

Uncovering Opportunities for Cost Containment and Operational Improvements via Shared Practices between Device Manufacturer and Hospital

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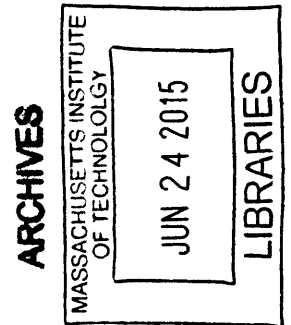
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Background

Medical device manufacturers (suppliers) and hospitals (providers) face financial and operational stressors exacerbated by recent healthcare reform. Providers now face the prospect of decreased reimbursements and financial penalties associated with quality of care metrics while suppliers must cope with product commoditization and increased scrutiny of device cost. To address these financial and operational pressures, suppliers and providers will need to uncover opportunities for cost savings and improvements in clinical care. The consumer packaged goods (CPG) industry provides insight into a vehicle for achieving such results as there exist cases in which collaboration between suppliers and customers have been able to generate financial and operational gains.

Question

Given such cases of collaborative success within the CPG space and parallels in supply chain environments between the CPG and medical device industries, we ask: what are the opportunities for cost savings and operational efficiencies that can be realized via collaborative supply chain practices between medical device manufacturers and hospitals?

Methodology

We implement a two-step approach to constructing a model that identifies such opportunities. First, to establish the foundational framework for this model, we propose several hypotheses (H1, H2, H3) that relate to the CPG and medical device domains based on existing theory as well as interviews and observations at Device Company X, a leading device manufacturer, and at Hospital X, a Harvard Medical School affiliated teaching hospital. These hypotheses are:

H1: Shared practices between suppliers and customers can generate cost containment and operational improvements in the CPG domain.

H2: The operating environments between CPG and medical device companies share similarities with respect to operational goals, product characteristics, and logistical pressures.

H3: Supply chain shared practices between US medical device companies and hospitals can generate cost containment and operational efficiencies.

Second, we propose a collaboration model that can be leveraged to test H3 by building on the core principle of shared practices that underlie a pre-existing collaboration model within the CPG space. To create this model, we examined operations within a procedure suite at Hospital

X. This entailed assessing the process steps required for inventory replenishment and product consumption while noting the role of Device Company X in facilitating task execution.

Findings

The CPG domain and medical device industry may share similarities within their operating environments. As such, collaboration practices within the CPG space may provide a template for financial and operational solutions that medical device companies and hospitals can benefit from. Building on a prior model used within the CPG space, we propose a collaboration model with three operational levers for hospitals and device manufacturers that may represent sources for cost containment and operational efficiencies. These operational dimensions include physician practice standardization, inventory replenishment, and space utilization. Our model calls for redefining the roles of medical device company personnel within clinical care territories to include greater participation in hospital value-add activities.

Next Steps

Device manufacturers and hospitals can test the feasibility of sources for cost containment and operational efficiencies within the proposed collaboration model by implementing survey based modalities to uncover enablers and barriers to collaboration. For both parties, conducting low-stakes, time friendly pilot studies offers a compelling route to “testing the waters” of collaboration.

Thesis Supervisor: Steven J. Spear
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Message from the Author

Because of the potentially sensitive nature of working with stakeholders on both the hospital and medical device domains for this project and my background as a physician, in the spirit of full disclosure and transparency for any potential conflicts of interest, I want to make it known that while drafting this thesis publication, I have been taking part in paid project assignments for Boston Scientific and Pfizer.

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1. Introduction

1.1 The Problem

Responding to a Changing Landscape

Healthcare delivery in the United States faces significant financial and operational challenges. These challenges have intensified due to recent healthcare reform such as the Affordable Care Act (ACA) which has placed new demands on the delivery of patient care [1]. Such legislative reform was intended to curb high levels of healthcare costs which represented 16.9% of US GDP in 2012 [2]. Compounding these financial pressures is a changing paradigm in reimbursement and accountability set forth by the Affordable Care Act in which hospitals are now scrutinized on a range of quality of clinical care metrics that dictate reimbursement levels and financial penalty severity [1]. The implications are obvious: All players within the healthcare value chain must take notice of a new business environment that requires uncovering opportunities for cost savings and operational improvements intended to enhance quality of patient care. For this manuscript, we will focus on two particular players- medical device manufacturers (suppliers) and healthcare delivery organizations (providers). Further, we will narrow the map for uncovering opportunities for cost savings and operational improvements to the supplier-provider supply chain.

1.2 Methodology

To construct a collaboration model that identifies opportunities for cost savings and operational improvements within the hospital-device manufacturer supply chain, a two-step approach is taken.

First, to formulate the foundational framework for a collaboration model, hypotheses (H1, H2, H3) about practices and conditions within the CPG and medical device domains are generated based on existing theory noted in literature as well as interviews and observations at Device Company X, a leading device manufacturer, and Hospital X, a Harvard Medical School affiliated teaching hospital. These hypotheses are:

H1: Shared practices between suppliers and customers can generate cost containment and operational improvements in the CPG domain.

H2: The operating environments between CPG and medical device companies share similarities with respect to operational goals, product characteristics, and logistical pressures.

H3: Supply chain shared practices between US medical device companies and hospitals can generate cost containment and operational efficiencies.

Second, to provide a tool for assessing the merits of H3 and unmasking opportunities for cost containment and operational efficiencies, we construct a collaboration model by building on the core concept of shared practices that underlie a pre-existing collaboration model used within the CPG space. We formulate our model based on observations of daily operations at the “Center for Advanced Endoscopy” (CAE) procedure area at Hospital X. In particular, we assess processes that relate to inventory replenishment and product consumption using a previously proposed

framework to scrutinize design parameters and help uncover sources of operational problems at CAE [3]. We also examine the existing and potential roles of supplier representatives from Device Company X in facilitating timely execution of tasks related to inventory replenishment and product consumption. Our analysis is based on interviews with hospital supply chain personnel and clinical staff, as well as observations of clinical procedure areas and receiving facilities. Further, to incorporate depth and understanding of the supplier perspective into a collaboration model, we conduct interviews with stakeholders at Device Company X, visit its local distribution facility, and review internal supply chain metrics and performances. In sum, we examine the supply chain milieu through the lens of both supplier and provider to analyze the process architecture at CAE. In doing so, we construct a collaboration model that identifies potential sources of cost containment and operational improvements within this industry.

1.3 Thesis Overview

This manuscript proposes a supply chain collaboration model to identify opportunities for cost savings and operational improvements that entail shared practices between medical device manufacturers (suppliers) and hospitals (providers). It is based on insights gleaned from the Consumer Packaged Goods (CPG) industry and lessons learned through observations at Device Company X, a leading medical device manufacturer and Hospital X, a Harvard Medical School affiliated teaching hospital. It is organized into six chapters, each written with particular objectives in mind.

Chapter 1, *Introduction*, notes that US healthcare is undergoing a transformational change in which cost containment and improvements in quality of care are now in vogue more than ever as a result of recent healthcare reform. As such, hospitals and device manufacturers are seeking additional opportunities to rein in costs and improve clinical care quality. An approach to constructing a collaboration model that identifies such opportunities is outlined. To establish the foundational framework for this model, hypotheses about practices and conditions within the consumer packaged goods (CPG) and medical device industries are generated via literature review and observations at Hospital X and Device Company X. In doing so, parallels in operating environments between CPG industry and the medical device space are uncovered. Operational similarities between these two industries may allow for extrapolating success drivers in the CPG space to the device-hospital supply chain space. To construct a collaboration model between hospital and supplier, an analysis of process architecture for inventory replenishment and product consumption at a procedure suite operated by Hospital X is carried out.

