) for question #4 is 47. There are several methods for identifying people with cardiovascular disease. Some methods are more accurate than others, but none are error-free.
    - Select a slightly larger sample size than needed to accommodate the inevitable discards.
    - If using the list for a survey, verify the diagnosis first. Patients can become alarmed when asked about their cardiovascular disease when they have not been told they have the disease.
2. **Divide the number for each answer or response by the denominator N, and multiply that number by 100.**

$$\frac{\text{Total number that gave a particular response}}{\text{Total number of eligible responses to the question (N)}} \text{ X 100 =}$$

EXAMPLE:

There were 47 respondents for question #4 (N = 47); and there were three possible answers with these responses:

yes	33
no	10
don't know	4

To calculate the rates for question #4's responses:

yes	(33/47) X 100 = 70%
no	(10/47) X 100 = 21%
don't know	(4/47) X 100 = 9%

3. Determine the best way to display the data

- Decide on how best to display each type of data and produce the graphs or tables. There are a number of relatively easy methods for displaying data in a clear way to enhance everyone's understanding of it. All of these display methods can be hand-drawn and will be just as effective as computer-generated versions.
- Display only the most important and relevant information. Highlight the most significant findings to support a powerful and convincing communication tool. Keep your displays simple with only one or two pieces of information per display, such as on a slide or a poster.
- The most commonly used data display methods include:

A written summary:

A summary is a narrative description of the aggregate results. The simplest way to do this is to enter the results onto a blank copy of your data collection form. Or, you could simply state findings as a bulleted list of items such as:

54% of patients report they have had a lipid panel in the last year.

A table:

This method can be an efficient way of summarizing a large quantity of data. Aggregate numbers can be displayed as shown below:

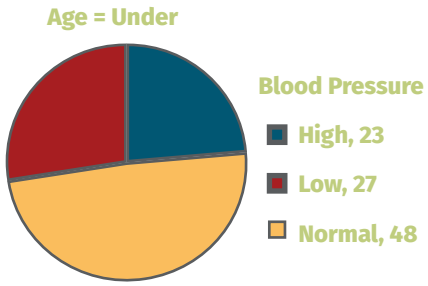
Survey question	Yes	No	I don't know	No response
"Does your provider talk with you about what you might do to make more healthy lifestyle choices?"	52%	46%	2%	0%

A graph:

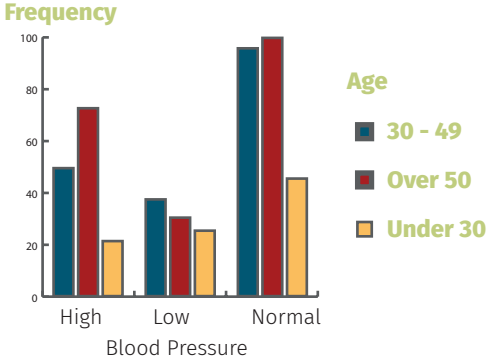
There are a variety of graphic formats you can use to illustrate your more interesting findings. All can be done with or without a computer. If you are using software or programs like Excel or Survey Monkey, all of them have tools to create these graphs using the data you have already entered. Play around with the options to determine which will best serve your purpose.

Examples are:

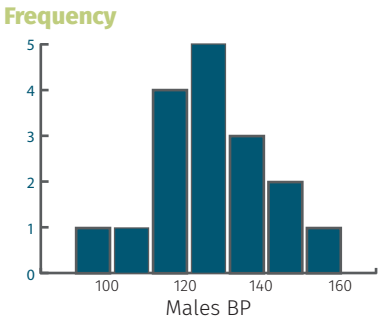
1. **Pie chart** - This simple graphic helps to demonstrate differences between separate parts of the whole (like pieces of a pie). Use this type of graph when you want to compare magnitudes or frequencies of individual data categories (e.g.: items described in percentage values) to the whole (the 100%).



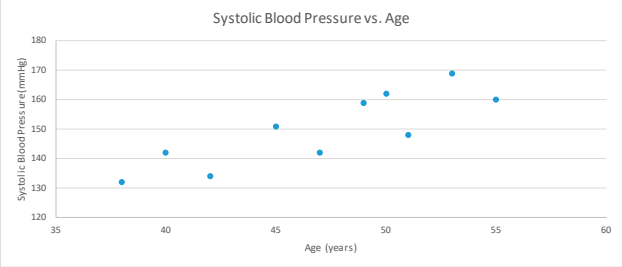
2. **Bar graph** - This is a simple way to display the number of units (such as number of patients) by discrete categories (such as gender or type of cardiovascular disease). The bar graph allows for easy comparison between characteristics.



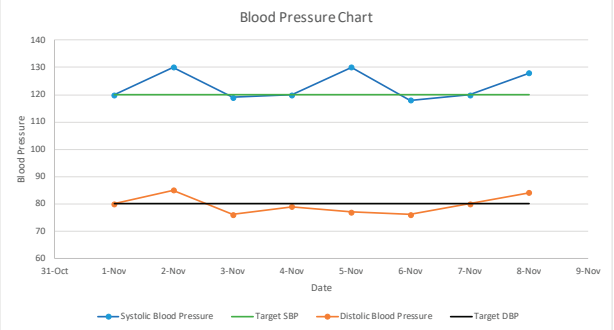
3. **Histogram** - This graph is used to display data about the number of units (such as number of patients seen) occurring along a continuous sequence (such as time or lab value) broken into intervals (such as a time range or range of values) to illustrate patterns or variations in a process.



4. **Scatter plot** - This graph displays one set of continuous values by another continuous set to illustrate any correlation between the two sets of values. An example would be to plot patients' weights by their average blood pressure to examine whether weight correlates with blood pressure. A dot on the graph would represent an individual patient. The distribution of the dots would indicate the type of correlation.



5. **Run chart or time plot** - This graph plots observation points (vertical axis) over time (horizontal axis) to illustrate a sequence of events or trends with time.



- **Infographic or word cloud:**
  There are programs that can help you create these images if you have the time and the skill. It is certainly not necessary.
- **A combination of the above:**
  Combining graphs, tables and written summaries provides the most complete description of the data and helps keep viewers interested in the content.

4. Make key observations about problems you observe with the current process

- Include your high level flow chart as part of the displayed data.
- Have the team brainstorm observations by making simple statements about the findings from the data summary and displays. Some of the questions to ask to get at the key observations are:
  - **Are there any surprises or unexpected results in the data?**
  - **What are the main problems with the process, and who is affected?**
  - **Under what circumstances do these problems occur?**
- Group, categorize, or rank order the list to identify the "key" observations – those that have significant impact on the process. Key observations will better describe a process or problem, further localize the problem, or identify patterns or variations in the process. They can also identify areas where processes are working well.

TIP: Steer away from blaming PEOPLE for problems or their causes. Use the data to demonstrate how problems are due to flawed PROCESSES, not due to the individuals working in an impaired and non-supportive system.

5. Determine root causes of each of the key observations

- The team's key observations will probably include symptoms of problems associated with the care process. But a symptom is not a primary reason for the problem. You need to identify the real underlying (root) cause and ask, "Why does this happen?" for each of your key observations.
- Review your key observations to ensure common understanding.
- Identify possible causes of the problems you identified are true underlying causes or merely symptoms of deeper problems.
- Continuously challenge the team to get at the root cause of problems by asking why each of the identified causes of problems occur in the first place. Root causes of problems should not be symptoms caused by other problems.
    - **Continually asking "why" helps to get to the root of things. Keep asking this question until the team has gotten beyond describing symptoms and has identified the real root causes for your problems.**

TIP: As mentioned earlier, diagnosing is a similar process. A patient may present with symptoms but the provider would not just treat the symptoms without first identifying the underlying cause which will then help determine the appropriate treatment.

- After identifying the possible root causes, rank order them in order of importance or impact to identify the "vital few" – those root causes thought to be the most significant contributors to the problems – AND those which may be changeable through your efforts.
- You may need to do this in a series of brainstorming and rank ordering sessions.

6. Review your high level flow chart to see where in the process the root cause of problems occur

- Assess the magnitude of the problems stemming from the root cause.
- Identify what processes appear to work well.

7. Communicate the team's conclusions

- You have now reached an important milestone in the effort to improve cardiovascular care. At this point, the team has undoubtedly learned a lot about the process of care. It is important that these results be shared, not only with the project Sponsor, but with everyone involved in order to:
    - **Build support for the team's work and for future changes**
    - **Promote and celebrate the team's progress and accomplishments**
    - **Allay any fears or anxieties regarding the team's work or its findings**
    - **Inform people about the current process and the problems that were identified**
    - **Provide an opportunity to answer questions, get feedback and hear people's concerns**
- Use visuals such as graphs or real examples to demonstrate your points.
- Present your results and encourage an open discussion. Emphasize the problems are due to faulty processes, to allay fears of being blamed. Be open and transparent about the team's activities. Keep people informed by:
    - **Regularly reporting at staff meetings**
    - **Displaying a poster or storyboard of your work**
    - **Circulating a report or newsletter regularly**
    - **Hosting a celebration to announce this and other milestones in your team's efforts**

- Build support for future changes by demonstrating the causes of problems and the need for improvement. Outline the team's next steps so it is clear that responsibility for improving the situation lies with the team but will require everyone's support. Support from our co-workers and management is essential to the success of implementing any system-wide improvements.
- Seek recognition for the team's hard work in uncovering these problems. The team's improvement goals, contributions and progress deserve to be recognized by everyone, including your patients.

TIP: Accepting the data and team's conclusions requires trust. Engage opinion leaders – those respected authorities or leading experts in clinical issues – in the analysis process to foster trust of the information collected and of your conclusions.

ACCELERATED QI OPTION

There really is no getting around this step if you have collected any data to know if a change is an improvement. Whatever data you collect should be subjected to the process of summary, analysis and communication. Even if you haven't collected any new data, you will still need to communicate what you will be using as a basis for any improvement decisions you and the team make.

RESOURCES

Managing Data for Performance Improvement

From the Health Resources and Services Administration

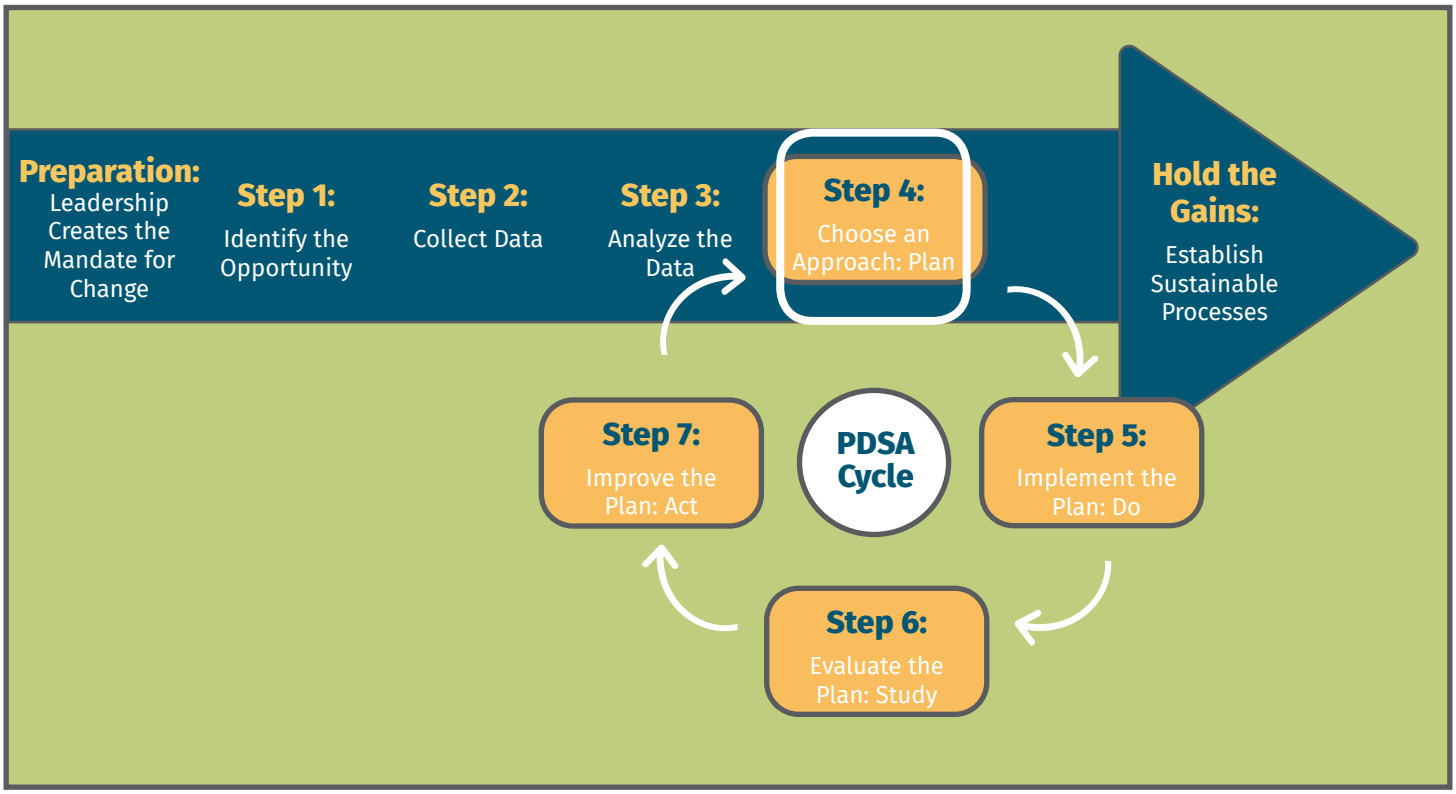
https://www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/managingdataperformanceimprovement.pdf

This document illustrates how a QI team can establish a plan and methods for gathering, analyzing, interpreting, and acting on data for a specific performance measurement.

STEP 4: CHOOSE AN APPROACH: PLAN

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

This is the Plan part of the process. Step 4 involves selecting an approach for making changes that will address the root causes you identified in Step 3. The team will have to decide the scope and direction needed to make improvements. Can you tinker with existing processes or will you need to design and organize an entirely new system? In what order will you make your changes and where do you start?

The team will develop a strategy that includes both an overall direction and specific changes that the team expects to show improvement. It will be helpful to look at best practice recommendations and success stories from other similar organizations to help identify strategies that have worked for other organizations like yours, keeping in mind that all organizations are different and have their own unique culture. The team will need to decide on a strategy that will fit their situation and ensure buy-in from leadership as well as providers involved in the improvement effort. Once the team has identified some improvement options and decided on an overall approach, you need to get organizational backing to make those changes.

As with the previous steps, Step 4 may require multiple meetings and work between meetings to accomplish this step. The team should be prepared for that.

As part of each meeting, you'll want to make sure to:

- Discuss next steps
- Review the meeting record and task assignments
- Evaluate the meeting and make changes to improve the meeting process where indicated
- Set a tentative agenda for your next meeting

Objectives

- To describe the desired care system and potential change strategies
- To plan the scope and direction of your improvement approach
- To obtain support and resources for your improvement plan

Preparation for Team Work

- Review the team's findings from Step 3
- Summarize the responses received from communicating the team's conclusions
- Examine your desired state and compare it to your current system as you now know it

Overview of Suggested Activities

1. Develop a vision of the desired care system
2. Determine the scope and direction of the improvement efforts
3. Identify potential strategies for making changes to achieve the vision
4. Outline an overall improvement plan
5. Secure the support and resources needed to implement the plan

Suggested Activity Details

During the QI Team meetings...

1. Develop a vision of the desired care system

- The team may have a strong desire to jump right in and start changing things now. If you have uncovered some simple problems that can be easily and quickly solved, by all means, do that immediately. There are often real benefits from making small changes – both for the morale of the team and for the support this may create for the more difficult changes ahead.
- However, your analysis in Step 3 will likely suggest that major, clinic-wide changes will be needed. The large scope of such changes demand careful planning.
- Start by forming a vision of the cardiovascular disease care system you want to create. Keep in mind this system is a model that should be usable for the care of any chronic disease.
- Examine the current system/processes and its problems as found in Step 3. It may help to display the team's model care system in a diagram or flowchart.
- Perform a care system review to compare what you have currently with what you want.

2. Determine the scope and direction of the improvement efforts

- Compare the current care system with the model to get a sense of the magnitude of changes needed to reach that vision.

  There are basically three choices:

  - **Build a new system from scratch.**

    This approach is most desirable if you discover there is no system at all. The team will need to decide where to start and how rapidly to build this new system.

  - **Re-organize existing pieces and improve some of them.**

    This is an approach to take if parts of your system are already in place, but it is not well coordinated, is missing parts, is incomplete or operates poorly. This is a major renovation, but it will not be as large as building a whole new system.

  - **Make selected improvements.**

    This approach assumes your clinic either has a reasonably good system in place OR creating a whole new system is not desirable or possible. In either case, major improvements can still be made by concentrating on a few areas needing the most attention.

- Get a reality check from your Sponsor. Is this degree of change even possible? What scope of change would clinic leadership and staff likely support?

