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Quality Improvement Processes: Efforts in Care to Augment Access to Quality, Equitable Diabetes Care

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Abstract

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Objective: This literature review aims to assess the use of quality improvement processes (QIPs) as a methodology for improving access to quality, diabetes care in response to the growing prevalence of diabetes mellitus within the United States.

Methods: A literature search was conducted utilizing QIP's terminology to first develop a comprehensive understanding of the methodology. An additional query was then conducted across three search engines employing terminology associated with diabetes, cross-referenced with QIP terminology to identify recent studies that could be assessed to corroborate QIPs applicability to expanding access to quality, equitable diabetes care. Five exemplars were identified and included to represent QIP methodologies such as Root Cause Analysis, Lean methodology, and Six Sigma methodology applied to the three primary branches of diabetes care: prevention, management, and treatment.

Discussion: Though the availability of exemplars examining the intersection of QIPs and diabetes care was found to be limited, the studies reviewed were found to demonstrate improved clinical outcomes for patients with diabetes. Based on improved clinical outcomes, interpreted as augmented quality, the study authors and implementation teams generally support the use of QIPs to expand access to quality care for patients with diabetes. Studies reported that the implemented QIPs did not yield changes in the equity of care, and thus cannot currently support the use of QIP methodology to promote improved access to equitable diabetes care.

Results: The literature review was utilized in this thesis to develop the Solutions Manual for Quality Improvement Process Implementation within healthcare settings aiming to improve the quality of diabetes care provided. The Manual provides recommendations by QIP methodology and suggests the best practices for each by implementation setting, by desired outcome type, and by consideration of available resources.

Implications: The novelty of QIP methodology implores the need for additional studies assessing its applications and impact within the sphere of healthcare. Though QIPs demonstrate the potential for successful application to expand access to quality, diabetes care; further research is necessary to develop the use of QIPs as a standard operating procedure or common practice in healthcare facilities.

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Glossary

ACO……Accountable Care Organization

ADA……American Diabetes Association

CCM……...The Chronic Care Model

CGM……..Continuous Glucose Monitors

CMS……...…….Centers for Medicaid and Medicare Services

DFM……..….Defects Per Million

DKA…….Diabetic ketoacidosis

DMAIC……..Define, Measure, Analyze, Improve, Control

EHR……..…….Electronic Health Record

IHI……. Institute for Healthcare Improvement

LCL……..…Lower Control Limit

MMA……Medicare Prescription Drug Improvement and Modernization Act

PDSA[1]……...… 'Plan, Do, Study, Act'

SCV…….…Special Cause Variation

SIPOC Diagram……..….Suppliers, Inputs, Process, Outputs, Customers Diagram

SPCC……...……...Statistical Process Control Chart

RCA……..…Root Cause Analysis

T1DCI……...Type 1 Diabetes Care Index

T1DCS……...…..Type 1 Diabetes Composite Score

T1DM…….Type 1 diabetes mellitus

[1] The 'PDSA' Cycle, 'Plan, Do, Study, Act," may be used interchangeably with 'PDCA' Cycle, 'Plan, Do, Check, Act."

T1D EQIC……....Exchange Quality Improvement Collaborative

TQM……...…Total Quality Management

UCL……..Upper Control Limit

QIP……..…Quality Improvement Processes

Introduction

Imagine a health system in which people with diabetes are given access to a health system simply as a result of their status as a resident within a country with universal health coverage (UHC). Given that acceptance and implementation of UHC in the United States is nearly unfathomable, there is need and room for improvement in the prevention, management, and treatment of diabetes with the existing health structure of the United States. Annually, nearly 1.5 million Americans receive a diabetes mellitus diagnosis (ADA, 2021). This translates into a rate of 6.9 newly diagnosed cases of diabetes per 1,000 persons, which contributes to the growing figure of 34.2 million Americans diagnosed with the disease and an additional 7.3 million that remain undiagnosed (CDC, 2020).

The burden of disease for diabetes remains high despite improvements made in diabetic care and treatments over the years. Diabetes was the seventh leading cause of death among Americans in 2017. While listed as the seventh leading cause of death, the ADA expects that a failure to adequately identify and report deaths associated with diabetes has caused an underestimation of deaths attributable to the disease. The American Diabetes Association claims that only 10-15% of diabetic patients' death certificates listed diabetes as the primary cause of death and only 35-40% of death certificates included a mention of diabetes at all (ADA, 2021). Adjusting disease prevalence to account for the underreporting of deaths associated with diabetes, the ADA expects that diabetes would become recognized as a more significant cause of death, shifting its position from the seventh leading cause of death to a higher position on the list.

In addition to underreported deaths, the burden of diabetes extends to reduced life expectancy and significant economic impacts. A study conducted by Preston et al. found that incidence of diabetes reduces life expectancy for men by 0.83 years and for women by 0.89

years. When adjusting for race, life expectancy with incidence of diabetes varies as demonstrated by an expected reduction of 1.05 years for black women (Preston et al., 2018). Additionally, disproportionate occurrence of diabetes in low socioeconomic populations suggests inequities in health care access and diabetes prevention. In 2018, the ADA reported that people with diagnosed diabetes averaged medical expenditures 2.3 times higher than individuals without diabetes, further exasperating financial burden for low socio-economic individuals. The added medical expenditures total an economic burden of 237 million dollars for direct medical costs and an additional 90 billion dollars in lost productivity (ADA, 2021). The inequitable prevalence of diabetes across race, socio-economic status, and additional social determinants of health indicates a pressing need to address disparities expanding the gap in access to managed, quality diabetic care.

The access gap illustrates the need to develop and engage methods that can improve diabetes care and management for all patients to mitigate the impact of social determinants of health. Improvements in diabetic care have largely failed to take an equitable, systems level approach. The failure to consider social determinants of health during the implementation of advanced diabetes management techniques, new drug regimens, and improved education programming perpetuates the gap in equitable access to quality diabetic care. For instance, blood glucose monitoring (BGM) frequency is a diabetic care management process that can aptly demonstrate how social determinants of health enable inequities in the reception of quality diabetic care. The CMS places daily limits on blood glucose monitoring supplies for both insulin dependent diabetics and non-insulin dependent diabetics for patients with Medicare Part B coverage. For those with Part B Coverage, whose doctor has indicated they are dependent on insulin, CMS will cover supplies for BGM up to 3 times daily. For non-insulin dependent

diabetics, CMS will cover supplies for BGM up to 1 time daily. As patients with diabetes often conduct BGM more frequently than 1-3 times daily, this CMS policy can be exclusive and fails to adequately propagate care for those who are faced with additional financial hardships and are unable to purchase additional BGM supplies to meet recommended or desired BGM frequency. Restrictive policies such as CMS' Part B formulary exemplifies current inadequacies of existing health system processes to provide quality and accessible diabetic care. The failure to equitably implement processes, such as BGM, that improve diabetes management for patients, demonstrates the need to explore new methods to improve access to quality diabetic care.

The health quality movement is a promising intervention that can contribute to the revolutionizing of accessible, quality, and equitable diabetic care. Within the quality movement, quality improvement processes (QIPs) are utilized to implement iterative processes that utilize existing infrastructures and resources to create change. Efforts to engage physician leadership, methodize quality measures within organizations, standardize practice, and evaluate the utilization of infrastructure enable QIP's ability to revolutionize prevailing systems by facilitating awareness and opportunity for change (Marjoua & Bozic, 2012).

The health quality movement and the utilization of QIPs have been championed by those who apotheosized the life work of health pioneers such as Nightingale and Semmelweis.[2] To date, applications of the health quality movement and the use of QIPs have primarily revolved around health hygiene initiatives abroad; however, the United States has begun to take interest and apply components of the quality movement to the current iteration of the health system. At

[2] Ignaz Semmelweis: 19th century obstetrician credited for propagating the importance of hand washing. Florence Nightingale: revolutionized modern nursing through work during the Crimean War by implementing hospital and field hygiene practice that reduced the mortality rate by two-thirds. Marjoua & Bozic, 2012

the broad US system level, CMS represents a quality improvement measure that the US government implemented with the intent to extend and standardize health insurance coverage to the low-income and elderly. Further QIPs employed to mitigate equity gaps in health care quality and accessibility within the US system include the Experimental Medical Care Review Organizations, Peer Review Organizations, and Quality Improvement Organizations. Such organizations take an administrative approach to QIPs and utilize Lean principles, a type of QIP, to make improvements largely within the provider/payor concerns of health care. Within local health and hospital systems, QIPs are often used to reduce adverse patient safety events or increase hospital efficiency. (Marjoua & Bozic, 2012)

The Institute for Healthcare Improvement proposes an actionable, cyclical model for Quality Improvement Processes implementation that aims to address gaps and failures in the clinical components of health care delivery rather than the provider/payor, administrative components. The IHI's Plan, Do, Study, Act' (PDSA) model utilizes Lean and Six Sigma strategic principles to enact change to reduce costs, improve patient safety, and implement programs that benefit the needs of health workers, administrators, and patients thus promoting improved quality and accessibility of health care (IHI, 2021). One application of the PDSA model that has been used in the health industry involved the development of hand hygiene protocols within health institutions as a method for staving off the rate of infection, subsequently improving patient safety and quality of health care received (WHO, 2009). Demonstrating measurable impact in broad spectrum health care, QIPs are applicable as a method of improving access to quality care within clinical approaches. At present, the application of the 'PDSA' cycle within clinical care settings has largely been focused on patient safety and the improvement of

health organizations' operating outcomes, with limited applications specified to a particular disease such as diabetes.

Given limited knowledge surrounding the application of QIPs to clinical care, this thesis asserts that QIPs may facilitate a prominent increase in access to equitable, quality diabetic care and diabetic health outcomes. A systematic review of existing literature will serve to outline the background and methodology of utilizing QIPs. Such an outline will aim to validate QIPs with regards to diabetic care, and will identify and synthesize current practices, successes, and need for improvement within clinical care settings specific to varying aspects of diabetes management. The systematic review will work to assess QIPs in regard to accessing preventative care, diabetes care and management services, and pharmaceutical access. Following systematic review, a qualitative needs-based assessment will occur in a low-resource, health institution to assess the potential of QIPs as an adequate tool for mitigating disparities in access to care for low-resource, diabetic patients. Additionally, further discussions with subject matter experts and QIPs implementers will ascertain the strengths and weakness of improving access to quality care for diabetics through the IHI's 'PDSA' cycle. It is the intent of this research to devise a QIP to be implemented within low-resource settings as a solution for increasing accessibility and equitable quality of care for diabetic patients.

Literature Review

Overview

Conducting a literature review is necessary to comprehend and assess the practicality of Quality Improvement Processes (QIP) as an efficient method for promoting change across industries. The scope of this literature review will provide an overview of QIPs followed by a review of applications to health care and diabetes care when applicable. The review will seek to apply specific QIP methodology to the areas of preventive care, diabetes management, and diabetes treatment. Analysis of the aforementioned applications of QIP practices will prove the most efficient assessment of their capacity to improve and strengthen access to quality, equitable health care for patients with diabetes.

Quality Improvement Methods

Quality Improvement Processes Background

QIPs have origins deeply rooted in the discoveries, advancements, and progression of modern medicine. The term Quality Improvement Processes refers to processes that inspire change whether it be for 'good' (progressive change that positively advances health care or health access) or for the 'bad' (regressive changes that make health care access less equitable or reduces care quality). It is necessary to note that initiatives may be classified as QIPs when the actions, plans, or programs implemented are intentional (Panteli et al., 2019).

Health care practitioners such as Ignaz Semmelweis and Florence Nightingale demonstrated early conceptualization of QIP practices. Conceptualization occurred long before the methodology was standardized and recognized as a formal practice for introducing quality improvement methods into the health care industry. Semmelweis, a 19th century obstetrician

credited for propagating the importance of hand washing discovered that implementing hand hygiene protocol introduced during pre-natal visits and the birthing process reduced the rate of maternal mortality by 8.87% or a reduction in 1 maternal death for every 11 women (La Rochelle & Julien, 2013). Similarly, Florence Nightingale; revolutionized modern nursing through her work during the Crimean War implementing hospital and field hygiene practices that reduced field mortality rates by two-thirds (Marjoua & Bozic, 2012).

Following the early improvement measures taken by Nightingale and Semmelweis, commitments to the improvement of the health care system for both providers and for patients has become a pressing issue that has inspired formation of committees to devise solutions for change within health systems. Following reviews conducted within New York hospital systems in 1984, it was estimated that approximately 98,000 individuals die within the US as a result of preventable errors made under the treatment or immediate care of medical professionals (James, 2013). Following the publishing of the report indicating nearly 100,000 preventable deaths on an annual basis, the National Demonstration Project on Quality Improvement led by Donald Berwick, MD, MPP, drew committed visionaries to formulate the Institute for Healthcare Improvement formally incorporated in 1991 (IHI, 2021-a). The IHI was developed to enact change that would revise the health system to instill one that yielded fewer errors, less waste, greater sustainability, and fewer delays in care (IHI, 2021-a).

During formation and conceptualization of the organization's vision and goals, the IHI sought to adopt a model for quality improvement that would utilize principles of management and health care operations to promote equitable, quality changes within health care settings. The

IHI found that combining the philosophies of W. Edwards Deming[3] and Avedis Donabedian[4] would incorporate inductive and deductive approaches into the learning and improvement cycle, thus promoting actionable change.

Deming, an American who was prominent in management consulting at a global scale, devised 14 key principles of management that drive the intentions and methodologies of those seeking to implement critical changes in management operations. The principles were designed for the bettering of business operations to reduce error, waste, oversight, and eliminate barriers in operations and human resource management that inhibit quality and productivity. (IHI, 2021-b)

While Deming promulgated Principles of Management that could be applied to unspecified industry, Avedis Donabedian, an Armenian physician, developed a model that sought to similarly reduce error, waste, oversight, and eliminate barriers in operations and human resource management that inhibit quality and productivity. Donabedian's Model for Quality in Care was developed in regard to specific applications to health care practice (Berwick & Fox, 2005). Both philosophies for promoting quality and change are outlined below.

---

[3] W. Edwards Deming. 20th Century. An American engineer, statistician, lecturer, and management consultant. Keen senses for management yielded fourteen key principles that inspired the Total Quality Movement which would later be utilized to guide the Quality Movement within health care. Known for revolutionizing Toyota business operations and the implementation of the Lean business principles. (The W. Edward Demings Institute, 2021)

[4] Avedis Donabedian. 20th Century. Armenian physician who founded the movement for quality within healthcare outcomes. Credited with founding the Donabedian model that suggests that in examining existing faulty structures, identifying inadequate processes, and determining desired outcomes, revisions can be made to the structures and processes to improve outcomes. (Berwick & Fox, 2005)

Summary of Formative Models for Quality Improvement

Figure 1. **W. E. Deming 14 Principles of Management Summarized**

1. Creating constant drive to improve produce and service creates competition to remain in business and provide jobs.

2. Adopt the philosophy that we are in a new economic age that requires Western management to accept challenges, learn responsibilities, and appreciate leadership.

3. Forgo quality inspections by assuming a degree of quality is already built into the product.

4. Build contractual relationships on loyalty and trust versus price to increase quality in product and relationship.

5. Continuous improvement in production and service decreases costs by improving quality and productivity.

6. Utilize on the job training.

7. Supervision's purpose should be to help people/machines do a better job, rather than to overhaul management and producers.

