A Framework for Improving Preconception Health Care Interventions Using Continuous Quality Improvement

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Abstract

Continuous Quality Improvement (CQI) is an organizational management process used to continually monitor and implement improvement processes. CQI is distinguished by a focus on customer satisfaction, systematic process, and process measurement and decision making.

The Infant Mortality Rate (IMR) is a leading health indicator used in public health that is reflective of maternal health and socioeconomic inequalities such as access to health care. IMRs and racial and ethnic disparities among them have been a public health priority for decades. Research for effective, evidence-based methods to reduce overall IMRs and disparities is on-going. Preconception care (PCC) is a leading public health intervention based on the Life Course approach, which aims to improve the health of all women capable of reproducing, therefore improving birth outcomes and reducing IMRs.

Despite the effectiveness of CQI in other industries and promising improvements in some CQI public health interventions, CQI has yet to be applied to PCC practices with any form of standardization or consistency. This paper will explore the application of CQI in public health and in PCC, determine if guidelines for applying CQI to PCC exist, and suggest a framework for applying CQI to PCC interventions at the state and local level.

Introduction and Background

Infant Mortality

The infant mortality rate (IMR) is one of the most important and frequently used health indicators in public health. IMRs are reflective of socioeconomic conditions and inequalities, such as access to care, quality of care, and maternal health status (MacDorman and Mathews, 2008). Following nearly a century of steady decline, the IMR did not change significantly from

the years 2000-2005 due to an increase in preterm birth-related deaths (MacDorman and Mathews, 2008). Alarming disparities in the IMR between African American and Caucasian women have existed since health officials first began monitoring the health indicator. A number of factors contribute to racial and ethnic health disparities including socioeconomic status, individual health behaviors, and psychological and social stress (Hauck, Tanabe and Moon, 2011). Even with periods of sharp decline for the overall IMR, the rate of decline among African American women was less than the rate of decline among Caucasian women. This resulted in persistent and, at times, worse IMR disparities (Singh and Yu, 1995).

Preconception Care

Preconception care (PCC) is one of the leading approaches in public health to improve birth outcomes and reduce IMR disparities. PCC aims to improve birth outcomes by improving women's and couples' health prior to conception. Improvements are achieved by addressing specific risk factors that lead to poor birth outcomes, regardless of the intent to become pregnant (Centers for Disease Control and Prevention [CDC], 2006). PCC is unique in that it addresses multiple pregnancy related risk factors for a larger population of women, in contrast to-interventions that address single risk factors among women planning conception or who have already conceived. For example, PCC recommendations are more inclusive, addressing multiple chronic diseases such as diabetes, HIV/AIDS, hypothyroidism, and epilepsy; whereas alternate interventions might only target the risks associated with Type II or gestational diabetes among women in a specific age range. Only two of the CDC's (2006) ten PCC recommendations suggest incorporating quality improvement (QI) efforts, but do not provide explanation on the implementation of QI efforts, which could be used to further improve birth outcomes.

Continuous Quality Improvement

Continuous quality improvement (CQI) is defined as an organizational, leadership-led, management process where all personnel are involved in planning, executing, and continually monitoring and improving quality to exceed the expectations of communities (Sollecito and Johnson, 2013, Chapter 1; Lesneski, Massie, and Randolph, 2013, Chapter 16). In the last decade, the public health system has made concerted efforts to improve the quality of public health services and health outcomes using CQI. Today, the utilization of CQI practices in public health is driven by the progression towards national voluntary accreditation through the Public Health Accreditation Board (PHAB), whose accreditation process is built upon CQI principles. PHAB accreditation is supported by other leading public health organizations such as the Robert Woods Johnson Foundation (RWJF), the Centers for Disease Control and Prevention (CDC), the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO) (Public Health Accreditation Board, 2012). Additionally, the federal government is a catalyst for CQI and preventive care through the Affordable Care Act, which includes provisions specific for public health efforts on improving quality and addressing racial ethnic disparities (Andrulis, Siddiqui, Purtle, and Duchon (2010).

Common characteristics of organizational CQI include: "a link to key elements of the organization's strategic plan; a quality council that includes the organization's top leadership; training programs for personnel; mechanisms for selecting improvement opportunities; process improvement teams; staff support for process analysis and redesign; policies that motivate and support staff participation; and application of the most current and rigorous techniques of the scientific method and statistical process control" (Sollecito and Johnson, 2013, Chapter 1, pp 4-5). CQI is also comprised of 18 key philosophical and structural elements, and five elements

specific to health care that guide the organization, implementation and operation of CQI initiatives (Sollecito and Johnson, 2013, Chapter 1). A number of the key CQI elements are directly applicable to PCC practices, including: a focus on customer satisfaction, health outcomes and instruments for monitoring; emphasis on the system that provides services; data driven and measureable (evidence-based) analysis of system operation and performance; emphasis on identifying multiple causation (root causes); emphasis on continual improvements; utilization of process improvement teams; utilization of the seven basic CQI tools; statistical analysis of variation; and the use of benchmarks or performance targets (Sollecito and Johnson, 2013, Chapter 1). Structural and philosophical CQI elements will be further explored later in this paper.

The aim of this paper is to explore current CQI methodologies in public health and, more specifically, the use of CQI in reducing infant mortality rate disparities. Does current literature recommend a framework for continuous quality improvement and preconception health care that impacts each aspect of preconception care? This paper will suggest a framework that integrates CQI with the CDC's PCC recommendations with hopes of improving the preconception care process.

Methods

The literature review for this paper was performed using the Google Scholar search engine, Web of Science and PubMed electronic databases, and the electronic journal database through the University of North Carolina's Health Sciences Library (HSL). Research assistance was provided by HSL librarians using the "Ask a Librarian: Chat" function.

Electronic literature was selected based on its relevance to current or recent evidence-based or promising practices related to CQI or infant mortality. Literature on studies and interventions were limited to publications from the last 10 years with several exceptions.

Keywords used often during searches include: CQI, preconception health, preterm birth, health outcomes, infant mortality, infant mortality disparities, evidence-based, and implementation fidelity. Reviewed literature includes primary public health or health care studies, literature reviews, commentaries, editorials, and text books. Other sources include fact sheets, reports and recommendations from public health and health care organizations.