3. Identify potential strategies for making changes to achieve the vision

- Change strategies are high level ideas or concepts for improving a process. After the team has discussed the ideal system they envision, consider these ideas as possible ways to implement various parts of the system.
- Note, some of the changes have a broader scope than others. In choosing strategies, it is important to recognize that each is a small part of the care system you plan to build or improve. Although these strategies work synergistically, you will need to eventually implement most of them in order to have a complete care system. Simply following some of them will NOT result in sustainable, high impact improvements.
- The most appropriate change strategies are those that help meet your improvement goals, are feasible, and are acceptable to those most affected by the change.
- The team can further define the scope and direction of the improvements by choosing some broad strategies that have led to improvements in other sites. Research what strategies have already been used elsewhere and brainstorm new ideas.

  See* Focus On: Change Strategy Examples *on the next page, as well as the resources at the end of this module to help generate some ideas.

Focus On: Change Strategy Examples

Listed here are some examples of strategies to improve cardiovascular care processes.

Develop a systematic approach to providing all the recommended elements of care for people with cardiovascular disease, rather than having different approaches for each clinician and seeing those approaches applied inconsistently.

> **EXAMPLE:** This strategy will require multiple solutions that include building shared protocols, information systems and supporting processes, delegating duties and involving the patient in the process.

Make the cardiovascular disease clinical practice recommendations very visible to patients, clinicians and staff.

> **EXAMPLE:** Display the recommendations on the wall in each exam room and imbed them in the EHR.

Put standing orders in place and imbed in the EHR for as many clinical care tasks as possible.

> **EXAMPLE:** Display the recommendations on the wall in each exam room and imbed them in the EHR. Use standing orders to empower nurses or other qualified health care personnel to ensure the standardized clinical practice recommendations are being met.

Provide ongoing education to all clinical personnel.

> **EXAMPLE:** Build education into usual communications about the care of individual patients.

Use a multidisciplinary care delivery team approach.

> **EXAMPLE:** Consider expanding the care team to include an educator, a dietitian, a pharmacist, a mental health provider and/or specialists such as a cardiologist.

Employ multiple methods to reach out to patients and ask their preferred method of communicating to reduce follow-up losses.

> **EXAMPLE:** Use phone, text, and e-mail reminders to help reduce no shows and follow-up losses. If you have a patient portal on your EHR, encourage people to use it to ease the communication process. Also use these methods for ways to connect with patients about changes in therapy when a full visit is not required.

Develop and maintain a patient registry of people with cardiovascular disease and use it to help prioritize both individual as well as broad-based interventions.

> **EXAMPLE:** Target patients for interventions based on criteria such as those with high blood pressure. If a large percentage of the population is above target on blood pressure, engage in a system-wide initiative to address blood pressure across the board.

Use all office visits, regardless of the reason for the visit, as a way to reinforce and track the patient's care.

> **EXAMPLE:** Educate staff to routinely check whether the patient needs any labs or see if there are other things that may need to be checked on while they are in the clinic.

4. Outline an overall improvement plan

- Select among the options and prioritize. There are a number of factors for the team to discuss when choosing from a number of options or change strategies to determine the overall approach.

  These include:

  - **Clinical importance**
  - **Cost benefit**
  - **Impact of the care delivered**
  - **Effectiveness (will it improve the process?)**
  - **Time benefit**
  - **Applicability to other disease conditions or clinical services**
  - **Feasibility or ease of implementing**
  - **Permanence as a solution (is it sustainable?)**
  - **Fit to the team's mission and objectives**
  - **Shortest timeline for implementing and realizing results**
  - **Measurability of process changes, impact and outcomes**
  - **Solution to root causes of problems or unmet needs**
  - **Acceptability to those most affected by the change**

- Summarize the improvement approach and its benefits. Sketch out the main steps to implementing the approach. Once the team has made the overall decision on an approach, you will still need to plan how to get these. Regardless of the approach you choose, you will need to decide:

  - **Where to start**
  - **Which processes to build or modify**
  - **In what sequence**
  - **Over what period of time**

- At this point, your plan should be "high level," implying you sketch out the steps you will likely need to take to put the approach into action. Your improvement plan should outline the following elements:

  - **The team's vision of the desired care system**
  - **The overall improvement approach being recommended**
  - **The steps needed to make all the proposed changes**
  - **A timeline for developing and implementing all the proposed changes**
  - **The resources (human, time, and financial) that would be needed to implement and maintain the changes**

- Try to summarize your plan on a single page. Your next step will be to present the plan to the rest of the staff. Since everyone is pressed for time, a brief synopsis of the plan will more likely be read and accepted. But be prepared to supply supporting documentation to those who request it.
- Be sure the approach you select will satisfy your mission and improvement objectives (including the Aim statement) and will address the needs and root causes you identified.
- Make sure your approach represents substantive rather than cosmetic changes. For example, many teams choose provider and patient education as the extent of their approach, believing that these will result in better care. However, training is not likely to lead to behavior change unless there are many other system changes to support the desired new behavior. Take the broadest possible approach at this point.

5. Secure the support and resources needed to implement the plan

- Seek input and support for your plan. Ongoing support by your colleagues and management is key to the success of implementing any system-level improvements. As in Step 2, it is essential to communicate with everyone in the clinic about your progress.
- This is another opportunity to promote the team's hard work and accomplishments. Just in the effort of collecting data and outlining an improvement plan, the team has made a significant contribution. Your progress deserves to be recognized by everyone, including your patients.
- Work with the Sponsor to sell the plan to management and clinic personnel who would be affected by the changes. Use this step as an opportunity to get valuable suggestions. Seek everyone's buy-in, ideas, and feedback.
- Identify potential barriers to moving forward with the plan. Encourage discussion of the ramifications for the proposed approach to get people's reactions, to help allay fears and to identify potential implementation barriers. But most importantly, seek consensus to move forward on your plan from everyone in the organization. If strong opposition is encountered, the team may have to re-think the overall improvement approach.

TIPS: There are a number of ways to communicate your progress within practice:

- **Through a presentation to leaders and/or at a staff meeting.**
- **By writing an article in an internal newsletter or by circulating a brief memo/report.**
- **By displaying a poster or storyboard describing the team's activities in a conspicuous location for staff and patients to view. For example, some sites have discovered that posting such displays in the restrooms was a good way to reach everyone. They dubbed it the "Potty Press."**
- **By hosting a celebration to announce milestones in the team's efforts.**

- Investigate what resources are available and secure leadership commitment of these resources. At this point, the team will not have a detailed work plan with a budget, but it should be able to offer a vision for making the system-level changes that will clearly improve the quality of care. Seek your sponsor's advice as needed to help the team prepare to solicit resources from your organization's leadership.
- Once you have an improvement approach that everyone can support (or at least live with), the team will be ready to plan, design and test the details of that approach in Step 5.

ACCELERATED QI OPTION

Deciding among alternative directions in making changes is important regardless of the pace you are taking. It requires an answer to the question "What changes can be made that will result in an improvement?" Answering this question is vital to developing an overall improvement plan. Without such a plan, there is considerable risk that the many rapid change strategies you will test in Step 5 will not fit together or contribute to system-level improvements. Thus, the objectives and activities described in this section need to be completed.

RESOURCES

Plan-Do-Study-Act Resources

Plan-Do-Study-Act (PDSA) Worksheet

From the Institute for Healthcare Improvement

http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx

This page describes the PDSA cycle and provides a worksheet to document a test of change. Brief videos explaining PDSA cycles are also available on the page.

Science of Improvement: Testing the Changes

From the Institute for Healthcare Improvement

http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx

This page describes the Science of Improvement: Testing the Changes.

Guidelines related to Million Hearts®, a national initiative to improve the nation's cardiovascular health through evidence-based practices and prevention

Million Hearts® Resources for Clinicians

http://www.homehealthquality.org/Cardiovascular-Health/Million-Hearts-Resources.aspx

This is a collection of high-impact Million Hearts® materials for clinicians, including numerous sets of protocols, action guides, and templates to create your own protocols.

The Million Hearts Initiative: Guidelines and Best Practices

Mazurek, B.M., et al (2016). The Million Hearts initiative: guidelines and best practices. The Nurse Practitioner, 41(2): 46-53. doi: 10.1097/01.NPR.0000476372.04620.7a

https://journals.lww.com/tnpj/Fulltext/2016/02000/The_Million_Hearts_initiative__Guidelines_and_best.7.aspx

This article from the journal, *The Nurse Practitioner,* reviews the ABCS of Million Hearts and describes recommendations for clinical practice, education, research, and health policy.

Million Hearts™: Preventing a Million Heart Attacks and Strokes through Public–Private Collaboration

Wright, J.S. (2013). Million Hearts™: preventing a million heart attacks and strokes through public–private collaboration. Future Cardiology, 9(3):305-307. https://doi.org/10.2217/fca.13.15

https://www.futuremedicine.com/doi/full/10.2217/fca.13.15

This interview published in *Future Cardiology* describes the Million Hearts™ Initiative, its progress, and expected impact.

Million Hearts® Progress Report 2012-2016

From the Centers for Disease Control and Prevention and the Centers for Medicare & Medicaid Services

https://millionhearts.hhs.gov/files/MH-meaningful-progress.pdf

This report describes the progress made by the Million Hearts® initiative through 2016, describing the activities and policies supported by the initiative as well as the outcomes.

Million Hearts® Progress Report 2012

From the Centers for Disease Control and Prevention and the Centers for Medicare & Medicaid Services

https://millionhearts.hhs.gov/files/MH_YearinReview_2012.pdf

This report describes the progress made by the Million Hearts® initiative in its first year, focusing on the implementation of partnerships, strategies, and activities.

Guidelines on High Blood Pressure

Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults

https://www.ncbi.nlm.nih.gov/pubmed/29159416

This article published in the *Journal of the American Medical Association* describes the 2017 guidelines for the prevention, detection, evaluation and management of high blood pressure in adults.

High Blood Pressure in Adults: Guidelines for the Prevention, Detection, Evaluation and Management

From the American College of Cardiology

https://www.acc.org/guidelines/hubs/high-blood-pressure

This site has many resources regarding the 2017 guidelines for the prevention, detection, evaluation and management of high blood pressure, as well as how to implement the guidelines.

Guidelines on Heart Failure

2017 Guideline for the Management of Heart Failure

Yancy, C.W., et al (2017). 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation, 136:e137– e161. DOI: 10.1161/CIR.0000000000000509

https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000509

This article published in *Circulation* describes the 2017 guidelines for the management of patients with heart failure. The guidelines were developed by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America.

Guidelines on Atrial Fibrillation

2014 Guidelines for the Management of Atrial Fibrillation

January, C.T., et al (2014). 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation, 130:e199–e267.

https://doi.org/10.1161/CIR.0000000000000041

This article published in *Circulation* describes the 2014 guidelines for the management of patients with atrial fibrillation. The guidelines were developed by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society.

Other Guidelines

Best Practices Guide for CVD Prevention

From the Centers for Disease Control and Prevention

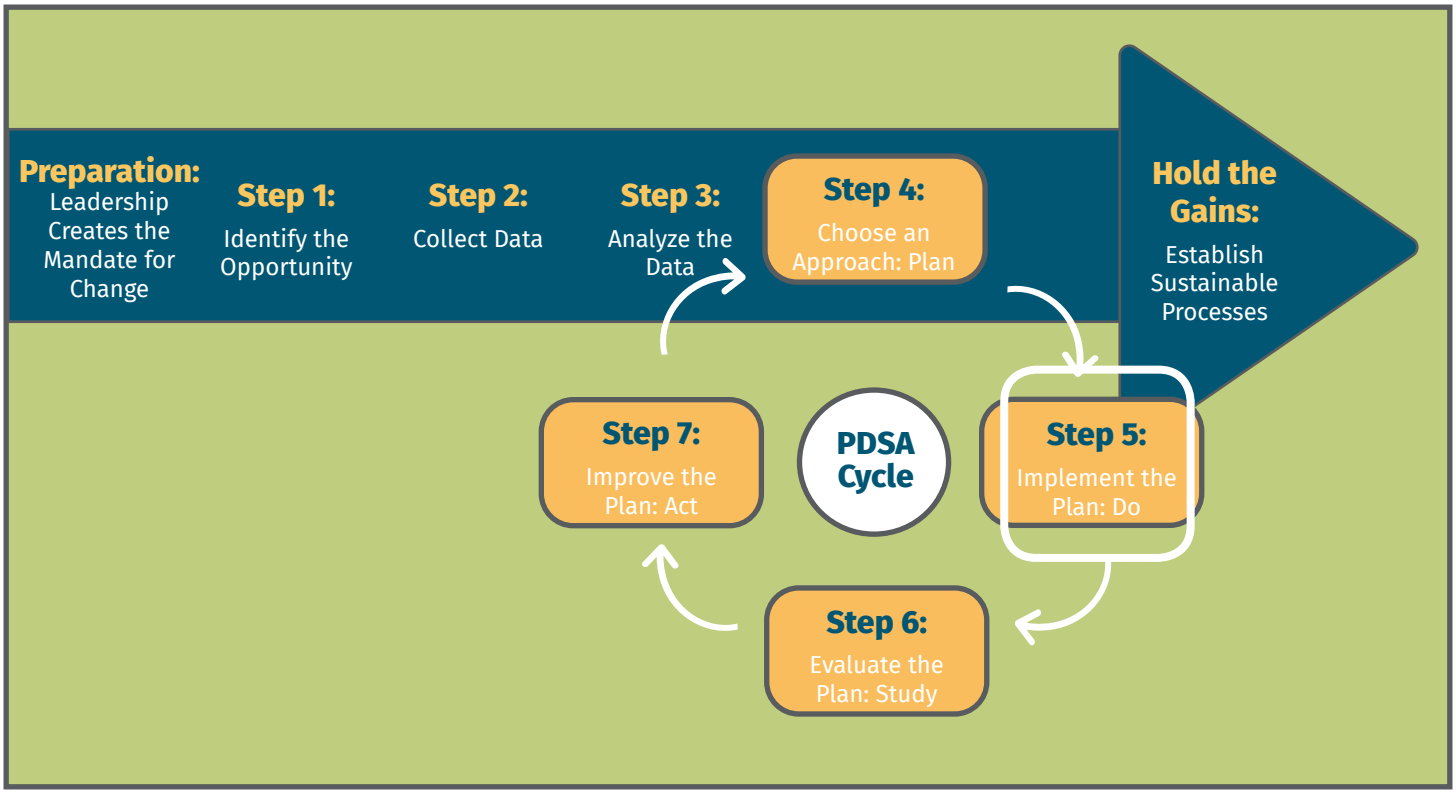
https://www.cdc.gov/dhdsp/pubs/docs/Best_Practices_Guide_intro_508.pdf

This guide highlights effective strategies for widespread control of hypertension and hyperlipidemia, focusing on health care systems interventions and community programs linked to clinical services.

STEP 5: IMPLEMENT THE PLAN - DO

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

Step 5 is the Do part of the process. It is when you build your proposed approach into a workable process that leads to systematic improvements. It is when you test your plan. These are the kind of changes that have a good chance of working long-term. In Step 5 you will outline the improvement process(es), and test and refine them in preparation for implementation.

As the team starts outlining the details of the new approach, keep in mind that you need to develop the processes, not just the tools. For instance, if you are creating an Information Summary within the EHR that will be shared by all on the care team, you will need to all agree on the purpose it will serve, and how it will accomplish your goals. Secondly, consider the process by which the Information Summary will be completed: how, when, by whom, etc. Then work on the content. If you ignore the process for actually working with this new change, you risk creating more unused documentation or uncompleted tasks.

Objectives

- To translate your improvement approach into a workable process
- To pilot test and refine those processes

Preparation for Team Work

- Review with the team the Plan you developed in Step 4
- Secure the resources you will need to develop and test the improvement(s)
- Ensure that your improvement approach and intentions are adequately communicated

Overview of Suggested Activities

1. Set objectives describing what the new improvement process(es) should accomplish
2. Develop detailed flowcharts to illustrate each new process
3. Pilot test, evaluate, and refine new processes
4. Secure the tools and resources needed to implement the new process(es) system-wide

Suggested Activity Details

During the QI Team meetings...

1. Set objectives describing what the new improvement process(es) should accomplish

- Identify what processes are involved with each process from your Step 4 improvement plan.
- Ask how this new process will meet customer needs and solve the root causes identified.

  For example, an Information Summary might be intended to serve the following purposes:

  - **To have all information needed during an encounter with a patient**
  - **To have all the same information collected for all cardiovascular disease patients**
  - **To have the information quickly and easily accessible**
  - **To have the information current at all times**
  - **To facilitate monitoring one type of information (such as blood pressure or lipids) over time and to relate that to other information (such as medication changes)**
  - **To facilitate audits to assess the care process and outcomes**
- As the team develops specific objectives such as those above, ask whether they will meet the root causes of problems identified in Step 4.