8. Eliminating fear in the workplace creates more effective workflows.

9. Eliminate barriers in communication between departments.

10. Eliminate standards that vilify those who make errors, as to reduce adversarial work relationships. Replace productivity quotas and management with leadership.

11. Remove barriers that decrease pride in workmanship that would otherwise emphasize quantity over quality.

12. Remove barriers that decrease pride in workmanship for managerial staff such as merit rating systems.

13. Initiate programs to promote education and self-improvement to create quality within the workflow.

14. Transformation within the workplace must be accepted by and worked for by all within the company.

(Deming, 2018)

Figure 2. **The Donabedian Model for Quality of Care**

Structure: physical and organizational characteristics where healthcare occurs.

↓

Process: focus on the care delivered to patients e.g., services, diagnostics, or treatment.

↓

Outcomes: effect of healthcare on the status of patients and populations.

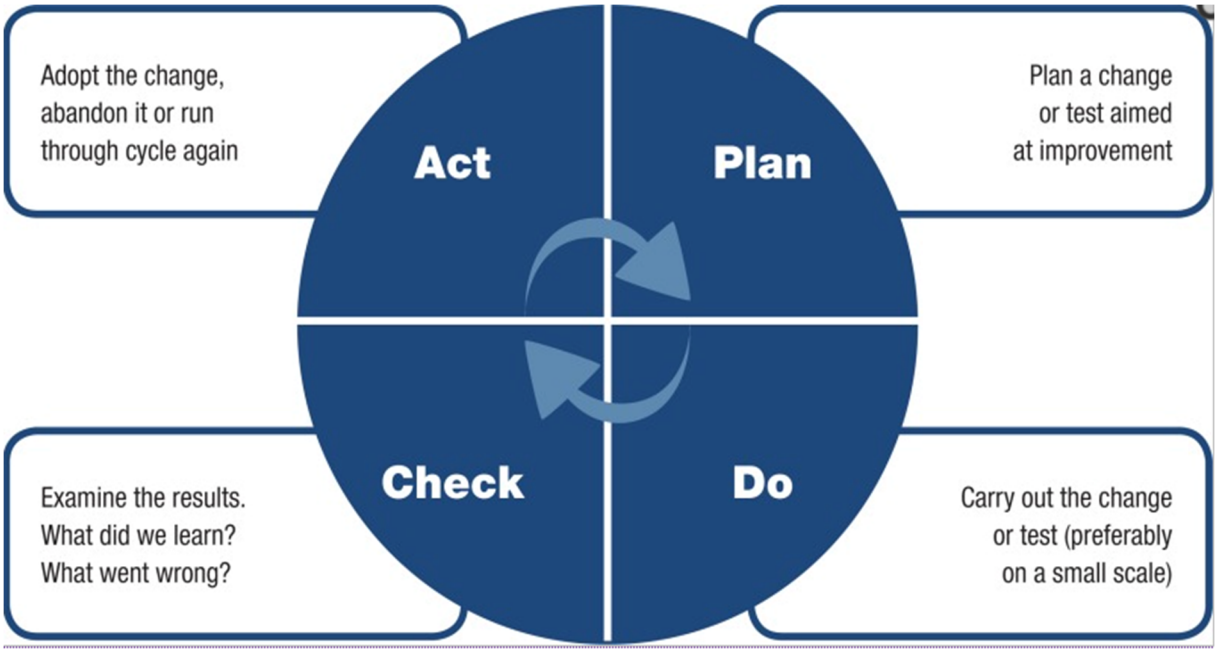
(NHS England and NHS Improvement, 2005)

'Plan, Do, Study, Act' Cycle Adoption as a QIP

Utilizing the foundations for quality improvement set forth by both the model proposed by Deming and Donabedian, the IHI has adopted the practical 'Plan, Do, Study, Act' cycle (model). Applicable across varying industries and within each industry's multitude of levels, the model encourages systems-based learning to "introduce, evaluate, and progressively adapt changes (IHI, 2021). Published in 1993 by Deming, the 'PDSA' cycle is hinged on a reliance on iterative processes to establish lasting, sustainable change (Pruitt & Imam, 2021). Under the 'PDSA' cycle exist several techniques for iterative assessment strategies for measuring change (Panteli et al., 2019). These strategies include, but are not limited to audits, feedback, the IHI's Breakthrough Series[5], and external assessment strategies (Panteli et al., 2019). Given that sought after outcomes within health care settings most frequently stem from alterations made to structure and processes, garnering results is often a time-consuming process that yields results that are not immediately discernible (WHO, 2009). The 'PDSA' cycle is applauded for its ability to counteract slow progress. Its emphasis on making changes at the structure and process level and its capacity to provide real-time feedback through its iterative nature, enabling the 'PDSA' cycle and the life work of Deming and Donabedian to become an invaluable technique for devising changes within industries, including health care (WHO, 2009).

[5] IHI Breakthrough series. A collaborative approach established by the IHI to bring together leaders of healthcare facilities to discuss exceptional care and short fallings within current practices to establish practice needs and potential solutions to address the needs. (IHI, 2003)

Figure 3. Steps of the 'PDSA' Cycle Explained



(Taylor et al., 2014)

'PDSA' Implementation

The IHI suggests that when utilizing the 'PDSA' cycle to promote change within an industry setting, it is critical to rely on questions to define the aims of the changes being implemented and the intended outcomes. The 'PDSA' cycle proffers 3 questions that should be answered by change implementers/implementation teams prior to execution of the 'Act' stage of the cycle.

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

It is expected that by applying the above 3 questions to desired changes, change implementers will be able to avoid extraneous iterations of the 'PDSA' cycle by having achieved desired success at a faster pace. (Langley et al., 1996) Additionally, the IHI recommends a further

dichotomous approach to crafting aim statements to aptly enable change within industry settings. The institute recommends that when answering the above questions, implementers should also set forth to make the aims concise, numeric, and generally follow a cause and effect approach (IHI-b).

'PDSA' Methodology

Following the development of the aims of the change to be implemented is the execution of the devised action plans. Subsequently measurement of the success and failures of the implemented initiatives is critical to assessing whether future iterations of the 'PDSA' cycle is needed for change to occur. While it is ultimately the judgement of the implementers, stakeholders, patients/clients, or recipients of the change who may decide whether the resulting transformation is the desired outcome or if successful, there are varying tools for measurement that can be employed within QIP practices that may assist in determining the efficacy of the intervention.

Prior to determining which QIP methodology is most appropriate to determine change, it is critical to decide what values are to be measured. When choosing values for measurement, it is recommended to choose those that yield usefulness rather than perfection and to sample, utilize qualitative and quantitative data, and use plots of recorded data to identify trends in data over the course of each iterative change implemented (Hamby, MD., 2021). It is further recommended to avoid over selecting measures to observe during a period of time, and rather limiting the number of measures to accelerate the rate of improvement (IHI, 2021-c).

Figure 4. IHI's Guide to Utilizing Measurements for Change Propagation

	Measurement for Research	Measurement for Learning and Process Improvement
Purpose	To discover new knowledge	To bring new knowledge into daily practice
Tests	One large "blind" test	Many sequential, observable tests
Biases	Control for as many biases as possible	Stabilize the biases from test to test
Data	Gather as much data as possible, "just in case"	Gather "just enough" data to learn and complete another cycle
Duration	Can take long periods of time to obtain results	"Small tests of significant changes" accelerates the rate of improvement

(IHI, 2021-c)

While keeping the above recommendations in consideration, the IHI further recommends selecting measurements that are specific to QIPs in both applications to general industry and the health care industry. An adept understanding of the below measurement types and their nuisances are critical to choosing an appropriate measure to assess change as related to the aims set forth by the change implementers.

- *Outcome Measures*: assesses impact of implemented change at an individual or population level.

  Example within health care: average A1C measurement for patients with diabetes in a population.

- *Process Measures*: assesses the impact of functions or steps performed within settings to impart change.

  Example within health care: percentage of patients who received referrals for diabetic retinopathy in a year following a care visit.

- *Balancing Measures*: assesses formation of new problems or challenges within a system as a result of implementation of a change/QIP.

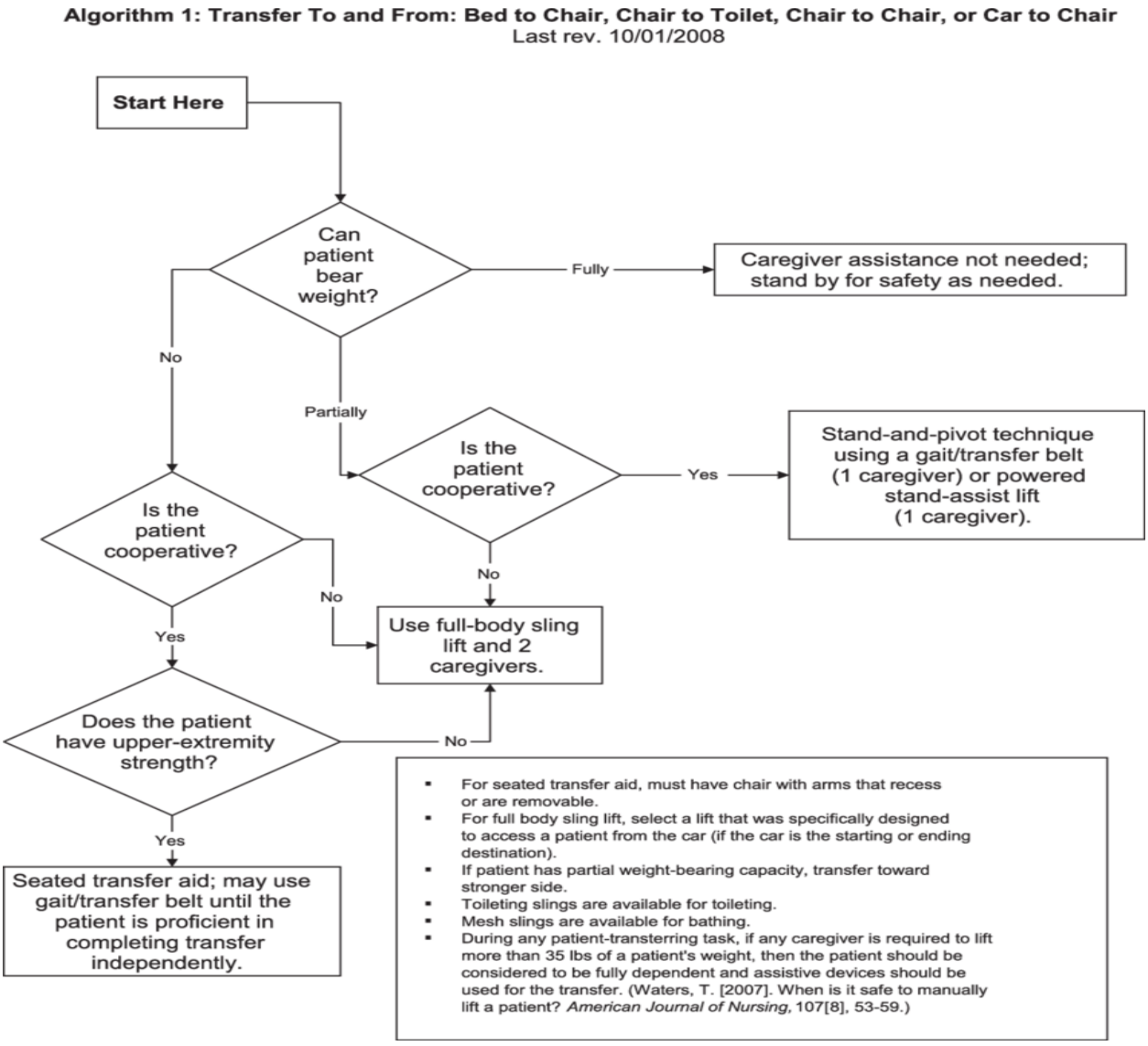
> Example within health care: for reducing number of medications taken by diabetic patients; assess risk of adverse drug interactions prior to administration of medications.

(IHI, 2021-c)

**For the intentions of this literature review aiming to address the merits of Quality Improvement Processes to promote quality, and thus equity in health care. The following review of specific QIP methodology will solely discuss those with the capacity to enable process measurement.*

Upon selecting a form of measurement, the change implementer is then tasked with designing a change intervention to propagate the desired outcomes. Process mapping is an activity that is recommended to assist the change implementer and those who will be tasked with enacting upon the change, to visualize the change process and the path to improvement (Hamby, MD., 2021) Formation of a process map should assess where the process for change would begin within the industry setting, and then assess all steps and processes that may influence the outcome. Process maps should define all potentially influencing characteristics by applying shapes and colors to represent constraints, supportive processes, and notations of potential changes to make to the implementation process in future iterations of the 'PDSA' cycle. (Hamby, MD., 2021)

Figure 5. Example of A Process Map in Health Industry



(Yum, 2015)

Following the construction of process maps to demonstrate where measurements within the change process or QIP may occur, the challenge for implementers is to determine a valid measurement methodology to implement during the 'study' component of the 'PDSA' cycle. The following section intends to review varying QIP practices, that when applied to the aims set forth for a 'PDSA' cycle should assist the change implementer in determining how impactful the processes outlined in the process map are to the overall change attempting to be implemented.

QIP Methods for Use Consideration in the ‘PDSA’ Cycle

Root Cause Analysis

Root cause analysis (RCA) is a structured process determined to identify causes of an adverse outcome in a retrospective manner. Efforts to assess physical, human, and latent causes can be further used in a proactive measure to assess change interventions or process maps prior to implementation. The evidence-based approach aims to use the method as a management tactic to predict and correct preventable deviations in process that could otherwise lead to reduced efficiency and quality. (Healthcare Quality Improvement Partnership, 2020)

During the time/resource dependent process, the RCA seeks to identify a root solution by proposing the questions (Hamby, MD., 2021):

1. *What happened?*
2. *Why did it happen?*
3. *How can it be prevented from happening again?*

It is necessary to note that unlike QIP methods, RCA is a retrospective tool for measurement impact that occurs following an iteration of the ‘PDSA’ cycle, whereas other methods seek to conduct measurement during a cycle iteration to as not delay revisions to the process for change (UNC School of Medicine, 2021). As a method of measurement, RCA serves as a process measurement in that it reports the success or failure of the utilization of a process designed into the process map of a ‘PDSA’ iteration (Healthcare Quality Improvement Partnership, 2020).

