Introduction

The past fifty years have seen unprecedented medical progress, with new procedures and medicines available for most of the common causes of morbidity and mortality worldwide. However, despite this progress, it is widely acknowledged that the U.S. health care system delivers suboptimal quality. Much of the evidence for what works is slow to be implemented in practice. At the same time, costs continue to rise with substantial variation by region in the total cost of care and use of resources. Health disparities remain despite improvements in insurance coverage and access to care ushered in by the Affordable Care Act (ACA).

With its groundbreaking report “To Err is Human,” the Institute of Medicine (IOM) brought these deficiencies to light in 1999. This report, and the subsequent publication “Crossing the Quality Chasm,” led to a range of efforts to address these deficiencies through improved safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of health care delivery. In 2007, the Institute for Healthcare Improvement (IHI) defined an ambitious agenda for health care quality improvement, known as the Triple Aim, focused on three specific goals: improving patient experience; improving health of populations; and reducing per capita costs.

Quality in Primary Care

Primary care is an essential element of the health care delivery system and has a key role to play in improving quality and achieving the Triple Aim. Many view primary care as the foundation upon which to build a more effective and efficient delivery system while improving
health outcomes and reducing cost\textsuperscript{4,8}. With its emphasis on first contact care that is coordinated, continuous, and patient-centered, primary care is a logical place to focus improvement efforts and to seek solutions to many of the deficiencies of the current system.

However, gaps between evidence and practice are as pronounced in primary care as they are in other health care delivery settings. Studies have found that in ambulatory care, adult patients receive evidence-based, guideline-recommended care only 55 percent of the time\textsuperscript{6} and 47 percent of the time for children\textsuperscript{7}. In addition, screening rates for common conditions continue to be low, and outcomes are poor for treatable chronic illnesses such as hypertension, coronary artery disease, and diabetes.

Efforts to improve primary care delivery have recently focused on the Patient Centered Medical Home (PCMH) model with its emphasis on systems transformation to improve patient experience and embed evidence-based, team-based care in the ambulatory setting\textsuperscript{8}. While some preliminary evidence suggests the potential for this model to improve quality\textsuperscript{9}, results have been modest and uptake of the model has been slow\textsuperscript{10}.

The imperative to embrace change in primary care has been brought about by an explosion in the field of health information technology (HIT) combined with new payment models, integration and consolidation among large-scale delivery systems, and increasing emphasis on accountable care and value. However, primary care faces particular challenges in improving quality. Most primary care is still delivered in small practices of two or fewer physicians\textsuperscript{11}. Unlike hospitals and large delivery systems, these practices often lack the resources and expertise to take on complex systems transformation and adopt new, collaborative, HIT-enabled practice models. Few primary care physicians take part in formal quality improvement training\textsuperscript{12} despite the fact that primary care practices are increasingly being called upon to make significant reforms such as becoming more patient-centered, improving care coordination, integrating with behavioral health care, adopting health information technology tools and electronic health records, implementing evidence-based care processes, and embracing new payment models centered on value. Against this backdrop, it is no surprise that primary care providers feel caught in a whirlwind of competing initiatives, incentives, and opportunities, while struggling to meet their patients’ day-to-day needs.

**Improvement Science**

Given the complexity of the current health care environment and scope of change needed, new approaches are essential. As stated in Crossing the Quality Chasm over a decade ago, “Trying harder will not work.”\textsuperscript{2} The IOM has recently noted the need for care delivery organizations to apply systems engineering tools and process improvement methods to improve operations and care delivery processes\textsuperscript{13}. Formal quality improvement approaches are needed to help practices adopt new processes and adapt to them to their local contexts. While such approaches are increasingly being applied in hospital settings and within large delivery systems, few primary care practices, particularly smaller practices, are engaged in formal quality improvement work\textsuperscript{14}. For primary care to play a key role in achieving the Triple Aim, a robust quality improvement approach is required, capable of engaging practices of different sizes and staff compositions, and supporting them through the change process.
The scientific approach to quality improvement, pioneered by the work of Shewhard, Demming, and Juran, has been effectively applied across a wide range of industries, resulting in greater efficiency and quality in areas from car manufacturing to delivery of financial services. Over the past two decades increasing attempts have been made to adopt these types of quality improvement strategies for health care. How can these strategies be applied more broadly to improve outcomes at the delivery system level? The widely publicized work of the Veterans Health Administration (VHA) strongly suggests that they can be.

