The Care Process Design System:
Using Operations Management Methodologies and Process Management Automation to Operationalize Clinically Integrated Organizations

*White Paper*

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**INTRODUCTION**

Much activity has taken place since the passage of the Affordable Care Act in 2010 to organize providers into clinically integrated organizations (CIO). Also, many government and commercial payers have introduced value-based reimbursements in the last few years. These incentives, such as the value-based purchasing program for hospitals, have further hastened the pace of organizational and structural changes around clinical integration.

With the passage of the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015 and the resultant alignment of hospital and physician providers around value-based care delivery, the tipping point seems to have been reached.

The question now becomes how to operationalize the many existent clinically integrated organizations (CIOs). In particular, how should these entities go about designing and managing clinical and non-clinical processes within the healthcare system, measuring and reporting quality performance, accurately measuring costs of care delivery, lowering costs while sustaining or improving quality and patient safety, creating savings that can be used to finance CI operations, and capturing marketing share of available value-based reimbursements (VBR).

The organizational development of CI entities has been adequately covered elsewhere, and many such organizations have done so successfully. This paper will, therefore, describe a comprehensive and systematic approach to operationalizing CIOs which will, in turn, allow these structures to realize the overarching goal of clinical integration, i.e., to improve value, defined as quality per unit of cost, production by the care delivery system.

**CI TO DATE**

As mentioned, the emphasis to date has been on the organizational and structural development of clinically integrated organizations. Many multi-specialty provider groups have now met the criteria to function as clinically integrated networks or CINS, and those that are participating in Medicare Shared Savings Programs are commonly now referred to as accountable care organizations or ACOs.

In the primary care specialties, many providers groups are now functioning as patient-centered medical homes (PCMH), and some have participated in the multi-payer Comprehensive Primary Care (CPC) and Comprehensive Primary Care Plus (CPC+) programs.

Organizational restructuring, however, of traditional provider groups will not be enough to ensure success in the healthcare marketplace of the future. CI structures containing business and clinical activities designed to drive volume in an acute care model won’t align organizational
and operational strategies. Instead, the care delivery system must retool to produce high-value care and compete in a value-based reimbursement environment.

Providers must also learn from prior unsuccessful attempts to operationalize CI entities that have either used poorly structured methods or have been unable to overcome significant obstacles. For instance, efforts to standardize care through mandated use of standard order sets or care guidelines have met with great resistance by providers who understand that medical practice is not a one size fits all proposition. Furthermore, initiatives that purport to apply operations management techniques such as Lean or Six-Sigma to healthcare delivery without first addressing the artificial, i.e., man-made, variability inherent in patient flow commonly result in failure. Additionally, it is usually hard to get everyone, especially providers, indoctrinated into LEAN programs. Next, and perhaps most importantly, the use of IT systems to support data-driven process improvement in healthcare have been stymied by seemingly insurmountable problems creating interoperability between disparate EHRs and other data systems. Finally, transient initiatives are common in many CI programs, and if lasting and continuous improvements in value production are to occur systemic and permanent changes in the delivery system must be utilized.

**Optimizing Effectiveness and Efficiencies of Current Care Processes**

A better understanding of care processes should be the first step in operationalizing CIOs. This comprehension can be accomplished through the use of process mapping techniques and by utilizing the latest innovations in process management systems that ideally are automated and non-disruptive. These systems should also be capable of achieving accurate real-time process visibility with continuous stakeholder communication metrics regarding the existing processes. Even without implementing changes in existing processes, the enhanced awareness, visualization, and feedback regarding the myriad steps involved in care delivery can produce efficiencies and improved outcomes.

Particular attention at this point should be given to identifying and eliminating or mitigating artificial variability in patient flow that can impede operational performance. As an example, smoothing the elective surgical schedule has been shown to improve throughput within many surgical or procedural areas, such as hospital operating rooms, ambulatory surgery centers, imaging centers and endoscopy suites. Also, eliminating the day-to-day variability in elective schedules can have a significantly positive downstream effect in hospitals, where mid-week peaks in patient flow can add costs, create patient or provider dissatisfaction and, of greatest concern, increase morbidity and mortality rates.

Lean manufacturing systems categorize waste into eight areas including transportation, inventory, motion, waiting, over processing, defects, and human potential. Any CIO should
scrutinize their activities during this step to allow for the systemic elimination of waste and inefficiency, which is inherent in the healthcare delivery system.

**DESIGNING NEW PROCESSES OF CARE**

In many situations, providers will have to design new processes of care to meet the challenges of achieving the now well-accepted Triple Aim of Healthcare Delivery—Patient Care, Population Health, and Cost Containment. Care process design will require providers to develop novel and innovative ways of delivering care, especially in the area of population health management.