2. Develop detailed flowcharts to illustrate each new process

- When developing the process for operating under each improvement, it is usually helpful to flowchart the new process in detail.
- Assign individuals or a small work group to develop a first draft of a detailed flow chart for each process. This will help ensure that each individual process fits together into one integrated system. It will also improve the individual process by exposing their flowcharts to the variety of viewpoints and experiences of the team.
- Have the entire team review and revise the flow chart. As the team reviews a process flowchart, ask two questions:
  - **Does the process meet the purposes/objectives described for it?**
  - **Is the process as simple as possible?**

3. Pilot test, evaluate, and refine new processes

- Don't skip this step! Pilot testing is essential and too often gets left out. Pilot testing is especially important because you are proposing to make system-wide changes that could have broad impact and ramifications to staff and patients. A pilot test will enable the team to better evaluate the impact and effectiveness of the proposed solution, identify potential barriers, and determine whether you have the adequate resources to support full implementation. Your team can then refine the solution and generate a detailed plan to implement the improvements across the entire practice.
- Before you pilot test any process, consider what you most want to learn from the test. The type of information you need should be easy to collect. For example, even testing with 2-3 patients may help you learn:
  - **Whether the new process was used at all**
  - **Whether the process was used consistently**
  - **What the participants thought of it**
  - **What problems and advantages they experienced using the new process**
  - **What suggestions participants have to improve the process**
- There are a number of ways to pilot test a process:
  - **Stage a mock run of the process. For example, have people play the roles of the various members of the care team to determine whether the new process can be followed.**
  - **Ask several people to try out the whole process or parts of it for a short time or for a few patients. For example, to understand how something like an Information Summary is used, you could look at 5-10 patient charts from the pilot test and see if the form has been used as intended. Answers to other questions can be obtained using a short questionnaire or brief interviews of the test participants.**
- Based on your evaluation of the pilot test information, you should be able to refine the processes and/or tools to prepare them for full implementation. If you make substantial changes, you may want to retest and re-evaluate the process.

4. Secure the tools and resources needed to implement the new process(es) system-wide

- In Step 4, the team solicited leadership commitment for support for the proposed improvement approach. Now the team should be able to create a detailed list of what resources will be needed to implement the new processes.
- If you haven't done this already, now is the time to create a line-item budget and collect those tools and resources.

  Consider the following:
  - **Supplies and materials, including maintenance**
  - **Personnel, time, and expertise**
  - **Space (for meetings, trainings, patient group sessions as appropriate, etc.)**
  - **Services, such as IT, for anything related to the EHR**
  - **Scheduling**
  - **Trainings**
- Brainstorm potential sources of the resources needed, and enlist your Sponsor to secure the resources. Cost is often a limiting factor and pilot testing your process is a good way to determine the costs of implementing and sustaining the changes. Be prepared to test alternative methods at reduced costs. If cost appears to be the only barrier to implementing a good idea, consider soliciting funds from external sources like pharmaceutical companies, government agencies, and private foundations. External funding may help launch improvements, but you will still need to develop the financial capacity for sustaining the changes internally.
- With all the elements to consider in this step (what processes to improve, the objectives, flowcharts, resources, pilot testing, and evaluating the pilot tests) you may find it beneficial to draft a written plan. This would aid in communicating your intentions to leadership and others.

ACCELERATED QI OPTION

Step 5 is where the alternative rapid approach differs from the more methodical steps to quality improvement. It avoids planning an entire multi-component process in great detail before implementation. Instead, it relies on a more incremental approach.

To accelerate Step 5, simple changes from the overall improvement design from Step 4 are tried out on a trial basis, one at a time. Each trial includes simple measurements to evaluate its success. For the process you want to test out, such as the Information Summary, you will need at least one provider and care team to agree to test it out. They will need to provide you feedback on how the process went, including an approximate amount of time it took to complete the tasks. If tests and improvements are made in rapid succession, you can more rapidly get to your goal with something that can be implemented system-wide. For many processes, this should only take weeks rather than months.

The keys to this accelerated approach involve four principal activities:

1. Plan small strategies that can be tested within a week's time. Be sure each change is compatible with the overall improvement plan, and that each trial would help to answer concerns about the new process. Ask one or two people to undertake the week-long test and provide them with the instructions, information, and tools they will need. Carefully choose a few measurements to evaluate the trial. Make sure the data will be simple to collect.
2. Try one or more changes on just a small number of cases (usually 5-10).
3. Evaluate the results of the trials.
4. If the trial is successful, refine the process to prepare it for full implementation (which will happen in Step 6).

Rethink those strategies that did not work well and make the necessary improvements.

RESOURCES

Plan-Do-Study-Act Cycle

Plan-Do-Study-Act (PDSA) Worksheet

From the Institute for Healthcare Improvement

http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx

This page describes the PDSA cycle and provides a worksheet to document a test of change. Brief videos explaining PDSA cycles are also available on the page.

Science of Improvement: Testing the Changes

From the Institute for Healthcare Improvement

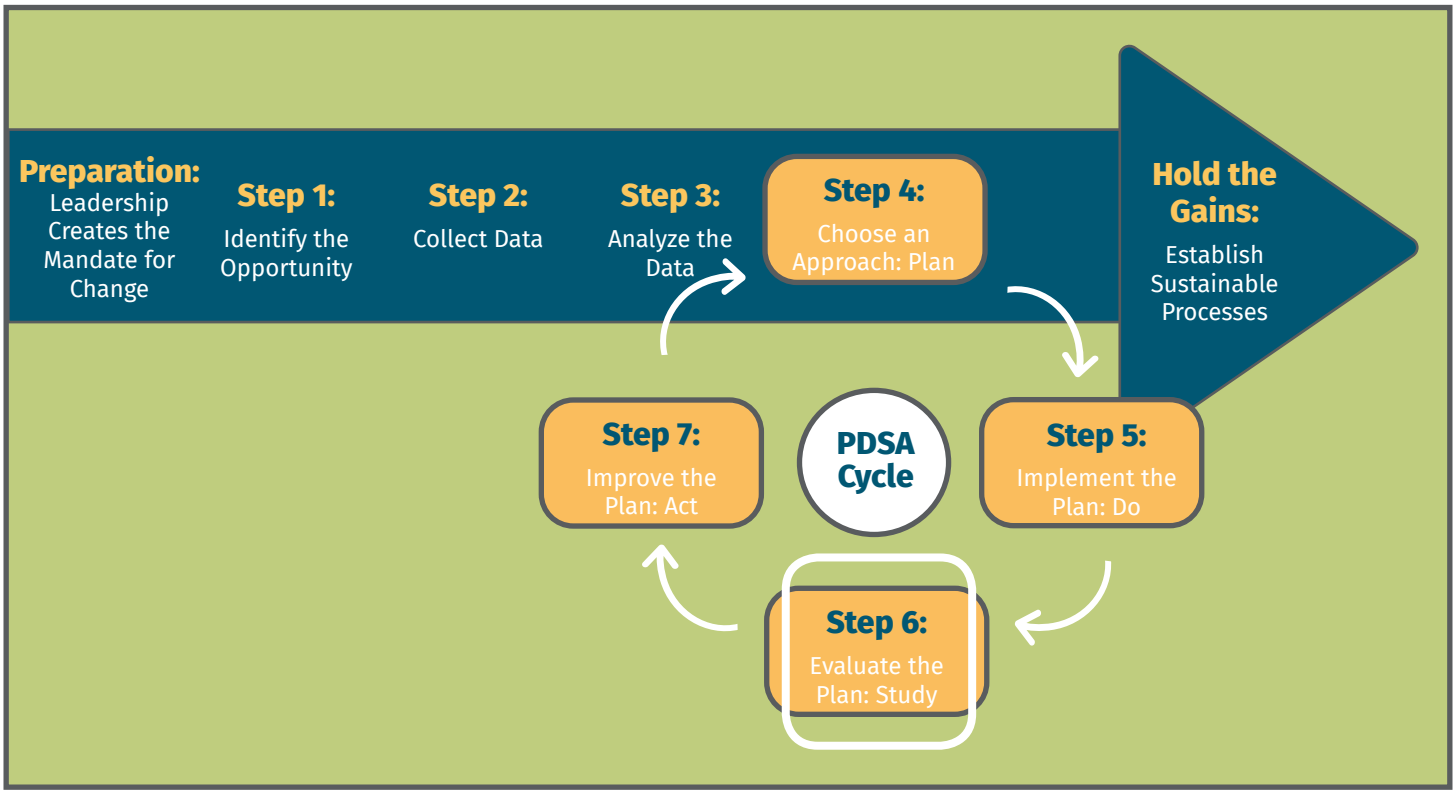
http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx

This page describes the Science of Improvement: Testing the Changes.

STEP 6: EVALUATE THE PLAN - STUDY

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

Congratulations! By now the team has successfully tested and tweaked the improvements and you are ready to evaluate it to determine if it is ready for full implementation. After monitoring the implementation of your improvements in your pilot test, you will have some sense of the short-term results of your changes. Confirm your observations by thoroughly assessing the impact of the changes and whether the desired outcomes are being achieved.

Using your initial goal statement and the data you collected in the pilot testing done in Step 5, you will determine whether or not your plan resulted in the improvement you were expecting and by how much. You will want to evaluate whether the change was worth the effort before you spread it across your entire system. You will want to review any trends. You will want to determine if there were any unintended consequences of the change.

Objectives

- To evaluate the impact of your changes
- To communicate the results of the changes

Preparation for Team Work

- Review the data collection process used in Step 2 and your baseline results
- Review the results of your pilot test and monitoring activities

Overview of Suggested Activities

1. Prepare an evaluation plan
2. Evaluate the results to determine if Aim and objectives were met
3. Communicate the evaluation findings and accomplishments

Suggested Activity Details

During the QI Team meetings...

1. Prepare an evaluation plan (if you haven't already).

- Begin by identifying process or outcome measures. These should include the baseline measures you collected in Step 2 so that comparisons can be made.

  In addition, consider what measures will answer questions about the effects of the changes such as:

  - **Are the changes working as you envisioned?**
  - **How well did the improvement approach meet the mission and objectives established by the team?**
  - **What have you learned about the process you are trying to improve?**
  - **What does the process look like now?**
  - **Is the change that was piloted something that can be spread across the whole system and is it sustainable?**
- As part of your evaluation plan you will need to determine the following:
  - **What to measure and re-measure from baseline.**
  - **What data collection tools you will need.**
  - **You will need to outline the specific data collection tasks, person responsible, and time lines.**
- Your evaluation plan should include measures that assess how well the QI process worked.
  - **What were the most important parts of the process? Could any steps be eliminated?**
  - **How effective was the team in accomplishing each of the QI steps?**
  - **How can you improve the QI process for the next improvement effort?**

2. Evaluate the results to determine if Aim and objectives were met

- Once you have collected your data, you and the team will need to evaluate the results according to your evaluation plan:
  - **Analyze the results and determine the impact**
  - **Brainstorm ways of documenting what worked and what didn't with the QI process**
  - **Determine whether your Aim and objectives have been met**

- It takes time to see system-level change, especially when looking for improvements in patient health outcomes.
  - **Some processes and outcomes, like patient satisfaction or blood pressure measurements, may be measureable within a few months.**
  - **Other process measures, such as annual lipid profiles, may take longer to yield evidence of change on the population level.**
  - **Still others, like the integration of processes or patient behavior changes, may not be significant or observable for several years.**
- Change – for better or worse – also occurs over time as part of the natural evolution of practice. Changes may also be lost or become obsolete.
  - **For these reasons, it is important to review your progress by comparing results to the baseline data and by charting your measures over time.**
  - **Data collection over an extended time period will enable your team to see gradual gains and hold on to solutions. It also provides important information to support further improvements.**
  - **You can easily visualize change over time by displaying measures on a time plot or run chart as described in Step 3.**

3. Communicate the evaluation findings and accomplishments

RESOURCES

Plan-Do-Study-Act Cycle

Plan-Do-Study-Act (PDSA) Worksheet

From the Institute for Healthcare Improvement

http://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx

This page describes the PDSA cycle and provides a worksheet to document a test of change. Brief videos explaining PDSA cycles are also available on the page.

Science of Improvement: Testing the Changes

From the Institute for Healthcare Improvement

http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx

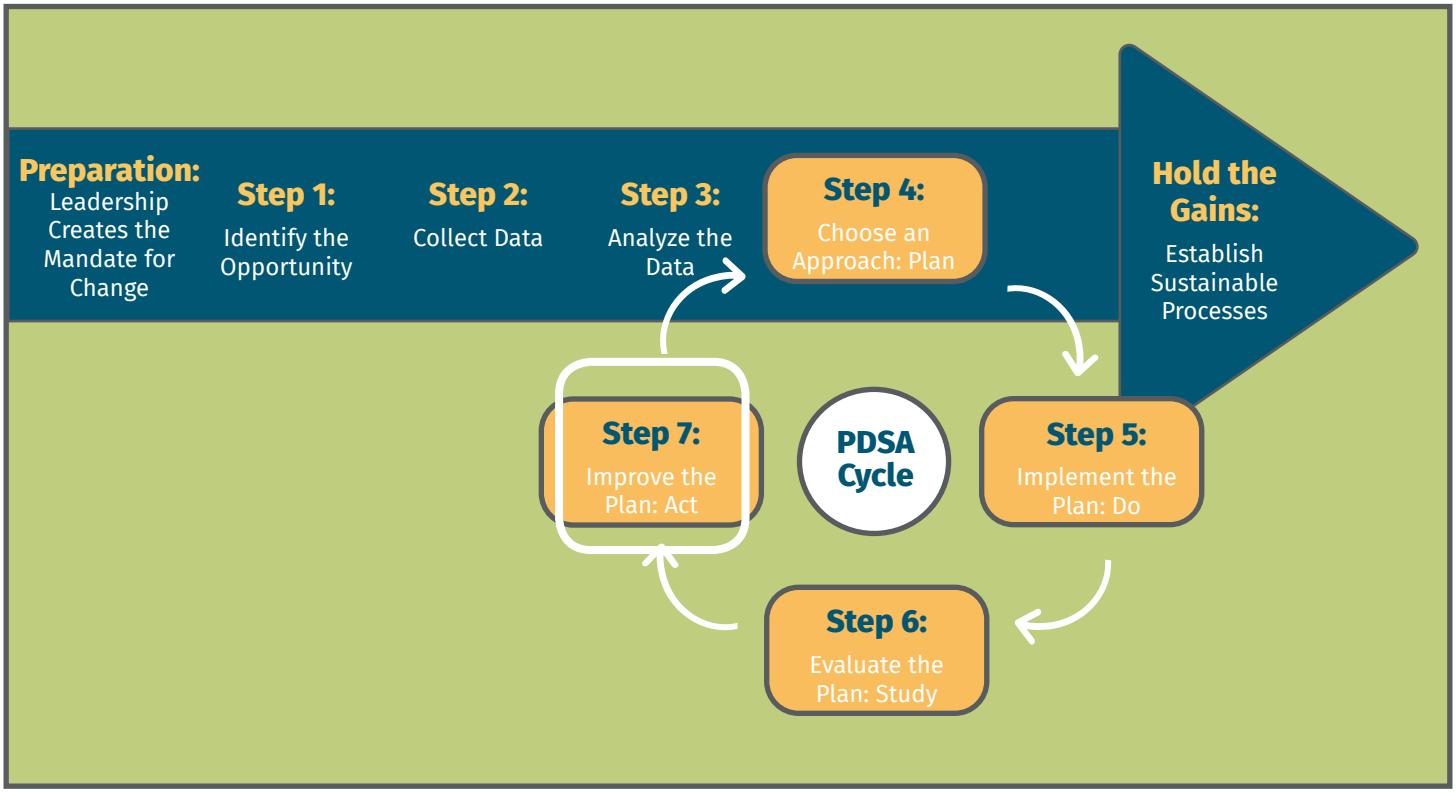
This page describes the Science of Improvement: Testing the Changes.

STEP 7: IMPROVE THE PLAN - ACT

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:

- About this Step
- RESOURCES



About this Step

Purpose

If your team determined the improvement was a success during the pilot phase, you will want to implement it widely across the entire system. In a sense, much of this work will be the same as what you have done already only on a much larger scale. It will also be important to share the results of the pilot so that people will know it has been tried and proven.

If your team determined the plan did not result in the improvements you were hoping for, you will need to go back to Step 4 and begin the process over again.

To integrate the changes into routine practice, consider doing the following:

- Standardize the process.
- Determine what needs to be done to spread this widely.
    - **For example, with the Information Summary, you will need help from the IT department to ensure it is functioning system-wide within the EHR.**

- **There will also likely be a need for training those who were not involved in the pilot. Put together a plan for how this will happen and who will do it.**
- **Communicate your accomplishments and plans for moving forward to internal and external stakeholders.**

- See **Appendix F** for examples of policies and processes from South Dakota healthcare facilities.