Led by Ken Kizer in the late 1990s, the VHA’s sustained focus and the broad application of quality improvement tools have resulted in substantial improvements in a range of outcomes, leading some to identify the VA health system as among the best in the country\(^\text{15}\). Similar efforts in other settings such as Geisinger Healthplan\(^\text{16}\), HealthPartners\(^\text{17}\), and Virginia Mason Hospital\(^\text{18}\), further demonstrate the potential for sustained, system-wide improvements in efficiency, safety, and quality.

Choosing which improvement method to apply to the health care setting has become more challenging. An increasing number of approaches has been described such as Total Quality Management (TQM), Continuous Quality Improvement (CQI), IHI’s Model for Improvement, Lean, and Six Sigma. These approaches differ in many ways. TQM and CQI emphasize systems, data, and an ongoing, integrated approach to identifying and preventing quality problems over time. Lean, with its focus on eliminating waste and engaging all members of a team or unit, has inherent appeal in the health care setting. Six Sigma is grounded in statistical process controls and using data to drive improvement by eliminating defects.

IHI’s Model for Improvement has been widely applied to health care\(^\text{19}\), most prominently in the Bureau of Primary Healthcare-funded Health Disparities Collaboratives (HDC), a multi-year initiative that engaged over 915 Federally Qualified Health Centers (FQHCs) to improve chronic disease and other outcomes while reducing disparities for medically underserved populations\(^\text{20,21}\). The model encourages front line teams to identify change ideas, test them using rapid-cycle tests of change (“plan-do-study-act” cycles), and use measures and metrics to evaluate their effect. The model is appealing in its relative simplicity and its focus on front line care teams to lead improvement.

Another improvement approach, Clinical Microsystems, may have particular relevance to primary care. The Clinical Microsystems approach, developed by researchers and improvement specialists at Dartmouth, emphasizes the importance of small, frontline units of staff called microsystems\(^\text{22}\). These “smallest replicable units” of a delivery system are, according to this approach, where quality outcomes are determined and where emphasis must be placed in order to achieve significant quality changes. Such teams, when trained, supported, and guided, are capable of improving quality at the local level with potential for system-wide effects as key findings are adopted and spread. Clinical Microsystems emphasizes improvement coaching, data, and the use of basic improvement methods such as the plan-do-study-act (PDSA) cycle to identify improvement priorities, test ideas, and implement process changes to achieve better outcomes. The Clinical Microsystems approach has resulted in significant improvements in hospital systems\(^\text{18}\),
integrated delivery systems\textsuperscript{16}, and community health centers\textsuperscript{23}. The approach played a key role in a decade-long, improvement effort in Jönköping County, Sweden, resulting in a range of care improvements at the population level\textsuperscript{24-26}.

Despite some differences, these quality improvement approaches share a set of characteristics that are most relevant to achieving improvement in health care. Each approach features a cycle of change where the problem is identified, and measured, and a rapid change is implemented and tested. Each approach emphasizes the importance of leadership involvement and the use of improvement tools. Perhaps most importantly, each approach relies on the content expertise of front line staff\textsuperscript{27}.

Key Elements for Successful Quality Improvement

With these characteristics shared across approaches, the specific improvement approach may matter less than how the approach is applied. Key contextual factors likely contribute more to the success or failure of an improvement effort than the details of the method used to achieve the improvement\textsuperscript{28}. With this reality in mind, a set of essential characteristics can be identified that, if adhered to, will generally ensure successful ongoing improvement efforts in the primary care setting. Rather than focus on the specifics of any one method, primary care practices engaged or interested in improving quality need to incorporate the following into their improvement efforts:

1) Learning is vital to improvement\textsuperscript{26}. The 2013 IOM report “Best Care at Lower Cost” highlighted the importance of creating “learning health care systems,” capable of capitalizing on the potential of health information technology, patient empowerment, and staff engagement to achieve high quality care at lower costs\textsuperscript{13}. In the learning health system, data are used to assess and evaluate improvement, and team members continually evaluate performance, test changes, and learn from their experiences in order to improve quality. New data systems make this vision possible with the ability to capture all aspects of the care experience electronically and make the information more understandable and actionable for learning and improvement. The rapid increase in the use of HIT has made available a vast array of data to inform health systems and create learning environments. As described by the IOM, “A learning health care system constantly refines complex care operations and processes through ongoing training and skill building, systems analysis and information...
development, and creation of the feedback loops for continuous learning and system improvement.”