Chapter 2, *Background*, notes pressures that stakeholders within the device company- hospital context are experiencing. Specifically, healthcare providers are in many cases operating in a low margin environment. Payers are responding to the increased burden of a new stream of previously uninsured patients. Medical device manufacturers are tackling issues of commoditization and obsolescence of products. Compounding these pressures on all parties are healthcare reform mandates that scrutinize quality of clinical care.

Chapter 3, *Consumer Packaged Goods Industry: Insights & Relevance*, introduces hypotheses that serve as the foundational framework for constructing a collaboration model applicable to

device manufacturer and hospital. These hypotheses are formulated by examining the CPG domain to uncover the CPFR model, which embodies shared practices between supplier and customer. Shared practices, as noted by this model, have generated operational and financial gains for companies within the CPG space. Furthermore, there exist commonalities within the operating environments of CPG and medical device companies that relate to inventory goals, customer preferences, and commoditization of products. The existence of these operating commonalities suggests that shared practices between hospitals and medical device companies may be used to possibly generate operational and financial gains in this sector as well.

Chapter 4, *Process Design Case Study*, analyzes the process architecture at the “Center for Advanced Endoscopy” (CAE) procedure area within Hospital X as it relates to inventory replenishment and product consumption. Specifically, present day symptoms at CAE include high inventory burden and expired product levels, difficulty locating products, and disruptions or delays in patient care as a result of poor inventory transparency. The drivers for symptoms include poor understanding by clinical personnel in recognizing the conditions in which process goals should be accomplished including consideration of time delays, minimization of inventory, reduction of “open but unused product” and expired product levels. Clinical staff complete process steps in an impromptu, haphazard manner with ambiguous and non-standardized approaches to work. A prescription for operational inefficiencies at CAE may necessitate cultivating shared practices between CAE and Device Company X. Both parties may wish to rethink the roles of supplier representatives within clinical care territories to include participation in CAE value add activities. These recommendations allow for the synthesis of a collaboration model with three operational levers that represent opportunities for cost containment and

operational improvements. These three dimensions are: Physician practice standardization, inventory replenishment, and space utilization. Further, this model is predicated on expanding supplier personnel participation in hospital value add activities.

Chapter 5, *Discussion*, notes industry implications based on findings at CAE. Recommendations are proposed for hospital and supplier collaboration to involve a reassessment and realignment of supplier representative roles. Hospitals may wish to leverage supplier personnel to achieve pre-defined provider value add activities by engaging with those suppliers that have demonstrated a propensity for reciprocity. Providers may further consider making it a pre-requisite for suppliers to participate in hospital value add activities as a condition for being granted access to clinical staff.

Chapter 6, *Conclusion*, recapitulates the hypotheses that serve as the foundational framework for a proposed collaboration model. This model may be used to test the hypothesis that shared practices between hospitals and suppliers can generate cost containment and operational improvements. Further, implementing survey based modalities to assess receptiveness to the notion of shared practices among clinical staff and supplier personnel may be a prudent antecedent step prior to initiating collaboration partnerships. Lastly, hospitals and suppliers may wish to engage in small “low risk” pilot studies to validate the feasibility of the proposed opportunities for cost containment and operational improvements.

2. Background

2.1 The Stakeholders

Various stakeholders, ranging from public to private entities, collectively help deliver healthcare to patients in the United States. They act in concert to provide patients acute medical interventions and therapeutics as well as longitudinal and preventative services. We focus our discussion on one segment of healthcare delivery- the application of medical devices for diagnosis and treatment of patient disease states. The following table summarizes the most notable participants based on their roles within the supply chain, and the operating environment pressures they encounter.

Table 1 Summary of Key Players, Roles, and Operating Pressures

Supply Chain Member	Role	Operating Environment Pressures
Healthcare Providers	Deliver patient care requiring medical devices	Low operating margins, financial penalties tied to quality of care metrics
Payers	Fund patient care costs, and hospital and physician services	New stream of previously uninsured patients due to healthcare reform
Medical Device Manufacturers	Develop and commercialize medical devices	Commoditization and obsolescence of products

Medical Device Manufacturers

The US medical device domain is characterized by ample market size and diverse product offerings. US device companies are competing for a piece of a roughly \$110 billion industry opportunity [4]. A key player within this industry, Johnson & Johnson, generated \$28.5 billion in 2013 sales via one of its business segments that sells devices, among other products [5].

Additionally, the product portfolios of device companies overall can be broad, extending across multiple organ systems and spanning a wide umbrella of disease severity and patient populations.

In addition to the variety of products marketed by device companies, the product landscape is far from static as existing products can get outdated within a matter of “eighteen to twenty-four months”, albeit with newer entrants that have only minor upgrades [6]. Additionally, in this environment of cost-consciousness, providers may be placing less emphasis on these minor upgrades, a trend that may be driving commoditization within the medical device arena.

Healthcare Providers

Healthcare providers are the eventual recipients of the products sold by medical device companies. For purposes of this manuscript, we will narrow the scope of healthcare providers as referring to the 5686 hospitals in the United States recognized by the American Hospital Association which may be stand-alone entities or part of broader health systems or health networks [7].

US healthcare providers, although abundant in number and reach, receive less than a passing grade for financial performance. According to a Standard & Poor’s Ratings report that outlined financial trends amongst a cohort of healthcare delivery organizations, operating margins for a sample of providers suffered a decline from a 2012 level of 2.6 percent to 2.1 percent in 2013 [8]. In fact, operating margins have consistently remained low in this sample of providers, having ranged from 1.8 percent to 2.7 percent during the 2008-2013 time period [8].

Payers

Payers in the US health system fund and finance patient care costs, including inpatient and outpatient expenses, as well as prescription care programs. Healthcare providers rely on payers to fund hospital and physician services. The payer landscape in US Healthcare can be divided into two cohorts: Public and Private. The following table outlines the key players within each group:

Table 2 Largest US Healthcare Payers

Selected US Healthcare Payers	
Public	Private
Medicare	Employer Sponsored
Medicaid	Non-Employer Sponsored
Other (VA, CHIP Programs)	

Source: U.S. Census Bureau, Health Insurance Coverage in the United States: 2013 [9]

US healthcare payers play a critical role in impacting reimbursement rates for products sold by device companies and services offered by hospitals. Return on investment of new products for medical device companies is heavily predicated on achieving appropriate pricing and reimbursement from payers. Hospitals may also be incentivized to reduce patient care costs that may not meet thresholds for reimbursement from payers. Therefore, it is no surprise that device manufacturers and hospitals pay close attention to policies set by payers.

2.2 Healthcare Reform

Recent healthcare reform has placed new financial and operational pressures on hospital and medical device companies. Cost containment and quality of care have moved to the front of the line of business objectives as a result of specific mandates imposed by the Affordable Care Act (ACA). The following table provides specific section headings as written in the Affordable Care Act that emphasize the shift to quality driven care, and its impact on hospital reimbursements.

Table 3 Emphasis on Quality of Care by ACA

“Sec. 2702. Payment Adjustment for Health Care-Acquired Conditions.”
“Sec. 3001. Hospital Value-Based purchasing program.”
“Sec. 3002. Improvements to the physician quality reporting system.”
“Sec. 3004. Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs.”
“Sec. 3007. Value-based payment modifier under the physician fee schedule.”
“Sec. 3008. Payment adjustment for conditions acquired in hospitals.”
“Sec. 3025. Hospital readmissions reduction program.”

Source: Patient Protection and Affordable Care Act [1]

On the supplier side, one provision directly affecting device manufacturers calls for a tax of 2.3 percent on devices sold by manufacturers [10]. Although attempts have been made to repeal such legislation, device manufacturers to date are still grappling with the financial costs imposed by such a tax.