RESOURCES

Plan-Do-Study-Act Cycle

Plan-Do-Study-Act (PDSA) Worksheet

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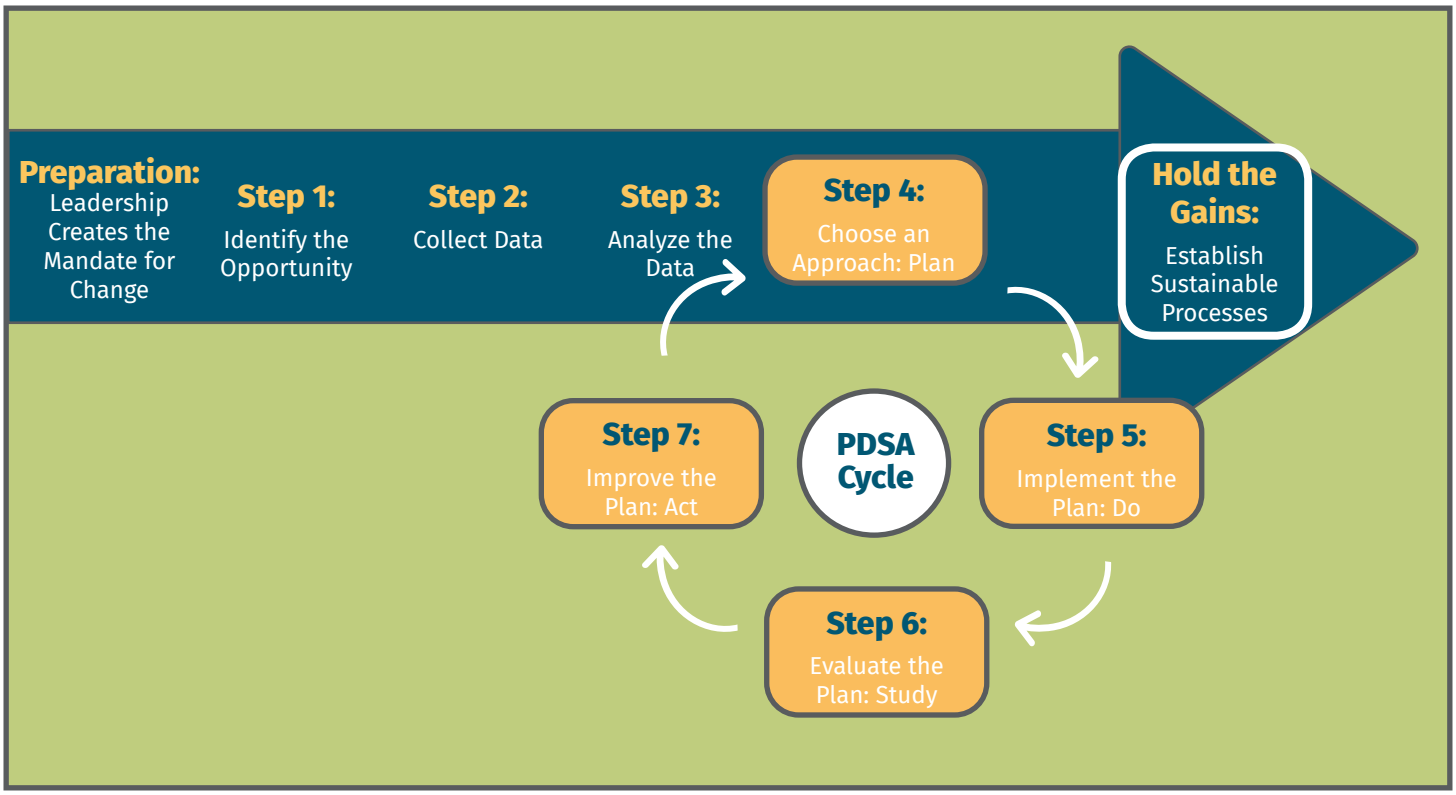
HOLD THE GAINS: ESTABLISH SUSTAINABLE PROCESSES

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

THE QI APPROACH:



About this Step

Purpose

It is time to celebrate! It is always important to celebrate success and acknowledge those who did the work. The feeling of accomplishment and recognition for the work will go a long way in keeping the momentum going. This team can become a group of champions for further improvement efforts in the future.

Now that you have achieved your goal, you want to maintain it. The true test of system change is whether it can be sustained over time. Too often teams assume that once an improvement has been successfully implemented, nothing more needs to be done. It will be important to make QI a continuous process and ongoing pursuit in your organization. QI should become a standard operating procedure, incorporating it as a way of moving forward, expanding to other areas of opportunity, and holding your gains.

Overview of Suggested Activities

1. Integrate changes into routine practice
2. Communicate your accomplishments
3. Expand the improvements

Suggested Activity Details

1. Integrate the changes into routine practice

- Transfer ownership and supervision of the new process from the team to usual operations people. The team should be integral to this transfer by training and coaching them in the beginning to ensure a smooth transition.
- Encourage everyone who works within the process to continue some type of monitoring and evaluation activity.
- Ensure that the new process is incorporated into the new employee trainings, job descriptions and employee performance appraisals.
- Ask clinic management to reinforce people's attention to cardiovascular disease by hosting in-services and other events.
- Replicate the team's QI approach by making improvements in other care processes.
- Setting facility-wide QI policies can be a way to institutionalize QI efforts and ensure sustainability. See **Appendix F** for examples of policies and processes from South Dakota healthcare facilities.

2. Communicate your accomplishments

- Communication has been an important task at every step of the improvement process. At this point it is especially crucial to:
  - **Maintain strong leadership support for the QI process**
  - **Continue to build awareness and reinforce the improvements**
  - **Take the next process improvement steps**
- This is also a time to emphasize clinic-wide ownership of the new care process and to downplay any alienation that people may feel as the result of not having been a member of the team.
- There are a number of ways to publicize the accomplishments and instill a sense of ownership:
  - **Celebrate and promote the accomplishments as a practice by publishing a newsletter to all stakeholders, or by displaying a storyboard of the activities. Storyboards used as a presentation tool have been shown to be strongly correlated with perceptions of the improvement.**
  - **Hold a milestone celebration to kick-off implementation. See Appendix G for more information on milestone celebrations.**
  - **Look for opportunities to present the results of the improvement efforts at internal and external forums.**
  - **Document the improvement methodology, observations and results and consider publishing them.**
  - **Encourage those involved in the improvement effort to share their views and anecdotes of their experiences. Consider writing a handbook or guide for future team efforts.**
  - **Recognize and thank everyone for their efforts and support of the improvement process.**

Expand the improvements

- Process improvement is a repeating, continuous cycle. To begin a new cycle of improvements, have the team review their mission and ask themselves:
  - **Has the team met all of their objectives?**
  - **Has the team fulfilled its mission?**
  - **Are there other parts of the care system that need attention?**

- If other parts of the system need improvement, review what you have learned in the root cause analysis you performed and determine your next area of focus. Then move quickly through Step 4 – Step 7.
- If you are unsure whether additional parts of the system need improving – that is, you can't answer the questions above – you may need to collect more data first.
- If you have satisfied your cardiovascular disease care process mission and objectives, then consider expanding the improvement process to include other chronic conditions or processes that need improvement. This may involve cycling through all or part of the improvement steps once again.
- There are a number of benefits to repeating this experience:
  - **The process will be easier**
  - **The team will have greater confidence and credibility**
  - **There will be less resistance to the changes**
  - **Opportunities for improvements will be more obvious**
  - **By building on previous solutions, you will likely improve the efficiency of the work as well as the quality of care**

You now have the skills to improve any process in your system, and there is always room for improvement. Train others in these skills by involving more of them in continued, team driven improvement efforts.

ACCELERATED QI OPTION

Rapid cycling through the QI process requires immediate evaluation of every change that is made. However, this doesn't eliminate the need for a thorough data collection to assess overall improvement from baseline. You will still need to prove that the small changes contributing to a new approach have indeed resulted in improved care. Therefore, the actions described above will apply. The only difference is that you will already be reasonably confident that the changes are working; you will need only demonstrate the outcomes.

Remember, you are not only changing the process, but also the behaviors of many people, including patients. Look at short term outcome indicators, such as patient and care giver satisfaction, and continue monitoring the progress of changes while you wait an appropriate interval before measuring longer-term outcomes, like the provision of cardiovascular disease services which can be measured within 6-12 months, or patient outcomes which may take 1-3 years to see population and system-level changes.

RESOURCES

Holding the Gains in Quality Improvement

From the American Academy of Family Practice

https://www.aafp.org/fpm/1999/0500/p29.html

This article describes how to keep momentum going and find further needed improvements.

AVERA ST. BENEDICT HEALTH CENTER IMPROVES THE MANAGEMENT OF HYPERTENSION

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

QI TOOLKIT CASE STUDY:

- About Avera St. Benedict Health Center
- About the interviewees - Melissa Gale and Heather Bowar
- What is the focus of this QI initiative?
- What challenge or problem does this QI initiative address? How did you know this problem existed?
- Why was this a priority for your facility/organization?
- What was the role of leadership in supporting this work?
- How did you Iimplement this QI initiative?
- When implementing this approach, what went well?
- What were some of the challenges?
- What did you learn along the way? What changes, if any, did you have to make to your approach?
- What were the outcomes of this QI initiative? Is this process still in place? If so, how did you make that happen?
- How did QI help you and your team make your changes?
- What advice do you have for others who are considering starting the QI process?

Thank you to Melissa Gale and Heather Bowar of Avera St. Benedict Health Center for sharing this case study.

About Avera St. Benedict Health Center

Avera St. Benedict Health Center is a 25-bed Critical Access Hospital with surgical and obstetrics capabilities. Under one roof are the attached Parkston Certified Rural Health Clinic; a 47-bed long term care facility that provides skilled nursing services; a 27-bed assisted living facility; and a physical therapy wing with wellness center. Avera St. Benedict also owns and operates a licensed daycare off site as well as the Certified Rural Health Clinics in Tripp and Lake Andes, SD. Outreach to area nursing homes, Hutterite colonies, and consultations at other healthcare facilities are also a part of Avera St. Benedict's medical staff duties.

This project is from the team at the Avera St. Benedict Health Center's Parkston Certified Rural Health Clinic site.

About the Interviewees – Melissa Gale and Heather Bowar

Our role for this project was clinic quality. In clinic quality, we review data, implement change based on Plan-Do-Study-Act cycles, and track changes and adjust processes over time with each project or area for improvement. The physicians, advanced practice providers (APPs), clinic nurses, and other clinic ancillary staff are all considered our team.

What is the focus of this QI initiative?

Hypertension management at the Avera St. Benedict Health Center's Parkston Certified Rural Health Clinic site.

What challenge or problem does this QI initiative address? How did you know this problem existed?

Our challenge was improving hypertension control rates among adults served by the Parkston clinic. We discovered this was a problem when we were able to start using clinical informatics to look at the numbers of the population.

Why was this a priority for your facility/organization?

- This was made a priority when the numbers were taken to the physicians. We basically thought that we did very well with hypertension management until we were able to look at the entire population.
- A move to value based arrangements, Merit-based Incentive Payment Systems (MIPS), Medicare Access and CHIP Reauthorization Act (MACRA), and shifts to population health models also influenced the priority level. Since these changes meant payment to Avera was based on quality measures performance, it became a bigger priority for the organization as a whole.

What was the role of leadership in supporting this work?

- The facility CEO was very supportive of the focus on this area.
- The decision to address it came from a provider led approach, so then all nurses, ancillary clinic staff, and clinic quality staff were on the same page. This was then introduced at clinic nurses' meetings and clinic staff meetings.
- We were transparent with the data to help promote change with "friendly competition." Everyone involved wanted to do their best for their patients.

How did you implement this QI initiative?

- We used the Plan, Do, Study, Act (PDSA) format for the process.
- We focused on each nurse being consistent with how they were taking blood pressures, charting blood pressures, and taking a second set of vitals manually.
- We also integrated blood pressure magnets on the clinic door frames for those patients that needed additional blood pressure readings taken. By doing all of these things, we were able to take the variables that we could control out of the equation.

When implementing this approach, what went well?

- Training and education went well. Everyone was on board with the project.
- Staff learning the PDSA process also went well.

What were some of the challenges?

- It does take extra time in a busy clinic day to take extra blood pressure readings and to make sure the standards of taking the blood pressures are followed.
- Utilizing data and being able to pull reports from the electronic medical record (EMR) was an ongoing challenge, including validating the data.

What did you learn along the way? What changes, if any, did you have to make to your approach?

- We learned how to take change one small step at a time, implement the change process consistently, and allow for deviation as needed as the EXCEPTION, not the rule.
- We also learned that taking blood pressures on vital machines were inconsistent and that we had to validate them and order some new cuffs for the best readings.

What were the outcomes of this QI initiative? Is this process still in place? If so, how did you make that happen?

- Blood pressure control was tracked for over a year with percentages of blood pressure control improving by 20-30%.
- The process is not just hard wired into clinic operations. We review the blood pressure data each month with chart audits and trouble shoot problems if there is a lot of variability.
- Training and retraining takes place often. All quality numbers, which blood pressure control is a part of, are reviewed at nurse's meetings, quality meetings, and medical staff meetings.

How did QI help you and your team make your changes?

We learned we have created a framework for quality and change management with this first project that we were then able to use with other clinical quality measures, such as hemoglobin A1C control, flu shots, pneumonia vaccination, cancer preventative measures, etc.

What advice do you have for others who are considering starting the QI process?

- Start with one measure or process.
- Communicate with the staff about the why and how of the process.
- Train and retrain as needed.
- Keep the data in front of staff in a variety of ways all the time (verbal, written, experiential, etc.).

STROKE ALERT! FAST HELP FOR STROKE VICTIMS AT BROOKINGS HEALTH SYSTEM

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

QI TOOLKIT CASE STUDY:

- About Brookings Health System
- About the interviewees - Sandra Ruesch and Karen Weber
- What is the focus of this QI initiative?
- What challenge or problem does this QI initiative address? How did you know this problem existed?
- Why was this a priority for your facility/organization?
- What was the role of leadership in supporting this work?
- How did you implement this QI initiative?
- How did you communicate your results?
- When implementing this approach, what went well?
- What were some of the challenges?
- What did you learn along the way? What changes, if any, did you have to make to your approach?
- What were the outcomes of this QI initiative? Is this process still in place? If so, how did you make that happen?
- How did QI help you and your team make your changes?
- What advice do you have for others who are considering starting the QI process?

Thank you to Sandra Ruesch and Karen Weber of Brookings Health System for sharing this case study.

About Brookings Health System

Brookings Health System, located in Brookings, South Dakota, includes a 49-bed hospital, the 79-bed The Neighborhoods at Brookview nursing home, Brookhaven Estates senior living apartments, Yorkshire Eye Clinic, and medical clinics in Arlington, White and Volga, South Dakota. It is a non-profit, city-owned facility that offers the community a full range of inpatient, outpatient, emergency and extended care services. In 2019, Brookings Health System was named a Top 20 Rural Community Hospital from the National Rural Health Association. This was the second time in three years that the organization has received this prestigious award. The mission at Brookings Health System is to provide high quality, compassionate, personalized health care.

About the Interviewees – Sandra Ruesch and Karen Weber

Sandra Ruesch, MSN, RN, CEN, CPEN, SANE-A is the Quality Director, and Karen Weber, ADN, RN is the Medical Surgical & ED (Emergency Department) Director at Brookings Health System.

What is the focus of this QI initiative?

- We have been collecting internal stroke data since 2015. Our team was interested in implementing a stroke alert response.
- The QI team included members from our hospital-based ambulance, radiology, ED providers, ED nursing, registration, and quality.

- The EMS (emergency medical services) team uses the FAST (Facial drooping, Arm weakness, Speech difficulties, & Time to call 9-1-1) exam in the field during pre-hospital care. When a patient screens positive during the FAST exam, EMS initiates the stroke alert. This verbiage is used during radio report back to our ED. EMS also calls the ED receptionist via cell phone to provide patient demographic data to expedite the registration process.
- The FAST exam was created by the American Stroke Association. Our ED and EMS Directors learned about the stroke alert at a regional conference. The decision was made to implement the process at our facility.
- We used a defined pathway based on resources available from the American Stroke Association's best practice guidelines.

What challenge or problem does this QI initiative address? How did you know this problem existed?

- Centers for Medicare and Medicaid Services (CMS) core measures have looked closely at stroke care. We have been tracking door to CT (computed tomography) times less than 20 minutes, door to CT result times less than 45 minutes, and door to alteplase (tPA) administration times less than 60 minutes. These goals have been set forth by the American Stroke Association as best practice.
- Internally, we have also been tracking our documentation for last known well time, as well as if the stroke alert was activated. Over time, our team has noted inconsistencies with our performance. We wanted to assure that each one of our stroke patients received treatments within the outlined timeframes.

Why was this a priority for your facility/organization?

- Being a rural hospital, we have a small volume of patients that fall into the CMS stroke measures. One missed opportunity may mean that we fall well below state and national benchmarks.
- Around the same time, a nurse's husband had a stroke. This hit a personal chord with our team and became an internal inspiration for implementing the stroke alert.
- We realized the biggest opportunity would be receiving the CT results in a timelier fashion. With EMS calling ahead, our radiology team is ready to receive the patient in their department directly from the ambulance bay in order to obtain a head CT. While en route, EMS ensures every patient has a blood glucose and EKG (electrocardiogram) prior to arrival at the hospital in order to rule out other potential causes for the patient's neurologic symptoms.

What was the role of leadership in supporting this work?

- Because this became a CMS measure, it became a priority from a performance standpoint.
- Data was shared at department meetings, all-staff email updates, and with the Board of Trustees.
- Leadership also supported this project because it is an issue that is viewed as a priority for the communities we serve. Stroke is the second-leading cause of death in the world and a leading cause of adult disability.

How did you implement this QI initiative?

- We used a combination of Evidence-Based Practice and the Plan, Do, Study, Act framework for process improvement.
- A PICO question was developed: "Will implementing an evidence-based stroke alert protocol improve our timeline metrics (Door to CT, Door to CT results, and Door to tPA) for patients experiencing symptoms of a stroke?"
- We studied the evidence from the National Stroke Association, American Stroke Association, CMS, and National Institutes of Health.
- Baseline data was collected:
  - Retrospective convenience sample chart review
  - Interviewed staff to identify opportunities in workflow
- Our team created a policy and made edits to our electronic medical record.

The PICO Model is a format to help develop a clinical question.

Problem or Population

Intervention

Comparison

Outcome

- Our pharmacy team developed a stroke medication box, which included the fibrinolytic medication, dosing calculator, and supplies.
- Nurses obtained their certification for the National Institutes of Health Stroke Scale.

How did you communicate your results?