Literature Review

Continuous Quality Improvement

CQI is categorized into four types of improvement processes: localized improvement efforts to address a specific problem or opportunity for improvement; organizational learning where policies and procedures are developed based on CQI practices; process reengineering or radical transformations to organizational practices; and evidence-based clinical and management practices based on the review of professional literature (Sollecito and Johnson, 2013, Chapter 1). The philosophical and structural CQI elements of CQI can be easily and directly applied to PCC practices in public health, further improving the care processes and birth outcomes.

The main features of CQI are the focus on customers, the system, and measurement and decision making (Sollecito and Johnson, 2013, Chapter 1). Process measurement and data analysis is an integral feature of CQI, and is used in planning process improvements as well as evaluating program outcomes and improvements. In CQI, the customer refers to the user of an output or product, and can be internal or external to the organization. For example, the customers of a billing specialist in a local health department might include the women served, third-party payer groups (external customers), and the nurse educator and project coordinator (internal customers). The system focus emphasizes managerial and professional processes rather

than individual responsibility or blame. With managerial guidance, the system is redesigned to generate the desired outputs. Data are collected and measured to identify causes of variation and to understand the system (Sollecito and Johnson, 2013, Chapter 1).

Variation is "the extent to which a process differs from the norm" or the desired and expected outcome (Kelly, Johnson, and Sollecito, 2013, Chapter 3, p. 79). The purpose of the statistical tools and methods of analysis used in CQI is to better understand the types and causes of variations, which guides managers to modify processes that lead to improvements rather than to changes that generate the same or worsened outputs (Kelly, Johnson, and Sollecito, 2013, Chapter 3). CQI tools can be classified as numerical, conceptual, or analytical frameworks or methodologies depending on the purpose for which they are used. Table 1 lists CQI tools used to collect and measure data to assess for variations or improvements.

Numerical analysis CQI tools	Check sheets, control charts, histograms, Pareto chart, scatter diagram, stratification
Conceptual analysis CQI tools	Fishbone diagram, affinity diagram, brainstorming, GANTT chart, flow chart, story board, logic model, benchmarking
Analytical frameworks or methodologies	PDSA, Rapid Cycle Improvements (RCI), the Balanced Scorecard, Lean, Six Sigma, the Baldridge Assessment, Model for Improvement

Table 1: CQI tools, Adapted from Tews, Sherry, Butler, and Martin, 2008, p. 36

Performance measures are selected during the planning process and monitored throughout a CQI project. There are three key performance measures: 1) process measures, which reflect the capabilities and on-going performance of the project; 2) outcome measures, which reflect short-term goals our outputs; 3) and impact measures, which reflect long-term goals (Issel, 2008, Chapter 10). In planning, it is important to select multiple program measures that are relevant to the project, and equally reflect the process, as well as outcomes and impact of the CQI project. The most appropriate performance measures follow the S.M.A.R.T. guideline,

and are Specific, Measureable, Attainable, Realistic, and Timely. Performance measures are essential to the improvement process, as they are also the factors that are monitored to evaluate variation (Kelly, Johnson, and Sollecito, 2013, Chapter 3).

CQI processes also include the following: a strategic focus with a mission, values, objectives and prioritized efforts; involvement of personnel from each process of the delivery system; an emphasis on system-benefiting solutions; an emphasis on organizational learning and personal growth; and a parallel organization (separate management structure) to monitor and implement CQI (Sollecito and Johnson, 2013, Chapter 1). Philosophical and structural CQI elements were previously mentioned regarding direct applicability to PCC. The 10 philosophical elements of are the basic constituents, or foundation of CQI processes, and must be included in any CQI effort. Structural elements are those which support the organization and execution of CQI efforts. Most CQI efforts utilize many, if not all of the structural elements. Table 2 categorizes the philosophical and structural elements of CQI, as well as elements specific to CQI process in health care.

Table 2: Philosophical and Structural Elements of CQI (Sollecito and Johnson, 2013, pp. 11-13)

Philosophical	**Structural**
Strategic Focus: A mission, values, and objectives that guides improvement processes	Process Improvement Teams: Forming and empowering teams of employees to deal with existing problems and opportunities
Customer Focus: Patient, provider and payer satisfaction, and health outcomes as performance measures	Seven CQI tools: Use of one or more CQI tools frequently cited in literature: flowcharts, cause-and-effect diagrams, histograms, Pareto charts, run charts, control charts, and regression analysis
Systems View: Analysis of the whole system providing a service or influencing an outcome	Parallel organization: A separate management structure or quality council to monitor CQI strategies and implementation
Data-driven: Gathering and using objective data on system operation and system	Organizational leadership: Leadership at the top levels and throughout the

performance	organizations fostering the integration of CQI into the institutional fabric of the organization
Implementer Involvement: Personnel from each system component are involved to provide understanding of the delivery process	Statistical analysis: Use of statistics, including statistical process control, to identify and reduce unnecessary variation in processes and practices
Multiple Causation: Identification of the multiple root causes of a set of system phenomena	Customer satisfaction measure: Utilizing market research instruments to monitor customer satisfaction ; includes social marketing
Solution Identification: Seeking a set of solutions that enhance the overall system performance	Benchmarking: To identify best practices in related and unrelated settings to emulate processes or use as performance targets
Process Optimization: Emphasis on optimizing a delivery process to meet customer needs regardless of existing precedents…territories and fiefdoms	Redesign of processes from scratch: Utilizing quality function deployment and process reengineering
Continuing Improvement: Emphasis on continuing the systems analysis even when a satisfactory solution to the presenting problem is obtained	(This space intentionally left blank)
Organizational Learning: To enhance the capacity of the organization and foster personal growth	(This space intentionally left blank)

In addition to the philosophical and structural elements, several elements are specific to CQI efforts in health care. Health care-specific elements include: epidemiological and clinical studies as a foundation of evidence-based medicine; involvement of medical staff for committees and peer review; use of risk-adjusted outcome measures; use of cost-effective analysis; and use of quality assurance and risk management data (Sollecito and Johnson, 2013, pp. 13-14). A basic understanding of the core elements of CQI and their application may increase the likelihood of successful CQI process.