Implementing RCA

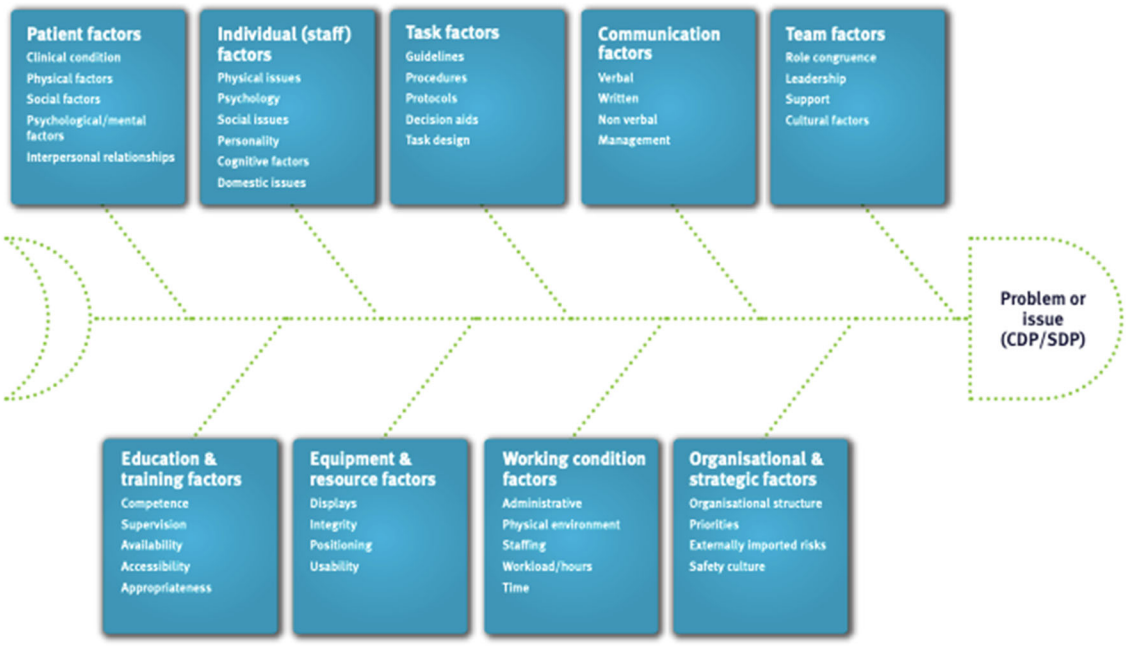
Upon conclusion of a change cycle or iteration of the 'PDSA' cycle, it is necessary that the change implementer/designer or those who were tasked with the physical change implementation be alerted to the occurrence of a process failure or adverse event. In the case that implementers do not become aware of the failure or adverse event, there will be an inability to address failure at its source, and thus will perpetuate innate failures into the process design (UNC School of Medicine, 2021).

Upon identification and notice of a process failure or adverse event, the individual or team responsible for the process design and implementation is advised to form a team of individuals who regularly work with the process or the system that the process is designed to impact. Direct partnerships are expected to be the most efficient method of receiving feedback to identify shortcomings, what worked, and room for improvement (Healthcare Quality Improvement Partnership, 2020). Insights garnered from those who work closely with the process on a regular basis should be able to provide guidance that can best strengthen the process capacity, efficiency, and quality at a higher level than an individual or team who does not regularly interact with the process or the system in which the process is expected to reform (Hamby, MD., 2021). While discussions of analysis and investigation into the failures/adverse events are largely expected to occur at the implementation team level, it is recommended to have an outside, trained facilitator present to prevent oversight that may occur with a team solely operating under an insider's perspective (Health Quality Improvement Partnership, 2020).

During RCA of the process failure/adverse event, it is expected that a summary of findings be reported to the change implementer/designer prior to the start of an additional 'PDSA' iteration (Hamby, MD., 2021). A summary of findings is expected to present plausible

causes of the event and propose effects when adjusting the process map for future iterations. Frequently, such reports are presented in the form of a fish bone diagram which details the identified causes and effects of all identified/unidentified processes. The fish bone diagram is designed to highlight potential process design flaws that may affect the outcomes of newly implemented processes. The fishbone diagram is a deliverable of RCA that is expected to assess what happened prior to process failure, assess contributing factors, and later be used to develop recommendations for further process changes, measurements, and redesign as needed. The diagram is a collaborative measurement tool that is expected to facilitate conversation and comprehension regarding the feasibility and capacity of changes to be implemented to drive improvement within industries. (Healthcare Quality Improvement Partnership, 2020)

Figure 6. Fishbone Diagram Representing Report Format during Root Cause Analysis



(Coleman & Hodson et al., 2013)

Evaluating Merits of RCA as A QIP Method

Pros: The collaborative nature of conducting RCA allows both the change implementing team and recipients of the interventions to regularly develop interventions that are not clouded by internal/external biases (Hamby, MD., 2021). The method's requirement of examining failures or adverse events at the root, further permits the identification of room for additional improvement within an industry system. Lastly, RCA allows processes to be compartmentalized, limiting the likelihood that actions taken to rectify process failures/adverse effects may disturb existing processes already operating in a seamless fashion (Healthcare Quality Improvement Partnership, 2020).

Cons: Unlike most other QIPs, the retrospective nature of RCAs prevents the acceleration of progressive change valued by the Quality Improvement Movement (WHO, 2009). Furthermore, the compartmentalization of processes during RCA, inhibits systems-level thinking, preventing comprehensive analysis of the interactions of processes under review for QIPs.

A3 Problem Solving

A3 problem solving is a QIP method that was adopted from the Toyota Motor Corporation as a sustainable approach for addressing recurrent or likely problems in an industry to promote improvements (Ghosh, 2012). Originally implemented by Toyota, the process measure draws on principles proposed by Deming to propagate the 'PDSA' cycle (Bassuk & Washington, 2013). The A3 method seeks to identify issues to be addressed, assesses the current operating conditions, utilizes RCA to hypothesize ideal improvements to be made, and serves as a guide to perpetuate the intended changes through everyday actions and operating processes.

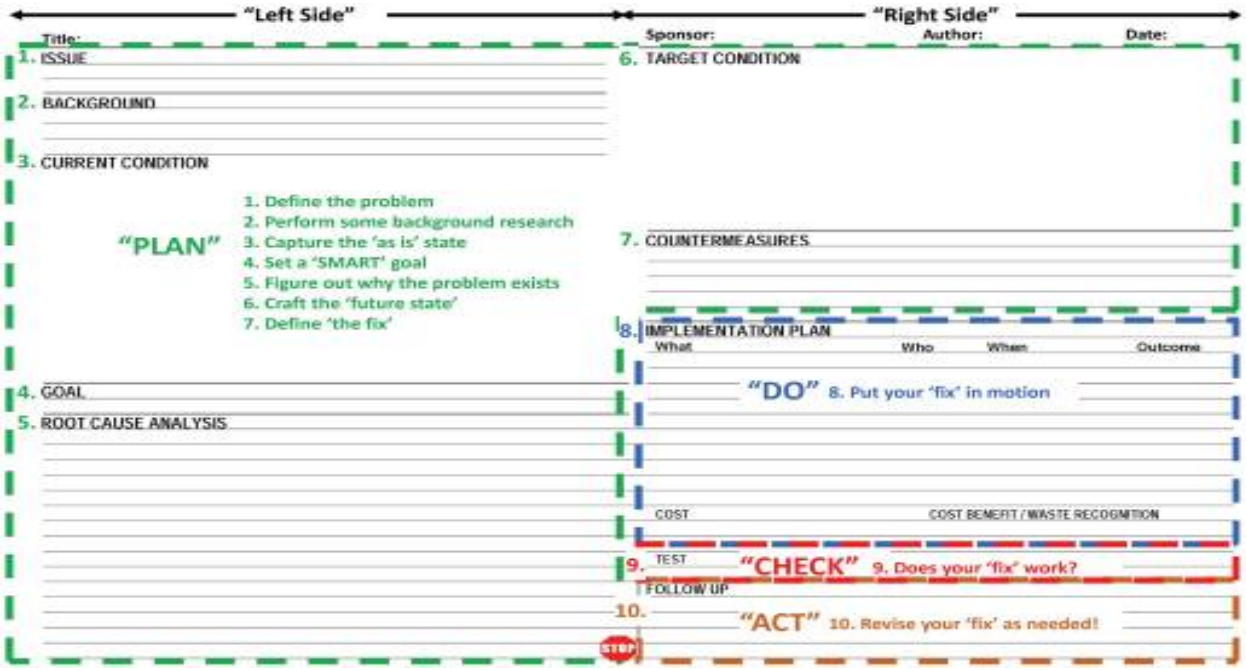
Implementing A3 Problem Solving

A3 problem solving is accomplished by formulating a 'PDSA' plan for improvement on only the front side of a piece of A3 (11"x17") paper (O'Toole, 2021). Written exclusively in pencil, the document entails a cohesive assessment of the system upon which improvements are to be made (O'Toole, 2021). The use of pencil embodies the iterative nature of the IHI's PDSA cycle by allowing the change implementation team to review and revise processes not already yielding satisfactory improvement. During construction of an A3 problem solving guide, the left side of the document is traditionally dedicated to identifying the problem and its root cause in accordance with the planning stage of the 'PDSA' cycle. The right side of the problem-solving guide outlines methods and measures to implement changes to improve the targeted processes, following the 'Do, Study, and Act," requisites of the 'PDSA' cycle. Progressive change to be made during use of the A3 Problem Solving methodology requires 9 steps to be completed by the change implementation team when drawing up the A3 guide. These steps include:

1. *Identify the problem, issue, or topic around which all executed actions will aim to address.*
2. *Ascertain who will be responsible for implementing and sustaining the changes made to improve the processes identified by the implementation team.*
3. *Assess critical background information that is pertinent to the immediate workplace and context in which the problem is to be solved.*
4. *Characterize current conditions and the state of the problem by presenting data utilizing graphs, pictures, etc. to indicate areas of measurable improvement.*
5. *Summarize the goals or targets of the desired improvements to clarify expectations and types of measurements (quality, cost, delivery, etc.) that will indicate improvement.*
6. *Conduct RCA to assess if the plan set forth in the A3 guide will generate desired improvements.*
7. *Develop countermeasures to address root causes and perpetuate changes through new and improved operating procedures.*
8. *Manage an implementation plan by assessing the actions, individuals, and resources that will enable change propagation.*
9. *Assess potential hindrances to progressive improvement and devise learning plans for applicable uses or future iterations of the 'PDSA' cycle.*

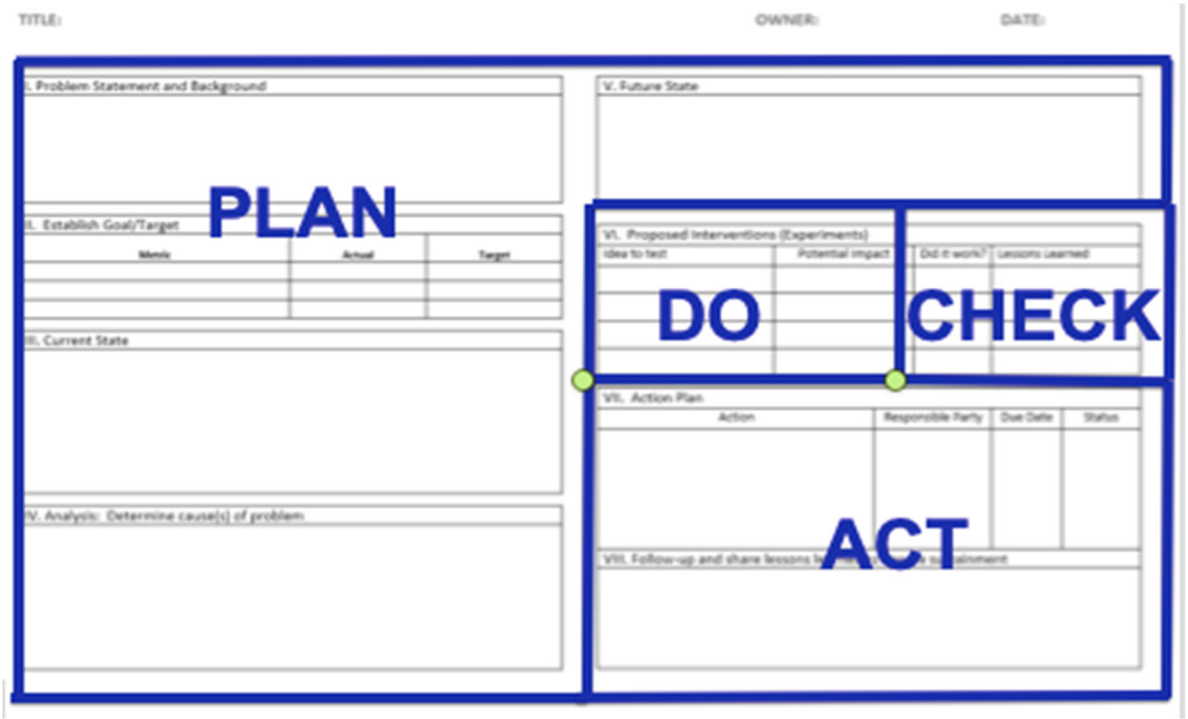
(Create Value, 2010)

Figure 7. Model of A3 Formatting



(Bassuk & Washington, 2013)

Figure 8. Demonstration of How A3 Problem Solving Follows the 'PDSA' Cycle



(O'Toole, 2021)

Evaluating Merits of A3 Problem Solving as A QIP Method

Pros: The comprehensive nature of A3 problem solving encourages the continuity of progressive change that is encouraged with practice of the 'PDSA' cycle. Presented on a single paper, the totality creates an easily referenced document to guide change. The flexibility of the methodology enables rapid implementation of solutions, while encouraging all staff, stakeholders, and the implementation team to take an active role in the generation of the 'PDSA' cycle (O'Toole, 2021). Furthermore, the methodology which occurs within the everyday work environment supports A3 methodology as a feasible and sustainable mode of encouraging quality improvement processes across varying industries and sectors (Create Value, 2010).

Cons: While A3 problem solving generates solutions in regard to industry or scenario context, the rather small planning space forces one topic or issue to be under review for improvement at one time.

Lean Methodology

As a process measurement, Lean refers to a QIP method that places significant value in creating and promoting efficiency to generate improvements in quality (Womack et al., 2007). As with previously explored QIP methodology, the fundamentals of Lean strategy originate within the Toyota Production system (O'Toole, 2021). Lean principles seek to incorporate process mapping procedures to identify inefficiencies in systems where quality has been limited by inefficient and inconsistent operations (Healthcare Quality Improvement Partnership, 2020). Lean expects that by incorporating value added activities[6] to the work flow and eliminating waste, work environments are likely to become more responsive and flexible to newly implemented quality improvement initiatives (HQIP, 2020). Operating under the premise that quality improvement must stem from initiatives implemented at the place of work, Lean places emphasis on changes that can be made to the work environment flow, rather than the quality of tools already existing within the environment (O'Toole, 2021). The intentions of Lean processes to drive quality improvements requires adherence to five principles that proliferate the 'PDSA' cycle.