3. Consumer Packaged Goods (CPG) Industry: Insights & Relevance

3.1 CPG Industry: Uncovering a Model for Supply Chain Collaboration

We aim to uncover a model for collaborative supply chain practices within the CPG space that outlines actions and conditions associated with financial and operational benefits. To that end, we review supply chain developments within the CPG space as noted in existing literature and subsequently conclude with a working hypothesis that addresses the following question:

Q1) What collaborative supply chain practices are associated with financial and operational gains within the CPG domain?

Expanding communication channels between supplier and customer can help cultivate value-add collaborative activities for both parties. For example, Kellogg Company and Tesco supermarkets jointly leveraged “point-of-sale” information to determine causes for “out-of-stocks” events at Tesco, and collaborated together to generate financial gains for Tesco [11]. From a broader perspective, this example illustrates the utility of information sharing in mitigating unfavorable inventory events such as stock outs. Further, this strategy may also help alleviate the increasing fluxes in demand as one moves upstream within a supply chain, a phenomenon commonly referred to as the bullwhip effect [12].

Information sharing can be leveraged to affect a myriad of supply chain and operational activities. A broader model used by CPG companies that expands on information sharing is the collaborative planning, forecasting, and replenishment (CPFR) tool. The CPFR model, summarized below, outlines steps in which supply chain partners work together to create sales

and order forecasts which can help to achieve operational goals for companies [13]. In this model, two supply chain partners such as a supplier and customer first establish a joint business agreement detailing the terms of collaboration and then generate appropriate sales and order forecasts, while making sure to work together to reconcile differences in forecasts [13]. Further, collaborating together to harmonize sales and order forecasts can facilitate appropriate operational planning for both parties [14]. The willingness to communicate and share information that would otherwise not be available to a supply chain partner is a critical driver in realizing the value proposition behind this model.

CPG companies have demonstrated operational and financial gains using the CPFR model. In particular, a pilot study between Wal-Mart, Warner Lambert and others using CPFR practices resulted in improved service levels, lead times, and sales [15]. Another pilot study involving Nabisco Inc. and Wegman's Food Markets, in which CPFR practices were leveraged, led to improvements in sales, service levels, and inventory levels [14]. Gains from CPFR have also included "more predictable order cycles, reduced costs, more receiver-friendly loads, reduced product damage" [16].

Peeling away the outer layers of the CPFR model leaves at its core the concept of shared practices between suppliers and customers. For this manuscript, we leverage this core message to develop an understanding and subsequent hypothesis for actions that have provided financial and operational benefits for CPG companies. To that end, we generate the following hypothesis:

(H1) Shared practices between suppliers and customers can generate cost containment and operational improvements in the CPG domain.

3.2 CPG and Medical Device Operating Environments

We aim to uncover commonalities between operating environments within the CPG and medical device domains to make the case that lessons learned in one domain (CPG) can indeed be applicable to another arena (medical device industry) due to congruence in operating conditions and business climate. This comparative analysis is based on existing trends noted in literature as well as first hand observations of practices at Device Company X and Hospital X. We focus our investigative efforts on three levers within these industries- products, customers, internal operations. Lastly, we leverage our findings to propose a hypothesis for the following question:

Q2) How do the medical device and CPG supply chain operating environments compare to one another?

Products

Important parallels exist between product landscapes within the CPG and medical device industries. CPG companies operate in a product ecosystem where offerings in many cases are commodity type items [17]. Even in the setting of innovation, most products yield less than ideal financial gains as “new product innovation failures range from 53 to 86 percent” [18].

Additionally, innovation appears to be gradual in nature, as “brand extensions continue to represent the lion’s share of new product launches” [19]. These trends appear strikingly similar to those in the medical device domain where many products have become commoditized, and

where innovation may be plagued with high failure rates prior to and following commercialization.

Customers

Analogous to the trend towards cost mitigation unfolding in healthcare, the CPG industry is also responding to a more cost conscious customer who now places greater import on “value” related interests [20]. Additionally, customers in the CPG space are now considering factors beyond price and include attributes that supersede the immediate purpose of the product. For example, in the CPG domain, “sustainability” and “self-driven health & wellness”, are two such attributes that the consumer is now considering when making purchasing decisions [19] . Such trends make it clear that CPG companies must consider the entire range of value propositions associated with their products given changing customer preferences. In the same vein, hospitals are more than ever considering quality of care thresholds when evaluating new products from medical device manufacturers. As such, favorable cost of product is necessary but no longer sufficient to win over customers in both the CPG and medical device domains.

Operations

Medical device manufacturers and CPG companies may sell diametrically different products, but they strive to achieve similar operational goals in related contexts. Both groups of companies are keenly interested in improving service levels, reducing excess inventory, and preventing stock-outs. Logistics costs can be of concern to both as well. CPG companies must ensure their supply chains can navigate a range of products that include perishable items for grocery retailers to apparel items in the background of demand volatility. The diversity of products as well as the

ebbs and flows of demand require logistical oversight that can impose cost pressures. On the other hand, medical device companies must also create logistical processes that can align with time sensitive needs of hospitals as well as variable product specification needs due to varying patient characteristics.

Table 4 Commonalities in Operating Environments of CPG and Medical Device Companies

Commonalities in Operating Environments of CPG and Medical Device Companies	
1	Commoditization of products
2	Slow pace of transformative innovation
3	Customer frugality
4	Customer needs for alternative value propositions
5	Strive to improve inventory levels, service levels, stock-out levels
6	Logistical pressures imposed by customer behaviors and product variability
7	Volatility in Demand

Given these parallels between the CPG and medical device space, we construct the following hypothesis:

(H2) The operating environments between CPG and medical device companies share similarities with respect to operational goals, product characteristics, and logistical pressures.

3.3 Collaboration for the Device Manufacturer-Hospital Supply Chain

Thus far, we have generated the following two hypotheses based on a survey of existing literature and observations at Device Company X and Hospital X.

(H1) Shared practices between suppliers and customers can generate cost containment and operational improvements in the CPG domain.

(H2) The operating environments between CPG and medical device companies share similarities with respect to operational goals, product characteristics, and logistical pressures.

H1 is based on the core take away of shared practices that serves as the foundation for the CPFR model noted in the CPG space. This model has also been studied through the healthcare lens.

One study explored the application of the CPFR model within the context of hospitals and drug suppliers in Taiwan [21]. Additionally, another study used a system dynamics approach to study inventory impact of the CPFR model as well as collaboration practices based on data from a hospital in the Netherlands [22]. Our intention is not to directly apply the CPFR model to the healthcare setting. Rather, we peel off the outer layers of this model to identify a core fundamental concept: Shared Practices. It is this concept that we choose to build upon and leverage in constructing a collaboration model for device companies and hospitals

Given the parallels in operating environments between CPG and medical device domains, we contend that shared practices, postulated to generate supply chain benefits in the CPG space, can

lead to similar financial and operational benefits within the medical device-hospital supply chain space. As such, we extend our initial insights that allowed us to construct hypotheses H1 & H2 to formulate the following hypothesis:

(H3) Supply chain shared practices between US medical device companies and hospitals can generate cost containment and operational efficiencies.

To construct a model that can be used to test this assertion and identify opportunities for cost savings and improvements in patient care, we analyze process design components as they relate to supply chain practices at a Harvard Medical School affiliated teaching hospital, Hospital X, and Device Company X, a leading device manufacturer.

4. Process Design Case Study

4.1 Process Design & Investigative Frameworks

Our approach to constructing a collaboration model that identifies opportunities for cost containment and operational improvements between medical device manufacturer and hospital entails disentangling process design components within a procedure area at Hospital X, paying particular attention to areas that supplier and provider can both have impact. We bound our investigative efforts to supply chain pressures at Hospital X. To conduct this process design study, we apply frameworks noted by Steven J. Spear in *The High-Velocity Edge*. In his analysis of various operational problems, Spear proposes a lens in which processes can be evaluated based on four design elements¹, which are noted below [3].