Infant Mortality

Infant mortality is one of the most important and frequently measured indicators of overall population health. Infant mortality rates reflect maternal health and social inequalities

such as inadequate access to quality medical care (MacDorman and Mathews, 2008). The Infant Mortality Rate (IMR) is defined as the rate at which infants die prior to their first birthday per 1,000 live births (MacDorman and Mathews, 2008). Socioeconomic conditions are correlated with population health status, and poor economic status is a risk factor for poor birth outcomes (Singh and Yu, 1995). Throughout the 20th century, IMRs followed a steady decline due to improved socioeconomic conditions, advancements in prenatal and neonatal care, improved quality and access to care, as well as improved public health practices. A review of recent literature did not associate significant declines in IMR directly to CQI practices. In fact, the majority of literature on evidence-based practices to improve birth outcomes or reduce IMRs made no mention of quality improvement. Despite improved conditions and medical advancements, the IMR rate of decline has slowed, and even remained virtually unchanged between the years 2000-2005 due to an increased incidence of preterm birth-related deaths among very preterm (less than 32 weeks gestation) and late preterm (34-36 weeks gestation) births, and variations in the implementation of preventive interventions (MacDorman and Mathews, 2008; CDC, 2006). Since 2006, small declines in overall IMRs have been observed, largely due to a decrease in the percentage of preterm births, dropping from 12.8 in 2006, to 12.3 in 2008 (Mathews and MacDorman, 2012). Prevention of preterm births has proven a difficult challenge for public health officials, with preventive interventions showing few improvements in birth outcomes (Iams, Romero, Culhane, and Goldenberg, 2008).

The three leading causes of infant mortality (IM) in the U.S. are congenital defects, malformations or chromosomal abnormalities, conditions followed by disorders related to short gestation and Low Birth Weight (LBW), and Sudden Infant Death Syndrome (SIDS) (Hoyert and Xu, 2012). Among African American women however, the leading cause of infant mortality is

shortened gestation and LBW, a trend that has persisted since at least 1991 (Singh and Yu, 1995; Mathews and MacDorman, 2012). Preterm birth accounts for roughly 75% of all perinatal deaths, and accounts for over 50% of the disparity between African American and Caucasian IMRs (Ananth and Vintzileos, 2006; MacDorman and Mathews, 2011; Hauck, Tanabe, and Moon, 2011). Therefore, interventions that aim to reduce preterm birth are likely to have a greater impact on infant mortality rates.

Risk factors for preterm birth include a history of previous preterm birth; maternal health status such as a chronic or acute disease, genitourinary infection or sexually transmitted diseases (STDs); maternal socioeconomic status; obesity; and tobacco and alcohol use (Ananth and Vintzileos, 2006; Mathews and MacDorman, 2011). The CDC (2006) lists 13 risk factors for routine screening as part of PCC; nine of those factors are behaviors, chronic diseases, or disease treatments (a prescription medication) that are directly associated with preterm birth or LBW (Dunlop et al., 2008).

Preterm birth is typically classified into two categories: spontaneous preterm delivery following early onset of labor or preterm Premature Rupture of Membranes (PROM); and medically indicated preterm birth. Preeclampsia, placental abruption, intrauterine growth restriction, and fetal distress are the conditions that frequently necessitate medically indicated preterm delivery, but each of these could also trigger early onset of labor. Risk factors for PROM and preterm birth overall are very similar and include a history of previous preterm birth, and maternal health such as a chronic or acute disease or infection (Ananth and Vintzileos, 2006). Numerous interventions aimed towards reducing specific risk factors associated with preterm birth, especially those related to behavioral modification and chronic disease management, but as noted previously, few efforts noted utilized CQI.

Infant Mortality Rate Disparities

Public health models used to explain IMR disparities include the racial-genetic model, health-behavior model, and psychosocial stress model. The racial-genetic model is infrequently referenced today because race is increasingly understood to be a social construct rather than a biological determinant. Also, research has shown that the birth-weight patterns of African-born Black women in the U.S. were more similar to the birth-weight patterns of U.S.-born Caucasian women, indicating that IMR disparities are driven by other factors (David and Collins, 1997, 2007). The significance of this finding is that researchers can develop and implement effective interventions that target IMR disparity factors that are amenable to change, as is the intention of PCC. The Health-Behavior model examines individual behaviors such as diet, exercise habits, sex practices, and use of tobacco and alcohol. The Psychosocial Stress model examines stress associated with the individual and social environment (e.g. depression, anxiety, poor social support) and racism (Dressler, Oths and Gravlee, 2005). The Psychosocial Stress model and racism provides some understanding as to why IMR disparities persist even among African American women with higher socioeconomic status and education after controlling for factors such as maternal care, parity and maternal age (Hauck, Tanabe, and Moon, 2001).

The Field Model by Evans and Stoddart is primarily associated with community health initiatives, but it is very much applicable to IMR disparities because it takes into account all of the social determinants of health, all of which impact birth outcomes. The Field Model examines the impact of the following: social environment, physical environment, genetic endowment, individual response (behavior and biology), health care, disease, health and function, well-being, and prosperity (Evans and Stoddart, 1994). PCC addresses IMRs from the Life Course

approach, which takes into account factors from the Health Behavior, Psychosocial and Field models.