1. *Specify value in relation to the expectations of consumers/stakeholders as pertaining to products/services.*
2. *Identify the value stream by mapping out the inputs and outputs of processes in order to identify sources of waste to be eliminated.*
3. *Incorporate value adding processes to generate sustainable waste elimination practices.*

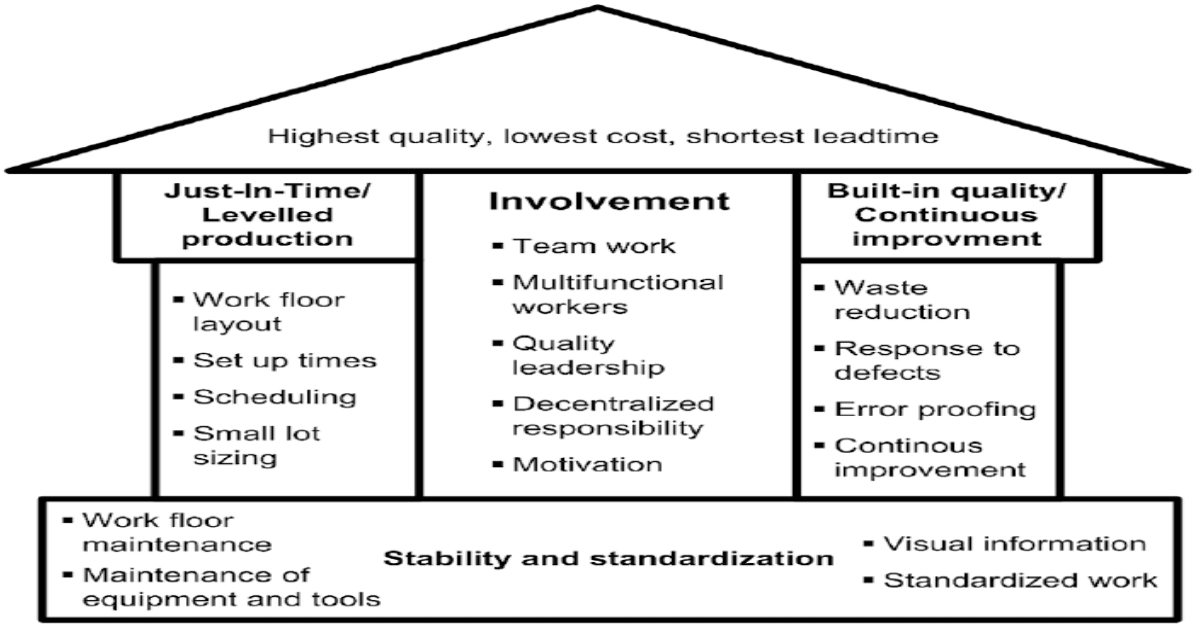
[6] Value added activities are those that maximize capacity, efficiency, or effectiveness that promote positive changes in the work environment by reducing the need to focus on unnecessary tasks, wasteful practices, or that which may otherwise reduce the quality of product/service/care (O'Toole, 2021)

4. *Allow processes to coincide with the demands of the consumers or stakeholders to avoid surplus.*
5. *Pursue perfection within the workflow by encouraging continuous process improvement.*

(Nightingale, 2005)

Activities organized by change implementation teams, individuals within the organization, or stakeholders that follow the 5 Principles of Lean by reducing waste within the *gemba* practice QIP methods under the House of Lean. The House of Lean is the summative strategy of rapidly implementing stability and standardization through waste elimination to generate superior quality at low costs.

Figure 9. House of Lean Diagram



(ResearchGate, 2019)

Implementing Lean Fundamentals

Targeting the operating quality of the working environment, Lean takes a structured approach to QIP by enabling action planning to effectively revise present operations (HQIP, 2020). While Lean focuses on the 'real place'/working environment or *gemba*, it is necessary to note that Lean subdivides 'the real place of work' into 3 separate categories:

1. *The real place of work.*
2. *The real process.*
3. *The real data and facts.*

(Nightingale, 2005)

Comprehending and understanding the nuisances between the varying 'real environments' of the workplace or industry is critical in the ability to formulate an effective quality improvement solution. Originating in Japanese philosophy, the majority of Lean principles purport that one should become as familiar with the source of a problem/issue, before attempting to implement a solution (O'Toole, 2021). Allowing familiarity with the environment to grow allows for the planning phase of the 'PDSA' cycle to be brief and informed, further reducing the need to incorporate additional phases of 'studying' and 'acting' of the 'PDSA' cycle.

In addition to understanding the 'real place' of work or the context in which QIP initiatives are to be implemented, Lean as a QIP methodology further relies on Japanese concepts and the strides taken towards quality improvement by the Toyota Production System. The concepts of Mura, Muri, and Muda represent quantifiable opportunities for process measurement to occur.

Mura: inconsistency in operations.

Muri: overburdening of equipment or employees.

Muda: activities in the work process that reduce the value of processes or do not contribute to quality improvement.

(Nightingale, 2005)

During QIP implementation, the above concepts may serve as valuable process measures upon which change implementation teams may conclude the success or failure of a change initiative. While *Mura, Muri, and Muda* all demonstrate the capacity to be utilized as process measures for implementation of the 'PDSA' cycle, *Muda's* ability to be executed with minimal oversight or planning delineates methods for reducing waste or 'value subtracting activities' causes *Muda* to be a favorited among the Lean fundamentals for implementation. *Muda* may be further broken down into what is referred to as '8 Types of Waste,' that are value subtracting or consistently decrease efficiencies within the work place's context.

8 Types of Waste

1. *Defects: errors that demand additional time, resources, or personnel to correct.*
2. *Overproduction or batching: producing more than is needed.*
3. *Waiting: time is inadequately utilized due to interruptions, delayed decision making, or poor information handling.*
4. *Unclear standards: for personnel or production operations.*
5. *Transportation: excessive or unnecessary movement of product, personnel, or resources that further delays the flow of operations.*
6. *Inventory: is mishandled, unsaleable/unusable, or is misplaced.*
7. *Motion: efficiency is reduced by requiring additional movement, searching, or traveling to reach, identify, or complete steps in a process.*
8. *Extra processing: undue variation causing delay, added costs, or additional resources to complete a process step.*

(O'Toole, 2021)

Evaluating Merits of Lean as A QIP Method

Pros: The requirement that Lean principles be implemented in context of the working environment or the *gemba* allows QIPs to be inherently unique and customized to the specific needs of the industry or organization. The accessible nature of Lean methodology enables the principles to be readily employed to propagate change. Furthermore, while devising the plans for implementing QIPs, certain changes may require advanced insights or management to compile a comprehensive, strategic approach, while the simplistic nature of the changes driven by Lean principles encourages continuous improvement and growth. Lean principles are unique in that they specifically assess attempts to remove unnecessary processes hindering quality improvement, whereas other QIP methods generally seek to add processes or revise processes to accomplish change for improvement.

Cons: The accessible nature of Lean, while meant to encourage individuals across management levels to take initiative to implement positive change, the bureaucratic nature of industry organizations seldomly allows individuals to take unilateral changes to implement QIP. Additionally, as Lean seeks to eliminate wastes even within minute processes, the lack of formal Lean methodology to assess the effectiveness of changes to improve quality mitigates the ability to use Lean in a holistic manner.

Six Sigma Methodology

Six Sigma is a process measurement tool first developed in the 1980's to promote improvement in processes by the Motorola Corporation. The methodology was developed to assist the company in meeting customer expectations and remain a leader in their market (Hamby, 2021-a). Since initial implementation, Six Sigma has evolved to become a process measurement tool that serves to increase industry efficiencies by limiting variation in process outcomes. As the methodology has further been incorporated into the standard operating procedures of large corporations such as Kodak, IBM, Cardinal Health, etc., Six Sigma has demonstrated applicability across industries and has been favored for its ability to promote improvement regardless of application (Hamby, 2021-a).

Six Sigma generally refers to a process that is well controlled and has eliminated the majority of defects or variation that could result from an uncontrolled process (Purdue University, 2021). Six Sigma's variation threshold detects how far processes deviate from the ideal or perfect operating expectations. The Six Sigma standard of quality for acceptable variation aims to detect no more than 3.4 defects per million opportunities or 99.9997% accuracy (American Society for Quality, 2021).

Implementing Six Sigma Philosophies in Industry

Six Sigma relies on a problem-solving framework to generate quality improvement processes by assessing iterations of the 'PDSA' cycle. The following framework exemplifies how Six Sigma utilizes facts, data, and statistical analysis to improve industry processes by eliminating variation (Hamby, MD., 2021-a).

1. *Defining the aims and scope of the processes to be measured.*
2. *Measuring variation in the selected process. Six Sigma measures quality performance in defects per million (dpm) opportunities. A Six Sigma or controlled process will detect less than or equal to 3.4 dpm opportunities, equivalent to a 1.5 sigma mean shift.*
3. *Analyze data collected at each step of the process to assess those upon which Lean fundamentals or RCA can be applied to streamline the activities and yielded fewer DPM.*
4. *Improve upon solutions to develop process control measurements that are not reliant upon completion of the process, but rather can be accomplished throughout the course of the process to ensure that control is maintained throughout all steps.*
5. *Control should be documented by applying statistical control charts to ensure that the effectiveness of new processes does not waver over time.*

(Hamby, MD., 2021-a); (Purdue, 2021)

Six Sigma philosophy operates under the assumption that all process outcomes can be expressed as a function of the inputs incorporate into the process (American Society for Quality, 2021). Utilizing the above framework, Six Sigma assumes that continuous review and monitoring of process implementation may reduce risk for process control to be lost.

Applicable across all industries in which process input may be altered and controlled, Six Sigma may present as a valid and desirable process measurement in businesses or industries looking to introduce process control measures (Hamby, MD., 2021). However, the approach taken to introduce Six Sigma may vary between industries.

One approach is to introduce a Six Sigma Initiative in a short term initiative. In this approach, the aim of the initiative is to control variation as pertaining to a specific process that has demonstrated lacking quality due to too much variation in outcomes, inefficiencies, or

challenges the process presents the work environment. The initiative may result in the training of a few key individuals within the industry/organization capable of running statistical analysis and undergoing Six Sigma training. It is necessary to note that the introduction of Six Sigma Initiatives is unlikely to sustain control over a process variation or to inspire further projects to review additional process controls. (American Society for Quality, 2021)

The second and more lauded approach is to develop a Six Sigma infrastructure within the organization or industry. While this approach does require additional training and commitment to ensuring that the culture within the industry is dedicated to implementing controlled processes, the added efforts from the start of the QIP ensures that the need to revise implemented processes and produce further iterations of the 'PDSA' cycle be limited. (American Society for Quality, 2021)

Regardless of whether the approach to implement Six Sigma as a QIP measure occurs during a single process improvement initiative or is embedded into the operating procedure infrastructure, the methodology incorporates Total Quality Management principles[7] to generate improvement. Regardless of the length of Six Sigma implementation, the methodology consistently is driven by the customer, focuses on the process quality, and improves the overall quality of the bottom line and the business as a whole (Hamby, MD., 2021-a).

Six Sigma efforts are often summarized into a comprehensive Suppliers, Inputs, Process, Outputs, Customers Diagram (SIPOC Diagram).

[7] Total Quality Management (TQM) is a management principle that suggests that quality is driven by internal performance in the areas of production and service. TQM relies on a collaborative culture within an organization to promote overall quality improvement. TQM was developed prior to Six Sigma, as it lacks the statistical analysis component that further sets Six Sigma apart from other QIP measurement methodologies. (Hamby, MD., 2021-a)

Suppliers: The supplier's section of a SIPOC diagram should outline all influencers of the process to be assessed using Six Sigma. This should include past implementers of the process, those who currently implement the process, management, etc.

Inputs: The inputs section of a SIPOC diagram should incorporate all additional people, materials, resources, or secondary processes that enable the process to regularly occur.

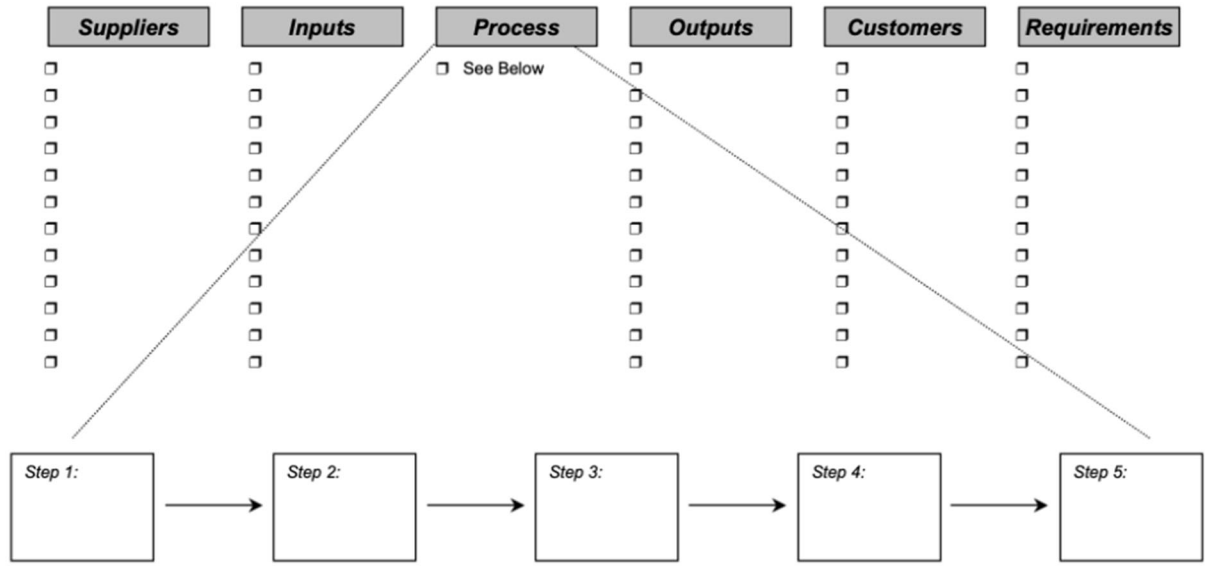
Process: The process section of a SIPOC diagram should outline the aims of the process in its current state and identify areas potentially responsible for the unsatisfactory process variance. This section should further outline what a further iteration of the process would look like by utilizing 'PDSA' cycle methodology. Aprocess map is recommended to clarify and provide visualization of the intended changes.

Outputs: The outputs section of the SIPOC diagram should not reframe the desired outcomes of the process revised using Six Sigma methodology. Rather this section should embody the 'Study' component of the 'PDSA' cycle as it should contain all outputs of the process including, but not limited to paperwork, surplus materials, etc., in order to be referenced to and examined for further sources of quality improvement processes.

Customers: The customers section of the SIPOC diagram is designed to be a redundant tool so that during implementation of Six Sigma methodology, all actionable changes are done so with the principle of always having the needs and satisfaction of the customer as the forefront driver of all intended changes driving quality.

(Hamby, MD., 2021-a)

Figure 10. Sample SIPOC Diagram



(Simon, 2020)

Six Sigma efforts defined using the DMAIC problem solving framework are exemplified in SIPOC diagrams that utilize statistical process control charts (SPCC) to assess the evolution of the process. SPCCs are appropriate for use when assessing out of control processes, developing an expected range for process variation, or assessing if special cause variation (SCV)/unusual events are responsible for variation as opposed to an inherent flaw in process design or implementation.

Control charts aim to plot the outcomes of processes over time across upper and lower control limits with a median line in the middle. Assessment of SPCC requires analysis of data plotted around the median, between the upper control limit (UCL) and lower control limit (LCL) and outside of both the UCL and LCL. Analysis of the data follows five rules to determine if a process is out of control or if it fails to meet the standard of less than 3.4 dpm imposed by Six Sigma principles. (American Society of Quality, 2021-a) If any of the SPCC criterion for

variations exists on a plotted SPCC, then it reasonable to request future iterations of the 'PDSA' cycle be initiated to improve quality.