While the scientific evidence base can inform this care design process, many of the questions that need to be answered have not been subjected to clinical trials and, therefore, the evidence base to support most of these new processes is sorely lacking. Those involved in the design process will, therefore, need to apply their knowledge, experience, and innovative ideas to the questions at hand to at least establish baseline guidelines, which can then be continuously improved over time via an iterative process.

Coordinated and highly efficient care delivery across the care continuum will require input from many clinical and non-clinical disciplines. Their focus should be on the Care Process Unit (CPU) which may be any commonly performed process or procedure with a clearly defined start and stop point. CPUs can be as simple as an office visit in a primary care clinic to as complex as a surgical procedure in a hospital operating room. Multi-disciplinary care process design teams should be assembled around these CPUs, and the design process should be done in a non-hierarchical collaborative fashion that optimally should also include patients to ensure the design of a patient-centered care experience.

The input of providers will be essential. Hence, the process development must be inclusive. The constant lament by providers that their patient population, practice location, facilities, staff, or equipment is terminally unique should also be acknowledged, and care process design activities should be customized down to the individual provider, care team, and care location level.

Finally, design teams must recognize that care delivery no longer occurs solely within the four walls of a traditional healthcare facility. Those providers who cannot utilize care processes within non-traditional settings, such as the community, home, or virtual environment (mobile technology, the internet, etc.) will not be able to advance the Triple Aim.

**OUTCOME MEASUREMENTS — QUALITY AND COST**

The very essence of clinical integration is the measurement of both the numerator and denominator of the value equation where value = quality/cost.
Quality measurement in healthcare remains a very nascent science. However, the industry seems to be gravitating toward a generally accepted set of metrics known as the Healthcare Effectiveness Data and Information Set (HEDIS) recommended by the National Committee for Quality Assurance (NCQA), which are especially relevant to hospitals. These metrics will need to be further refined and expanded, going forward, especially with regards to the inclusion of true patient and disease defined outcome as opposed to process measures. Furthermore, providers and others involved in clinical integration will need to develop custom metrics that they feel are most valuable in guiding improvements in their particular processes or procedures. This input is particularly important for the surgical and medical specialty practices.

The standard methodologies used to measure costs in healthcare are even less accurate and reliable than those used to monitor quality performance. Few healthcare systems and even fewer hospitals or physician practices have felt the need to invest in sophisticated cost accounting systems. This position is understandable, given that until relatively recently, there has been minimal downward pressure on reimbursements, which especially in the commercial sector virtually assured profit margins for even the most inefficient care providers. The move toward value-based reimbursements, however, has dramatically changed this situation; and VBRs, such as bundled or capitated payments, have required providers to measure costs more carefully and attempt to eliminate those that are non-value added.

Time-driven, activity-based, cost accounting (TDABC) is now considered to be the most accurate way of measuring the true costs related to the delivery of healthcare services. TDABC is certainly far superior to notoriously inaccurate proxies for estimating costs, such as charge-to-cost ratios or labor RVUs. TDABC is also very useful for measuring costs related to specific clinical conditions or care processes and procedures. More traditional managerial accounting methods allow for tracking of expenses at the departmental or nursing unit level but do not track costs across the continuum of care for any specific clinical condition or procedure. Accurately pricing bundled or capitated payments will require a cost accounting methodology such as TDABC that can provide this kind of clinical condition/process specific information.

**Refinement of Care Processes**

Theoretically, any care process or procedure can be improved as to its value (quality/cost) production. This ideally is done via a systematic data-driven process improvement methodology, such as the Plan, Do, Study, Act (PDSA) embedded in the Model for Improvement popularized by the Institute for Healthcare Improvement (IHI).

CI programs attempting to iterate care processes must, however, first understand their care process units (CPUs), which can be accomplished by utilizing a modified Lean process mapping technique that outlines the specific steps in any CPU. More importantly, they must have access to near-real time quality and cost outcome data that can be used to measure results of any
changes or modifications in the CPU. Finally, the iterative improvement process for any CPU must be done in a methodical, standardized, and continuous basis. Haphazard changes in the care process or implementing changes, such as cost eliminations, without measuring results will only lead to chaos and confusion.

**IT SUPPORT OF CI OPERATIONS**

Implicit in the recommendation that CIOs practice data-driven process improvement is the need for IT systems that can support this effort. Many CI programs have found electronic health record (EHR) platforms to be inadequate to this task and attempt to connect disparate EHR systems through health information exchanges (HIE) have only led to further disappointments with both the ultimate functionality and costs of these networks. Similar obstacles have stymied efforts to utilize integrated practice management systems (PMS) to measure cost data across CIOs. Finally, trying to obtain either cost or quality data through paid claims analytic systems has been met with resistance from payers who loathe sharing this paid claim information. Further, the fact that even when the claims are available, the ability to use payer information to measure and monitor clinical care processes in a timely and accurate fashion is profoundly limited.