- The team discussed the data at quarterly measurement meetings.
- The ED committee and EMS director hold regular meetings.
- We created a poster and put it in the ED to remind our team of the best practice guidelines.
- Our marketing department created a patient video testimonial and newspaper ad. This was posted on our webpage and social media pages.

When implementing this approach, what went well?

- Buy-in: Key players from all departments were excited about the idea and willing to try implementation of the plan. We were fortunate in that we did not have any challenges with staff engagement throughout this project. We are lucky to have a team with so many invested members.
- We had efforts in place before our process was formalized. Staff knew how to take care of stroke patients; the knowledge-base was already established. We just needed to create a protocol and formalize it.
- We now have the integration of the EMR with a stroke alert order set.

What were some of the challenges?

- We needed a system to securely transfer the virtual images to the radiologist to be read. The hurdle was getting patient information entered into the system to transmit the images. At times, this was the delay in care. We changed the process so EMS now has a cell phone with a protected phone line to transmit the patient demographic information so they can pre-register a patient.
- To prioritize the CT scan for prompt reading, the radiology technician puts a header on top of the requisition for the radiologist that this is a “stroke alert” patient. The images are then tagged for a 15-minute turnaround.
- We also had to set up the documentation process in the electronic medical record so we could clearly identify our timeline.

What did you learn along the way? What changes, if any, did you have to make to your approach?

- We realized documentation was critical to our success. This included the clear documentation of our timeline metrics and a stroke alert order set. It needed to be automated to make it as simple as possible to initiate.
- The CMS inclusion criteria is different than our internal data, but we made a decision to be more inclusive with a longer last known well time to better support our rural community. The neurointerventionist at our stroke referral center suggested this process change. He provided continuing education to our physicians, midlevels, and nursing staff.

What were the outcomes of this QI initiative? Is this process still in place? If so, how did you make that happen?

- This is still in progress. Due to our small patient population, we are continuing to work on improving our process using rapid cycle improvement strategies. Every missed metric is seen as a learning opportunity.
- We are adapting the process for situations when a patient comes in by private vehicle or if the stroke occurs while in the hospital.
- We are taking the opportunity to provide community education about stroke, such as the FAST exam. Time is brain, and it is our hope that the general public is able to identify the symptoms of a stroke so they do not delay essential medical care.

- We are also looking at other opportunities for improvement such as our ST-Elevation Myocardial Infarction (STEMI) and sepsis response.

How did QI help you and your team make your changes?

- Completing a chart review was very helpful to better understand our existing process. Because we have a small population, we can look at every case.
- We looked for root causes when things did not go as expected. The findings from the review assisted us in tweaking our response plan.
- Having defined process improvement steps provided us with structure.

What advice do you have for others who are considering starting the QI process?

- Be sure all key players/stakeholders are getting the results – know what the problems are and involve them in creating the solution.
- When communicating with the various stakeholders, make sure you provide the appropriate level of information for each audience. Each audience has a different role in the process and a different "why" (e.g. CMS measures vs. patient outcome/experience).
- Stay focused on the patient versus the regulation side when making the case.

SANFORD HEALTH-SIOUX FALLS REGION IMPROVES THE TECHNICAL QUALITY OF THEIR ECHOCARDIOGRAMS THROUGH PEER REVIEW

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

QI TOOLKIT CASE STUDY:

- About Sanford Health
- About the interviewees
- What is the focus of this QI initiative?
- What challenge or problem does this QI initiative address? How did you know this problem existed?
- Why was this a priority for your facility/organization? What was the role of leadership in supporting this work?
- How did you implement this QI initiative?
- How did you communicate your results?
- When implementing this approach, what went well?
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- What did you learn along the way? What changes, if any, did you have to make to your approach?
- What were the outcomes of this QI initiative? Is this process still in place? If so, how did you make that happen?
- What advice do you have for others who are considering starting the QI process?

Thank you to Sandy Josko, Susanne Parks, Elliot Nelson, Sarah Johnson, Bridget O'Brien, and Jill Swanson of Sanford Health for sharing this case study.

About Sanford Health

Sanford Health is a large network/enterprise with sites in SD, NE, MN, IA, MT and worldwide. They are an integrated system with hospitals, clinics, and a network of services. This project is from the Sioux Falls region.

Quality process and metrics are important to Sanford Health as a whole, and in the Sioux Falls region there is an annual Performance Improvement (PI) Fair/Symposium. Every department is expected to submit a poster to highlight work they have been doing over the past year. It's gotten quite large – over 200 projects. Other areas, outside the Sioux Falls region, have their own fair/symposium as well, and sometimes the different departments will go to them to share ideas amongst other enterprise sites.

About the Interviewees

Interviewees and QI project team members include:

- Sandy Josko – Project Sponsor, Echo Department Manager
- Susanne Parks and Elliot Nelson – Project Leads, Echo Lab Leads
- Sarah Johnson – Administrative Assistant
- Bridget O'Brien – Director of Cardiovascular Services
- Jill Swanson – Education and PI Projects

What is the focus of this QI initiative?

This QI project focused on improving the technical quality of echocardiogram (echo) images and the reports.

What challenge or problem does this QI initiative address? How did you know this problem existed?

This is a busy department doing 80-120 echocardiograms per day. The project began as the result of comments from physicians who read the echo images on a daily basis. They indicated concern about the quality of the images and brought their concerns to the manager of the echo department. In discussing their concerns, the physicians offered suggestions for improvements. There was also a recognition from the sonographers and staff themselves that they could do better.

We developed an Aim statement to:

- Improve the quality of images
- Improve the patient history in the reports
- Improve the equipment use

We focused on what a textbook image looks like and what information the physician needs.

We didn't have a specific target percentage of improvement in mind at the beginning because we wanted to first see where we were. We wanted to keep high numbers high and improve in other areas.

Why was this a priority for your facility/organization? What was the role of leadership in supporting this work?

Quality is a priority for Sanford Health and is well supported. Each department at Sanford is allocated 4-8 hours per month for QI work. We believe that Sanford's emphasis on QI instills it as a value of how we all approach our work as a constant process of improvement. The organizational backing is phenomenal.

How did you implement this QI initiative?

We use Plan, Do, Study, Act (PDSA) cycles at Sanford.

Pre-work:

- First, we identified the issues – the things that needed to be looked at for improvement.
- We collected data to know where we were so we would be able to measure any improvement when the changes were made.
- We reviewed the American Society of Echocardiography (ASE) guidelines, created an outline, and collected data to see where we needed to start.
- We have a team with QI representation from every department at Sanford. Echo representatives go to a PI meeting every month.
    - For this project, we had echo representatives and we added lead sonographers to the PI meetings.
    - Our meetings were in person, and included the manager, Sandy, and both leads, Susanne and Elliot. It was a big team effort. Frontline staff were there to discuss barriers, how to improve, and how to implement change. We needed to allow staff to determine how they will work at the bedside.
    - Leadership involvement helped keep things going.

Plan:

- The Manager, Sandy, and the two Leads, Susanne and Elliot, were primarily involved in making the plan.
- Our Clinical Learning & Development Specialist, Jill, guided the education process, making sure the education included what needed to be covered to make the desired improvements.
- The Project Sponsor, Sandy, gave them ideas of what she wanted to see and advised the team on how to do it – they thought of how to do it, and what they wanted to change. The team would then meet about it and take it from there.

Do:

- We looked at random studies to review the quality of the echo images and the reports. The two lead staff chose one random study per quarter per sonographer. They tried to mix them up by cardiologist reading the study/leading scans to ensure a cross section of all cardiologists over time.
- We initiated education of staff, which included reviewing cases with sonographers to talk about how to improve. The intervention included:
    - Unit meetings to present information and obtain feedback.
    - Meeting outside of the unit meetings if special coaching was needed.
    - Having Leads available for questions and to give pointers.
    - If a sonographer had a question, Leads would do research to find the answer and share it with the entire team to educate them on the issue.
    - Leads were constantly updating the team with things that came up along the way as well.
- We gathered feedback from frontline staff along the way:
    - We held monthly meetings with discussion of the quality of echo images as a regular agenda item. We asked physicians and sonographers for input.
    - We created an open environment for staff to put forth suggestions outside of meetings to improve workflow.
    - Providers reached out to the Manager and Leads directly to ask questions and to provide ideas.
    - We hold an echo conference every month with fellows, sonographers, etc. to present interesting and challenging case studies. There is an open discussion and a great opportunity to get feedback from physicians, thoughts on what is going well, and ideas to improve.

Study:

- We reviewed for five quarters. The first two quarters were the actual intervention and the second three quarters focused on reviewing and fine-tuning the process using rapid-change.

Act:

- We are continuing this process. Studies are reviewed every quarter with sonographers (24 of them). The quality is monitored with constant feedback as needed to continue improving the work.
- ASE guidelines change every year, so we are trying to stay on top of techniques to improve information for physicians and patients. Education about any changes are presented in meetings with any new criteria and notes. We do this annually, biannually, or as needed.
- Every patient and every scan is a little different, so education is ongoing to find ways to improve.

How did you communicate your results?

- In unit meetings, we passed along positive feedback from physicians.
- During monthly meetings, we discussed follow up, where we've seen improvement, and thanked people for their work
- We have shared ideas and communicated with other echo departments at Sanford but haven't recommended that they do this yet. We would be open to sharing it. Other projects get shared among the enterprise (system-wide), it just depends on the topic and the need.

When implementing this approach, what went well?

- Staff had an open mind – everyone acknowledged the problem and wanted to fix it.
- Staff realized they have someone available to help them figure out solutions.
- The images were reviewed with improvement in mind, not to be punitive. This interaction between lead and sonographer improved overall atmosphere in the lab.
- Susanne and Elliot have great passion for their work. As leaders for the team, they believed in what they were teaching and doing – this made their investing in it important.

What were some of the challenges?

- Some sonographers, who have been there a long time, were a little slower to come along, but they came on board when they saw the improvements being made.
- We have a very large lab where we do 80-120 studies per day. It was challenging to have the time to take samples and review enough scans from each sonographer. We needed to do enough to have a fair sample but also have enough time to do it and give feedback.
- It was challenging to get all players together at the same time (sonographers, physicians, leads).

What did you learn along the way? What changes, if any, did you have to make to your approach?

- We can't think of any changes we would have made to this approach.
- Moving forward, it would be helpful to set specific measurable goals for improvement. We didn't set a SMART goal for improvement and that would be helpful in the future.

What were the outcomes of this QI initiative? Is this process still in place? If so, how did you make that happen?

- The technical quality was greatly improved by this process.
- The team felt an accountability for ensuring the study was filled out correctly, the report for physicians was ready to go, and the machine was used to the best ability to get images for the physician. Axis quality improved by 35%.
- Use of the medication perflutren was decreased, possibly because we had better images so maybe did not need as much.
- This is the way we now do the work. It was not just a short-term project, but an ongoing process. We review studies every quarter with sonographers (24 of them) and monitor the quality and constantly give feedback if needed to continue improving their work.

What advice do you have for others who are considering starting the QI process?

- Start small. It can be hard to get started because ideas are so big. Ask staff what the pebbles in their shoes are. Even the smallest changes make huge impacts.
- Collect measurable data.
- Share improvements as you go. Make it visible for the staff you are working with so they see their efforts are making a change. Staff get excited when they see the graphs indicating change.
- Staff buy-in is very important. Changes are sustainable if staff feel like these changes will positively impact their work.

GREAT PLAINS QUALITY INNOVATION NETWORK: A HEALTHCARE QUALITY IMPROVEMENT RESOURCE

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

QI TOOLKIT CASE STUDY:

Thank you to Nancy McDonald for sharing information about Great Plains Quality Innovation Network.

About Great Plains Quality Innovation Network

- Great Plains Quality Innovation Network (QIN) is the Quality Innovation Network-Quality Improvement Organization (QIN-QIO) for Kansas, Nebraska, North Dakota and South Dakota. The development of Great Plains QIN resulted from changes to legislation requiring state QIO programs to create regional partnerships. Serving as the state QIO, the South Dakota Foundation for Medical Care (SDFMC) formed an alliance with the QIOs in Kansas, Nebraska and North Dakota to advance healthcare quality improvement collaboration across the region.
- Great Plains QIN Mission: Great Plains QIN uses the collective knowledge and resources of its members to achieve the aims of better healthcare, improved health, safer care and lower healthcare costs.
- Great Plains QIN Vision: Through collaboration and partnership, Great Plains QIN aspires to make health in our region the best in the nation.

About the Interviewee

Nancy McDonald, RN, BSN, CPHQ

Director of Quality Improvement

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(605) 234-4144

As Director of Quality Improvement for the South Dakota Foundation for Medical Care and State Program Director for the Great Plains Quality Innovation Network (QIN), Nancy McDonald provides leadership and guidance for the many healthcare initiatives in all healthcare settings across the state.

Her passion for quality improvement and reduction in patient harm is evident and her vast healthcare experience spreads across the spectrum of care from nursing to compliance and includes expertise related to critical access hospitals, ambulatory surgical centers, Indian Health Services, inpatient psychiatric facilities and the inpatient prospective payment system.

An active member of the South Dakota Association of Healthcare Quality, she has served in multiple roles including president and secretary/treasurer and was selected as the Quality Coordinator of the Year in 2015. Her leadership and passion are clearly seen in her energetic, value-based drive for quality improvement. Nancy McDonald is a certified professional in healthcare quality (CPHQ), a Master Trainer in Team STEPPS, and holds a Bachelor of Science degree with a major in nursing from South Dakota State University.

What does Great Plains QIN do?

- Great Plains QIN works with healthcare providers and communities to implement data-driven quality initiatives to improve healthcare. We offer technical assistance, tailored education, best practices, tools and resources. The ability to collaborate with healthcare facilities and providers across the region provides broader insights while maintaining valuable local relationships.
- Through these efforts, we strive to impact the broad aims set forth by the Centers for Medicare & Medicaid Services including adverse drug events, care transitions, chronic disease management, patient safety and nursing home care at the local and regional levels.

What work is specific to cardiac health?

- Great Plains QIN works with providers, patients, partners and stakeholders to implement evidence-based practices that support the national Million Hearts® initiative, which includes promoting preventive cardiovascular best practices – ABCS (Aspirin Therapy, Blood Pressure Control, Cholesterol Control and Smoking Cessation).
- Our content experts help identify high-impact quality improvement opportunities by reviewing and analyzing available data.
- We provide education and technical assistance for cardiac health and all other quality improvement inititiatives. Education opportunities provided since January 2019 included teach back, blood pressure protocol training, and the Know Your Diabetes by Heart initiative.
- Healthcare professionals and community organizations receive support in developing referral programs and promoting chronic disease self-management education programs which empower patients to take charge of their health by developing and maintaining healthy lifestyle behaviors.

What are the benefits of engaging with Great Plains QIN?

- As the QIN-QIO, our diverse and experienced staff are available to provide technical assistance, tools and resources to advance quality improvement efforts at any healthcare facility with the intent of achieving better health care, improved health, safer care and lower healthcare costs.
- We focus on data-driven, high-impact opportunities and provide guidance on implementing evidence-based interventions with proven results.
- Access to regional and national content experts allows us to offer a broad range of valuable educational opportunities and credible tools and resources.
- Having established relationships with entities across the state and region, we recognize trends and common goals which allow us to facilitate collaboration and reduce duplication of efforts.
- As a neutral entity, we routinely collect and distribute best practices from across the state and region for the benefit of all.
- We actively engage and seek input from patients and families on healthcare impact and improvements.

What education and resources does Great Plains QIN offer?

We have a a variety of channels available to access educational opportunities and other valuable resources.

- Great Plains QIN Website: *https://greatplainsqin.org*
- Facebook: *https://www.facebook.com/GPQIN/*
- LinkedIn: *https://twitter.com/greatplainsqin*
- Twitter: *https://twitter.com/greatplainsqin*

How do I get involved?

Great Plains QIN has a broad range of quality improvement initiatives that engage community and healthcare professionals in every healthcare setting. Anyone interested may contact our office directly at (605) 336-3505 or find information on our website at *https://greatplainsqin.org*.

ADDITIONAL RESOURCES

SOUTH DAKOTA CARDIOVASCULAR COLLABORATIVE

ADDITIONAL RESOURCES

Quality Improvement

Quality Improvement for Institutions: QI Toolkit

From the American College of Cardiology

https://cvquality.acc.org/Clinical-Toolkits/QI-Toolkit

This toolkit provides information and resources about the entire QI process, including worksheets and other tools.

Cardiovascular Health Improvement Initiative

From Home Health Quality Improvement

http://www.homehealthquality.org/Cardiovascular-Health.aspx

This page provides an overview of the national Million Hearts® initiative and links to a recording of the initiative's kick-off webinar.

Quality Assurance / Process Improvement (QAPI) Tool Framework

From the Center for Medicare & Medicaid Services

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/ProcessToolFramework.pdf

This chart describes five key elements of QAPI and provides tools related to each element.

Quality Improvement Methods

National Nursing Home Quality Improvement Campaign

https://qioprogram.org/nursing-home-resources/

This website provides information, tools, and resources about a variety of QI methods.

Clinical Outcomes Assessment Program (COAP)

From COAP, a program of the Foundation for Health Care Quality

https://www.qualityhealth.org/coap/

https://www.qualityhealth.org/coap/participating-hospitals/

COAP is a regional quality collaborative that leverages medical leadership and clinical, administrative, and financial data to establish and drive best practices in cardiac care. The COAP website describes the collaborative and their activities.