SPCC Criterion Indicating an Abundance of Variation/Out of Control Processes

1. *A single point exists outside either the UCL or LCL.*
2. *Two of 3 successive points are greater than 2 sigma from the median line.*
3. *Four of 5 successive points are greater than 1 sigma from the median line.*
4. *8 points are in a row regardless of position to center line.*
5. *A persistent, yet unusual pattern tracks regardless of location to median line.*

(Hamby, MD., 2021-a)

Figure 11. Example of Statistical Process Control Chart

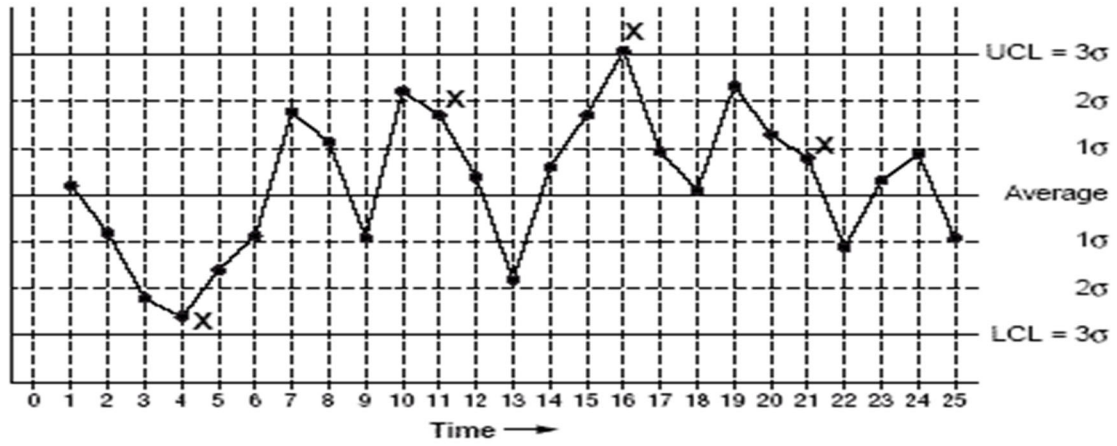


Figure 1 Control Chart: Out-of-Control Signals

(American Society of Quality, 2021-a)

If upon evaluation of a SPCC, it is determined that one or more of the conditional criteria has been met, then it should be concluded that future iterations of the 'PDSA' cycle need to occur to reach a quality, controlled process. If the criterion has not been met, change

implementers may conclude that the planned actions taken to improve processes driving quality, in fact aligned with the aims and goals set forth during the planning stage of the 'PDSA' cycle. (Hamby, MD., 2021)

Evaluating Merits of Six Sigma Problem Solving as A QIP Method

Pros: Six Sigma is often appraised to be the gold standard of QIP measures (American Society for Quality, 2021). The incorporation of statistical analysis when assessing process implementation can generate unsurmountable evidence for a process measure to be determined quality or in need of further iterations. Additionally, the statistical approach encourages the methodology to be utilized in QIPs relating to cost improvements, one of the most frequently sought after sources of quality improvement for both the industry and its consumers (Purdue University, 2021). Furthermore, continued use of SPCC as a delineator for having reached Six Sigma quality and its ability to identify areas for future improvements propagates quality (Healthcare Quality Improvement Partnership, 2020).

Cons: While credited for being one of the most sought after and applicable QIP measures due to its ability to clearly define success and failures during QIP implementation, it is also one of the more unattainable methodologies. Proper conduction of Six Sigma requires specialized method training and certification beyond traditional abilities to conduct statistical analysis. Therefore, industries seeking to utilize Six Sigma methodology are often challenged to outsource the analysis process or spend time and resources to conduct training internally (Purdue University, 2021). This stipulation can best exemplify the variance in the possible implementation approaches outlined above.

QIP Methodology Summary

Process measurements, not limited to those referenced above, are critical to a change implementation teams' ability to decide whether implemented changes successfully yielded improvement. If deemed that the resulting and measured changes implemented were unsatisfactory, change implementation teams, stakeholders, industry members, and consumers, must collaboratively adopt additional changes to implement during an additional iteration of the 'PDSA' cycle. This action is meant to resolve the question, *"what change can we make that will result in improvement,"* and further enable the utility of the 'PDSA' cycle (Langley et al., 1996). While process measurements may decisively conclude efforts to a quality improvement process initiative, decisions to seek out additional industry processes in need of improvement that propagate quality and consistency in quality throughout industry. Proliferation of additional change measurements should aim to eliminate waste, improve work flow, optimize inventory, change the *gemba*, reduce production time and variation, proof for errors, and focus on improving customer/service interactions, and the overall product or service yielded from the industry (Langley et al., 1996).

Additional change steps for consideration:

Modify input

Combine steps

Eliminate failures between steps

Eliminate steps

Reorder steps

Change elements to change the process

Replace a step with a value adding alternative

Redesign service/product according to knowledge, use, and need

(Hamby, MD., 2021)

Literature Review Methodology

Developing the solutions manual to guide the implementation of innovative QIPs across healthcare settings, I found it best to include exemplars of previously executed QIP projects within the literature review. As this literature review seeks to specifically guide QIP projects that increase access to quality care for patients with diabetes, I sought to exclusively identify studies that examined a QIP methodology in context of a primary branch of care for diabetes: prevention, management, or treatment.

My initial intention was to identify studies for each reviewed QIP methodology to corroborate applicability to the three primary branches of diabetes care. I began by identifying potential sources of studies to be reviewed including Emory University's Library Database, Google Scholar, and the Institute for Healthcare Improvement's Resource Repository. Across Emory's Database and Google Scholar, I utilized QIP methodology key terms such as: RCA, Lean, Six Sigma, A3 Problem Solving, process improvement/changes, change implementation, quality changes; cross referenced with terminology pertaining to diabetes such as diabetes (mellitus), prevention, treatment, management, insulin, A1C, blood sugar/glucose, glucometer, diabetes medications, etc. to identify studies. Searching the IHI's Resource Repository, only terminology relating to diabetes was utilized as it was already given that studies would relate to QIP methodology. After identifying studies containing the above search terms, I ensured that all studies were published in 2017 or later to keep with the innovative nature of QIP methodology.

Following the process of utilizing the search terminology and then using publication dates as additional criteria, I was able to identify 27 potential exemplars. Screening the 27 studies, I first assessed which QIP methodology was utilized in the study and then determined which aspect of diabetes care was examined in the study. If a study failed to explicitly describe a

QIP methodology reviewed above, or if it failed to apply the methodology to a project improving access to quality diabetes care, then the study was excluded from the *Application of QIP Measures in Diabetic Care* section. When reviewing the studies, only 5 of the 27 studies successfully described the intersection of a primary branch of diabetes care and the implementation of QIP methodology and were therefore included as a component of the literature review. I assessed the 5 studies to garner the author's/implementation team's initial study intentions, review the study design and QIP implementation methodology, and analyze the results and implications of the research.

The identified and selected exemplars best demonstrate the intersection of QIPs utilized in context of diabetes care. Determining the order to present the exemplars, I found that presenting the exemplars in accordance with the inherent progression of prevention, management, and treatment, would be best to express QIPs capacity for expanding access to quality care for patients with diabetes.

Applications of QIP Measures in Diabetic Care

Applications to Diabetes Preventive Care

[Applying RCA Process Measures to Diabetes Preventive Care]: *Root Cause Analysis of Diabetic Ketoacidosis Admissions at a Tertiary Referral Pediatric Emergency Department in North India*

Jayashree, M., Sasidharan, R., Singhi, S., Nallasamy, K., & Baalaaji, M. (2017). Root Cause Analysis of Diabetic Ketoacidosis Admissions at a Tertiary Referral Pediatric Emergency Department in North India. *Indian journal of endocrinology and metabolism*, *21*(5), 710–714. https://doi.org/10.4103/ijem.IJEM_178_17

Across Northern India, diabetic ketoacidosis (DKA) is a leading cause of death for children diagnosed with Type I diabetes mellitus (T1DM) accounting for 57-87% of all DKA related deaths. As delayed recognition of the condition or additional comorbidities are contributing factors to death or severe complications, the study conducted by Jayshree et al. aims to assess the referral process utilizing Root Cause Analysis to determine where improvements could be made to reduce adverse health effects. Conducting the RCA, children admitted between the ages of 1-12 years diagnosed with DKA were entered into the study and followed for 45 days. During this time period, study participants as well as referring clinics and health institutions providing diabetes care were interviewed regarding the referral and diagnosis process. Study participants were categorized by whether they had a DKA diagnosis at time of admission, their socioeconomic strata, and if they had/had not been previously diagnosed with T1DM at onset of DKA.

The study concluded that 50% of the 30 enrolled participants belonged to a lower socioeconomic stratum while 73% of the children had an indication of DKA at time of admission

to the emergency department. Additionally, the RCA found that of enrolled patients, 87% had received referrals to clinics, yet only 30% of patients had parents who were aware of the diabetes. Of those who were aware, only 50% were knowledgeable of the need to strictly follow insulin regimens and other care plans. It was found that only 41.7% of the enrolled children were receiving appropriate treatment as a result of non-compliance in medication therapy. Through the interview process with patients and providers, the RCA identified carelessness, lack of supervision, and poor blood glucose monitoring records as contributing causes that lead to delayed diagnosis and an over-abundance of DKA related complications. Specific to the referral process, the RCA found that referrals did not happen in an appropriate manner due to lack of access to facilities, due to cases that developed to be too challenging for the skills/resources of facilities initially referred to, and due to financial constraints. Overall, the study concluded that those not previously diagnosed with diabetes were more likely to present with DKA and more severe complications than those previously diagnosed with diabetes and partially aware of steps needed for treatment.

Formative research indicates that the study findings of Jayashree et. al. are comparable to those conducted in other regions. Mallare et. al. similarly found that incidence of DKA increased as socioeconomic status decreased. While the Mallare et. al. study validates the outcomes of the Jayashree et. al. study, the paper does not utilize RCA as the methodology to determine the causes of process failures.

Jayashree et. al. takes an apt approach to utilizing RCA methodology to identify processes in need of improvement to promote equitable quality in diabetes care. From initiation of the study, the authors decisively aim the papers focus at assessing processes within the referral system that are inhibiting patients presenting with DKA from avoiding death or other severe

complications. Employing direct interviews to chronologically sequence patients' and practices' experiences and procedures regarding the referral systems, the researchers were able to ascertain the root causes of process failures limiting quality diabetes care. The researchers were able to determine that inadequate access to referral systems, costs, and needs extending beyond the capacities of facilities acted as barriers to quality care.

Researchers were unable to provide solutions or next steps for improvement for the root causes that were identified. Identifying root causes of process failures within North India's diabetes referral program validates RCA as a QIP measurement tool. However, it is unclear to as whether RCA is adequate for use in the 'PDSA' cycle based on this study. The methodology of using RCA in this particular study allowed researchers to only 'Plan, Do, and Study;' failing to incorporate guidance on how to proceed to implement further QIPs. Furthermore, researchers concluded that their ability to accurately conduct RCA regarding referrals for patients with diabetes in Northern India was compounded by other stresses and logistics of the existing health system; or factors not pertinent to the scope of the RCA in this study.

This study conducted to identify processes that can improve access to equitable, quality diabetes care demonstrates the overall potential of RCA to be used as a process measure by determining whether processes designed to promote quality do so in an effective manner. It's necessary to note that the outcome of this study, as well as the retrospective nature of the methodology, suggests that RCA may be most aptly used for assessing existing health infrastructures and areas of improvement versus being used to propagate future iterations of the 'PDSA' cycle and new or revised processes to implement quality processes in health care for patients with diabetes.

(Jayashree et al., 2017)

[Applying Six Sigma Process Measures to Diabetes Preventive Care]: *Improving Diabetic Retinopathy Screening Among Patients With Diabetes Mellitus Using the Define, Measure, Analyze, Improve, and Control Process Improvement Methodology*

Kollipara, U., Varghese, S., Mutz, J., Putra, J., Bajaj, P., Mirfakhraee, S., Tessnow, A., Fish, J., & Ali, S. (2020). Improving Diabetic Retinopathy Screening Among Patients With Diabetes Mellitus Using the Define, Measure, Analyze, Improve, and Control Process Improvement Methodology. *Journal for Healthcare Quality*, *43*(2), 126-135. https://doi.org/10.1097/JHQ.0000000000000276

Preventive care represents an opportunity to minimize complications for patients with diabetes. Diabetic retinopathy is one of the most frequently presenting complications for patients with diabetes. The complication, frequently resulting in loss of vision, presents in nearly one-third of patients with diabetes over 40 years of age. Through annual/biennial screenings, the ADA and American College of Ophthalmology expect that 88% of severe diabetic retinopathy cases may be detected and that 87% of cases could be successfully treated. Under this guidance, the risk of blindness associated with diabetic retinopathy is expected to decrease by 56%. At present, biennial exam adherence rates sit between 56%-80% throughout the US.

In an effort to validate the finding that preventive care can enable a reduction of diabetic retinopathy, a large Accountable Care Organization (ACO) in Texas, applied QIPs to stimulate an increase in adherence to the recommended frequency of eye screenings. The ACO's efforts to standardize exam documentation, increase referrals, and ensure timely patient scheduling improved the endocrinology clinic's screening rate for diabetic retinopathy from 49% to 72%. Six sigma methodology was selected for use during the study as the ACO found that the implemented improvement processes allowed for greater use of statistical analysis than

previously experienced. As such, project implementation followed the DMAIC framework below.

Define: all involved staff at the ACO set forth to define a project charter that included timelines, organization charts, and development of improvement methodology aimed to improve screening percentage outcomes by 10-59% over a six-month time period in accordance with a baseline screening percentage of 49%.

Measure: Utilizing the clinic and its ambulatory locations' diabetes registry, the implementation team sought to measure the frequency of preventive care procedures such as retinal or dilated eye examinations for a patient population between ages 18-75.

Analyze: The QIP implementation team used the ACO's diabetes registry to identify areas of improvement to be targeted by the intervention. Analysis of the registry and its current uses yielded a need to strategize improvements in the areas of patient identification, alerting patients in need of an examination, streamlining ophthalmology referrals, consistent EHR documentation, and merging exam results from external providers to the ACO's records.

Improve: The development of process maps guided the strategic overhaul of the ACO's endocrinology workflow to improve the percent of patients with diabetes being seen for annual/biennial eye examinations. The implementation team sought to identify patients in need of an eye exam by reviewing medical records of patients with appointments scheduled no later than two weeks away and by assessing the diabetes registry for patients overdue for an eye exam. Those who were overdue for an eye exam were contacted automatically through the EHR's automatic messaging system. Patients who did not have access to the system or did not respond to the messaging were contacted

directly to assess the recency of their last eye exam. For those patients who responded favorably to the request to schedule an eye exam, a referral was automatically generated in advance of the patient's endocrinology appointment or was discussed at the time of the appointment. Upon arrangement of the referral and completion of the eye exam, EHR documentation was completed using revised and stringent coding procedures. In the instance that the referral for the eye exam was completed outside of the ACO, support staff was trained to conduct outreach to obtain and scan exam results into the ACO EHR network.