Evidence-Based Practices in Infant Mortality Reduction

Numerous approaches have been utilized in public health and health care to reduce IMRs, but to date none have achieved the desired or anticipated outcomes. In the 1990s and even today, interventions frequently focused on preventing Low Birth Weight (LBW) and preterm deliveries by targeting associated maternal risk factors such as cigarette smoking, low maternal weight and low weight gain, maternal infections, and a history of poor pregnancy outcomes (Shiono and Behrman, 1995). More recent approaches to reduce IMRs continue to focus on improved medical care in the neonatal intensive care unit (NICU), as well as mitigating the impact of maternal risk factors through continued behavioral interventions and additional clinical interventions. Clinical maternal interventions to prevent preterm birth frequently include early risk assessment and early detection of labor or PROM using the fetal indicator, fibronectin, early intervention for women with previous adverse pregnancy outcomes, chronic disease management (primarily diabetes and hypertension), general prenatal care, antibiotic treatment (for genitourinary infections associated with preterm birth), progesterone and corticosteroids, cervical cerclage for shortened cervixes, and tocolytic therapy to suppress labor (Iams, Romero, Culhane, and Goldenberg, 2008; Sanchez-Ramos, Delke, Zamora, and Kaunitz, 2009). Research however shows that many clinical interventions to prevent or delay preterm birth demonstrate inconsistent or little benefit and in some cases (i.e. tocolytic drugs) may worsen infant morbidity (Iams, Romero, Culhane, and Goldenberg, 2008; Briery, et al., 2011; Andrews and Goldenberg, 2003). Two-thirds of the decline in IMR among very LBW infants is due to effective respiratory and cardiovascular treatments in the NICU (Rogowski, Staiger and Horbar, 2004). With the

exception of interventions executed through the Multistate Learning Collaborative, a quality improvement network for public health organizations, few interventions aimed at maternal risk factors integrated CQI. PCC in conjunction with CQI provides public health practitioners the opportunity to develop preventive interventions to target maternal risk factors that are not mediated through secondary and tertiary clinical care.

The use of pulmonary surfactant to treat respiratory distress syndrome is an evidence-based clinical practice frequently used in NICU care. Clinical studies on the use of pulmonary surfactant demonstrated a 30-40% reduction in infant mortality (Kliegman, 1995). Evidence-based hospital referral (EBHR) is another NICU practice with a strong potential for reducing IMRs. EBHR is a process that considers variations in the quality of care between hospitals, and aims to reduce IMRs by referring high-risk patients to hospitals with high-quality NICUs for delivery and care. Studies have shown that infants are more likely to survive if delivered and treated at hospitals with a high volume of critical patients and more experienced NICUs (Leapfrog Group, 2008).

Clinical practice guidelines for tobacco cessation include recommendations based on evidence-based practices but do not include CQI. These are general guidelines for tobacco cessation within managed care organizations, and are not specific to maternal care or IMR reduction. The key feature of evidence-based tobacco cessation is the 5-A's system: ***Ask***, to identify tobacco users at each visit; ***Advise***, to strongly urge tobacco users to quit; ***Assess*** tobacco user's willingness to quit; ***Assist*** tobacco users with quitting; and ***Arrange*** follow-up appointments to assess cessation progress (Taylor and Currie, 2004). The 5-A's approach has been successfully integrated with public health interventions aimed at improving maternal and infant health (English, Merzel and Moon-Howard, 2010).

Studies have shown that the use of evidence-based approaches to improve birth outcomes is effective, given that implementation fidelity is maintained, which can be improved using CQI. CQI was infrequently cited as a component of evidence-based interventions for infant mortality or birth outcomes. Studies that made use of CQI typically targeted care processes in the NICU such as treating and preventing infections and respiratory disorders, improving neonatal nutrition, and monitoring prescription drug therapy (Rogowski, Staiger and Horbar, 2004; Kuzma-O'Reilly et al., 2003; VanLooy, Schumacher, and Bhatt-Mehta, 2008) Evidence-based interventions that incorporate CQI have shown to be effective at improving maternal, infant and child health outcomes, but such interventions appear to be infrequently used (Olds, 2002).

Preconception Care

Preconception care (PCC) is defined as "a set of interventions that aim to identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcome through prevention and management" (CDC, 2006, p. 3). A key feature of PCC is that it is a major contributor to the Lu and Halfon (2003) Life Course Perspective approach to addressing racial-ethnic disparities in IMRs and other health indicators. The Life Course Perspective encourages public health practitioners to implement strategies that impact behaviors, risk factors and exposures throughout an individual's life that ultimately affect birth outcomes (Fine, Kotelchuck, Adess, and Pies, 2009). Keeping with this approach, PCC targets all women capable of conceiving, regardless of their intent to become pregnant. PCC is designed to be incorporated with routine preventive care from a primary physician or regular health care provider. The goals of PCC are: to improve the knowledge, attitudes and behaviors of women and men related to preconception health; to assure that all women of childbearing age receive PCC screenings, counseling and interventions to ensure optimal health at the time of conception;

to provide targeted interconception care (intensive interventions, counseling, and specific risk reduction) to women with histories of adverse pregnancy outcomes (CDC, 2006). The Life Course approach and PCC address limitations of many public health interventions that begin after organogenesis, rendering them essentially ineffective. Table 3 lists the 10 recommendations from the CDC to improve preconception health care for women in the United States.

	Table 3: CDC Recommendations to Improve Preconception Health Care (CDC, 2006, pp 9-16).
1.	Individual responsibility across the lifespan: Every man, woman and couple should have a reproductive life plan (RLP)
2.	Consumer awareness: Increase public knowledge of preconception health behaviors and services
3.	Preventive Visits: Provide risk assessment and educational and health promotion counseling to all women of childbearing age
4.	Interventions for Identified Risks: Increase the proportion of women who receive interventions as follow-up to preconception risk screening
5.	Interconception Care: Use the interconception period to provide additional intensive interventions to women who have had poor pregnancy outcomes
6.	Prepregnancy Checkup: Offer, as a component of maternity care, one prepregnancy visit for couples and persons planning pregnancy
7.	Health Insurance Coverage for Women with Low Incomes: Increase public and private health insurance coverage for women with low incomes to improve access to preventive women's health and preconception and interconception care
8.	Public Health Programs and Strategies: Integrate components of preconception health into existing local public health and related programs
9.	Research: Increase the evidence base and promote the use of the evidence to improve preconception health
10.	Monitoring improvements: Maximize public health surveillance and related research mechanisms to monitor preconception health

Michael Lu and his colleagues (2010b) developed a 12-point plan (see Table 4) also based on the Life Course approach to address factors that impact pregnancy outcomes, including those that specifically contribute to racial-ethnic IMR disparities. Lu's model is similar to the CDC's recommendations in that it addresses many of the limitations of traditional approaches to reducing IMR disparities. For example, early initiation of prenatal care and promoting safe-sleep

practices cannot overcome other socioecological factors such racism and poverty which impact the living environment of women and is associated with poor birth outcomes. As with the CDC's recommendations, Lu's 12-point plan makes little mention of CQI use to improve outcomes; CQI methods were only suggested as a means to improve the quality of prenatal care for African American women. CQI is applicable to and potentially effective to other recommendations from Lu, including deep-rooted and broad issues such as "undo racism" where public health practitioners can apply methods such as social marketing and measure changes in perceptions or knowledge.