2) Quality improvement work requires active engagement and participation of both senior and middle management in order to be successful\textsuperscript{29-33}. Leadership must first create an environment that is supportive of continuous learning, teamwork, and collaboration\textsuperscript{13}. Leadership also plays a critical role in defining agency goals and objectives, and ensuring that appropriate resources are dedicated to improvement work. Furthermore, leadership is best able to bring strategic focus to the improvement team and understand critical contextual factors such as payment models, regulatory issues, and the larger policy environment. Leadership plays an essential role not only in setting priorities and communicating about improvement work across an agency, but also in highlighting results and celebrating successes.

3) Improvement must be not only “top-down” but also “bottom-up”\textsuperscript{25,26,29}. While senior leaders are essential to quality improvement, front line staff have an equally central role. All improvement work requires detailed knowledge of systems and processes, knowledge held by the staff members who do the day-to-day work. Front line staff must be trained and prepared for improvement work. Basic training in quality improvement methods allows staff to participate fully as active team members and to understand the processes in which they are engaging. In addition, time must be allocated for teams to undertake quality improvement activities; those activities must be seen as an integrated element of staff’s day-to-day responsibilities. Most importantly, improvement work requires a level, safe environment, free of hierarchies. In such an environment, a receptionist or medical assistant should feel as free and empowered to contribute to the process as a physician or senior leader. Formal facilitation techniques and meeting structures that encourage such interactions are critical features of successful improvement efforts and can be applied in nearly any setting.

4) Physician involvement is an equally important factor for successful improvement efforts\textsuperscript{31,34}. Physicians, who are often looked to as the leaders of the care team, have an essential role to play implementing new processes. New models emphasizing team-based care, care coordination, and integration with other disciplines require significant modification of existing processes and have a major impact on the day-to-day work of the physician (and other clinicians) and their role on the care team. The actively engaged physician sets the tone for the care team, sending a message that improvement work is important and valued. In addition, active participation by the physician in quality improvement is associated with lower levels of physician stress and burnout\textsuperscript{35}.

5) Improvement efforts can fail if not aligned strategically with agency priorities and larger national priorities\textsuperscript{25,36}. Quality improvement can’t be viewed as an “add-on” but rather must be in synch with other initiatives such as PCMH recognition, achieving federal “Meaningful Use” certification, improving “pay for performance”
reimbursement or shared savings. This strategy of alignment is critical for ensuring broad-based support across departments and avoiding “change overload.” Alignment is critical for balancing a wide array of deliverables and priorities within the ever-changing environment of care and innovation. Leadership plays an important role in defining the strategic objectives for the organization, and communicating those objectives clearly to the staff.

6) Access to data is essential for effective quality improvement. HIT has for the first time made data-driven improvement possible in nearly all care settings. In the age of paper records, most clinicians would not have been able even to identify a population of patients with a specific condition such as diabetes, or determine which patients were overdue for a visit. Now, with the implementation of electronic health records moving ahead nationwide, and the acceleration of efforts to facilitate health information exchange across care settings, improvement teams have the potential to access accurate information on clinical and operational metrics to better inform their work and measure the impact of new or improved processes. Effective quality improvement initiatives require robust information technology systems and access to data and analytics so that teams can measure processes, assess the impact of changes, and make changes iteratively and empirically to refine and perfect newly developed processes. Some methods, such as Six Sigma, place a particularly heavy emphasis on data and statistical process controls to evaluate improvement; others, such as the IHI Model for Improvement, embed data collection in the process of testing a change (the “study” in the PDSA cycle). The IHI mantra, “how will we know that a change is an improvement?” serves as a grounding principle emphasizing the centrality of data and analytics to the quality improvement process.