Resources for Public Health Quality Improvement

From the Institute for Healthcare Improvement

http://www.ihi.org/resources/Pages/Tools/ResourcesforPublicHealth.aspx

This page provides a list of resources to help practitioners apply QI to programs and processes.

The Science of Improvement on a Whiteboard!

From the Institute for Healthcare Improvement

http://www.ihi.org/education/IHIOpenSchool/resources/Pages/BobLloydWhiteboard.aspx

These short videos discuss QI concepts including Deming's System of Profound Knowledge, the Plan-Do-Study-Act (PDSA) cycle, flowcharts, and more.

Quality Improvement Resources

From the Public Health Foundation

http://www.phf.org/focusareas/qualityimprovement/Pages/Quality_Improvement_Resources.aspx

This page defines QI and provides resources, tools, and case studies that facilitate application of QI principles.

5 Phases of Transformation

From the Virginia Cardiac Services Quality Initiative

http://vcsqi.org/wp-content/uploads/2017/11/The-TCPI-Journey-5-phases-roadmap-v3.pdf

The VCSQI is a consortium of hospitals that aims to improve quality of care and contain costs related to heart procedure programs. This document describes the five phases of transformation as part of the Transforming Clinical Practice Initiative.

South Dakota Cardiovascular Health and Quality Improvement Organizations

South Dakota Cardiovascular Collaborative

https://doh.sd.gov/diseases/chronic/heartdisease/state-plan.aspx

South Dakota Department of Health, Heart Disease and Stroke Prevention Program

https://doh.sd.gov/diseases/chronic/heartdisease/

South Dakota Association of Healthcare Organizations

http://sdaho.org/

South Dakota State Medical Association

https://www.sdsma.org/SDSMA/

American Heart Association

https://www.heart.org/

Great Plains Quality Innovation Network

https://greatplainsqin.org/

Community Healthcare Association of the Dakotas

https://www.communityhealthcare.net/

SOUTH DAKOTA
CARDIOVASCULAR
COLLABORATIVE

Quality Improvement Resource Guide

APPENDICES

Appendix A — Adult (Age ≥ 18) Heart Failure (HF) Guideline

Assess and determine adult patient's stage of HF

Risk Factors for HF Not Present

Guideline does not apply

Risk Factors for HF Present

AT RISK OF HEART FAILURE

American Heart Association (AHA) STAGE A
Asymptomatic Patients at High Risk for HF

Patient has no symptoms or structural heart disease but is defined as high risk due to the following conditions:

- Hypertension
- Diabetes mellitus
- Ischemic heart disease
- Obesity
- Metabolic syndrome
- Family history of cardiomyopathy
- Exposure to cytoxic drugs
- Obstructive sleep apnea (OSA)

Therapy for AHA STAGE A

Provide patient with maximum medical therapy:

- Hypertension (*Hypertension Guideline*)
- Diabetes (*Diabetes Guideline*)
- Lipid disorders
- Control metabolic syndrome

Provide patient education (**TABLE A / TABLE B**):

- Encourage to exercise regularly
- Smoking cessation
- Achieve normal body weight
- Avoid illicit drugs and alcohol in excess

Structural heart disease

AHA STAGE B
Asymptomatic Patients with Left Ventricular Dysfunction

Patient found to have left ventricular dysfunction from previous myocardial infarction (MI), left ventricular hypertrophy (LVH) with low ejection fraction (EF), asymptomatic valvular disease or other cause.

Therapy for AHA STAGE B

Provide patient with all measures listed under **Therapy for STAGE A**.

In appropriate patients, the use of angiotensin converting enzyme inhibitor (ACE-I)/angiotensin receptor blockers (ARB) **(TABLE C)** and/or beta-blockers **(TABLE E)** should be considered.

Screen for depression/anxiety, consider Behavioral Health referral.

Development of symptoms of HF

HEART FAILURE

AHA STAGE C
Patients with Known HF or Symptoms Suspicious of HF

Non-emergent patients with new symptoms suspicious for HF, with or without a past history of HF. This does include patients with known structural heart disease.

Therapy for AHA STAGE C

Provide patient with all measures listed under **Therapy for STAGE A**.

Refer to *Page 2* of *HF Guideline*

Refractory symptoms of HF at rest

AHA STAGE D
Refractory Symptoms of HF at Rest

Refractory HF requiring specialized interventions including patients who have marked symptoms at rest despite maximal medical therapy (i.e. those who are recurrently hospitalized or cannot be safely discharged from the hospital without specialized interventions.)

Therapy for AHA STAGE D

Refer to Cardiologist

Adult (Age ≥ 18) Heart Failure (HF) Guideline

CLINICAL PRACTICE GUIDELINE

AHA STAGE C: Assess Patient with Known HF or Symptoms Suspicious of HF

- Unrelieved shortness of breath with exertion or at rest
- Unexplained fatigue
- Orthopnea
- Paroxysmal nocturnal dyspnea
- Peripheral edema
- Decreased exercise capacity
- Weight gain of > 5lbs in one week
- Chest pain or tightness
- Palpitations
- Dizziness/lightheadedness/syncope

Patient Examination

Patient examination should include the following:

- Evaluation of jugular venous distention
- Palpation of cardiac apex and precordium
- Assessment for gallops or murmurs
- Assessment of cardiac rhythm
- Pulmonary examination for evidence of rales or effusion
- Abdominal examination for hepatomegaly or ascites
- Peripheral pulses
- Evidence of edema

Stable Patient

Obtain the following laboratory tests and diagnostic studies:

- CBC
- UA
- Serum electrolytes
- Calcium
- Magnesium
- BUN
- SCr
- Glucose/lipid profile
- Liver enzymes
- TSH
- BNP
- Chest Xray
- EKG

Unstable Patient

Patients who are clinically unstable should be immediately referred for emergency management and admitted if necessary

Echocardiogram

EF < 40%

Refer to Cardiologist

Initiate Therapies

- Initiate non-pharmacologic therapies (**TABLE A / TABLE B**)
- Initiate pharmacologic therapy beginning with ACEI/ARB (**TABLE C)** and/or beta-blocker (**TABLE D**)
- Add diuretic for evidence of volume overload (**TABLE E**)
- Consider aldosterone antagonist therapy (spironolactone) for refractory symptoms when ACEI/ARB, beta-blockers and diuretic therapy have been maximized/optimized **(TABLE H)**
- If EF< 35% after three months of maximal medical therapy, electrophysiology referral is indicated for sudden cardiac death risk evaluation and potential interventions
- If EF remains < 40% and still symptoms worsen, recommend changing ACEI/ARB to ARNI (Entresto)
- For comments regarding ivabradine (Corlanor), see “Clinical Pearls” section

EF 40-49%

Initiate therapies

Stress Testing and/or Cardiology Referral IS Indicated

Initiate Therapies

- Initiate non-pharmacologic therapies (**TABLE A / TABLE B**)
- Initiate pharmacologic therapy beginning with ACEI/ARB **(TABLE C)**, ARNI **(TABLE D)** and/or beta- blocker **(TABLE E)**
- Add diuretic for evidence of volume overload **(TABLE G)**

Failure to Respond

Refer to Cardiologist

EF ≥ 50%

Initiate therapies

Stress Testing and/or Cardiology Referral IS Indicated

Initiate Therapies

- **Focus of treatment should be vigorous blood pressure control** (see *Hypertension Guideline*)
- Utilize ACEI/ARB **(TABLE C)**, ARNI **(TABLE D)**, beta-blockers **(TABLE E)** or diuretic **(TABLE G)** based upon blood pressure and volume status

Adult (Age ≥ 18) Heart Failure (HF) Guideline

TABLE A: Non-pharmacologic Management in Patients with HF

- Dietary instruction regarding sodium intake for all patients. Instruction on diabetes, dyslypidemia or severe obesity in selected patients.
- Dietary restriction of sodium 2-3g for all patients with HF.
- Restriction of daily fluid intake < 2L in severe hyponatremia (< 130 mEq/L). Consider in all patients with difficult to control fluid retention despite high dose diuretics and low sodium diet.
- Recommend daily multivitamins in patients with diet restrictions; evaluation for specific vitamin/nutrient deficiencies is rarely necessary.
- Document naturoceutical products. Avoid products containing ephedra (ma huang), ephedrine, or its metabolites (increased mortality and morbidity). Avoid products with significant drug interactions with digoxin, vasodilators, beta blockers, antiarrhythmic drugs and anticoagulants.

TABLE B: Additional Therapies and Routine Health Maintenance

- CPAP in patients with sleep apnea (up to 50% of HF patients have sleep apnea)
- Supplemental oxygen not recommended in the absence of indication of underlying pulmonary disease. Evaluate for fluid retention of pulmonary disease if hypoxemic.
- Consider referral to Behavioral Health for difficulty with behavioral change and adherence
- Non-pharmacologic techniques for stress reduction
- Smoking cessation and limit alcohol to 2 drinks/day in men or 1 drink/day in women
- Pneumococcal and annual influenza vaccination
- Avoid NSAIDs

TABLE C: Angiotensin Converting Enzyme Inhibitors (ACEI) (First Line)

Patient Exclusion: allergy, angioedema, intolerable cough, hyperkalemia (K ≥ 5.0) severe aortic stenosis, shock, symptomatic hypotension, bilateral renal artery stenosis, pregnancy, SCr > 3 mg/dl

Initial Dose	Titration Steps	Target Dose
Captopril: 6.25 mg three times daily	Captopril: 12.5 mg or 25 mg three times daily	Captopril: 50 mg three times daily
Enalapril: 2.5 mg twice daily	Enalapril: 5 mg twice daily	Enalapril: 10-20 mg twice daily
Lisinopril: 2.5-5 mg daily	Lisinopril: 5 mg daily, 10 mg daily	Lisinopril: 20-40 mg daily
Ramipril: 2.25 mg daily	Ramipril: 5 mg daily	Ramipril: 10 mg daily
Quinapril: 5 mg twice daily	Quinapril: 10 mg twice daily	Quinapril: 20 mg twice daily
Fosinopril: 5-10 mg daily	Fosinopril: 20 mg daily, 40 mg daily	Fosinopril: 20-40 mg daily

Angiotensin Receptor Blockers (ARB) (if ACE intolerant) (Second Line)

Patient Exclusion: hypersensitivity, shock, symptomatic hypotension, hyperkalemia, bilateral renal artery stenosis, pregnancy

Initial Dose	Titration Steps	Target Dose
Candesartan: 4-8 mg daily	Candesartan: 16 mg daily	Candesartan: 32 mg daily
Losartan: 25 -50 mg daily	Losartan: 50 mg daily, 100 mg daily	Losartan: 150 mg daily
Valsartan: 20 - 40 mg twice daily	Valsartan: 80 mg twice daily	Valsartan: 160 mg twice daily

ACEI/ARB Patient Monitoring:

- Patients who cannot achieve target dose should be maintained on highest tolerated dose
- Titration steps are generally at 2 week intervals
- Monitor Na, K, BUN/SCr at least biweekly while titrating
- ACEI inhibitor therapy should not be discontinued unless serum SCr level rises above 30% over baseline during the first two months after initiation of therapy or hyperkalemia develops
- Check weights frequently and monitor volume status, as diuretic requirements may be altered
- Notify provider if symptomatic hypotension (mild hypotension, SBP 80-90, may be acceptable if tolerated without significant symptoms)
- ACEI/ARB are Class D in pregnancy, but probably safe in lactating females

TABLE D
Angiotensin – recepter/neprilysin inhibitor (ARNI)
***First line therapy if symptoms worsen on ACEI or ARB**

Patient Exclusion: Allergy, angioedema to ACEI or ARB, concomitant use of ACEI or Aliskiren, hyperkalemia > 5.0, symptomatic hypotension, pregnancy

Initial Dose	Titration Steps	Target Dose
Sacubitril/valsartan: 24/26 mg BID	49/51 mg BID	97/103 mg BID

ARNI Monitoring (see ACEI/ARB monitoring for comparison)

- Patients who can not achieve target dose , maintained on highest tolerated dose
- Titration every 2-4 weeks
- Monitor sodium, potassium, BUN/SCr one week after titration
- Check weights
- Notify provider
- Class D in pregnancy
- When changing from any ACEI to ARNI, stop taking ACEI and allow a 36 hour washout before starting ARNI
- When changing from any ARB to ARNI, stop taking ARB, and ARNI can be administered next scheduled dose
- Recommend changing from ACEI/ARB to ARNI if symptoms worsen

TABLE E
Beta Blockers

Patient Exclusion: cardiogenic shock, unstable or decompensated HF, symptomatic bradycardia, symptomatic hypotension, 2nd/3rd degree heart block without pacemaker, severe reactive airway

Initial Dose	Titration Steps	Target Dose
Carvedilol: 3.125 mg twice daily	Carvedilol: 6.25 mg twice daily, 12.5 mg twice daily	Carvedilol: 25 mg twice daily, 50 mg twice daily if weight > 85 kg
Metoprolol (sustained release): 12.5-25 mg daily	Metoprolol (sustained release): 50 mg daily, 100 mg daily, 150 mg daily	Metoprolol (sustained release): 200 mg daily

Beta-Blocker Patient Monitoring:

- Patients who cannot achieve target dose should be maintained on highest tolerated dose
- Titration steps are generally at 2 week periods
- Daily weights: Patient should compile daily weight log and notify if weight increase 3-5 or more pounds in 1 week
- Symptoms: Notify MD if symptomatic hypotension or bradycardia develops
- Blood pressure and heart rate; if SBP < 80 mmHg or HR < 55 bpm, assess carefully for signs of hypoperfusion
- Diuretic dosage: If volume overload develops, continue beta-blocker unless the following develops:
  - O Cardiogenic shock
  - O Symptomatic hypotension
  - o Narrow pulse pressure
  - o Cold, clammy skin
  - o Rising BUN, serum SCr
- Use of only approved beta blocker in HF recommended
- Mild hypotension (SBP 80-90) may be acceptable if tolerated without significant symptoms

TABLE F
Vasodilators

- Vasodilators are used in combination with ACEI/ARB/ARNI or single therapy in patients with chronic kidney disease.
- The combination of hydralazine and isosorbide dinitrate is recommended to reduce morbidity and mortality for African American patients with a NYHA III to IV HF and EF < 40% despite optimal therapy with ACEI and beta blockers
- A combination of hydralazine and isosorbide dinitrate can be useful to reduce morbidity or mortality in patients with current or prior heart failure with reduced EF who cannot be given an ACEI or ARB because of drug intolerance, hypotension, or renal insufficiency

Initial Dose	Titration Steps	Target Dose
Hydralazine 25 mg TID	50-75 mg TID	75 mg TID
Isosorbide Dinitrate 10 mg TID	20-30 mg TID	40 mg TID

- Vasodilator patient monitoring:
  - Titration every 2 weeks
  - BP Monitoring

TABLE G: Volume Overload – Loop Diuretic Dosing	
Signs: rales, JVP evaluation, positive hepato-jugular reflex, S3, sacral or lower extremity edema **Symptoms:** dyspnea on exertion, PND, orthopnea, weight gain, abdominal bloating, decreased appetite, extremity swelling	
Initial Dose	**Maximum Dose**
Furosemide: 40 mg once daily	Furosemide: 160-200 mg per day
Bumetanide: 1 mg once daily	Bumetanide: 4-8 mg per day
Torsemide: 10 mg once daily	Torsemide: 100-200 mg once daily
Diuretic Maintenance Dosing	**Action**
Weight returned to baseline (identifiable cause for weight increase, e.g. non-adherence)	Resume original dose
Weight returned to baseline, but patient failed original dose previously, or no known cause for weight increase	Continue at current increased dose
Weight returned to baseline, but required two or more diuretic titrations	Resume dose prior to last increase (down one titration level)
Symptoms improved but weight has not returned to baseline	Continue at current increased dose
Persistent symptoms with no change in weight	Continue next titration level
Persistent or worsening symptoms, and/or increase in weight, and/or history of frequent hospitalizations for volume overload	Consider adding metolazone, IV diuretic, or hospitalization. PO metolazone may be added in resistant cases for no more than 3 days, then reassess

Volume Overload – Loop Diuretic Dosing/Patient Monitoring:

- Indicated for fluid overload (edema, ascites, dyspnea, weight gain)
- Volume status and electrolytes must be closely monitored with adjustment or when on multiple diuretics; daily chronic use of metolazone should be avoided if possible
- Increasing administration frequency to 2 or even 3 times per day will provide more diuresis with less physiologic perturbation than larger single dose
- Determine from patient subjective diuretic effect when adjusting dosage. If good response noted, increase dose frequency. If no diuretic response noted, increase dose.
- Instruct patient on maintaining sodium-restrictive diet, and limiting fluid intake < 2 L/day when serum sodium <130 mEq/L
- Daily weights
- With recent adjustment of dose, electrolytes, BUN, SCr should be monitored (weekly with each titration)
- If worsening renal function occurs, patient re-evaluation is required
- Assess volume status on every visit; watch for hypovolemia/ over diuresis

Volume Overload – Metolazone Dosing	
Initial Dose	**Maximum Dose**
Metolazone: 2.5 mg daily	Metolazone: 5 mg daily

Volume Overload – Metolazone Dosing/Patient Monitoring:

- Use only when volume overload refractory to maximal loop diuretic therapy
- May use daily initially for 3 days, but chronic daily use is discouraged. Target no more than every other day or 3 times per week.
- Metabolic derangements (hypokalemia, renal failure) may be substantial. Weekly Na, K, BUN/SCr should be monitored weekly initially, or after dosage titration, until stability assured.
- Risk of sudden volume shifts is significant. Monitor weights and blood pressure closely.