Table 4: A 12-point plan to close the Black-White gap in birth outcomes: A lifecourse approach (Lu, et al.,2010, p. S2-63)
1. Provide interconception care to women with prior adverse pregnancy outcomes
2. Increase access to preconception care to African American women
3. Improve the quality of prenatal care
4. Expand healthcare access over the life course
5. Strengthen father involvement in African American families
6. Enhance coordination and integration of family support services
7. Create reproductive social capital in African American communities
8. Invest in community building and urban renewal
9. Close the education gap
10. Reduce poverty among African American families
11. Support working mothers and families
12. Undo racism

The March of Dimes also presented recommendations for to improve birth outcomes and described promising practices for PCC (Berns, 2011). Their suggestions regarding PCC are based on the initial recommendations from the CDC. Many of the recommendations include QI, specifically recommendations for surveillance, research, and clinical care at various pregnancy stages (preconception, prenatal, intrapartum). Although their recommendations stressed the importance of QI, they do not describe the managerial process of CQI; their recommendations do

however indicate the applicability and feasibility of integrating CQI into PCC and other components of maternal and infant care.

Many barriers to PCC are known, though they are not all well understood and are difficult to address. Individual and system level barriers to care are often attributed to unsuccessful public health initiatives or interventions. Recent research suggests however that removing known barriers to care does not ensure intervention participation and that unexplored factors also act as barriers to care (Hogan et al., 2012). Despite an incomplete understanding of factors and interactions that inhibit participation in PCC, addressing barriers to care is still important in the provision of PCC. Known barriers to PCC essentially mirror the barriers to traditional maternal health care such as socioeconomic factors and access to care (transportation, health insurance, child care restrictions, maternal employment and scheduling conflicts), cultural and language barriers, and maternal education and reading level (Hogan et al., 2012). Barriers to PCC regarding intervention planning and implementation include: inability to provide services to those with the greatest need, fragmented provision of services, and lack of available treatment services for high-risk behaviors, poorly received health promotion message by women and couples, and limited data to support preconception interventions for health conditions associated with risks (Atrash, Jack, and Johnson, 2008, p. 586).

Women's perception of what constitutes routine prenatal health care is a very significant PCC barrier to address. Unique challenges are associated with promoting healthy infants to women who are not yet considering motherhood. A major misconception among women is that issues regarding pregnancy and motherhood should only be addressed during the pre-pregnancy period (the time when a woman is actively trying to become pregnant), or during and following a pregnancy. A woman's intent to become pregnant is the strongest indicator of her receptiveness

to PCC (Squiers et al. 2013). The terminology used and the setting in which PCC is delivered are also very important because they can act as facilitators or barriers to the intervention. Women without intentions to become pregnant are put-off by obstetrical terms and the title "preconception care". Women without intent to become pregnant would receive PCC from their primary health care provider. Ultimately, healthy women, teens, and women with poor access to health care are not guaranteed to see a health provider regularly (Squiers et al. 2013). In planning PCC interventions, public health workers must consider such barriers, and ensure that components of the intervention are tailored specifically for women based on their intent to become pregnant and other characteristics that may limit efficacy.

It is possible that one of the most difficult PCC barriers to overcome is mental models. Mental models are the beliefs or perceptions specific to individuals, cultures, and populations that guide their decision-making process. Mental models provide some explanation as to why some public health interventions are unsuccessful even when barriers are eliminated and educational services are provided.

CQI and Infant Mortality Reduction

Public health interventions to reduce IMRs focus on prenatal and postnatal care or typically target risk factors related to maternal behavior. Initiating early prenatal care and safe-sleep practices are two behaviors frequently addressed in public health initiatives. Women who receive inadequate, poor-quality or no prenatal care at all are at a significantly higher risk for poor pregnancy outcomes or infant death (Krueger and Scholl, 2000). Modification of maternal behaviors is a major component of prenatal care interventions. Public health practitioners employ CQI with infant mortality efforts in the same fashion as with other public health interventions. In general, practitioners seek to identify the root causes of undesirable events or

trends (i.e. missed opportunities for tobacco cessation intervention), to apply solutions based in evidence and improve standard processes (i.e. the 5-A's methodology), and monitor improvements using performance and outcome metrics.

Today, the IMR disparity has reversed and widened; advancement in NICU care produced a smaller decline in preterm IMR among African American infants than Caucasian infants (Haucke, Tanabe and Moon, 2011). The cause of this gap is not clearly understood since the infants theoretically receive the same clinical care in the NICU setting, but the gap suggests that the quality of care for African American infants could be improved. Patient demographics also play an indirect role in the quality of NICU care received. Frequently, women give birth at hospitals in close proximity to their residence, unless health insurance requirements dictate otherwise or the pregnancy was high-risk and referred to a high-risk obstetrician with arrangements for delivery at a specific hospital in advance. The hospital location and the care level of the NICU are two factors shown to be associated with IMRs. Recommendations to further reduce IMRs associated with NICU care include incorporating CQI into neonatal care practices and utilizing selective referrals so that high-risk infants are delivered at or transferred to hospitals with high-level NICUs (Rogowski, Staiger and Horbar, 2004).