Table 5 Process Design Parameters

1.	“System Output”
2.	“Pathway design: flow of materials, information, and services”
3.	“Connection design: linkages between adjacent process steps”
4.	“Methods for individual task activities”

Source: *The High-Velocity Edge* (2009), Steven J. Spear [3]

Additionally, Spear cites the use of a methodology² to tackle process related problems which includes explanation of “background”, “current condition”, “root-cause analysis (diagnosis)”, “countermeasure treatments”, “target condition”, “actual outcomes”, and “gap analysis” [3].

¹ As noted in *The High-Velocity Edge* (2009), Steven J. Spear, pgs. 166-169

² As noted in *The High-Velocity Edge* (2009), Steven J. Spear, pgs. 196-197

When applicable, we apply these investigative optics to unmask supply chain collaboration opportunities between device manufacturer and hospital.

4.2 Introduction to the Center for Advanced Endoscopy (CAE) at Hospital X

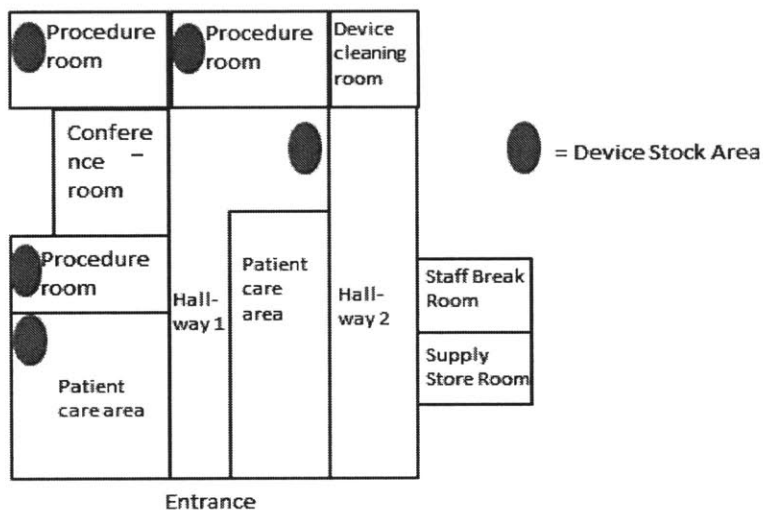
We explore process design elements at Hospital X. In particular, we hone in on the day to day operations within the “Center for Advanced Endoscopy” procedure area (CAE) and confine our study to processes that relate to timely replenishment and consumption of medical device products for patient care within this area of Hospital X.

CAE performs a wide range of diagnostic and therapeutic endoscopic procedures with a particular focus on endoscopic retrograde cholangiopancreatography (ERCP). ERCP is a commonly performed medical procedure that allows diagnosis and treatment of a range of gastrointestinal ailments, including biliary and pancreatic conditions. Most procedures performed within CAE are elective and scheduled ahead of time, often completed during the hours of 8AM-5PM. It should be noted that this procedure area is open 24 hours around the clock as well to receive emergent inpatient cases at any time. Although operating seven days a week, volume is noted to be less during the weekends as compared to weekdays. On a typical weekday, patient care is provided by an average of five nurses, four radiology technologists, and up to four attending physicians who oversee four to five fellow physicians. Additionally, supplier representatives can also be found within the CAE domain. Their roles include checking their own supplier originated inventory within CAE as well as educating physicians regarding product use and characteristics. They may also replenish inventory using self-delivered on hand stocks,

commonly referred to as “trunk stocks” within industry. Nevertheless, the majority of new inventory arriving to CAE originates from deliveries carried out by a receiving dock located on the campus of Hospital X.

CAE’s floor plan is notable for three procedure rooms where physicians carry out diagnostic and therapeutic interventions. Patient care areas contain beds for those either waiting for procedures or receiving monitoring following procedures. The following figure highlights the physical real estate of CAE. Of note, there are device stock areas within the lab which are separate from stock areas that contain frequently used low value items (not pictured).

Figure 1 Floor Plan of CAE



CAE relies on timely availability of device stock to carry out gastrointestinal related diagnostic and therapeutic procedures for patients. Procuring and maintaining appropriate inventory is critical to clinical care excellence and containment of operating costs. CAE however has had difficulty in achieving these goals. In particular, it is plagued with haphazard and impromptu

processes that have led to minimal understanding and transparency in its own inventory and procurement practices. It faces a high inventory burden, and encounters excessive scrap product and stock out events. Most importantly, mitigating these problems will ensure that the quality of patient care will not be negatively impacted due to disruptions caused by locating product or product unavailability. We aim to uncover process design flaws that are contributing to the chaotic present state, with the goal of constructing a model in which we identify opportunities for cost containment and operational improvements.

4.3 Presenting Symptoms

We note several symptoms that CAE experiences. These symptoms have largely been undiagnosed, and untreated. As a result, CAE is at risk for spiraling cost burden or potentially worse, calamitous patient care outcomes.

Table 6 Presenting Symptoms of CAE

1	High levels of expired product
2	Difficulty locating products
3	High inventory burden
4	Disruptions or delays in patient care
5	Increased frequency of stock-outs
6	Delays in ordering and receiving products
7	Faulty order specifications

4.4 Examination of CAE

CAE exhibits poor inventory maintenance and replenishment practices. There is a propensity for haphazard and impromptu behavior on the part of clinical staff, a context that is complicated by the ambiguity of roles taken on by supplier representatives during the day to day operations of CAE. Akin to an exam of a patient conducted using an organ based approach, we examine symptoms at CAE using the previously discussed system design approach noted by Steven J Spear in *The-High Velocity Edge* [3].

Poorly Characterized End-Goal

End-Goals for inventory maintenance and replenishment are incompletely characterized. Staff is aware of the obvious goal of having product ready for patient care, but the conditions and circumstances in which this goal should be accomplished are not fully delineated and are replaced instead with ambiguity and complacency as the entire range of outcomes is not considered. Staff do not adequately address the following end goal considerations in their efforts to have product ready for patient care.

- 1) Have we minimized inventory levels?
- 2) Have we reduced “opened but unused” product?
- 3) Have we processed orders in a time effective manner?
- 4) Have we reduced the frequency of uncovering expired product?
- 5) Have we organized the physical space within CAE such that locating the next product can be done in a seamless manner?

Chaotic and Disorderly Processes

The individual processes required for completion of tasks are circuitous in nature, not clearly assigned to specific individuals in advance, and do not efficiently leverage existing real estate within CAE. This results in greater entropy in the steps required to achieve overall system goals, causing a domino effect in which staff find themselves “putting out fires”, more often than desired. Furthermore, time constraints are pushed to the edge as individual tasks require time consuming movements within the CAE physical space.

Improvisational Transitions between Processes

The transition mechanisms between processes within CEA are defective at best, and at worst, nonexistent. Staff execute responsibilities in a highly improvisational manner without clear precipitating signals for initiation of responsibilities. Furthermore, there is a paucity of knowledge exchange, either quantitative or qualitative, between process steps. These deficiencies compound the chaos, and in doing so, spawn rework and wasted resources.

Non-Standardized Work

There is a prevailing practice of work being a result “of anyone who gets to it” within CAE. Consequently, there is a high degree of variability in the work that is actually performed as different individuals are performing similar tasks in disparate ways. Furthermore, we note a deficiency of protocols and standardization when executing on tasks within the day to day operations at CAE.