TABLE H: Aldosterone Antagonists		
Initial Dose	**Titration Steps**	**Target Dose**
Spironolactone: 12.5 mg daily	Spironolactone: 25 mg daily	Spironolactone: 25 mg daily
Eplerenone: 25 mg daily	Eplerenone: 50 mg daily	Eplerenone: 50 mg daily

Aldosterone Antagonists Dosing/Patient Monitoring:

- Given complexity of therapy/monitoring, consider cardiology consultation prior to institution of therapy
- Metabolic effects and renal impact may be significant. Na, K, BUN/SCr should be monitored at 3 days, 1 week, 1 month, then at 3 months at initation, or after dosage change.
- Therapy should be held for K > 5.0, rapidly rising SCr, or absolutely if SCr > 2.0 in women, 2.5 in men or eGFR < 30
- Monitor closely for fluid and hemodynamic shifts (weights, blood pressure)

American Heart Association and American College of Cardiology's Staging System	
Stage	**Definition**
Stage A	At high risk for HF but without structural heart disease or symptoms of HF (pre-clinical)
Stage B	Structural heart disease but without signs or symptoms of HF
Stage C	Structural heart disease with prior or current symptoms of HF
Stage D	Refractory HF (heart failure) requiring specialized interventions

New York Heart Association (NYHA) Classification	
Class	**Patient Symptoms**
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

CLINICAL PEARLS

•Maximizing dosing of ACEI/ARB and beta-blocker dosing is important for long-term benefits, irrespective of blood pressure levels, and lower blood pressures (SBP 80-90) if asymptomatic or minimally symptomatic should not deter up-titration of medication dosing.

•Ivabradine (Corlanor)

- •Ivabradine may be considered to reduce HF hospitalization for NYHA class II-III patients with EF ≤ 35% who are taking maximum tolerated dose of beta blocker, are in sinus rhythm, with HR ≥ 70 bpm

• Regarding HF with preserved LV function (EF > 50%):

- o No specific treatment has been shown to produce long term mortality benefit, and primary treatment should focus on vigorous blood pressure control, with use of diuretics as needed to control signs and symptoms of volume overload.
- o Ischemic heart disease may still be causal, and stress testing is indicated.
- o In the absence of ischemic heart disease or risk factors, consider hypertrophic (restrictive) cardiomyopathy and constrictive pericarditis.

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Appendix B Hypertension Treatment Protocol (18+ Years)

Clinical support staff check Blood Pressure at each visit per Blood Pressure Measurement Standard

Provider Identifies Patient Goal
- Diabetes: 140/90 (any age)
- Chronic Kidney Disease: 140/90 (any age)
- Vascular Disease: 140/90 (any age)
- Age ≥ 60: 150/90
- All others: 140/90

Provider **enters** goal into Goals Section of One Chart, indicating patient specific target

Is blood pressure **running** above goal?

NO → DONE

YES

Provider confirms elevation of blood pressure over time to make diagnosis of hypertension

Provider **adds** Hypertension to the problem list

Provider **orders** CMP, UA

Provider or Health Coach RN educate on:
- ❑ Hypertension
- ❑ Exercise
- ❑ Low Sodium Diet
- ❑ Other Therapeutic Lifestyle Choices
- ❑ Home Blood Pressure Monitoring
  - ❑ ORDER Home Blood Pressure Cuff

Provider **decides** if treatment will be started today?

NO → Recheck within the next 3 months

YES

HANDOUTS
- What is High Blood Pressure?
- Exercise for Healthier Heart
- Tips for Using Less Salt
- Checking Your Own Blood Pressure

Patients that may NOT be appropriate for RN managed protocol:
- Those who may need lower doses or more time between titration do to other factors [extremely elderly &/or those with fluid dynamic issues (eg. CHF)]
- Those with initial BP>160/100 where provider would like to start two medications initially
- Those with allergies to the protocol medications
- Pregnant Patients

Provider **decides** if patient can be RN managed?

YES → **RN**: Is the patient Black?

NO → Provider → Is the patient Black?

YES → **Initiate** "Female (non-Diabetic) or Black" Provider Treatment Protocol (page 2)

NO → Is the patient diabetic?

YES → **Initiate** "Male (non-Black) or Diabetic" Provider Treatment Protocol (page 3)

NO → **Initiate** provider treatment protocol by Gender (page 2 or 3)

- Per patient self-identified race
- If mixed race, if one of the races is black, use the Black Protocol

YES → **Provider places order** for RN Hypertension Protocol "Female (non-Diabetic) or Black" (page 4)

NO → **RN**: Is the patient diabetic?

YES → **Provider places order** for RN Hypertension Protocol "Male (non-Black) or Diabetic" (page 5)

NO → **RN**: Is the patient Male?

YES

NO

Provider Hypertension Treatment Protocol – Female (non-diabetic) or Black

PAGE 2 ♦ This protocol is used when the **provider** is managing the patient ♦ **PAGE 2**

EVALUATION AND TREATMENT

Used for all Blacks (even if Diabetic or mixed race) & Female without Diabetes

- Visit every two weeks until controlled
- Dose/medication adjustment at every visit until controlled
- Controlled defined as BP to goal on all readings, including in clinic value
- Assess for non-adherence/medication understanding at each visit
- If home blood pressures are controlled, but clinic blood pressures are not, consider ambulatory blood pressure monitoring

Visit & Treatment Schedule

1	○ Start HCTZ 12.5mg daily in morning • Give HCTZ handout
2	○ BMP Today ○ If not to goal, increase HCTZ to 25mg daily in morning
3	○ BMP today ○ If not to goal, add amlodipine 5mg daily in evening • Give amlodipine handout
4	○ If not to goal, increase amlodipine to 10mg daily in evening
5	○ If not to goal, add lisinopril 10mg daily • Give lisinopril handout
6	○ BMP Today ○ If not to goal, increase lisnopril to 10mg twice daily ○ If cough has developed, discontinue lisinopril, switch to losartan 25mg daily • Give losartan handout
7	○ BMP Today ○ If not to goal, increase lisinopril to 20mg twice daily ○ If using losartan and not controlled, increase to 50mg daily
8	○ BMP Today ○ If not to goal, consider further evaluation for underlying cause of resistant hypertension • SEE SIDEBAR
9	○ If not to goal, start Metoprolol XL 50mg daily ○ Do not initiate Metoprolol XL if: ▪ Patient has short gut or feeding tube (use non-XL formulation of beta blocker) ▪ Patient has heart rate of <60 • Give Metoprolol handout
10	○ If not to goal, increase Metoprolol XL to 100mg daily ○ Do not increase if heart rate is <60
11	○ If not to goal, increase Metoprolol XL to 200mg daily ○ Do not increase if heart rate is <60
12	○ If not to goal, referral to hypertension specialty clinic or nephrology depending on local resources

Other HANDOUTS as Needed

- Controlling High Blood Pressure
- Manage Stress with a Healthy Lifestyle
- Walking for Fitness
- Low-Salt Choices
- Tips for Quitting Smoking
- Coping with Smoking Withdrawal

Further evaluation of resistant hypertension

- If PCP is an APP, then APP will touch base with a doctor regarding the patient and the direction to proceed with evaluation/treatment.

Provider(s) should consider:

1) Further evaluation for secondary causes:
   a. Laboratory Studies including
      - TSH
      - PTH (if baseline Ca [prior to starting HCTZ] > 10.7)
      - Renin (done in AM)
      - Aldosterone
   b. Imaging with Renal Ultrasound with doppler
   c. Sleep Apnea evaluation
2) Other Contributing Factors
   a. Consider non-adherence or medication confusion
      - Obtain dispensing history from Pharmacy
      - Ask patient to bring in pill bottles & explain what they are taking & when
   b. Considering interfering agents (NSAIDs, allergy medications)
   c. Review alcohol, nicotine, recreational drug usage
   d. Evaluate for depression
   e. Evaluation for patient activation or engagement
   f. Diet/exercise patterns
3) Medication adjustment
   a. Consider change of HCTZ to Chlorthalidone if HCTZ does not seem to be achieving 24 hour coverage
4) Referral to
   a. Behavioral health regarding activation
   b. Designated hypertension specialist (HTN clinic, nephology, etc., depending on local resources)
   c. Dietician

Provider Hypertension Treatment Protocol – Male (non-Black) or Diabetic (non-Black)

EVALUATION AND TREATMENT

Used for <u>all</u> Diabetics (except Blacks) and <u>all</u> Men (except Blacks)

- Visit every two weeks until controlled
- Dose/medication adjustment at every visit until controlled
- Controlled defined as BP to goal on all readings, including in clinic value
- Assess for non-adherence/medication understanding at each visit
- If home blood pressures are controlled, but clinic blood pressures are not, consider ambulatory blood pressure monitoring

Visit & Treatment Schedule

1	○ Start lisinopril 10mg daily • Give lisinopril handout
2	○ BMP Today ○ If not to goal, increase lisnopril to 10mg twice daily ○ If cough has developed, discontinue lisinopril, switch to losartan 25mg daily • Give losartan handout
3	○ BMP Today ○ If not to goal, increase lisinopril to 20mg twice daily ○ If using losartan and not controlled, increase to 50mg daily
4	○ BMP Today ○ If not to goal, add amlodipine 5mg daily in evening • Give amlodipine handout
5	○ If not to goal, increase amlodipine to 10mg daily in evening
6	○ If not to goal, start HCTZ 12.5mg daily in morning • Give HCTZ handout
7	○ BMP Today ○ If not to goal, increase HCTZ to 25mg daily in morning
8	○ BMP Today ○ If not to goal, consider further evaluation for underlying cause of resistant hypertension • SEE SIDEBAR
9	○ If not to goal, start Metoprolol XL 50mg daily ○ Do not initiate Metoprolol XL if: ▪ Patient has short gut or feeding tube (use non-XL formulation of beta blocker) ▪ Patient has heart rate of <60 • Give Metoprolol handout
10	○ If not to goal, increase Metoprolol XL to 100mg daily ○ Do not increase if heart rate is <60
11	○ If not to goal, increase Metoprolol XL to 200mg daily ○ Do not increase if heart rate is <60
12	○ If not to goal, referral to hypertension specialty clinic or nephrology depending on local resources

Other HANDOUTS as Needed

- Controlling High Blood Pressure
- Manage Stress with a Healthy Lifestyle
- Walking for Fitness
- Low-Salt Choices
- Tips for Quitting Smoking
- Coping with Smoking Withdrawal

Further evaluation of resistant hypertension

- If PCP is an APP, then APP will touch base with a doctor regarding the patient and the direction to proceed with evaluation/treatment.

Provider(s) should consider:

1) Further evaluation for secondary causes:
   a. Laboratory Studies includining
      - TSH
      - PTH (if baseline Ca [prior to starting HCTZ] > 10.7)
      - Renin (done in AM)
      - Aldosterone
   b. Imaging with Renal Ultrasound with doppler
   c. Sleep Apnea evaluation
2) Other Contributing Factors
   a. Consider non-adherence or medication confusion
      - Obtain dispensing history from Pharmacy
      - Ask patient to bring in pill bottles & explain what they are taking & when
   b. Considering interfering agents (NSAIDs, allergy medications)
   c. Review alcohol, nicotine, recreational drug usage
   d. Evaluate for depression
   e. Evaluation for patient activation or engagement
   f. Diet/exercise patterns
3) Medication adjustment
   a. Consider change of HCTZ to Chlorthalidone if HCTZ does not seem to be achieving 24 hour coverage
4) Referral to
   a. Behavioral health regarding activation
   b. Designated hypertension specialist (HTN clinic, nephology, etc., depending on local resources)
   c. Dietician

References

1. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). *JAMA.* 2014;311(5):507-520. doi:10.1001/jama.2013.284427

Appendix C — Lipid Screening & Treatment Protocol

Primary Prevention – No Known Vascular Disease

EVALUATION AND TREATMENT

Age 18-21 → No Screening

Hyperlipidemia
- Total cholesterol > 240
- LDL > 190
- 10 year risk ≥ 7.5%
- Known vascular disease

Action: Put hyperlipidemia on the Problem List and the story of treatment decisions in the overview.

This symbol means Nurses can place these screening orders per nursing treatment protocol

Age 21-39 → Screen once during this time frame with Lipid Panel → Is LDL > 190 or TG > 500?

- NO → No further screen until age 40, unless further clinical considerations
- YES →
  - Screen for secondary causes of elevation
  - Draw TSH, BMP
  - Dietician Referral

→ Treat with **high** intensity statin

Most insurers, including Medicaid & most BCBS plans do cover dietician visits for hyperlipidemia. Medicare does not, but if the patient has a BMI of >30 they will cover with the diagnosis of obesity & generally the same topics will be covered by the dietician

Handouts: Cholesterol (controlling); Exercise for a Healthier Heart; Understanding Fat and Cholesterol; Recommendations for Laboratory Testing in Lipid Treatment

Age 40-75 → Diabetic?

- YES → Other CVD risk factors?
  - YES → Treat with **high** intensity statin
  - NO → Treat with **moderate** intensity statin
- NO → Check lipid panel & calculate 10 year ASCVD risk every 5 years → Is the 10 year ASCVD risk ≥ 7.5%?
  - YES →
    - Treat with **moderate** to **high** intensity statin
    - Refer to Dietician
  - NO → (back to Check lipid panel)

Consider treatment for risk >5.0% if family history, pre-diabetes & other known risks.

If risk factors change, recheck lipid panel & recalculate risk sooner than 5 years.

As age approaches 75, many patients will have risk > 7.5%. As always, a discussion of risk/benefit ratio of medications is appropriate.

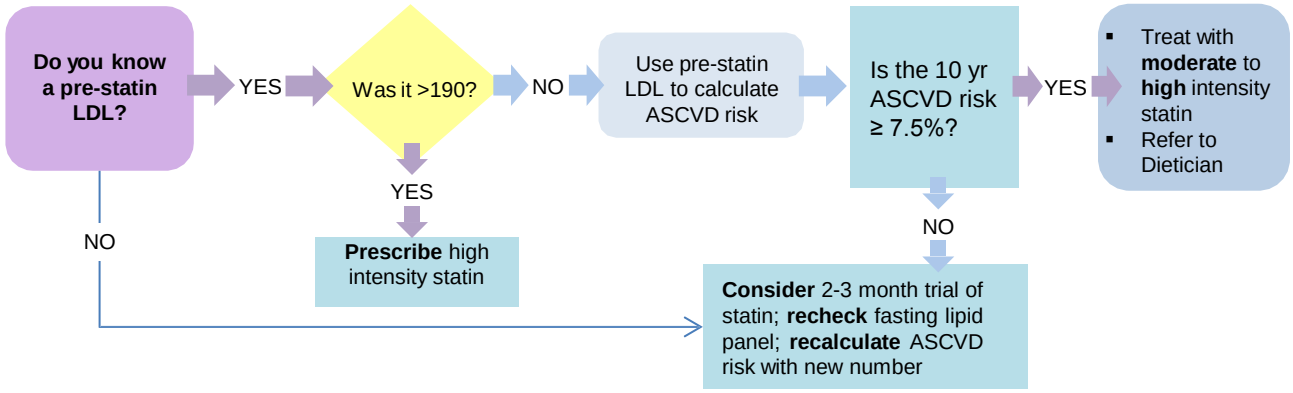
Age > 75 → No Screening Recommended → If previously met criteria for statin for primary prevention, consider discontinuation after discussing benefit/risk with patient.