7) Practice facilitators can help improvement efforts succeed. Also known as improvement coaches, these individuals have mastered the tools needed to guide an improvement initiative to a successful outcome. Quality improvement is a discipline that must be learned. While teams should be trained in the basic approaches and will learn more about quality improvement through doing the work, having a coach can markedly enhance team functioning. Individual team members may serve as content experts, but coaches are expert in the process of improvement. The use of a coach or practice facilitator has been associated with improved patient care and implementation of evidence-based care processes. Practice facilitators can play an important role in helping practices adopt the PCMH model as well. Some health care improvement experts have even called for a national initiative to train practice facilitators and deploy them to lead improvement efforts nationwide.

These core characteristics represent the essential elements needed for improvement. Embedding them in organizations and practices to improve quality will be critical to survive and thrive in the emerging health care environment.
Collaborating for Success

In addition, the power of collaboration can help small practices with limited infrastructure to engage in quality improvement work. Regional, collaborative organizations devoted to fostering practice transformation offer a potential means to promote change at the practice level.

Section 5405 of the ACA authorized the creation of a Primary Care Extension Program (PCEP) to support primary care providers in adopting evidence-based approaches and incorporating them into their practices. The PCEP was modeled after the agricultural cooperative extension service that helped farmers modernize by providing access to local change agents linked to a regional hub. The PCEP has yet to be funded, but several states have begun establishing similar models. Colorado has recently created a Health Extension Service (HES) to support education, training, and adoption of evidence-based practices at the community level. The HES will recruit and train a team of regional health connectors, practice facilitators trained in quality improvement and deployed to work locally across practices to support and promote innovation and system transformation. The Agency for Healthcare Research and Quality (AHRQ) has recently awarded IMPACT (Infrastructure for Maintaining Primary Care Transformation) grants to four states: New Mexico, North Carolina, Oklahoma, and Pennsylvania. These grants will support the development of a similar primary care regional extension service to assist primary care practice transformation.

In addition, The Centers for Medicare and Medicaid Services (CMS) have recently funded 39 Practice Transformation Networks aimed at supporting over 140,000 practices nationwide to adopt quality improvement strategies. These two initiatives will provide expertise and coordination across practices and care settings and promote sharing of resources. This “public utility” approach is one solution for building needed infrastructure to foster improvement and transform primary care.

Improvement collaboratives can also leverage the power of collaboration to achieve improvement in health care. These collaboratives are cooperative undertakings that engage practices of varied sizes and capabilities to implement specific processes or address specific improvement challenges. The Breakthrough Series Collaborative (BTSC), widely disseminated by the IHI, has resulted in a range of health care delivery improvements and has brought quality improvement to the front lines of health care. Collaboratives bring diverse practices and team members together and help them to share and learn together. Improvement coaches provide support and expertise to individual practice teams. Collaborative learning and resource sharing, combined with a focused, data-driven approach to implementing evidence-based care, are hallmarks of this approach. The significant time and resource costs of hosting and conducting collaboratives have been limiting factors to their wider use in health care. However, more recent efforts to employ technology have allowed virtual collaboratives to be carried out in a less resource-intensive manner with similar positive results. Such improvement collaboratives are important tools to employ as health care organizations become more closely aligned on outcomes and more effectively integrated.
Community Health Center, Inc. (CHCI) is a large primary care provider in Connecticut offering integrated primary medical, behavioral and dental care to over 130,000 medically underserved patients across the state. Its patients are generally of low-income and from racial and ethnic minority groups that have traditionally experienced poor health. CHCI provides care in over 200 locations in primary care practices, school, homeless shelters, and mobile outreach locations. Caring for this patient population and improving quality in such settings poses significant challenges.

Over the past four years, CHCI has invested substantial resources to develop the infrastructure and capacity to improve quality across the delivery system and create a learning health system able to adjust to the rapidly changing health care environment. These investments have resulted in sustained improvement in a wide range of outcomes, and the implementation of a highly efficient, data-driven system of care. CHCI is recognized as a leader in quality, training, and research.