Interventions related to improving pregnancy outcomes and reducing IMRs often target access to quality prenatal care, diabetes management, and smoking cessation. The National Network of Public Health Institutes (NNPHI) provides on its website QI storyboards on a variety of public health related topics, including infant mortality reduction, from states participating in the Multistate Learning Collaborative (MLC). The MLC was established to connect state and local health departments to foster learning and promote a culture of QI (NNPHI, 2010). In addition to the NNPHI site, the Public Health Quality Exchange (PHQIX) is an online

community for public health practitioners to share and learn from others CQI experiences, and lists summaries of CQI studies related to maternal and child health and other topics. The majority of the CQI efforts were directed at increasing the rate of pregnant women beginning prenatal care in the first trimester. Public health practitioners in Pierce County, Washington implemented a CQI intervention to address LBW births in their county by improving Maternity Support Services (MSS) among African American women. MSS is a community health program that connects women with a nurse, dietician, counselor, and other community health workers to screen for pregnancy risk factors and develops care plans and recommendations for a healthy pregnancy (WithinReach, 2012). The aim of this intervention was first to increase by 20% the number of women who receive a home or office visit within 20 days of their MSS referral. The project team utilized PDSA and Rapid Cycle Improvement (RCI), and tools common to CQI such as fishbone diagrams, flow charts, Pareto charts, root cause analysis, and run charts for their intervention. The percentage of women seen within 20 days of their referral went from 60% to 84%, exceeding the target of 75% (a greater than 20% increase). The team also observed an increase in the mean gestational age at the time of the first visit from 23.2 weeks to 21.6 weeks, but this did not meet their desired goal of 13 weeks (Pfiefer, 2012). This and other studies documented with the MLC and PHQIX provide evidence that CQI methods can successfully improve intervention outcomes based on achieved goals and measurable improvements, and potentially have a positive impact on pregnancy outcomes and IMRs.

A salient intervention outside of the MLC used CQI to improve data collection and performance measures, which are integral to all CQI processes to measure and evaluate change. Johnson and Little (1999) identified Pregnancy Risk Assessment Monitoring System (PRAMS) and Fetal-Infant Mortality Review (FIMR) for state agencies as useful tools for obtaining data

necessary to improve perinatal care. PRAMS is a surveillance system for maternal behaviors and experiences, while FIMR examines medical and social factors that influence infant mortality. The Jefferson County Department of Health (JCDH) in Birmingham, Alabama, developed an FIMR and integrated it with CQI to reduce fetal and infant mortality. The health department's three objectives were to identify women and infants who needed additional services and offer those services, to identify problems in their delivery of those services, and to involve an array of health department professionals, community organization representatives, policy makers and community members in improvement processes (Klerman, Cleckley, Sinsky, and Sams, 2000). JCDH did not report use of use of formal CQI methods or tools used such as RCI or fishbone diagrams for improvements. Instead the JCDH relied solely upon their technical review team to review cases of infant death for sentinel events, and to identify opportunities for individual or system-level improvements. A system-level opportunity was noted when a woman delivered a stillborn at home shortly after being discharged from the emergency room. The review team subsequently recommended that the local emergency department develop a protocol that women of a predetermined gestation automatically receive an obstetric consultation prior to discharge, a system-level improvement. The technical review team was lead by the county's Quality Improvement Director, and comprised administrators, pediatricians, nurse-midwives and social workers. Though the report of this intervention makes no mention of data collection and measurement, customer satisfaction and systematic improvements were focal points of their efforts. Furthermore, the JCDH incorporated other key elements of CQI such as the use and empowerment of an improvement team, and solution identification. Based on Jefferson County health officials perceptions and observations (program measures and program evaluation were

not reported), they achieved their desired objectives, improved department procedures, and increased community participation (Klerman, Cleckley, Sinsky, and Sams, 2000).

Patient education and disease self-management was identified as a strategy in several CQI interventions. The Diabetes Self-Management Education (DSME) task force maintains standards to ensure that efforts in diabetes education are driven towards quality (Mensing et al., 2006). Studies have shown DSME to be an effective, quality-based method for improving diabetes management and outcomes. In a study by Balamurugan et al. (2006), DSME was used and resulted in a decrease in the mean Hemoglobin A1c, a clinical measure of glucose control, by 0.45%, as well as a decrease in the number of hospital admissions and emergency department and outpatient clinic visits among their targeted population.

In Walla Walla County, Washington, public health practitioners applied CQI to an intervention aimed at reducing the incidence of teen pregnancy, a risk factor associated with adverse pregnancy outcomes (Walla Walla County Health Department [WWCHD], 2010). The county established a quality team of health educators and assessment coordinators to lead the project. The team utilized the fishbone diagram for root cause analysis, and used RCI to execute the intervention. The final intervention was a reproductive health education program targeting young women under age 20 who were sexually active. The intervention goal was for 95% of all participants to have a negative pregnancy test at the close of the intervention. The team exceeded this goal with 98.4% of participants having negative pregnancy tests; although participation declined by 50% by the close of the intervention. The team also observed an 18% increase in knowledge among participants.

Application of CQI in Public Health

Many prominent public health organizations offer assistance and technical support to state and local health departments seeking PHAB accreditation, which would also assist health departments to effectively establish the philosophical CQI elements, at a minimum.

A structural element of CQI involves the use of at least one of the seven CQI tools frequently cited in literature: Pareto charts, flow charts, fishbone diagram (cause and effect charts), histograms, run charts, control charts, and regression analysis (Sollecito and Johnson, 2013, Chapter 1). Shewart's Plan-Do-Study-Act (PDSA) cycle is the most frequently used CQI tool in public health. PDSA is often used interchangeably with PDCA, where the "C" indicates "Check" rather than "Study" (Sollecito and Johnson, 2013, Chapter 1). PDCA is the most frequently used CQI tool because of its broad applicability, ease of use and its success in various settings (NAACHO, 2011). Other CQI tools cited in literature that are used in public health include root-cause analysis, brainstorming, check sheets, frequency plots, check lists, and scatter diagrams, rapid cycle improvement (RCI), and stratification (Kelly, 2011; Kelly, Johnson, and Sollecito, 2013, Chapter 3; Tews, Sherry, Butler, and Martin, 2008). According to a national survey in 2010, local health departments less frequently reported use of methodology such as the Balanced Scorecard, Lean, the Baldridge Assessment, and Six Sigma (NACCHO, 2011). Increased utilization of CQI methods and tools has likely resulted from a greater number of health departments seeking accreditation through the PHAB. To date, PHAB has awarded five-year accreditation status to 11 public health departments, with many more health departments working towards obtaining accreditation (Public Health Accreditation Board, 2013).