Secondary Causes for Hyperlipidemia Most Commonly Encountered in Clinical Practice (see references)

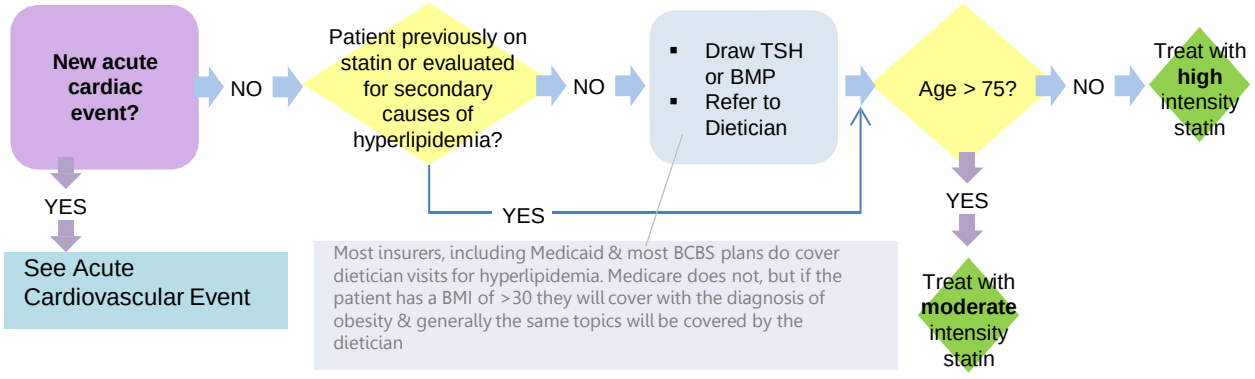
Secondary Cause	Elevated LDL-C	Elevated Triglycerides
Diet	Saturated or trans fats, weight gain, anorexia	Weight gain, very low-fat diets, high intake of refined carbohydrates, excessive alcohol intake
Drugs	Diuretics, cyclosporine, glucocorticoids, amiodarone	Oral estrogens, glucocorticoids, bile acid sequestrants, protease inhibitors, retinoic acid, anabolic steroids, sirolimus, rilaxifene, tamoxifen, beta blockers (not carvedilol), thiazides
Disease	Biliary obstruction, nephrotic syndrome	Nephrotic syndrome, chronic renal failure, lipodystrophies
Disorders & altered states of metabolism	Hypothyroidism, obesity, pregnancy	Diabetes (poorly controlled), hypothyroidism, obesity, pregnancy

Lipid Screening & Treatment Protocol (page 2)

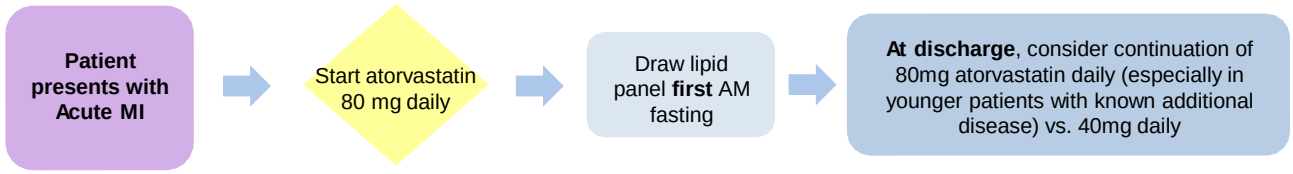
Primary prevention in **non-diabetics already on a statin**, but risk not previously calculated using ASCVD model & 2013 guidelines



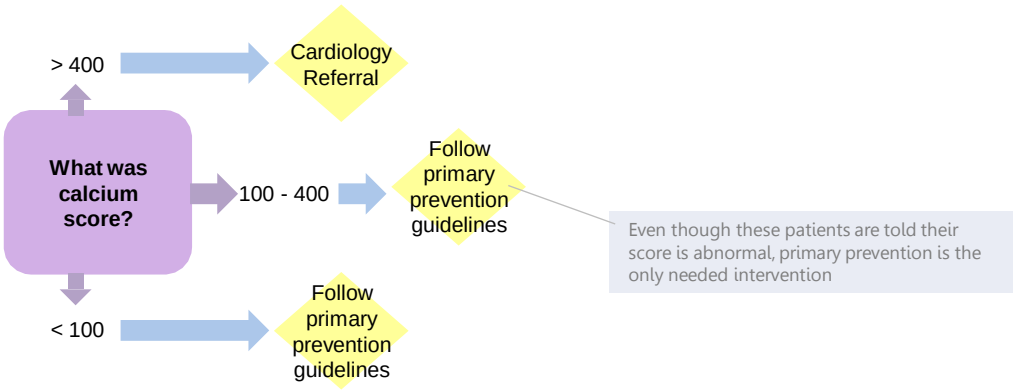
Secondary Prevention – All Vascular Disease: Cardiac, Stroke, Peripheral



Acute Cardiovascular Event



Positive Calcium Score



EVALUATION AND TREATMENT

Treatment of Lipids

Lifestyle modifications of diet & exercise recommended for all

Is the patient female of child bearing age?

YES → Patient can **not** be on a statin while pregnant. **Evaluate** risk of treatment vs. future pregnancy

NO

What **intensity** will be used?

MODERATE

Give Atorvastatin Handout

Prescribe Atorvastatin 10mg tablet

Recheck lipid panel with provider visit at 12 weeks

Give Cholesterol Quiz Handout

Did you get the expected decrease in LDL (30%)?

NO

Insufficient Response Evaluation - Assess for:
- Medication adherence
- Lifestyle change adherence
- Possible secondary causes of hyperlipidemia – at a minimum draw TSH if not already completed

Increase Atorvastatin to 20mg tablet

Recheck lipid panel at 8-12 weeks

Consider adding Ezetimibe 10mg

Give Ezetimibe Handout

If no response, refer to endocrinology or cardiology for use of newer injectable agents

HIGH

Give Atorvastatin Handout

Days 1-7	**Prescribe** Atorvastatin 20mg tablet, • tablet daily
Days 8-14	Then 1 full tablet daily
Days 15-28	Then 2 tablets daily
Days 29 & Beyond	Increase to one 80mg tablet daily
Week 12	**Recheck** lipid panel with provider visit at 12 weeks

Give Cholesterol Quiz Handout

Did you get the expected decrease in LDL (50%)?

YES Continue treatment. see Ongoing Lab Evaluation

NO

Insufficient Response Evaluation - Assess for:
- Medication adherence
- Lifestyle change adherence
- Possible secondary causes of hyperlipidemia – at a minimum draw TSH if not already completed

Consider adding Ezetimibe 10mg

Give Ezetimibe Handout

If no response, refer to endocrinology or cardiology for use of newer injectable agents

Ongoing Laboratory Evaluation

- Lipid Panel 1x Annually
- ALT/AST only if symptoms of hepatic toxicity (unusual fatigue or weakness, loss of appetite, abdominal pain, dark colored urine, yellowing of skin or sclera)
- CK should only be done if myalgias

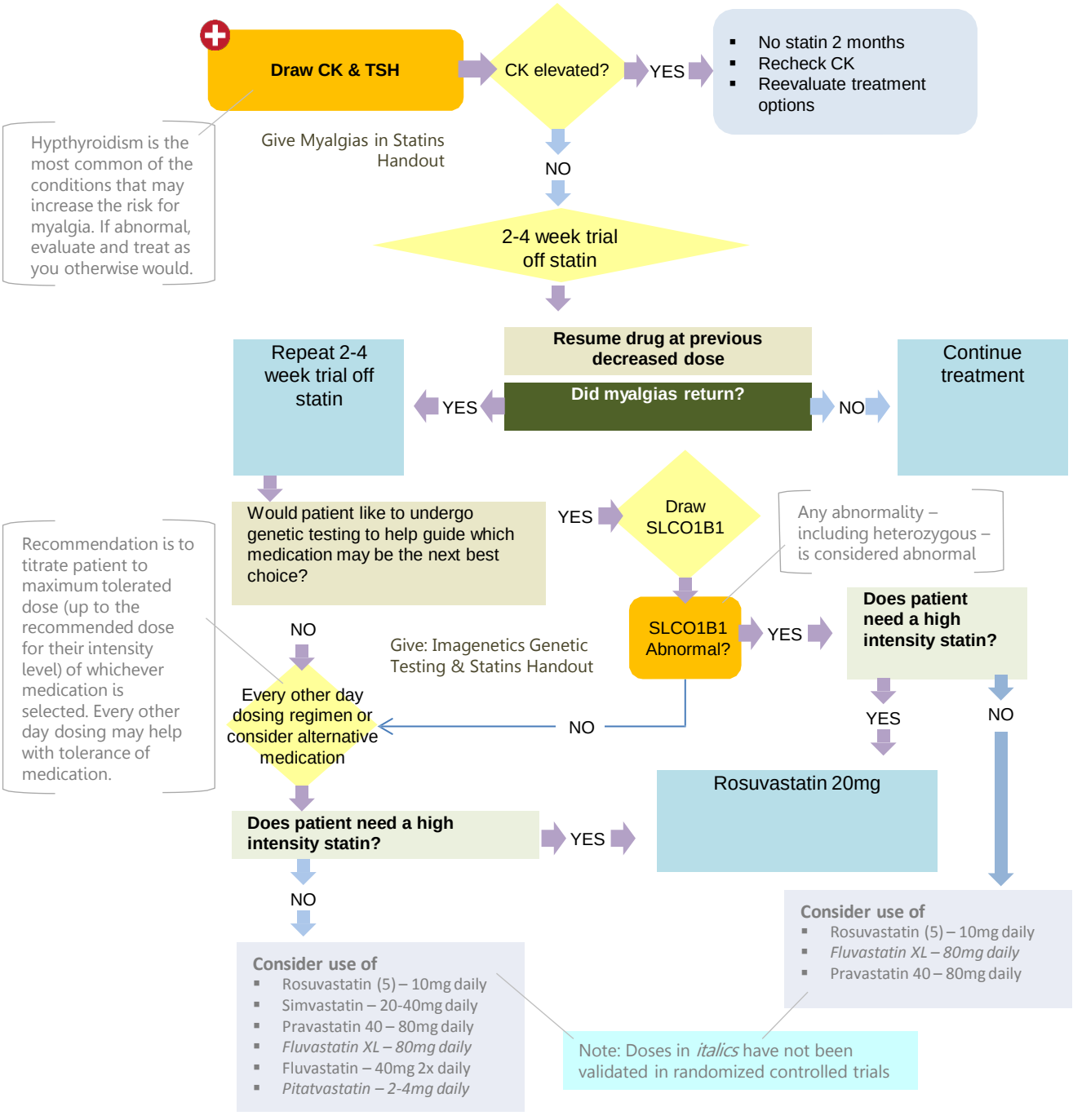
Nurses can help place lipid panel order every 12 months in stable dose med or 12 weeks after med or dose change.

Comments on Other Agents

- **Niacin**: If patient is on Niacin, this medication should be discontinued as it may increase death rate
- **Gemfibrozil** or other fibrates
  - Increases risk of muscle toxicity
  - Can be used for prevention of pancreatitis in those with elevated TGs, but there is no evidence to support using it for cardiac prevention
- **Ezetimibe** should not be used as mono-therapy unless no statin is tolerated. There is some evidence in secondary prevention literature that this may be of benefit.
- **Cholestyramine**: Recommended only for pregnant women with extremely high LDL who are felt to need treatment during pregnancy
- **Co-Enzyme Q10**: Debatable evidence for myalgia reduction with statin treatment
- **Omega 3 Fatty Acids**: No current evidence as to cardiovascular benefit
- **Vitamin E**: No current evidence as to cardiovascular benefit
- **Red Yeast Rice**: No proven benefit.

EVALUATION AND TREATMENT

Myalgia at any point in treatment



Clinical Pearls

1. Grapefruit juice inhibits CYP3AF; however, daily consumption of eight ounces of grapefruit juice, or one-half of a grapefruit or less, is unlikely to increase the risk of an adverse interaction or muscle injury. (See *Concurrent Drug Therapy* above.)
2. There is no evidence that atorvastatin is better taken in the evening. It can be taken at any time of day.
3. **Hypothyroidism and other disorders** — Enhanced susceptibility to statin-associated myopathy occurs in patients with hypothyroidism, acute or chronic renal failure, and obstructive liver disease. In one hypothyroid patient, the myopathy resolved promptly after discontinuation of pravastatin and before initiation of thyroid hormone replacement [54], but in a second case the myopathy persisted until thyroid hormone was replaced [55]. These reports suggest that hypothyroidism may predispose to the development of statin-associated myopathy and that use of statins may "unmask" hypothyroid myopathy. (See "Hypothyroid myopathy".)

References

1. 2013 ACC/AHA Guildeine on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults.
2. American Diabetes Association- Standards of Care in Diabetes—2015
3. Punzi L, Betterle C. Chronic autoimmune thyroiditis and rheumatic manifestations. Joint Bone Spine 2004; 71:275.
4. Bazzichi L, Rossi A, Giuliano T, et al. Association between thyroid autoimmunity and fibromyalgic disease severity. Clin Rheumatol 2007; 26:2115.

POLICY/PROCEDURE: Quality-Clinic			POLICY #:
DEVELOPED/REVISED BY:	**DATE:** 1/2018	**REVIEWED/REVISED:**	**REV/REV:**
DISTRIBTION: Clinic	**REV/REV:**	**REV/REV:**	**REV/REV:**

GOALS:

To provide high quality patient care through systematic, ongoing monitoring, thereby identifying problems or potential problems with that care or with individual competence and through the evaluation of the data collected, track sources of the difficulties and effect resolutions.

RESPONSIBILITY:

The Administrator shall be responsible for the implementation of the QAPI in the department. There shall be a designated quality assurance person in the department to help the supervisor carry out the implementation and functions of the Clinic QAPI program.

SCOPE OF PATIENT SERVICES:

The Clinic Department will provide services to all patients who have been recommended by a medical staff, consulting, or other qualified physician to have such tests performed.

FUNCTIONS:

The functions of the Clinic Department will be to:

1. To design effective mechanisms for identification, assessment, resolution, evaluation and performance improvement of nursing practice.
2. Providers will adhere to Government quality regulations (MACRA,ACO).
3. To develop effective systems for the documentation and dissemination of quality assessment and performance improvement activity findings to appropriate persons and /or committees.
4. To enhance skills and knowledge of health care through performance improvement and educational opportunities.
5. To minimize potential for malpractice and liability claims.

ACTION:

Clinic staff will perform a continual assessment of performance with implementation of solutions, assessment of the effectiveness of the solutions, and evaluations to determine what can be done better. If a problem is identified, an analysis of the cause will follow and action will be

taken to correct the problem with a follow-up to determine the effectiveness of the action. Any problem that cannot be resolved within the department shall be referred to the Administrator or QAPI Coordinator.

REPORTING:

The Clinic shall submit a report of its Quality Assessment and Performance Improvement Activities to the QAPI Coordinator on a scheduled basis or as indicated. This will consist of the results of monitoring, identification of problems based on an analysis of the results, steps taken to correct the problem and whether the problem was corrected.

PROGRAM EVALUATION:

The Clinic shall review their entire Quality Assessment/Performance Improvement Program on an scheduled basis for effectiveness, assessment of critical indicators, effective checking to ensure problems are not lost or ignored and sustained elimination or reduction of problems. The use of findings from the QAPI programs may be used in the individual clinical competence of its employees.

POLICY/PROCEDURE: Quality-Quality Assessment Performance Improvement			POLICY #:
DEVELOPED/REVISED BY:	**DATE:** 12/17	**REVIEWED/REVISED:**	**REV/REV:**
DISTRIBTION: Facility Wide	**REV/REV:**	**REV/REV:**	**REV/REV:**

GOALS:

The Patient Care Quality Assessment / Performance Improvement (QAPI) Program at Hospital is a part of the hospital wide QAPI program. The goal of the plan is to develop and establish a well defined, organized patient care service QAPI program designed to enhance patient care and assess appropriate allocation of healthcare resources through ongoing objective assessment of important aspects of patient care and the performance improvement of identified problems.

OBJECTIVES:

1. To assess the delivery of inpatient, surgical services, outpatient and emergency room care at an optimally achievable level of quality in a safe and cost-effective manner.
2. To design effective mechanisms for identification, assessment, resolution, evaluation and performance improvement of nursing practice.
3. To identify, assess and resolve problems in patient care areas.
4. To include in the quality assessment and performance improvement of the patient care departments, the review that nursing care practices and professional competency are routinely and reliably evaluated.
5. To develop effective systems for the documentation and dissemination of quality assessment and performance improvement activity findings to appropriate persons and / or committees.
6. To enhance skills and knowledge of nursing staff through performance improvement and educational opportunities.
7. To minimize potential for malpractice and liability claims.

MAJOR ASPECTS OF CARE:

1. To identify important or potential problems or related concerns in the care of patients.
2. To assess objectively the cause and scope of problems / concerns, including the determination of priorities for both investigating and solving problems.
3. To implement by appropriate individuals, or through designating mechanisms, decisions

or actions designed to reduce or eliminate identified problems.

4. To monitor activities designed to assess and improve desirable results that have been achieved and sustained.
5. To document and reasonably substantiate the effectiveness of the overall program to enhance patient care and assess and improve sound clinical performance.
6. To monitor discharge planning for continuity of care for the patient during the post hospital phase.

RESPONSIBILITY:

The Director of Nursing will appoint nursing staff to research and report on a specific quality assessment indicator needing improvement. The staff member(s) will give the completed report to the Director of Nursing.

Other responsibilities will include, but are not limited to:

1. Reviewing proposed monitoring activities to prevent unnecessary duplication, avoid conflicts within and outside the nursing department and assist in the identification of potential multi-disciplinary studies.
2. Facilitating and coordinating nursing monitoring activities.
3. Assisting in generating and coordinating ideas for monitoring activities.
4. Coordinating a schedule of monitoring activities based on their impact to patient care.
5. Assisting in the selection / development of criteria for monitoring activities.
6. Accounting for the completion of objectives of the Patient Care Quality Assessment / Performance Improvement Program.

ACTION:

Once a problem is identified, an analysis of the cause will follow and action will be taken to correct the problem with a follow up to determine the effectiveness and performance improvement of the action. Actions shall result in the sustained alleviation or elimination of the problem. Any problem that cannot be resolved within the department shall be referred to the Administrator or QAPI Coordinator.

REPORTING:

The Nursing Department shall submit a report of its Quality Assessment and Performance Improvement Activities to the QAPI Coordinator on a yearly basis. This will consist of the results of monitoring, identification of problems based on an analysis of the results, steps taken to correct the problem and whether the problem was corrected.

MEETINGS:

At the nursing staff meeting, the nursing staff members will report to the general nursing staff any outcomes of studies which may benefit or change any existing policies / protocols.

PROGRAM EVALUATION:

The Director of Nursing shall review the entire Quality Assessment / Performance Improvement Program on an annual basis for effectiveness, assessment of critical indicators, effective checking to ensure problems are not lost or ignored and sustained elimination or reduction of problems. The use of findings from the QAPI program may be used in the individual clinical competence of its employees.