Figure 2 Process Overview for Inventory Replenishment at CAE

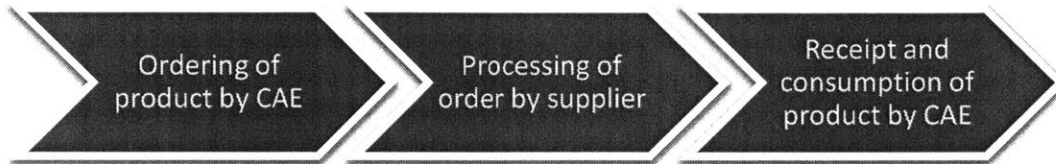
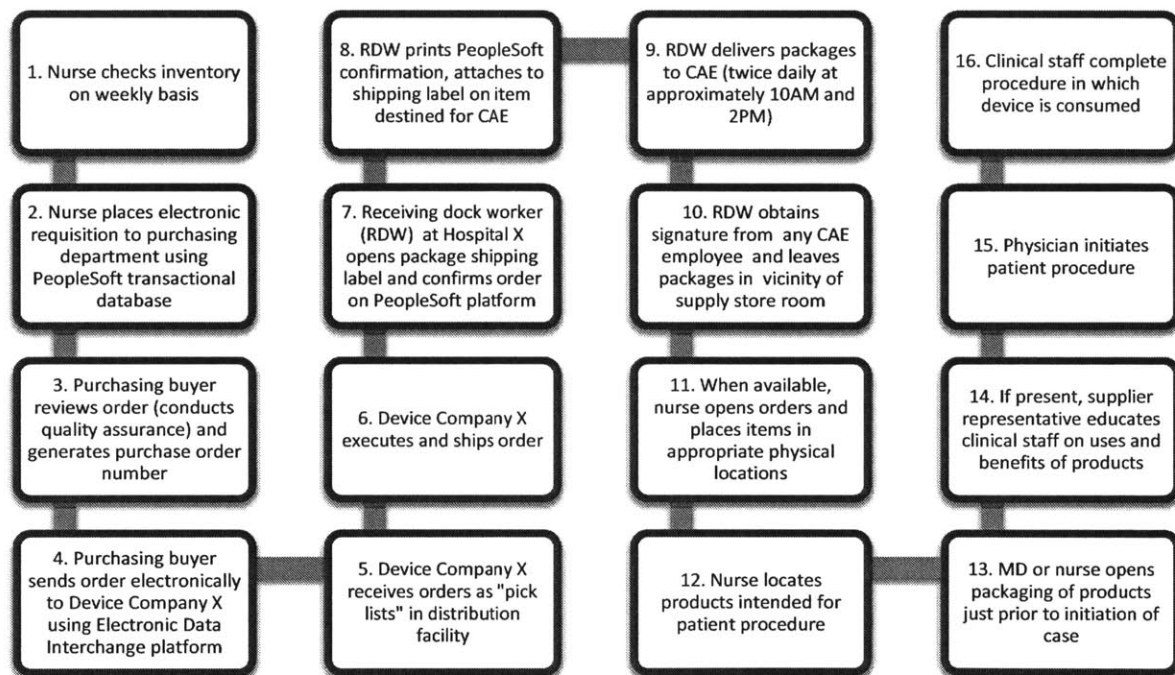


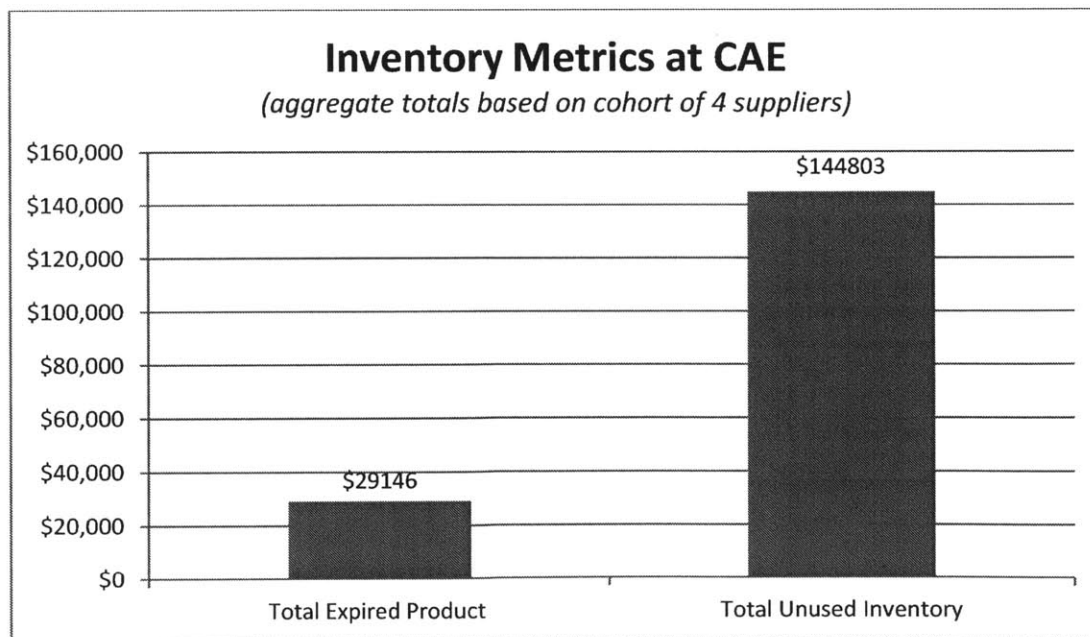
Figure 3 Process Steps for Inventory Replenishment at CAE



4.5 Diagnostics

Realizing the aforementioned symptoms and lack of transparency in inventory practices, CAE, in October 2014, implemented an inventory management system that utilizes a hand-held barcoding scanning system to monitor inventory and consumption levels. For the purposes of this manuscript, we leverage this initiative as a diagnostic tool rather than a corrective one to provide important “vital signs” for CAE. As a diagnostic tool, this initiative provides quantitative insight into the present day troubles CAE faces. The graph below provides a snapshot of “total expired product” discovered during an initial scan of inventory in October 2014 as well as “total unused inventory” noted during an approximate 3.5 month window following the initial scan. Of note, total expired product and total unused inventory levels below include only product originating from a group of four commonly used suppliers for CAE.

Figure 4 Inventory Metrics at CAE



4.6 Diagnosis & Treatment

On a high level, we have discussed the relevance of process design parameters as they relate to CAE. To diagnose the specific culprits for CAE's present day symptoms, we take a deeper dive into CAE operations. We focus particularly on the drivers behind CAE symptoms that are amenable to solutions that either require both supplier and hospital participation or impact both parties. We aim to identify collaborative solutions, as opposed to a singular party driven prescription for change.

Symptoms CAE faces are not independent of each other. For example, the underlining drivers for causing disruptions in clinical care can also be implicated in spawning excess expired inventory. We analyze the previously outlined process flow within CAE to identify deficiencies within this roadmap.