CHCI is a learning health system dedicated to creating and sustaining a culture of quality and accountability that penetrates every department and practice site. To accomplish this objective, CHCI created the Weitzman Institute, dedicated to improving the quality of care for the underserved through innovation, research, and quality improvement. This unique organization focuses on supporting and engaging staff at all levels in the pursuit of improved care quality. Staff from the Institute provide coaching and facilitation to improvement teams and projects across the organization and apply state-of-the-art improvement tools to harness the creativity and innovation of CHCI’s staff. The model used by the Institute has been developed and refined since 2010; it represents a hybrid approach that incorporates elements of Clinical Microsystems, Lean, and Six Sigma, and places emphasizes coaching, facilitation, and change management techniques.

Alignment of quality improvement (QI) work with the organization’s strategic goals and objectives is an essential element of the model. Each year CHCI’s Performance Improvement Committee, made up of staff from across the agency, establishes a core set of improvement goals, based on data from quality reports, patient satisfaction surveys, peer review, and staff satisfaction surveys. The goals take into account strategic priorities for growth, recognition by various quality agencies, and regulatory requirements. A Performance Improvement (PI) Plan is developed by members of the PI Committee including clinical leaders, department leaders, and frontline staff; the plan is reviewed and approved by the Board of Directors, a community-based board made up of patients and other local representatives.

Senior leadership is involved in all aspects of quality improvement. Leaders support QI both visibly and substantively, serving on improvement teams, sponsoring local improvement initiatives, and contributing to the development of the PI plan. Regular updates on all improvement team activity are provided to members of the leadership team through leadership meetings, PI Committee minutes, and a quarterly QI newsletter. In
addition, a QI project tracker, housed on the agency’s SharePoint intranet, allows all staff members to view the current status of all improvement projects at both the microsystem and ecosystem levels. In addition, an agency-wide performance improvement scorecard provides data on all quality measures including clinical, operational, and financial metrics.

CHCI’s quality improvement approach emphasizes change at both the microsystem and mesosystem levels. At the microsystem level, frontline improvement teams are located in practices and departments across the agency. These teams are sponsored by local and department leadership and supported by a trained improvement coach and a data analyst. The teams are composed of members of practice teams that work together regularly. They include receptionists, medical assistants, nurses, primary care providers, and often behavioral health staff, dental staff, and other members of the extended care team. Their purpose is to engage in continuous improvement work at the local level in alignment with agency’s performance improvement goals.

Teams meet weekly or biweekly to identify problems and design solutions. The expectation for each microsystem team is that they identify areas for improvement in their local site, conduct tests of change, and report regularly on their progress. In addition, each team is expected to be available to assist with local implementation of key agency initiatives. In such circumstances, teams are asked to assist with evaluating and adapting new processes and, if appropriate, to direct the implementation of the process at the local site. This process of engaging the microsystem team to support agency projects is referred to as “catch ball”.

Microsystem teams create a “bottom up” source of improvement ideas and solutions that improve quality at the front lines and often generate ideas of relevance to the wider organization. CHCI’s QI Department meets regularly with the microsystem coaches to provide training and support and to ensure that work is progressing and is aligned with the core objectives of the Performance Improvement Plan.

An agency such as CHCI also must conduct larger scale improvement projects that involve different departments and have a wider impact than at the microsystem level. These types of initiatives are referred to as mesosystem initiatives. Mesosystem teams are assembled to tackle large-scale change initiatives such as implementing new technologies, adopting new processes across the agency, or solving problems that are interdepartmental in scope. Mesosystem teams are supported by a senior improvement coach with advanced training in project management and in the use of tools such as Lean, Six Sigma, and Change Management. There are several different types of mesosystem interventions and approaches that can be used to address a proposed project. “Workouts,” “kaizens,” and workgroup improvement projects are three different types of projects. The decision about which intervention to employ is made based on the timeline, the amount of work required, and the makeup of the improvement team.