Figure 12. Process Map Detailing Formulation of Actions for Improvement

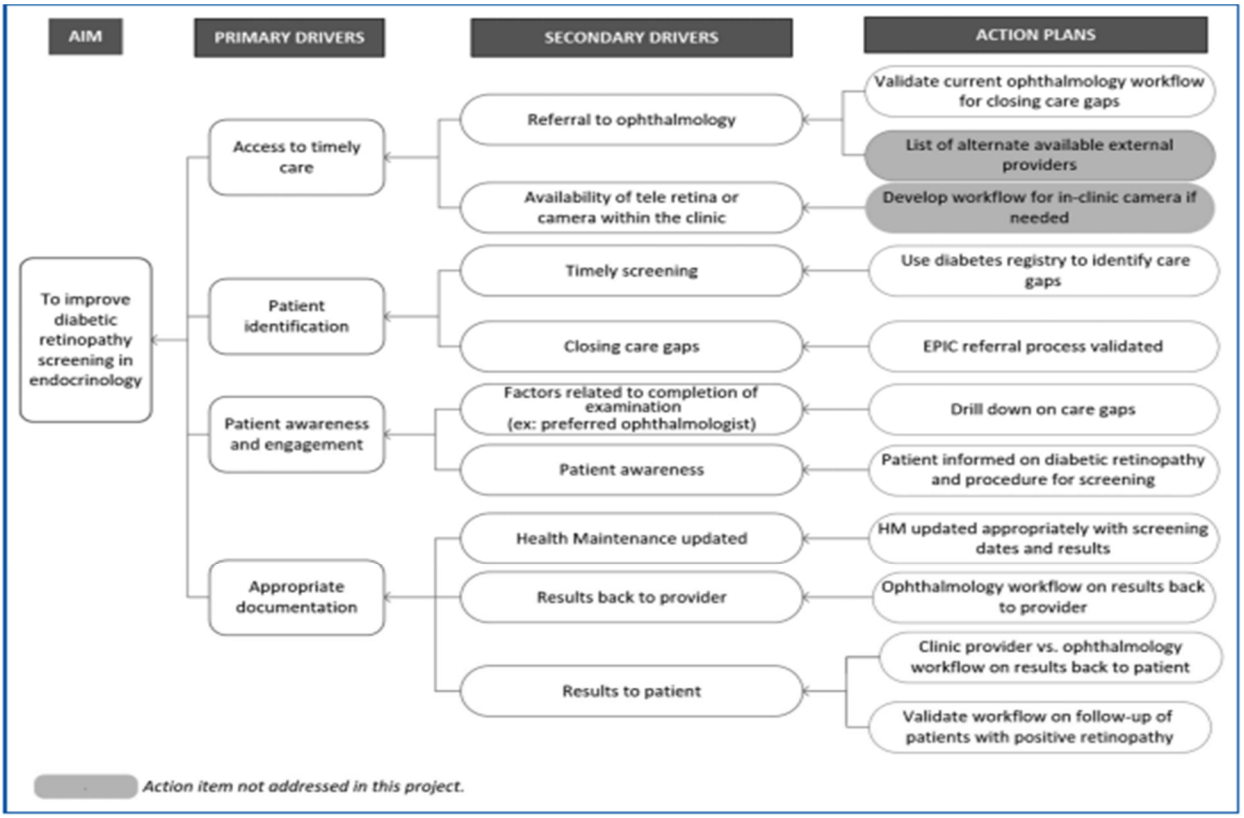


Figure 1. Key drivers for improving retinopathy. HM = Health Maintenance.

(Kollipara et al., 2020)

Control: The study assessed the percentage of patients with diabetes seen within the study timeframe that met the defined and recommended number of eye exams in relation to the ACO's overall number of patients listed on their diabetes registry.

Through the ACO's intervention implemented between January 1, 2018 and December 31, 2019; 4,364 patients engaged with the ADA's/American College of Ophthalmology's recommendation that patients with diabetes be seen for an eye examination annually/biennially. The steps engaged with during the six sigma DMAIC cycle yielded a 20% increase in eye exam screenings from 49% to 69%. Seeking to further augment the rate of screening within the clinic population, intervention implementers engaged in the 'Plan' and 'Do' steps of the 'PDSA' cycle, auditing the intervention and increasing the sustained screening fate to 71.65%. In addition to increasing the screening rates to limit the complications of diabetes and the severity of diabetic retinopathy, the study also found that engaging with the defined QIPs yielded 207 ophthalmology referrals and 37 new-patient visits, during which 81% were found to diabetic retinopathy pathology.

Six sigma methodology was selected for use in this study given past success applying the methodology to diabetes management care. Whereas this study's structure was based on previous successful applications to diabetes care, Kollipara et.al.'s (2020) study is the first to apply QIP to address diabetic retinopathy in a patient population. Previous iterations of QIPs utilizing six sigma methodology have largely concentrated on improving quality and access to care for A1C reduction and blood pressure stabilization.

The implementers of the intervention credit the ability to increase the percent of patients screened annually/biennially for diabetic retinopathy to the six sigma methodology and its

DMAIC framework. Kollipara et. al. identified the ACO's staffs' ability to collaboratively audit, assess, and revise current clinic operations as a key component of identifying processes that would enable more frequent screenings. The interconnectedness of the ACO's departments and the demonstrated proactiveness helped to engage and cement the new screening procedures into practice. The study helped validate the use of six sigma methodology as a sustainable QIP to improve access to quality health care for patients with diabetes given the increased percentage of patients who received annual/biennial exams.

Implemented in a large ACO, where the interconnectedness facilitated the success of implementing six sigma methodology, the study authors do express concern that the level of necessary facilitation may not occur in the absence of an ACO or in health care markets where only small primary care and tertiary care facilities operate. Additionally, while the methodology demonstrated success in achieving greater internal process efficiency to promote quality care, it is necessary to note that factors such as social determinants of health may impact patient ability to utilize QIPs in an appropriate fashion. For instance, in the Kollipara et. al. study, the authors purport that factors outside the actionable scope of the implementation plan, such as financial barriers, may have limited patients' ability to arrange for eye examinations even when patients had been successfully identified, referred, and counseled on the importance of annual/biennial eye exams for patients with diabetes.

Applications to Diabetes Management Care

[Applying Six Sigma Process Measures to Diabetes Management Care]: *Improving Diabetes Control Using Lean Six Sigma Quality Improvement in an Endocrine Clinic in a Large Accountable Care Organization*

Kollipara, U., Rivera-Bernuy, M., Putra, J., Burks, J., Meyer, A., Ferguson, S., Nelson, C., Mutz, J., Mirfakhraee, S., Bajaj, P., Kermani, A., Fish, J. S., Ali, S.; (2017, January 1) Improving Diabetes Control Using Lean Six Sigma Quality Improvement in an Endocrine Clinic in a Large Accountable Care Organization. *Clin Diabetes*; 39 (1): 57–63. https://doi.org/10.2337/cd20-0048

The study describes efforts to reduce the number of patients with poor glycemic control in a tertiary endocrinology clinic at the University of Texas Southwestern Medical Center. Unsatisfactory glycemic levels coupled with the knowledge that patients with infrequent A1C testing have poorer glycemic control, motivated clinical staff to assess clinic workflow processes for A1C[8] testing. Formative research in conjunction with observations conducted within the tertiary endocrinology clinic, led researchers to understand that failure to follow clinical guidelines and treatments for monitoring diabetes acted as barriers to improving glycemic control through A1C measurement (Blonde et al., 2017). Kollipara et al., sought to improve A1C testing, as the American Diabetes Association recommends patients with poorly managed diabetes to have an A1C run quarterly if treatment has changed or if treatment is not being adequately followed, and twice a year for patients adequately meeting treatment goals (ADA, 2019).

[8] A1C is a blood test for patients with prediabetes or type 2 diabetes. An A1C test takes the average blood glucose level for a 3-month time period. A1C measurements can be used to diagnose and to determine how well diabetes is managed. (NIH, 2015)

The study was designed to develop a quality process that would decrease the percentage of the endocrinology clinic's patient population with poor glycemic control from 26.4% in May of 2018 to 22.0% in December of 2019. The study utilized an A1C value greater than 9.0% to delineate poor glycemic control in accordance with ADA standards. Researchers elected to use Six Sigma as the selected QIP methodology due to familiarity and frequent use within the larger University of Texas Southwestern Medical Center. The project was framed utilizing the following DMAIC framework:

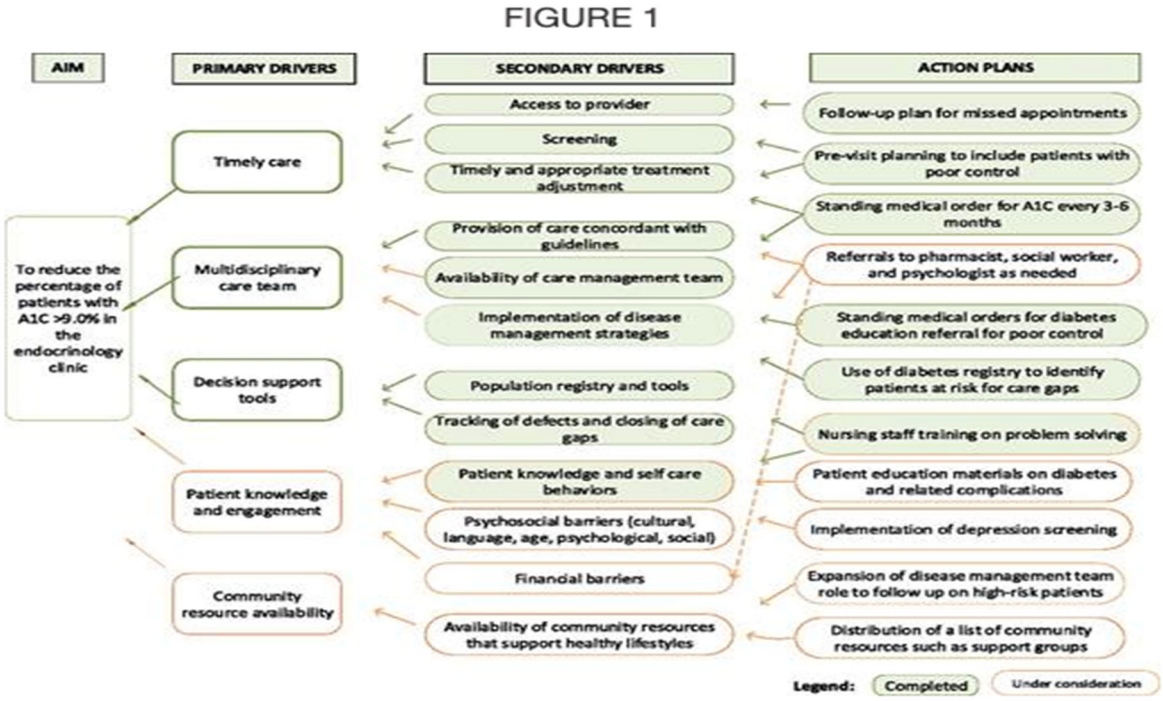
Define: project leaders set forth to incorporate all staff involved with the process of A1C testing to define the aims, stakeholders, timeline, and deliverables.

Measure: The QIP implementation team developed process maps that charted current workflows for processes relating to A1C measurements including pre-visit tasks, patient reminders, protocol for placing lab orders, referral processes, and discharge processes. Patients were included in the study if they were a patient of the clinic, were older than 18 years of age, and had a diabetes diagnosis listed on their problem list or visit summary.

Analyze: The study found that previously A1C tests had only been ordered as needed and were inaccurately reported. During a subjective brainstorming session involving all those working immediately with patients and the A1C process, issues of self-management such as diet and access to medications; and issues of clinical management such as access to appointments & glucometers, and language barriers became potential sources of improvement. In addition to the analysis, researchers also pulled data from patient charts to assess A1C testing frequency and completion of diabetes education visits. Assessment found that of patients with an A1C > 9.0%, 5% of these patients had comorbidities

diagnosed and charted, reported difficulties with self-management or attending appointments, and reported barriers to accessing care. Additionally, data concluded that the average time between scheduled appointments was 169 days and that 50% of clinic patients did not schedule a follow up appointment at the time of discharge from the clinic.

Figure 12. Process Map Developed During Assessment of Barriers to A1C Measurement



(Kollipara et al., 2017)

Improve: Researchers sought to establish new protocols to reduce the number of patients with uncontrolled diabetes as indicated by A1C measurements greater than 9.0%. Researchers implemented 3 initiatives to reduce the percent of the patient population with uncontrolled diabetes.

1. Clinic staff deemed it a requirement to have current A1C values present at time of appointment. When planning patient visits, it was noted in the format of a standing medical order that all patients must have an A1C panel

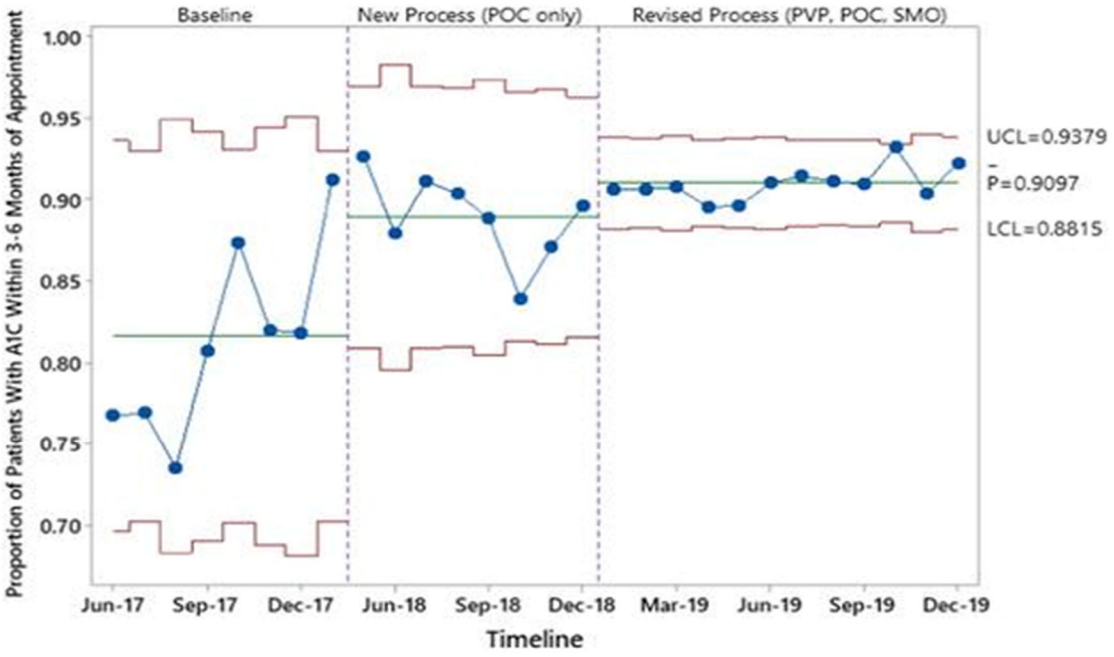
completed during the visit if past A1C values were missing or older than 3 months.

2. If a patient's A1C was greater than 9.0%, a standing medical order initiated a referral to a diabetes education program if there was not a class already pending completion or that had not been completed within the last year.
3. Clinic staff developed a protocol to follow up with patients who missed or cancelled appointments to remind them of the ability to self-schedule appointments and to mail letters as appointment reminders.

Control: Throughout the study, biweekly audits of 10 charts were used to relay process measurement feedback to clinical staff. Utilizing a newly established provider-level performance dashboard, clinic staff were able to assess both the percentage of patients missing A1C values and the percentage with values identified to be poorly controlled.

At the initiation of the study, researchers had found that 26.4% of the clinic's population had A1C values that indicated poor glycemic control. At the conclusion of the study following several mid-point analyses, there was a decrease in A1C values >9.0% from 16.53 to 12.89% indicating an improvement in percent of patients with managed diabetes. The percentage of patients missing A1C values decreased from 9.93 to 3.03%. Additionally, the population's average A1C decreased from 7.6 to 7.41%. with further improvement among patients with poor glycemic control as A1C in this sub-population decreased on average by 1.9%.

Figure 13. SPCC Demonstrating Proportion of Patients with A1C testing 3-6 Months Prior to Appointment



Sigma Z=2.34923, 1.94601, 0.846439. POC-point of care; PVP-pre-visit planning; SMO-standing medical order.