Implementation of Evidence-Based Interventions

Intervention implementation is an often overlooked component of quality practices in public health. Substantial research in identifying effective, evidence-based interventions exists, but a disconnection between identification and successful implementation of those interventions is apparent (Lobb and Colditz, 2013; Riley, Bender, and Lownik, 2012). In this use, the term intervention has a broad application, referring to a project in any of the four types of improvement processes previously discussed (localized, organizational learning, process reengineering, or evidence-based management), ranging from improving maternal vaccination rates to seeking national voluntary accreditation through PHAB. Implementation of public health interventions and CQI requires some degree of organizational change, and facilitating change is one of the most challenging tasks faced by organization leaders.

Brownson and colleagues (2009) identified leadership engagement and the expansion of training opportunities for personnel as two methods for overcoming barriers in the application of evidence-based methods. Since CQI is a leadership-led process, effective leadership is critical to successful implementation of CQI interventions. Effective leadership will guide organization staff through many of the barriers that impede organizational change, as well as facilitate transition through the stages of change associated with new organizational processes.

The six stages of implementation for evidence-based programs are: exploration and adoption of the program, program installation, initial implementation, full operation, innovation, and sustainability (Gotham, 2006). The initial implementation stage focuses on researching and selecting practices that are feasible and address the needs of organization. The installation, implementation and full operation stages focus on the creation of policies and procedures, training staff, and mitigating individual and organizational barriers to implementation. Factors

that inhibit successful implementation of evidence-based practices can be divided into three major categories: individual, organizational, and external. External factors are those outside of the organization which are not easily controlled, such as the political climate or stakeholder expectations.

Implementation fidelity overlaps between individual and organizational factors, and is one of the most important components of replicating evidence based interventions. The definition of implementation fidelity is "the degree to which an intervention has been implemented and delivered as designed" (Korda, H. 2013. p. 1). Fidelity is essential because it ensures that the intervention will achieve the same results achieved in research. Replication of each component and variable present in evidence-based research studies is difficult, the stronger the intervention fidelity, the greater the likelihood of achieving the intended outcomes among targeted populations. Intervention implementation comprises of six major components:

> 1) adherence, or implementation of the intervention as designed; 2) intervention dosage or the amount of intervention exposure participants actually receive in comparison with what was described in the original design; 3) the quality of delivery, or manner in which the trainer or facilitator delivers the intervention; 4) participant responsiveness and degree of participant engagement; 5) program differentiation and any unique intervention components that are essential to program success; 6) the overall structure and process of delivering the intervention (Korda, 2013, pp 1-2).

Any significant variation between the model intervention and the replicated intervention indicates a lack in implementation fidelity. Replication of an intervention implies a degree of simplicity for the practitioner because the framework and procedures are already designed, but

still significant implementation challenges and barriers exist. Practitioner adherence is a major barrier to implementation fidelity. Inadequate training, poor training and technical support and poor intervention competency all contribute to poor practitioner adherence. Organizational attributes that facilitate implementation fidelity include organizational stability, leadership, support and motivation for adopting the intervention, training resources and technical support (Korda, 2013).

Perceptions and mental models among leaders, managers and practitioners are another critical component to implementation fidelity; they appear to influence all factors that facilitate or inhibit intervention success (Eby, George, & Brown, 2012; Mosadeghrad, 2013). Perceptions and mental models play a crucial role in all organizational changes. Similarly to preconception health care barriers, perceptions play a major role. Organizational changes are facilitated by a perceived need for improvement. An organization that does not perceive a need for improvements will reluctantly pursue national accreditation and organizational CQI, or simply avoid it. On an individual level, a public health practitioner is less likely to fully-contribute to an implementation process if they do not perceive a need for the process or change is not supported by the facility, or if they perceive the changes to be a disadvantage. Practitioners have noted two perceptions proven to impact their actions and adherence to implementing CQI: their perception of management practices, and perceived fairness or support throughout the process (Eby, George and Brown, 2013). Practitioner's perceptions are influential in implementation sustainability, along with their attitudes and actions in the early phases. Perceptions and attitudes also influence the success of interventions and usefulness in later phases.

Discussion

A key finding of this paper is that, although recommendations exist for improving the quality of specific PCC components, none were identified that specifically suggest the integration of CQI to improve the entire care process of PCC. Also noted is that few studies mentioned the application of CQI to PCC from an organizational management standpoint, despite CQI being a management process and philosophy. The implementation of CQI at the organizational level (Big QI) could generate vast improvements in the delivery of PCC beyond the small improvements observed at the project level (little qi). Quality leadership skills are essential to the transition from project-level CQI to organization-level CQI, but further recommendations on leadership as a tool to improve CQI and PCC are needed. Health department leaders and managers would benefit from guidance or training that enables them to execute major, transitional changes to philosophies and practices within organizations. Additionally, more research is needed to assess the impact of organization-wide CQI on PCC.

The studies examined for this paper demonstrate that CQI can be effectively used to improve targeted interventions, as determined by measured outputs. The literature shows that CQI is increasingly utilized to improve infant mortality reduction efforts, but use of CQI appears disconnected and inconsistent among interventions.

The CDC (2006), Michael Lu et al. (2010b) and the March of Dimes presented the most extensive recommendations for practicing and improving PCC, yet were both limited in some regards. Only several of the CDC's recommendations reference the application of CQI to improve PCC services or programs. QI was a key focus of the March of Dimes' report, which provided the most extensive recommendations to improve PCC and perinatal outcomes as a whole; recommendations however were not specific for the managerial or ongoing-improvement

aspects of CQI. These findings indicate a substantial opportunity for a framework that guides the integration of CQI and PCC.

A limitation of this paper and the examination of current practices are that research methods were not exhaustive. A limited number of textbooks were reviewed, and recent graduate theses or doctoral dissertations were not reviewed at all. Consideration must also be given for research or recommendations that have been published since the start of this paper, or is work that is currently underway.

Recommendations

The following are proposed recommendations and suggested tools to aid practitioners with state and local health departments in developing and improving PCC practices. The recommendations are merely a starting point for health departments to implement high-quality interventions that best suit the needs of their organization and the population being served.