Figure 5 Poorly Characterized End-Goal: Diagnosis & Treatment

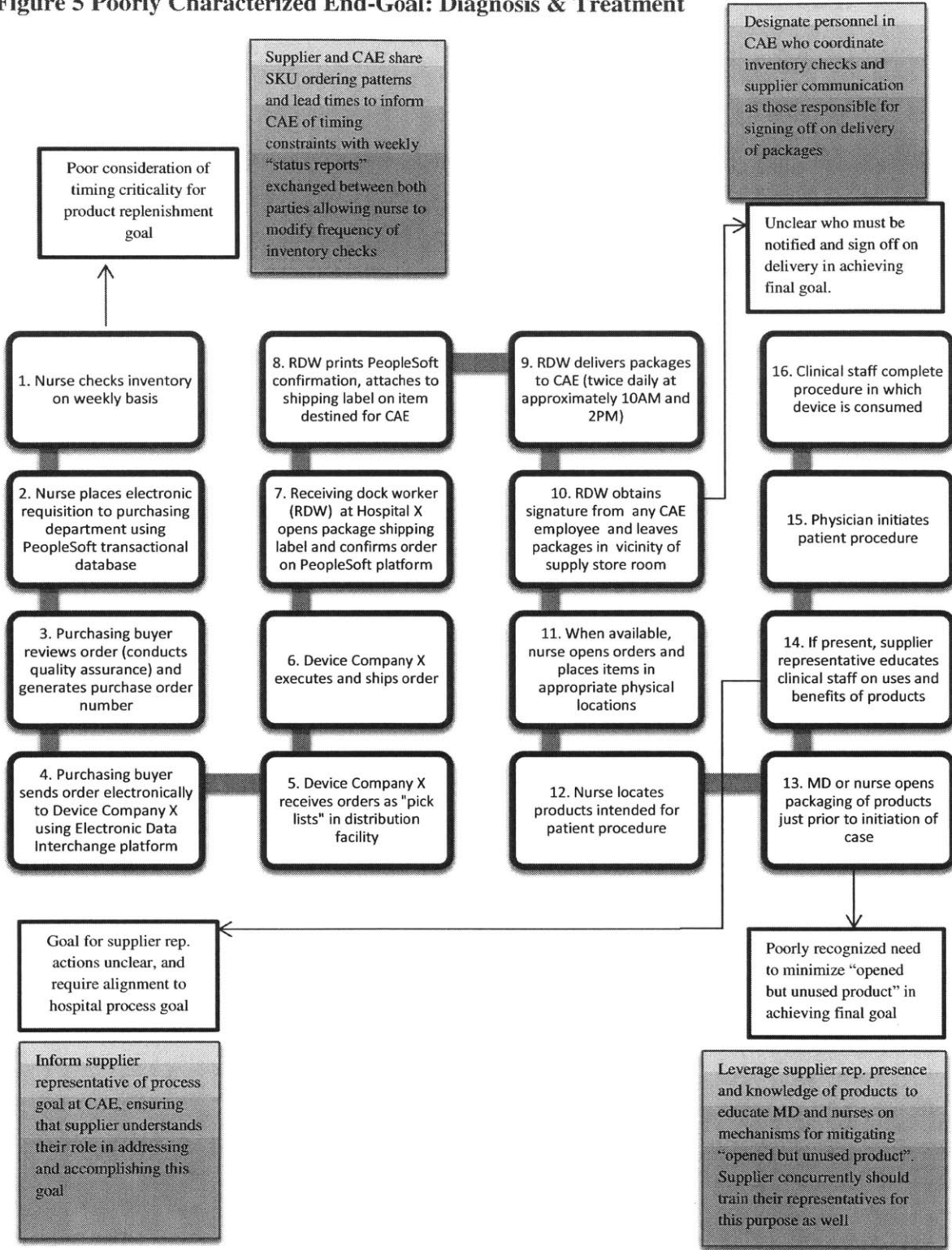


Figure 6 Chaotic and Disorderly Processes: Diagnosis & Treatment

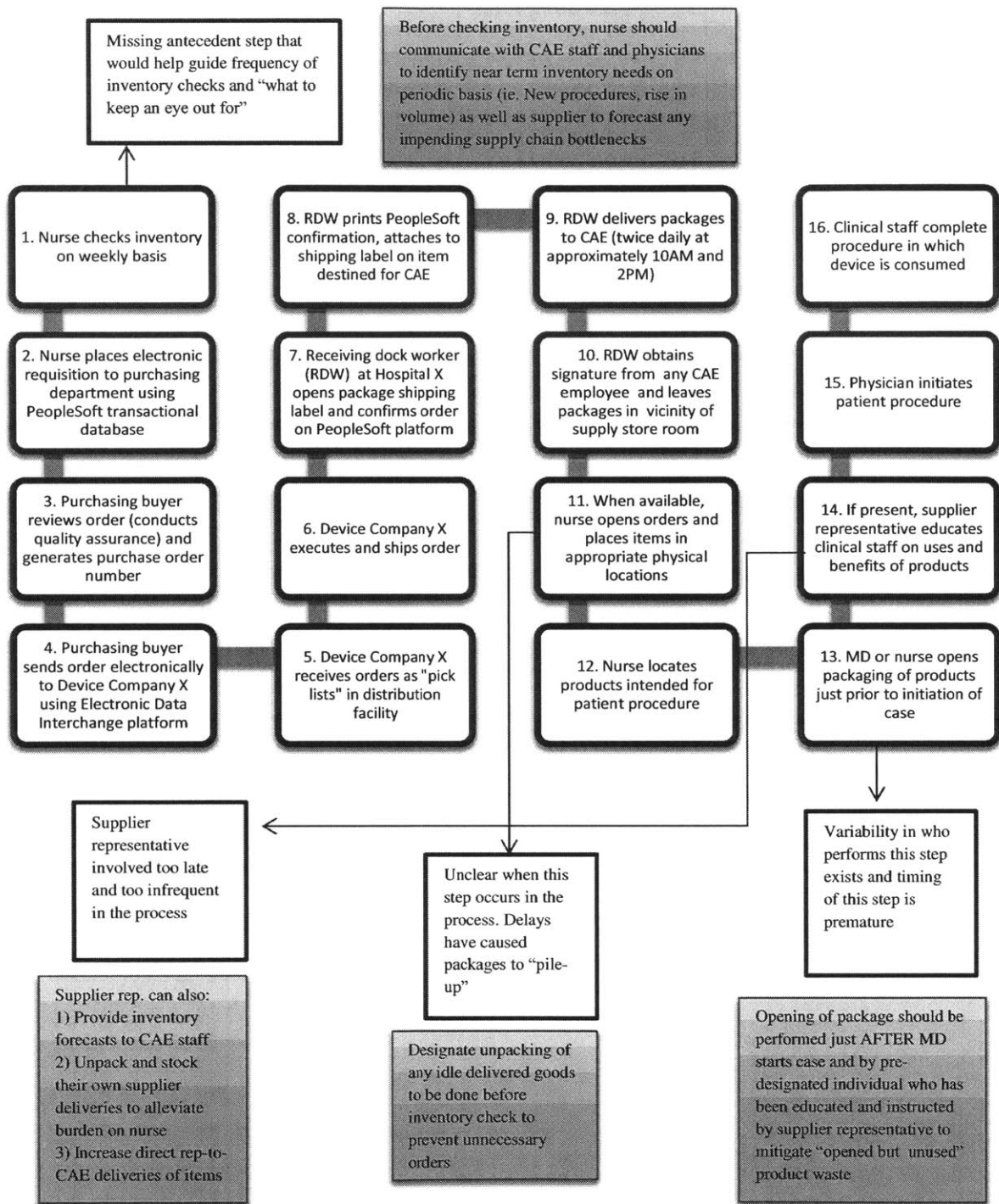


Figure 7 Improvisational Transitions between Processes: Diagnosis & Treatment

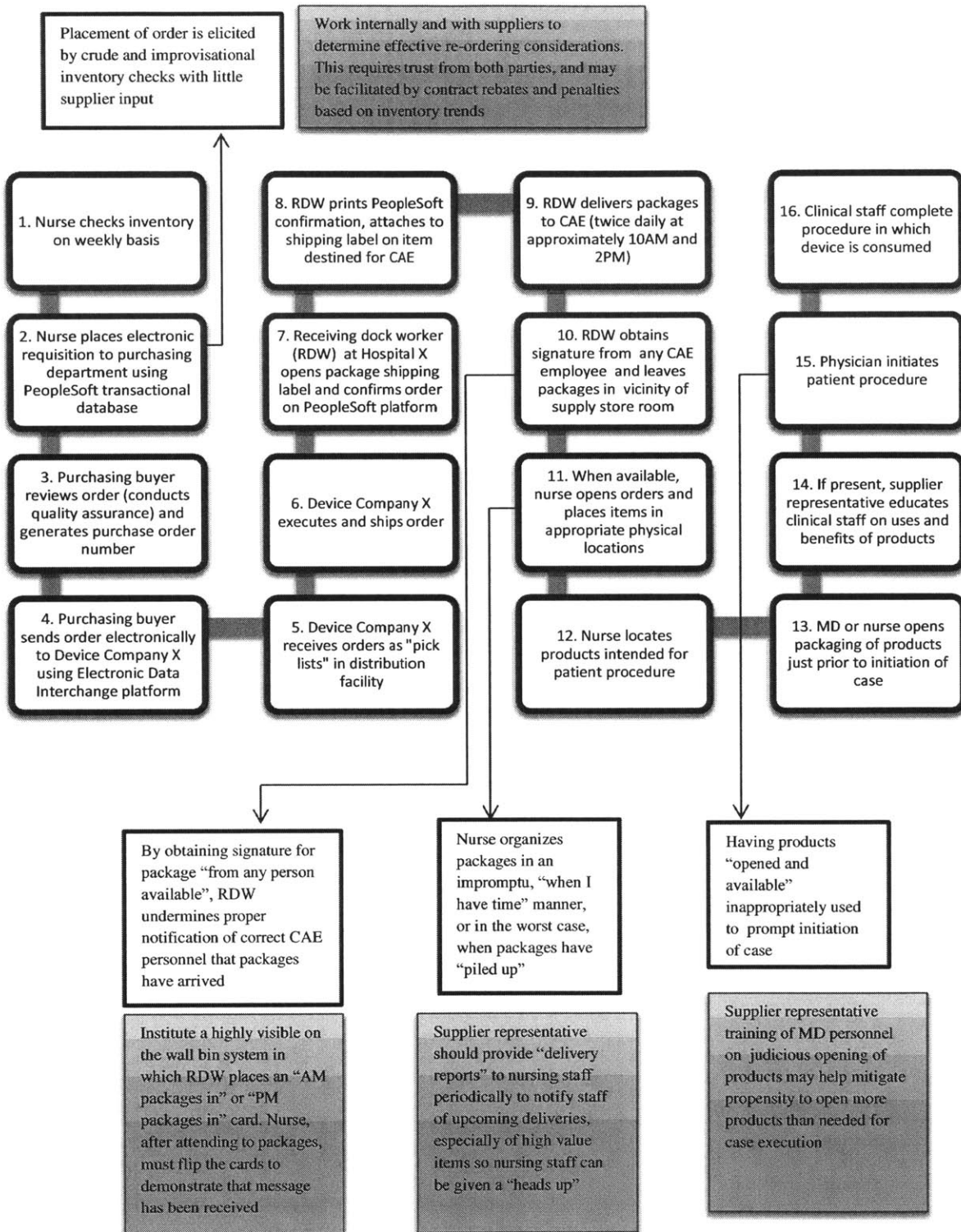
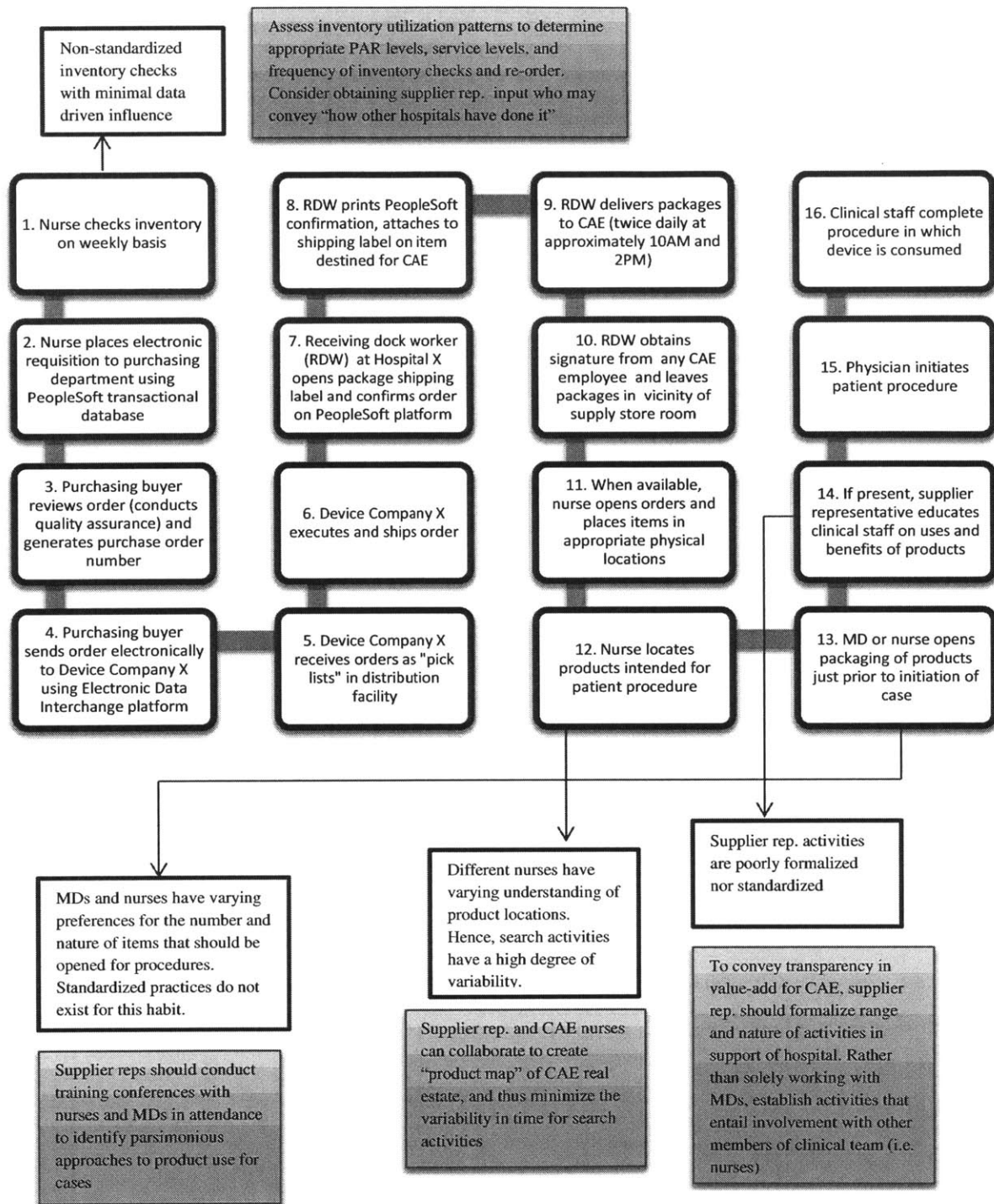


Figure 8 Non-Standardized Work: Diagnosis & Treatment



4.7 Summary of CAE findings

The underlying drivers for present day symptoms at CAE, and the subsequent suggested process architecture changes require supplier and hospital to recognize that symptoms at one node in the system (CAE) represent symptoms of the entire system (CAE+supplier). The prevalence of stock-outs, expired product, disruptions in clinical care, and space constraints, to name a few concerns, may be occurring at CAE, but the pain invariably impacts both parties. Irrespective of consignment structure, CAE can demand suppliers to provide compensation for hiccups in the system, whether that be in the form of exchanging expired product with un-expired product, requesting emergency orders associated with high supplier operational and logistics costs, or possibly even requiring concessions on future contracts from supplier. Therefore, both parties have ample reason to care.