(Kollipara et al., 2017)

The study found that introducing Six Sigma QIP methodology was effective in reducing the percent of endocrinology patients presenting with poor glycemic controlled. Utilizing the DMAIC framework, Kollipara et al. was able to introduce and revise clinic processes to improve diabetes management. Introducing processes to ensure more frequent A1C testing, access to diabetes education, and a reduction in missed appointments improved access to quality, equitable diabetes care. The standardization of practices limited patients' inability to obtain sufficient care related to educational and financial barriers. While the primary outcome of interest was a reduction in the patient population with poor glycemic control, researchers identified

simultaneous improvements in blood pressure measurements, further validating Six Sigma's utility as a QIP applied within the health care industry.

Kollipara et al. commentating on the use of the Six Sigma methodology found it critical to note that the use of the clinic's EHR system facilitated the project and made data collection more feasible. While the availability of an EHR system as a data source may simplify and accelerate data collection during a Six Sigma QIP in health care, the lack of an EHR system should not deter the ability to complete a project for quality processes improvement. Satisfied with the magnitude of improvement resulting from the QIP, Kollipara et al. goes so far as to recommend Six Sigma methodology to be utilized in other applications to quality improvement projects in health care.

(Kollipara et al., 2017)

Application to Diabetes Treatment

[Applying Lean Principles as an Improvement Method to Diabetes Treatment]: *Lean Six Sigma to reduce Medication Errors in hospitals*

Antony, J., Trakulsunti, Y., (2018, June). Lean Six Sigma to reduce Medication Errors in hospitals. *Department of Business Management, Heriot-Watt University*, https://www.researchgate.net/publication/325537553_Lean_Six_Sigma_to_reduce_Medication_Errors_in_hospitals

Errors in medication dispensing is a critical cause of significant medical harm resulting in approximately 7000 deaths globally in a year (Institute of Medicine, 2000). Flaws in processes to prescribe, transcribe, dispense, and administer all contribute to inadequate measures to ensure patient safety. While patient safety is a primary outcome of concern with medication dispensing errors, it is critical to note that secondary outcomes include increased health care expenditures amounting to $42 billion annually, equivalent to 1% of global health care expenditure.

In a literature review, Antony & Trakulsunti evaluate Lean methodology as a QIP to reduce errors made during medication dispensing processes to combat the negative health and financial outcomes of the errors. The review begins by promoting Lean as the appropriate QIP for the scenario due to it being lauded worldwide for the ability reduce costs, provide quality health services to patients, and be easily employed by health providers and health systems. Though demonstrating promising outcomes across health systems, Lean is a relatively new process that is only first beginning to be applied to the health industry. Of implemented Lean initiatives in health care, 57% have occurred in the US, 29% in the UK, 5% in in Australia, and 9% internationally. Authors founds that Lean has been applied to reduce missing doses in a

hospital's inpatient pharmacy which subsequently reduced excessive labor expenses and further reduced pharmacy expenditure by reducing errors and missed doses. The study referenced did not contribute to an understanding of how reducing errors in pharmacy errors subsidized reduction in adverse patient safety events or death.

Lean's ability to reduce medication errors largely results from workflow improvement, reduction of waste, and improvement of the physical locations in which medications are stored. For instance, in the example of Lean implemented in an inpatient pharmacy's sterile product area, the use of Lean principles helped to reduce mis-labeling of products by 83%, subsequently reducing the number of missed doses from 53 to 13.8 doses a day (Hintzen et al., 2009).

While Lean principles demonstrate feasibility in implementation, the adoption of Lean methodology may be met with resistance by management, practitioners, and administration as a result of lacking understanding of the significance of the new changes, fear of the unknown, and variation from routine. Heavy consideration must be placed into the decision of which Lean implementation strategies to utilize during process revision in order to assist with the transition to the new process and reduce the likelihood of workplace resistance. (Antony & Trakulsunti, 2018)

Figure 14. Table Identifying Lean Principles to be Used to Reduce Medication Errors

Table2: Lean tools used to reduce medication errors.

Improve medication flow	Identify causes	Eliminate non-value added activities and waste	Identify what customer needs
Value stream mapping Spaghetti diagram Process mapping Process observation	Cause and effect analysis 5 why root cause analysis	5S Visual process control Poka-yoke Two-Bin replenishment system Work cell optimization Computing minimum safe batch sizes Kanban Standard operating procedure	Voice of customer (VOC)

(Antony & Trakulsunti, 2018)

Lean principles are most appropriate for use in scenarios such as reducing errors in medication dispensing in which process changes can easily be implemented into the work place to provide near instantaneous improvement. Lean implementation therefore requires an innate understanding of the working environment, and thus necessitates full compliance in adopting the Lean methodology. In the absence of full support of management, practitioners, stakeholders, etc. Lean methodology will be unsuccessful as the identification of visual process controls, elimination of the 8 Wastes, and other tools such as process mapping will be rendered inefficient if completed by an implementation operating outside of their normal work environment.

The implementation of Lean methodology to reduce errors in medication dispensing assists in the validation of Lean as a QIP method to improve pharmaceutical dispensing and treatment for disease and chronic illness. While Antony & Trakulsunti exemplify use in an inpatient pharmacy, Lean methodology demonstrates potential to be applied to pharmaceuticals used in diabetic care and management.

(Antony & Trakulsunti, 2018)

[Applying Lean Principles as an Improvement Method to Diabetes Treatment]: *Quality Improvement in Diabetes Care: A Review of Initiatives an Outcomes in the T1D Exchange Quality Improvement Collaborative*

Ginnard, O., Alonso, G. T., Corathers, S. D., Demeterco-Berggren, C., Golden, L. H., Miyazaki, B. T., Nelson, G., Ospelt, E., Ebekozien, O., Lee, J. M., Obrynba, K. S., & DeSalvo, D. J. (2021). Quality Improvement in Diabetes Care: A Review of Initiatives and Outcomes in the T1D Exchange Quality Improvement Collaborative. *Clinical diabetes: a publication of the American Diabetes Association*, *39*(3), 256–263. https://doi.org/10.2337/cd21-0029

The use of pharmacologic agents such as insulin glargine is a widely accepted component of diabetes management and treatment for the nearly 1.6 million Americans diagnosed with Type 1 diabetes. Despite the availability of insulin, the ability for only 17% of youth and 21% of adults to reach appropriate A1C levels supports the theory that substantial gaps in care delivery and health system design inhibit patient access to treatment options. In an effort to minimize the discrepancies in expected clinical outcomes and actual outcomes, Ginnard et. al. conducted a systematic review of QIP interventions to identify impactful actions and initiatives, that could improve access to insulin and reduce psychological burden of a diabetes diagnosis. It was expected that improving access would yield a higher degree of health quality for all patients.

The identification of The Chronic Care Model (CCM) was the byproduct of researcher's participation in the IHI's Breakthrough Series[9] and utilization of the 'PDSA' QIP cycle. The CCM stressed that the integration of interventions supporting self-management practices, health system design, health decision guidance, and improved clinical information systems were more

[9] The IHI Breakthrough Series is a program sponsored by the IHI to engage healthcare leaders and practitioners in engaging with QIPs within their respective health settings to address one health or operations outcome. After a program defined time period, participants regroup to assess shortcomings and advancements made at an individual level prior to receiving feedback and recommendations from peers (IHI, 2003)

likely to yield a greater percentage of patients with diabetes who had the informed decision-making skills, access to resources, and understanding of the health systems components. The CCM and its subsequent T1D Exchange Quality Improvement Collaborative (T1D EQIC) presented the opportunity for implementers to apply initiatives previously used for Type 2 diabetes management (regulation of A1C levels), inflammatory bowel disease, and cystic fibrosis to Type 1 diabetes treatments.

The study occurred across the Nationwide Children's Hospital (NCH) network as a result of the development of the T1D EQIC. Quality improvement staff across facilities composed guidelines for the optimal delivery of diabetes care at the recommendation of organizations such as the ADA and International Society for Pediatric and Adolescent Diabetes. Under the developed guidelines, QI implementers were to assess nine outcome measures that would be available through the NCH network's EHR system. The selected outcomes were thought best to provide accurate insights into patients' ability to conduct glucose monitoring, manage insulin administration, and access patient-centered, clinical, and psychosocial care. Charted patient outcomes were scored against standards set forth by clinic staff after reviewing the guidelines for optimal diabetes care delivery. This analysis resulted in the formulation of two metrics that embody iterative nature of the 'PDSA' cycle.

Metric one: Type 1 Diabetes Care Index (T1DCI)

T1DCI was developed with oversight from the NCH network's QI implementation team to identify gaps in their standard of care and standard operating procedures. The metric further aimed to identify deviations from the provision of optimal care. Identified gaps were used to hone QIPs within the

hospital network exemplifying the ‘Study’ and ‘Act’ components of the ‘PDSA’ cycle.

Metric two: Type 1 Diabetes Composite Score (T1DCS)

T1DCS was developed as an aggregate score assessing nine clinical health outcomes. The health outcomes aggregate score was to be used as indicator of patients’ overall health. Each of the nine health outcomes were scored against the optimal guidelines for diabetes care and management identified for use by the implementation team. The highest of scores indicated that a health outcome such as a patient’s A1C was within range of the optimal care delivery performance according to the guidelines. Lower scores indicated that patients were not receiving the expected and desired levels of care.

Five clinics within the NCH network were selected to be in the study due to a high percentage of patients being seen for treatment for T1D. Conducting an assessment to inform best practices for data collection, the study saw the T1DCI score increase by 26 percentage points. The increase was attributed to a 91% increase in data collection following newly implemented QIPs. Following the improved T1DCI metric, the T1DCS metric further validated the use of the methodology upon a shift in metric score indicating an unspecified percent increase.

Utilizing the promising results demonstrated by the uptick in metric scores, treatment centers were selected to pilot initiatives that would further validate the use of the T1D EQIC initiatives. One such initiative involved the use of lean methodology to identify sources of inefficient clinic operations, thus diminishing clinics’ ability to reach optimal standards of care.

The initiative aimed to improve the usage of continuous glucose monitors (CGM) and insulin pumps among patients aged 12-26 years of age. CGMs with insulin pumps are frequently a preferred monitoring and treatment plan due their ability to improve glycemic levels in a passive manner. Lean principles applied within the clinic settings identified revamped and streamlined support roles to be an intervention that would assist in augmenting use of CGMs and insulin pumps. Eight of 10 clinic centers found CGM and insulin pump usage rates to increase by 12% after 20 months, following the hiring of staff to support patient navigation of insulin-dispensing options, insurance coverage, and device trainings.

Overall, Ginnard et. al. successfully managed to augment access to care through a series of improvement initiatives. Through the development of the T1DCI metric, the T1DCS metric, and study of CGM/insulin pump use; the implementers were able to assess QIPs as a valid approach to improving access to diabetes treatment and thus improving diabetic health outcomes. While implementers did not select a specific QIP to initiate changes in the care settings, it is beneficial to note that principles of lean appeared to frequently inform the decision-making process as the implementers worked through the 'PDSA' cycle.

The multi-modal approach taken by Ginnard et. al. throughout this literature review and review of implemented initiative suggests a degree of unfamiliarity or lacking confidence with QIP implementation. Further familiarization with the methodology in anticipation of initiative implementation may have garnered more profound clinical outcome improvements or a greater degree of provided analysis on how the use of QIP applied to T1D was successful/unsuccessful. It would have been prudent for the implementation team to select one specific QIP methodology to assess throughout the study. However, given the near inexistence of formative research

assessing QIPs applied to T1D treatment, it is not unreasonable for the researchers to have attempted to analyze several QIPs within the study.

Generally, the implementers achieved a degree of success through implementation of select QIPs. However, the success achieved did not seem to fall within the initial scope of the study. Whereas the background presented in the study addressed both clinical practices and social determinants of health as barriers to achieving optimal delivery of diabetes care, the implemented initiatives were largely clinically centered and did not work to challenge failures in care delivery outside the clinical setting. Ginnard et.al. attributes the partial undertaking of the scope to the lack of a gold standard when assessing QIPs in use with care management practices for patients with diabetes. Furthermore, the study's conclusion implies that the intervention implementation teams' assessment of how to address SDOH was met with unforeseen challenges that exceeded initial expectations and would need to be reviewed for future QIP implementation projects.

Given the absence of directionality within this study, it would be recommended for future iterations of the project to select a clearly defined QIP to begin the implementation process. Furthermore, a clearly delineated scope would be pertinent to achieving successful implementation regardless of the selected QIP. An additional application of the researcher's methodology that could be of interest would be to examine clinical outcomes of optimal diabetes care delivery in relation to the prescribing of insulin and other pharmacological diabetes treatments.

Discussion

Despite the abundance of literature regarding diabetes prevalence, prevention, complexity, and treatments, there is minimal published research detailing the efforts of projects implementing QIPs within the sphere of diabetes care. In order to prevent administrators, providers, health organizations, quality improvement implementation teams, and patients from being discouraged from implementing QIPs as a method of enabling superior care, it is critical to provide an understanding to as why there is a deficiency in published literature on the subject matter. One of the foremost considerations is the innovative nature of the application of QIPs to diabetes care. While history and advancements made across all fields are the result of progress, the formal act of reviewing a process to assess capacity and best practices to generate improvement were only solidified by Deming and Donabedian in the mid-twentieth century. Early uses of the formalized approach began in production industry with Toyota manufacturing prior to adoption by the IHI for applications to healthcare in the early 1990's. The recent acceptance of QIPS as common practice to advance healthcare access has thus, only begun to be explored. To this point, primary applications of QIPs in healthcare have largely been associated with improvements in patient safety, enforcement of hand hygiene protocols, and development of referral programs. Though applications have only begun to tackle disease specific access, quality, and outcome improvements; existing studies show promise for successful application of forthcoming QIPs to enable access to quality, and equitable care.

Furthermore, the inherent nature of improvement processes causes many QIP efforts to go unrecognized as a fortified effort to introduce change. Implementers who intentionally introduce changes to the work environment or healthcare setting may see improvement opportunities in day-to-day operations and therefore diminishing the likelihood of publishing

studies or the results of intentional QIP implementation. Additionally, regularly implemented QIPs may be seen as an internal function or operation. In such settings, recognition of an organization's ability to improve, may also be seen as recognitions of internal failures. The subsequent internalization of QIP implementation has likely resulted in an abundance of completed QIPs in health settings to have never been published. It is likely that the available data, studies, and other publications regarding QIPs applied to healthcare and diabetes care/treatment are only a sample of implemented QIP initiatives that have been successfully implemented (Ginnard et. al., 2021).

Taking the above considerations into advisement, the literature review is a rather complete and all-encompassing representation of what literature detailing the intersection of QIP implementation and diabetes care has been published were excluded if they failed to express interest in examining the intersection of QIPs and diabetes care. Publications assessed and included in the literature began no earlier than 2012 for a lack of previously completed, appropriate studies. The novelty of publications in the field further elucidates the lack of formative research and justifies the necessity to address gaps in access to quality, equitable care for patients with diabetes through the implementation of QIPs. The dearth of recently conducted QIP interventions in health settings caring for patients with diabetes serves to validate the methodology and its successes to other practitioners, implementers, and patients.