CQI is a leadership-driven approach, so the implementation of these recommendations should originate with leadership's commitment to quality improvement and learning. All CQI initiatives should originate from a leadership vision and stated goals or objectives, which will guide improvement processes. Once project-level CQI has been integrated with PCC practices, efforts should be made to expand to organization-level CQI; research shows that this approach is most effective (Riley et al., 2010). Organization leaders should at a minimum establish training programs and support processes for personnel, and develop a quality improvement team to oversee the improvement process. Further development and exercise of leadership skills will be essential to overcoming barriers associated with implementation of CQI practices.

Noted in the literature review was the lack of studies evaluating cost effectiveness and sustainability of CQI interventions. Also, none of the studies reviewed were long-term, highlighting the need to evaluate studies over an extended period of time. In order to generate sustained improvements, public health must develop initiatives that can be carried out over a period of years to actualize the greatest benefit.

Identification and selection of process measures are essential components of measurement and data analysis (Kelly, 2011). Table 5 provides suggested process measures or interventions for each PCC recommendation from the CDC.

Table 5: Suggested Process Measures and Interventions for CDC Recommendations

PCC Recommendation from the CDC (2006)	**Suggested Process and Outcome Measures or Interventions**
1. Individual responsibility across the lifespan and RLP	Process and Outcome Measures: The proportion of patients with a RLP; the proportion of patients taking active measures to follow their RLP (i.e., using contraceptives); the proportion of care providers providing support for RLP development and maintenance; the rate of unplanned pregnancies. Sample Project: Incorporate RLP development into all routine care practices offered at a facility. Design a process to screen patients for RLPs and to disseminate RLP tools and resources. The project goal is to observe a 30% increase in the number of patients with RLPs.
2. Consumer awareness	Process and Outcome Measures: Public knowledge and perceptions of PCC and RLPs, the number of programs targeting specific groups (i.e. middle and high school education campaigns, programs for Spanish-speaking women), the increase in PCC knowledge among targeted populations. Sample CQI project: Implement a social marketing campaign using Facebook and Twitter to increase knowledge about preconception care and health among targeted populations.
3. Preventive Visits	Process and Outcome Measures: The number of primary care facilities in a region with PCC screening methods integrated with routine care practices, the number of primary care facilities in a region with health promotion and health education practices, the number of health care providers (primary care and specialists) who have received training in PCC practices, the percentage of women receiving PCC

	through primary care visits. Sample CQI project: Develop and monitor a system for screening women for preconception risks that ensure that patients within a health care facility receive appropriate follow-up.
4. Interventions for Identified Risks	Process and Outcome Measures: The proportion of women in a region with previous adverse pregnancy outcomes who receive risk specific interventions, the number of health care providers (primary care or specialist) with a follow-up or referral process for women with identified risks, the pregnancy rate among women with chronic diseases. Sample CQI project: Develop a system that monitors women with identified risks for adverse pregnancy outcomes that ensures they receive the necessary education, counseling, or other form of intervention. .
5: Interconception Care	Process and Outcome Measures: The proportion of women with adverse pregnancy outcomes who receive interconception care, rates of specific adverse outcomes (infant loss, LBW, birth defects, etc) among women receiving interconception care, rates of subsequent pregnancies within two-years following a poor pregnancy outcome. Sample CQI project: Improve the proportion of women with previous adverse pregnancy outcomes who receive interconception care by 30%.
6: Prepregnancy Checkup	Process and Outcome Measures: The number of 3rd party payer or insurance companies used by residents that provide coverage for prepregnancy visits, the number of women lacking access to prepregnancy visits (women without insurance who don't qualify for Medicaid). Sample CQI project: Increase the number of women and couples who are educated on the value of pregnancy visits and their options regarding access to such care.
7: Health Insurance Coverage for Women with Low Incomes	Process and Outcome Measures: The number of women of child bearing age with no form of health insurance coverage; the number of women of childbearing age who receive health insurance coverage through federal options, waivers or the State Children's Health Insurance Program; the status or number of policy developments or changes that would expand health care coverage for women. Sample CQI project: Identify barriers to expanded health insurance coverage such as limited policies or limited awareness of resources. Increase the proportion of low-

	income women of childbearing age who receive Medicaid through family planning waivers by eliminating or reducing barriers.
8: Public Health Programs and Strategies	Process and Outcome Measures: The number of middle and high school health education curriculums that include preconception health and PCC; the number of community organizations (health care facilities, task forces, coalitions, etc) with PCC goals or aims; the number of state and local health department programs that offer pre- and interconception comprehensive risk screening, health promotion and family planning. Sample CQI project: Strengthen community partnerships and increase promotion of PCC at the community level. Improve training, educational materials and provide assistance for community health programs that promote or provide PCC.
Recommendation 9: Research: Increase the evidence base and promote the use of the evidence to improve preconception health	Process and Outcome Measures: The number of care providers that utilize evidence based methods; the number of care providers participating in task forces, coalitions, partnerships, and learning collaborative or information-sharing programs; Sample CQI project: Increase the number of care providers that participate in collaborative learning and information sharing programs. Identify the best method to educate providers on available resources and encourage participation.
Recommendation 10. Monitoring improvements:	Process and Outcome Measures: The number of preconception health indicators and risk factors that are monitored routinely, including the percentage of women who receive PCC and interconception care (postpartum care or visits etc.); the number of analytical tools available for monitoring (i.e. Perinatal Periods of Risk), the number of Healthy People 2020 objectives met or process towards that achievement. Sample CQI project: Increase the number of health departments or health care facilities that routinely measure and monitor preconception health indicators and risk factors through outreach. Disseminate educational materials and methods for data collection to all sites that provide PCC.

These recommendations are intended to be only a starting point for CQI within state and local health departments to improve PCC. The establishment of baseline process measures for PCC could however provide standardization within intervention practices and benefit numerous

health departments. Selection of process measures should enable CQI practitioners to monitor progress during the project, as well short-term and long-term success through outcome and impact measures. In conclusion, integrating of CQI with PCC is a promising approach to improving maternal health, birth outcomes, and even reducing IMR disparities. National recommendations should be amended to include not only QI for selected measures, but CQI for the entire PCC approach to generate the greatest impact on IMR and IMR disparities.

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