As with microsystems, CHCI’s QI Department monitors the work of all active mesosystem teams to ensure that they are addressing problems and developing solutions in alignment with the agency’s performance improvement goals. Work at the mesosystem level often
results in the creation of new processes that need to be implemented across the agency. All such new processes are fully described in a process “playbook.” Playbooks outline the details and highlight specific tasks for each staff member affected by the new process. Such new processes are implemented in a structured fashion using an implementation project plan incorporating change management tools to ensure effective adoption and sustainability.

Lean/Six Sigma is the primary method for improvement within any mesosystem intervention. This method emphasizes clarity in defining a problem and employs a measurement-driven approach for identifying, implementing, and evaluating solutions to achieve project goals. The assigned quality improvement specialist applies specific qualitative and quantitative techniques along with other Lean and Six Sigma tools to help teams implement process improvements. Common tools that may be used during a project include: process mapping/value stream mapping, root cause analysis/fishbone diagram, failure mode and effects analysis (FMEA), impact/effort grid, communication plan, stakeholder analysis, and other critical tools for an effective change management strategy.

CHCI has invested significant resources to develop a team of improvement coaches able to support quality improvement work across the agency. Improvement coaches are essential for the success of improvement efforts. Coaches receive training in a range of quality improvement methods and tools and are assigned to support frontline clinical microsystem teams across the agency. Coaches lead meetings, provide expertise in the QI process, and employ tools and techniques to support the collaborative process and help teams achieve their goals. All improvement coaches receive in-depth training in clinical microsystems, in areas including basic team functioning, ideal meeting skills, conflict management, and the use of core QI tools and approaches.

CHCI has made significant investments in building a robust data infrastructure to support improvement efforts and to provide information for evidence-based, data-driven care. A centralized data warehouse stores data from the electronic health record and practice management system, with data cubes to allow staff to create custom queries for specific data needs. With the warehouse as its platform, the information technology team has developed a range of data dashboards and scorecards that are used at the front lines to support the care team. Dashboards provide medical assistants, nurses, and clinicians with information on screening needs, chronic illness control, hospital admissions, and adherence to quality standards. An agency-wide scorecard contains a wide range of measures that are tracked and monitored by the quality improvement team and by senior leadership.

These tools and techniques have created the ideal environment for building a learning health system. Core elements such as a team of improvement coaches and a solid data infrastructure have been used to support an improvement process that is both top-down and bottom-up. An engaged leadership team sets priorities and remains actively supportive of and engaged with improvement teams, while front line staff are given time and resources to meet regularly and plan improvement work. Larger scale process improvement work uses Six-Sigma and Lean principles to make changes that are implemented widely across
Collaboratives allow even the smallest clinic to take part in quality improvement work and learn from others engaged in the same effort.

**Conclusion**

Good patient care involves the complex application of art and science to meet the needs of patients with varied backgrounds, beliefs, experiences, and health care needs. However, the quality of care that patients receive is far below what the evidence demonstrates to be possible. The gap between what is known and what is done in health care is large. While addressing this gap is complex, we know that the solution lies in a systems approach. Health care systems have inputs, processes and outputs that can be evaluated and improved upon using formal tools and approaches similar to those that have been used in other industries. As the health care system continues to evolve, it is essential that those engaged in care delivery develop the ability to learn, analyze, and improve, and to focus more on systems aspects to ensure that they apply what is known in order to meet patients’ needs. Regional extension services and organized improvement collaboratives can provide support at the local level and help bridge gaps in quality, particularly in smaller practices. States such as Connecticut can adopt methods to ensure that, as access issues are resolved, innovation and care transformation become the hallmarks of care.

We now have effective, evidence-proven treatments for many, if not most, major causes of human morbidity and mortality. While there will always be the need for new treatments, new procedures, and other medical advances, our focus needs to shift towards applying the care options we already have. Evidence-based approaches can significantly reduce practice variation and inefficiency in primary care.

Quality improvement is a discipline grounded in science. It blends the quantitative and the qualitative, emphasizing data and statistics along with theories of staff engagement and behavioral change. Health care has been late to adopt these approaches, and primary care has been among the slowest health care field to do so. It is time for Connecticut to realize its potential and become a hub of innovation and a center for practice excellence.

**Endnotes**


2 Committee on Quality of Health Care in America, Institute of Medicine. Crossing the quality chasm: A new health


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