Across implemented QIPs pertaining to diabetes care, the fulfilled interventions demonstrated a variety of impact for various stakeholders. One of the most defined impacts demonstrated throughout the studies, is the ability for QIPs to positively impact clinical outcomes. Studies found that the introduction of a QIP led to patients meeting guidelines for the management of diabetes set forth by the ADA and other professional health

associations/regulatory bodies. For instance, in the Kollipara et. al. study, implementers found that within a large ACO, patients experienced an average decrease in their A1C levels by 1.9% following the implementation of QIPs than enabled a greater percentage of patients to meet A1C testing frequency expectations. Similarly, other studies were demonstrative of patient impact as they were able to improve outcomes such as A1C, reduce blood pressure, patient weight, and others indicative of a patient with diabetes overall health. While the intent of the literature review was to assess QIP applied to preventive medicine, management, and treatment as related to diabetes, the vast majority of literature assessed ability to initiate progress for patients' access to quality, equitable care through clinical outcomes traditionally defined as measures of management for diabetes. The ability for patients to passively partake in the QIPs examined helps to facilitate patient participation and subsequent increases to their personal health quality. The majority of the reviewed studies operated on the assumptions that patients were willing to accept the changes to care plans arranged by implementation teams and that willing patients did not face unknown barriers limiting access to care.

Barriers to access to care was one component that all reviewed studies failed to account for during QIP design. Though implementation teams sought to address social determinants of health and other barriers to quality, equitable care; efforts to adopt equitable improvement processes remained largely unincorporated throughout studies' methodologies. Efforts to address equity were identified in project scopes, but were largely unintegrated into the improvement processes. In some studies that sought to address equitable access, the failure to do so was accounted for in concluding remarks. Ginnard et. al.'s statement regarding equity implied that the implementation team was met with unforeseen challenges such as conditions that inhibited patients' ability to adhere to the QIP intervention. One study alluded to financial constraints as a

factor diminishing QIPs ability to enable access to quality, equitable diabetes care. Kollipara et.al. insinuated that despite an ACO's ability to promote and engaged with enhanced A1C testing practices, patients may face constraints from insurers on the number of screenings permitted to be covered within a specified timeframe. Additional studies similarly echoed sentiments that the impact of QIPs was diminished by extraneous factors not under the immediate control of the care implementation team.

Overall, implementation teams orchestrating QIPs into their respective health systems seemed impressed with the impact QIP interventions were able to facilitate on patients' clinical outcomes pertaining to prevention, management, and treatment of their diabetes. Nearly all studies expressed interest in continuing the efforts of the implemented QIP intervention to further improve resulting clinical outcomes or target additional outcomes and measures of patient care. The implementation team's interest to pursue future QIP efforts suggests a comprehensive understanding of the iterative nature of the 'PDSA' cycle. However, implementers frequent inability to differentiate between and specify a QIP methodology for use suggests that implementers are not well-versed with varying QIP methodologies. This implies that competencies in QIPs lie primarily within comprehension and implementation of the 'PDSA' cycle. Improved comprehension of the QIPs reviewed throughout this literature assessment may enable implementers to select a specified QIP methodology and refine future iterations of QIP interventions. In addition to interventions targeting quality and equitable access to diabetes care, implementation teams concurrently recommend QIP as a valid method for promulgating progress throughout various sectors of healthcare.

Solutions Manual for Quality Improvement Process Implementation

Introduction

QIPs demonstrate the ability to facilitate access to quality care for patients with diabetes. Under the assumption that improved access to quality care is demonstrated by an improvement of health outcomes mirroring or aligning with the recommendations and standards set forth by subject matter experts; the application of QIPs yields access to quality healthcare in regard to the prevention, management, and treatment of diabetes. While data provides ample support for the use of QIP in regard to improved access to quality care for patients with diabetes; existing data and literature are too sparse to endorse the use of QIPs for developing access to equitable care for patients with diabetes with hopes of yielding an immediate impact.

For this reason, the extent of this solutions manual is developed to provide basic instruction for QIP implementation to healthcare providers/organizations and implementers seeking to utilize QIPs to improve access to quality care in respect to outcomes in diabetes prevention, management, and treatment. Though the scope of this solutions manual will not facilitate implementation of QIPs designed to improve access to equitable care for patients with diabetes, the manual wishes to encourage implementers to invest in and challenge the future of the QIP methodology by engaging in efforts to develop and use QIPs to facilitate access to equitable care.

This solutions manual will recommend best practices for implementers to reference when aiming to improve clinical outcomes for patients with diabetes through the use of a QIP intervention. Best practices will make recommendations for determining the motivations for the QIP, evaluating the aims of the ‘PDSA’ cycle, determining which QIP methodology to engage with in practice, and how to determine if further cycle iterations are warranted or desired.

Recommendations for best practices will be generated with consideration to implementing organization's practice size (ACO, hospital system, private practice, etc.,) identified aims, and selected methodologies.

Best Practices

QIP Motivations

Prior to improvement process implementation it is critical to assess factors motivating the project and the intended outcomes or changes desired to result from project implementation. As pertaining to the improvement of access to quality care for patients with diabetes, its recommended that clinicians, providers, or implementers establish baseline metrics for clinical outcomes such as A1C levels, frequency of referrals, mean blood pressure values, etc. Once baseline metrics are established, implementers should identify unsatisfactory metrics to improve upon. An unsatisfactory metric may be one that's baseline values are not up to standards set forth by subject matter experts or that implementers believe could be further improved for the greater health and well-being of patients. For example, Kollipara et. al., took to developing a QIP project surrounding improving the frequency of diabetic retinopathy screenings as it was determined that the rate of screening at the Texas ACO was did not meet the standards recommended by the American College of Ophthalmology.

Establishing the 'PDSA' Cycle

Implementers seeking to engage with the 'PDSA' cycle to induce changes impacting access to quality care for patients with diabetes should first seek to establish a plan for implementation. Establishing a plan for action, implementers must first decide what metric or

clinical outcome indicator should be the focus of the QIP. The aims of the implemented action plan should be those that are proportional to the implementer's organizational capacity and resource availability. The chosen aims should be based on a clinical outcome that is likely to yield significant changes in health outcomes for a few patients or may yield minor changes in health outcomes, but impact a larger patient population.

It is recommended that to achieve such impact, implementers should utilize the *SMART* goal framework to establish feasible expectations of the QIP. The *SMART* goal framework develops goals that are:

Specific: desired outcomes are clearly defined and definitive.

Measurable: desired outcomes are demonstrative of impactful change that can be validated through developed metrics.

Achievable: the scope of the project is designed with feasibility and organization capacity in mind.

Relevant: the outcomes or goals are oriented to the implementing organization's overall mission and values.

Time-bound: project goals incorporate a timeline for when goals are expected to have been met.

The application of the framework establishes attainable goals that may be monitored and evaluated to determine if a QIP approach is appropriate for garnering desired outcomes. Furthermore, the approach is designed to be easily comprehended and practiced by both novel and experience project implementation teams.

Enacting Upon the 'PDSA' Cycle

Following and carefully adhering to the framework may increase implementers' ability to timely conduct the QIP and subsequent evaluation. The *SMART* goal framework may prevent the course of the QIP from straying from the project's original intentions. Time and effort taken by project implementers to draft *SMART* goals should be considered a value-added activity that can increase the utility of the 'PDSA' cycle and reduce the number of cycle iterations needed to accomplish the overall aims of the QIP.

Studying the Implemented

While the *SMART* framework is not necessarily designed to guide project evaluation, the project outcomes may be validated against the *SMART* goals to assess a baseline level of project success. Though initial validation may be deemed sufficient in determining project success, true engagement with the concept of QIPs would engage a QIP methodology described above to substantiate the 'PDSA' cycle. At large, the QIP methodologies enable the identification of deviation between the attained outcomes and the expected outcomes post QIP implementation. Found deviation should be used to encourage further iterations and revisions of the 'PDSA' cycle until the QIP has been optimized and desired project outcomes have been produced.

The process of selecting a QIP methodology should be done with consideration to the process implemented and the types of outcomes desired. While A3 Problem Solving, Lean, and Six Sigma methodologies are effective tools to discern deviation and room for improvement, variations between the methodologies may be more effective in promulgating change depending on the specifications of a QIP project. Implementers should carefully regard the merits of each QIP methodology prior to beginning the QIP implementation project. Below, the varying QIP

methodologies are associated with project characteristics that when paired, would be expected to promote the overall aims of the QIP project. These recommendations are made with respect to the comprehensive review of the existing QIP literature detailing past applications to the prevention, management, and treatment of diabetes care. Given the individuality required by QIP interventions, these recommendations should be considered guidelines and to promote effective process design should not be definitively followed in all scenarios.

A3 Problem Solving

Is recommended and successful in scenarios where:

- The methodology is implemented within smaller healthcare settings. Small healthcare settings may be considered a private health practice, locally operated physician/care groups, or small practices.
- Project aims are oriented towards inducing change in access to quality care for patients with diabetes through sustainable actions that may be implemented on a daily basis. A3 is best for yielding immediate changes, however, to see significant impact, implementers should expect to engage with the methodology for an extended period of time.
- The actionable plan is designed to be implemented on a daily basis enabling the plan phase of the 'PDSA' cycle to rapidly evolve.
- The implementers are well versed and familiarized with the day-to-day operations of the healthcare organization, as the collective input from all staff drives successful implementation of daily action or revisions to the plan.
- The healthcare organization is financially challenged or has limited resources.

Is not recommended in scenarios where:

- Healthcare organization staff does not have the bandwidth to support the QIP process.
- The healthcare organization is expected to report metrics to another party or is managed by another party.

Is applicable to clinical outcomes such as:

- Those primarily related to preventive care.
- Appointment scheduling processes.
- Establishing patient counseling services.
- Prescribing practices of medications used to treat diabetes.
- Etc.

Lean

Is recommended and successful in scenarios where:

- The healthcare organization is of a sizable proportion such as larger physician networks, hospital systems, accountable care organizations, managed care organizations, etc. As Lean is designed to make revisions to processes within the *gemba* or work flow environment, organizations with largely established policies and procedures are ideal sites for identifying and revising processes that drive wasteful practices within care for diabetes.
- Projected aims of the project are designed to reduce wasteful practices and streamline processes granting access to quality care for patients with diabetes.
- A metric has been specified in the *SMART* goal and continuity of the project is not expected beyond achieving the metric set forth.
- Organizations have the personnel or resources to hire to conduct process analysis and identify any of the *8 Types of Waste*.
- The intended implementation team is well versed in The House of Lean methodology as well as diabetes care.
- The setting is large enough to where it may be feasible to implement a control and intervention group to compare impact.
- Settings in which resources are limited, as Lean aims to reduce the number of processes involved in care, thus not requiring additional resources.

Is not recommended in scenarios where:

- Standardization of care is not consistent.
- Policies and procedures are not well established.
- Bureaucratic processes inhibit autonomous action and calls for change implementation.

Is applicable to clinical outcomes such as:

- Those relating to the treatment of diabetes mellitus.
- Effective time to diagnose or treat diabetes.
- Reducing erroring in medication prescribing or general patient care.
- Etc.

Six Sigma

Is recommended and successful in scenarios where:

- Small to large healthcare organizations that have the capacity to systematically identify and record clinical outcomes.
- Clinical outcome data is quantitative in nature and lends to the feasibility of completing quantitative analysis. The defined project goals have utilized a baseline clinical metric and aspire to an improved metric or one that more closely aligns to the expectations and recommendations set forth by subject matter experts.
- System defects have been detected, but require further analysis to assess process aspects contributing to diminished quality of care.
- The outcomes of analysis are likely to be released to or are published for the benefit of a third-party audience or enterprise. For example, if results of statistical analysis are published and released and utilized to influence the outcome of a contract negotiation or grant awarding.
- If a healthcare organization or implementation team has access to or includes an individual trained and capable of completing Six Sigma statistical analysis.

Is not recommended in scenarios where:

- Healthcare organizations do not have access to an individual capable of completing advanced statistical analysis.

Is applicable to clinical outcomes such as:

- Those related to the management of diabetes mellitus.
- Processes contributing to the reduction of A1C values.
- Blood pressure.
- Etc.

Accepting the Iterative Nature of the 'PDSA' Cycle

Following the implementation of the above QIP methodologies, it should be expected and is encouraged for project implementers to utilize inherent failures, lapses in expectations, and gaps in improvement outcomes, found through use of the QIP methodologies, to induce further iterations of the designed quality improvement process. Addressing the differences in projected and actual outcomes, QIPs may aim to:

- *Revise the QIP's process design to assess sources of error that inhibited success in the previous iteration to engage with the initial goal and become closer to success.*

  Example: Project sets forth a goal of lowering a clinic's average A1C values from 9.1 to 7.0 over 1-year by flagging patients not seen within the last year. After implementation the average A1C is only brought down to 8.9. The implementation team revises the project design to flag patients not seen *within the last 6 months. The new iteration reduced average A1C to 7.5, closer to the desired clinical outcome.*

- *Revise the QIP after the initial iteration demonstrated significant promise to induce change and thus the process is effective and could be altered to fit to a different desired outcome.*

  Example: A project sets forth a goal of lowering a clinic's average A1C values from 9.1 to 7.0 over 1-year by flagging patients not seen within the last year. After QIP implementation the average A1C is only brought down to 7.0. The implementation team chooses to revise the project design to apply it to blood pressure screenings to stabilize the patient population's overall blood pressure level.

Summary

This solutions manual aims to facilitate access to quality care for patients with diabetes by providing summative guidance for the development of QIP project implementation. Though summative in nature, it should not be considered and exhaustive list of recommendations for best practices in applying QIPs to diabetes care prevention, management, and treatment. While the recommendations suggest that a QIP may be best aligned to one of the three areas for the caring of diabetes mellitus, project implementers should not be limited to the recommendations made in the manual.

The manual was predominantly constructed with the intentions of influencing access to quality healthcare for patients with diabetes based on the formal review of methodology and existing literature. However, project implementers are encouraged to construe the recommendations such that they may be expanded upon beyond the suggested clinical outcomes for diabetes and adopted to other applications of healthcare. Though QIPs require a degree of skill depending on the methodology employed; the creative margin, general adaptability, and lack of significant resources required for implementation implore healthcare organizations and implementers to utilize QIPs as a mechanism for positively impacting access to quality healthcare for patients with diabetes.

Implications

The promising results of applying QIPs to healthcare demonstrates a potential upon which has not been fully capitalized. The novelty of the methodology implores the need for further exploration into its uses, impacts, and applicability. As previously indicated, prior applications within healthcare have largely centered around measures taken to augment patient safety standards, hand hygiene protocols, and the development of referral programs. Formative work in the prevention, management, and treatment of diabetes suggests further applicability to the clinical outcomes of diabetes as well as additional chronic illnesses. The longevity of chronic illness uniquely situates chronic illnesses for further, expansive investigations into the utilization and effectiveness of QIPs. The prevalence and treatment paths of chronic illness plays into the iterative nature of the 'PDSA' cycle, enabling continuity in explorative implementation of QIPs. Continuous investigation of the use of QIPs in healthcare, can lead to the development of standard operating procedures for establishing quality healthcare for specific chronic illnesses. Though the longevity of disease may enable the publication of novel studies, interventions conducted to assess QIP impact on chronic disease may subsequently find a diminished return in impact due to unforeseen or uncontrollable factors often associated with chronic disease. For instance, if a study was to be conducted assessing the use of QIPs on heart disease; a QIP aiming to improve clinical outcomes may be unable to control for factors such as genetic predispositions to heart disease, factors that inhibit patients' ability to exercise, or social determinants of health that would influence clinical outcomes.

Though the example of chronic disease highlights the limitations and unpredictability that may be associated with further work with QIPs, it indicates the expansive potential that QIPs

have not only across industries, but within various healthcare fields as well. The scope of QIPs is limitless with no objective project goal too large or too small.

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