Given the limitations of using EMR or PMS technology to support a CIO’s PI efforts, what are the alternatives? Process management automation (PMA) technology, such as the Watershed system, developed specifically by Integrated Business Systems and Services (IBSS), offers a solution that allows organizations to define, execute, manage, and refine processes that involve human interactions, work with multiple applications, and handle dynamic process rules and changes.

PMA technology has the advantage over other IT systems currently being used in healthcare organizations in that it can provide managers and clinicians with both predictive and real-time awareness of clinical activities that allow for decisions to be made on the fly that drives both quality and efficiency. Furthermore, data can be captured on a PMA platform in an unobtrusive and automated fashion that can later be used to measure adherence with quality and safety guidelines, and to calculate costs (using TDABC).

Coupling the insights gleaned from PMA technology with efforts to minimize artificial variability in patient flow and Lean process engineering can then lead to the creation of a true continuous learning system that refines processes over time and results in higher and higher value production for the benefit of the patients served. This system then contains the characteristics of a continuous learning healthcare system put forth by the Institute of Medicine to include real-time access to knowledge, digital capture of the care experience, engaged and empowered patients, incentives aligned toward value, a leadership-instilled culture of learning, and supportive system competencies.
MARKETING AND SALES OF CI ACTIVITIES

The market for value-based healthcare services is growing and now includes government payers at the federal and state level, commercial payers, large self-insured employers, and other clinically integrated entities who may be looking to fill gaps in their specialty or sub-specialty networks. While this market has evolved at variable rates in different parts of the country, the announcement and now implementation of a value-based reimbursement system covering both the technical and professional sides of Medicare has particularly accelerated the move from a volume-based (Fee-for-Service or FFS) to a value-based (Fee-for-Value or FFV) business model across the country.

Another insight that many provider organizations are now realizing is that even in a FFS model, which may persist for some time in many areas, a focus on elimination of costs, particularly those deemed to constitute waste and inefficiency, can be of extreme value. FFS payments may linger, but they will not likely be increasing, and full payment (FFS payment plus a shared savings incentive) will likely be contingent on achieving quality or cost efficiency targets. In this model, the systematic identification and elimination of non-value-added costs can preserve margins and allow providers to maintain incomes.

As the FFV model becomes more the norm, CIOs will need accurate cost data to help price bundled payments and negotiate capitated rates. It should not be forgotten, however, that successful negotiations of VBRs will ultimately depend on the ability of the CIO to drive value at the bedside or exam room level through a systematic approach to care process transformation.

It will be important for CIOs also to realize that the volume to value shift does not necessarily imply that the need to provide services to a high volume of patients will necessarily lessen. In fact, given the aging of the population with their associated chronic disease burden and the enhanced access to health insurance brought about through the ACA, the demand for access to services will likely increase. Therefore, the challenge will be how to provide high volume and high-value services simultaneously. Further, the volume of market share may replace the volume of patient visits as the target that will ensure financial success over the long term, as population health management (PHM) agreements become more prevalent.

Large self-insured employers may be especially attracted to those CIOs who can reliably deliver high-value care, especially for those conditions that consume the majority of the employer’s healthcare dollars. For chronic diseases, such as diabetes, hypertension, heart failure, chronic obstructive pulmonary disease (asthma, emphysema, and chronic bronchitis) and expensive procedures, such as total joint replacement and cardiac interventions, providers can pursue methods to direct contract with these self-insured employers. Over time and as these clinically integrated providers learn how to provide high-value care delivery for both acute and chronic conditions, across all specialties and the entire care continuum, to include prevention and
wellness services, large employers may contract directly with these organizations for true population health management of their employee populations.

**CONCLUSION/SUMMARY**

Clinically integrated care delivery will require both an organizational and operational transformation of the healthcare delivery system. This change will not be easy or inexpensive. A systematic approach is needed to assure that the switch from a predominantly acute care delivery system paid for through fee-for-service reimbursements to a system utilizing value-based-reimbursements to incentivize the achievement of the Triple Aim, happens as smoothly and with as few disruptions as possible.

The Care Process Design System incorporates the knowledge and experience of a trusted national healthcare advisory firm (Coker Group) with modern operations management techniques (Variability Management, Lean) and process management automation technology (Watershed) to assist providers who recognize that inexorable change is happening and proactive moves to respond to this change are necessary.

In the end, the approach outlined in this paper provides a unique set of services that focus on the clinical care process unit, i.e., the frontlines of care delivery, overcome interfacing and interoperability issues that have bogged down many other attempts to effectively use IT systems to improve CI programs, avoids application of a standardized delivery system, and instead recommends standardizing the approach to care delivery/process improvement. The CPDS can be applied to all types of processes, procedures, conditions, episodes of care, locations of care, and payment models. Finally, the CPDS respects the fact that successful clinically integrated care delivery organizations will involve a multi-disciplinary approach where healthcare providers and non-clinical professionals work in a coordinated fashion to drive value.

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