Our prescription for change requires a shift in how supplier and CAE view one another- from that of an adversary to that of a business collaborator. This change requires both parties to step outside of the typical roles that have characterized their relationship thus far. In particular, we recommend a re-evaluation of the role of a supplier representative within the confines of CAE to emphasize responsibilities that extend beyond the typical day to day tasks customarily attributed to this stakeholder. Upon first glance, CAE may hold reservations in such a strategy which is not unexpected given longstanding undertones of hospital-supplier mistrust within the device manufacturer-hospital supply chain. However, at the core of not just our recommendations, but the very definition of collaboration, is the need to view each party as an ally. We assert that CAE serves to gain from expanded responsibilities of supplier representatives as it can extract operationally relevant value-add activities from such individuals, and “not just hear a sales

pitch”. From the supplier perspective, it offers a chance to not only demonstrate goodwill to customers, but understand their unique operational pain points. We summarize our recommendations pertaining to expanded supplier representative roles in the following table:

Table 7 Supplier Representative Responsibilities That Promote Collaboration

Supplier Representative Responsibilities That Promote Collaboration
1. Educate physicians and clinical staff on mechanisms to reduce “opened but unused” product
2. Conduct training sessions for clinical staff to share inventory management procedures and strategies seen at other hospital sites
3. Work with hospital personnel to provide supplier depth and perspective in the establishment of appropriate re-ordering levels and service levels
4. Provide periodic “status reports” of changes in supplier inventory and lead time of frequently used items and high value items.
5. Aid clinical staff in unpacking and organization of own supplier originated mail deliveries to procedure suite

Based on process design analysis, we propose a collaboration model for hospital and device manufacturer with three operational levers: Physician practice standardization, inventory replenishment, and space utilization. These operational dimensions may represent opportunities for cost containment and improvements in clinical care. Further, this model necessitates shared practices between hospital and device manufacturer which call for re-defining the roles of supplier representatives to include participation in hospital value add activities.

Table 8 Collaboration Model for Hospital and Supplier

Collaboration Model for Hospital and Supplier	
Opportunity Identified	Shared Practice
Physician practice standardization	Supplier conducts physician training sessions to inform MDs on product waste mitigation strategies (i.e. reduce “opened but unused products” frequency) and standardize practices
Inventory replenishment	Supplier coordinates with hospital staff to provide periodic written updates of changes in lead times or supply chain bottlenecks for frequently used items and high dollar value items.
Space utilization	Supplier works with hospital staff to organize physical real estate within procedure areas as it relates to supplier originated products. This can include working collaboratively to create “space maps”, or taking part in joint lean implementation programs.

To execute on this model, hospital and supplier may wish to consider the following collaboration guidelines:

- 1) Hospital identifies most pressing operational deficiency as it relates to physician practice standardization, inventory replenishment, or space utilization.
- 2) Hospital carries out vetting of suppliers to choose those most willing to participate in collaboration project. Factors to consider include existing supplier market share within hospital domain, prior business relationship milestones, or future operational goals.
- 3) Hospital and supplier identify appropriate short term and long term metrics for success as well as periodic “check-in” sessions during course of collaboration project to assess progress.

- 4) Hospital and supplier delineate nature of shared practices including strict parameters on supplier access to hospital personnel and territory.
- 5) Hospital and supplier conduct periodic surveys of each other's engagement and appropriate grounds for termination of collaboration project.

5. Discussion

5.1 Implications for Industry

The operational pain points that CAE faces are not endemic to Hospital X nor its supply chain partner, Device Company X. Improving physician practice standardization, inventory replenishment, and space utilization likely represent opportunities for other US hospitals as well given the common fabric of cost containment and quality driven clinical care that these organizations share. The drivers for these opportunities may partially be rooted in process flaws within the day to day operations at “ground-level” procedure suites. Most importantly, these process flaws are not the result of actions by one party but rather the manifestation of the complex interplay between hospital and supplier parties. As such, a panacea for operational and supply chain difficulties at the “ground-level” requires commitment and participation by both supplier and hospital.

Uncovering collaborative solutions may necessitate redefining the rules of engagement between supplier and hospital. In particular, hospitals may wish to rethink the level of participation and access it provides to supplier sponsored stakeholders within their operations. Specifically, clinical personnel can choose to leverage supplier personnel in achieving pre-defined hospital value add activities. Naturally, this requires supplier personnel to re-prioritize their objectives to include the operational objectives of their customer. Further, the privilege to work more intimately with their customer should not be abused by suppliers nor should it be granted without an appropriate vetting process for filtering the supplier base to choose “preferred suppliers” that have demonstrated a propensity for reciprocity. Even when engaging with a “preferred supplier”,

appropriate safeguards and incentive alignment must be constructed to ensure collaborative interests do not disintegrate into pursuit of ulterior interests. Supplier personnel should look beyond “making a sales pitch” and instead focus on “getting their hands dirty” by working with clinical staff.

Our recommendations for re-defining the roles of supplier personnel to facilitate achieving value add activities for hospital may be contrary to the prevailing trend of attenuating the influence and presence of suppliers within the physical confines of patient care and clinical personnel.

However, we propose making participation in hospital value add activities as a potential pre-requisite for supplier personnel to gain entry into the clinical care domains that they have been given mostly unencumbered access to date. This strategy can serve as an additional filtering mechanism in selecting and granting “preferred supplier” status to those suppliers that not just acquiesce to but embrace collaborative roles.

6. Conclusion

6.1 Take Away

We have constructed a series of hypotheses through the course of this manuscript to build the foundational framework for a collaboration model that is proposed. We first explored the consumer packaged goods (CPG) domain to identify that shared practices, as seen through the lens of the CPFMR model, provide a plausible route to achieving financial and operational gains for companies within this industry. Subsequently, we uncovered critical similarities in operating ecosystems between the medical device and CPG industries that include commoditization of products, customer frugality, and desire to improve inventory performance. We then applied our understanding to postulate that shared practices between device manufacturers and hospitals may engender financial and operational gain. To formulate a collaboration model that identifies opportunities for cost savings and operational improvements, we dissected internal processes within a procedure suite at a Harvard Medical School affiliated hospital as they related to inventory replenishment and product consumption. Our insights have enabled us to propose a collaboration model with three operational levers, physician practice standardization, inventory replenishment, and space utilization, in which suppliers and hospitals can work together to achieve cost containment and operational improvements. This model can also be used to test the assertion that shared practices between supplier and hospital can generate cost containment and operational efficiencies.

6.2 Next Steps

To test the proposed sources of cost containment and operational efficiencies as well as feasibility of generating shared practices between device manufacturer and hospital, we recommend a two-step approach. First, we advise implementation of survey based modalities to gauge clinical staff and supplier receptiveness to collaboration. Second, we propose hospitals conduct pilot studies for small “low risk” collaborative activities requiring supplier and hospital personnel participation. The proposed collaboration model may provide a framework for establishing joint activities.

Surveying supplier and hospital personnel for impressions pertaining to shared practices can offer a glimpse into the enablers and barriers to cultivating collaboration. Furthermore, it offers a chance to capture the viewpoints of clinical personnel at “the ground level” who may have the best pulse on suppliers most willing to collaborate and step outside of their typical roles.

Viewpoints of clinical personnel can also be used to validate “preferred supplier” decisions made by hospital supply chain management who do not have the ability to monitor day-to-day motivations and actions of supplier personnel. In the same vein, surveying appropriate stakeholders within a supplier organization can provide insight and clarity on readiness for collaboration, from operational and cultural perspectives.

Further, we propose leveraging knowledge gained via survey of clinical and supplier personnel to conduct small “low risk” collaborative pilot studies with suppliers who have been deemed “most committed” or “most vital” based on product share trends. Even with this strategy, we recommend a step wise approach in which suppliers and hospital personnel can initially focus on

easy to execute, time friendly collaborative tasks that require little to no capital expenditure or new technology. Such tasks may include but are not limited to streamlining inventory organization and delivery, or assisting with lean implementation procedures. Small initial pilot studies can help unmask operational and cultural bottlenecks to collaboration that would need to be resolved prior to initiating collaborative activities that are more time intensive or cost prohibitive. Sustainable collaboration between medical device companies and suppliers is a time intensive process, and perhaps an inevitability given the changing healthcare paradigm that favors cost containment and excellence in clinical care.

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