12-2013

Patient Risk and Data Standards in Healthcare Supply Chain

Paiman Farrokhvar
University of Arkansas, Fayetteville

Patient Risk and Data Standards in Healthcare Supply Chain

Patient Risk and Data Standards in Healthcare Supply Chain

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science in Industrial Engineering

By

Paiman Farrokhvar
Sharif University of Technology
Bachelor of Science in Materials Science and Engineering, 2010

December 2013
University of Arkansas

This thesis is approved for recommendation to the Graduate Council

_____
Dr. Nebil Buyurgan
Thesis Director

_____
Dr. Ronald L. Rardin
Committee member

_____
Dr. Manuel D. Rossetti
Committee member

ABSTRACT

Patient safety is one of the most important health care challenges. It is a big concern since 1 in every 10 patients around the world is affected by healthcare errors. The focus of this study is given to preventable adverse events that caused by the errors or system flaw that could have been avoided. In this study, simulation models are developed using Arena to evaluate the impact of GS1 data standards on patient risk in healthcare supply chain. The focus was given to the provider hospital supply chain operations where inventory discrepancy and performance deficiencies in recall, return, and outdate management can directly affect patient safety. Simulation models are developed for various systems and scenarios to compare different performance measures and analyze the impact of GS1. The results indicates that as the validation points are closer to the point of use, the number of recalled or outdated products administered to a patient are still reduced significantly so checking at the bedside or PAR is critical. But validation only at these points may cause some problems such as stock outs; therefore, validating in other locations is also needed.

ACKNOWLEDGEMENTS

I would like to thank my advisor, Dr. Nebil Buyurgan who helped me during my Master's studies. I appreciate all his guidance and support. I would also like to thank Dr. Manuel D. Rossetti for his help and contributions to my thesis. My deepest thanks to Dr. Ronald L. Rardin who supported me through my transition to graduate school. He created the opportunity of continuing my education at University of Arkansas. Also, many thanks go to all the faculty members and staff of the Industrial Engineering Department at University of Arkansas who created a very friendly environment for studying and success.

Very special thanks go to my sister, Leily Farrokhvar, who has been always a great friend and the best support for me in all aspects of my life. Without her help I would never be as successful as I am. I would also like to thank my great friend, Behrooz Kamali, who helped me a lot in my career. Finally and most importantly, I would like to thank my parents, Mahvash Khalilnaji and Behrooz Farrokhvar, for their endless care and support in my life.

This thesis is lovingly dedicated to my mom, Mahvash, for her unconditional love, support, and encouragement.

TABEL OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1

INTRODUCTION

Patient safety is one of the most important health care challenges. It is a big concern since 1 in every 10 patients around the world is affected by healthcare errors (Wen, 2008). Patient safety is defined as an issue in healthcare that tries to minimize the occurrence and influence of adverse events (also called patient safety events) and maximize recovery from them (Emanuel et al., 2008). An adverse event in healthcare is defined as an injury caused by medical management rather than by the underlying disease or condition of the patients (Tsilimingras, n.d.). Adverse events can be classified in different ways; in the context of this study, they are categorized as follows: (1) non-preventable adverse events, such as a first time allergic reaction to a drug and (2) preventable adverse events, such as a wrong dose of a medicine administered to a patient. Even though non-preventable adverse events have greater potential of morbidity and mortality, preventable adverse events offer better opportunities to learn and improve patient safety. These opportunities include identifying adverse events, analyzing their courses, and taking corrective actions to reduce the reoccurrence of similar events (Sasou and Reason 1999).

Preventable adverse events, which are the focus of this study, are defined as injuries, caused by an error or system flaw that could have been avoided. There are many terms in the literature that are relevant to patient safety. Among them, *errors* are the occurrences that do not necessarily harm patients and include other terms such as mistakes, near misses, active errors, and latent errors. *Near misses* are unplanned events that do not result in injury but have the potential to do so. An example of no harm or minor harm is administering an extra strength drug by mistake and an example of a serious injury and even death is performing a surgical procedure on a wrong patient (Ginsburg et al., 2009). *Active errors* typically occur when a patient interacts

with nurses. Examples of active errors include infections due to contaminated equipment or devices, using expired or recalled device or drugs, catheter-acquired infections (Attarian, 2008), and using a device for functions other than as intended due to misidentification. *Latent errors* include system defects such as poor design, incorrect installation, faulty maintenance of equipment and devices, poor purchasing decisions, and inadequate staffing (Thomas et al., 2003). Latent errors and active errors are main causes of adverse events that typically harm patients and causes injuries or damages.

A comprehensive study by Elder and Dovey (2002) classifies preventable adverse events in primary care in three groups: (1) diagnosis incidents, (2) treatment incidents, and (3) preventive service incidents. Diagnosis incidents typically include symptom or prevention-related missed diagnosis and delayed diagnosis. Treatment incidents may be drug-related cases such as administering incorrect drug, incorrect dose, delayed or omitted administration or non-drug-related cases such as inappropriate, delayed or omitted clinical actions, as well as procedural complications. Preventive service incidents are similar to the non-drug-related treatment cases. They too include inappropriate, delayed or omitted actions, and procedural complications but for preventive services.

The same study classifies the reasons of these events as follows: (1) clinician factors, (2) communication factors, (3) administration factors, and (4) blunt-end factors (Elder and Dovey, 2002). Clinician factors contain clinical judgment and procedural skill errors such as prescribing an incorrect drug to a patient. Communication factors, which are over half of the serious adverse events, include inadequate communication between healthcare providers or clinicians, as well as between clinicians and patients or family members. Any types of cultural or language barriers are examples of these factors. Administration factors typically are administrative problems in

clinician, pharmacy, ancillary provider (e.g. physical therapy) or office settings. For example, missing medical history of a patient or losing information. The last group is blunt-end factors which include personnel and family issues of clinicians and staff, government or insurance company regulations, size and location of practice, and general healthcare delivery systems-related issues.

Adverse event statistics over the years reveal enormous and astonishing number of errors. A study on adverse events by Troyen et al. (1991) analyzes hospitalizations in the state of New York in 1984 and reports that 3.7 percent of hospital patients experienced adverse events and 27.6 percent of those involved negligence. The same study indicates that over 70 percent of adverse events causes disability lasting less than 6 months, 2.6 percent results in permanent disability, and 13.6 percent of these events results in death. Another study by Thomas et al. (2000) estimates the incidence and types of adverse events in Utah and Colorado and reports the results similar to the previous study. The study finds that 2.9 percent of hospital patients experiences adverse events and 6.6 percent of them causes death. In Utah, 32.6 percent of adverse events are due to negligence whereas in Colorado it is 27.4 percent. (Thomas et al., 2000). Figure 1 illustrates the number of adverse event reports received by the U.S. Food and Drug Administration (FDA) Adverse Events Reporting System (FAERS) in different years.

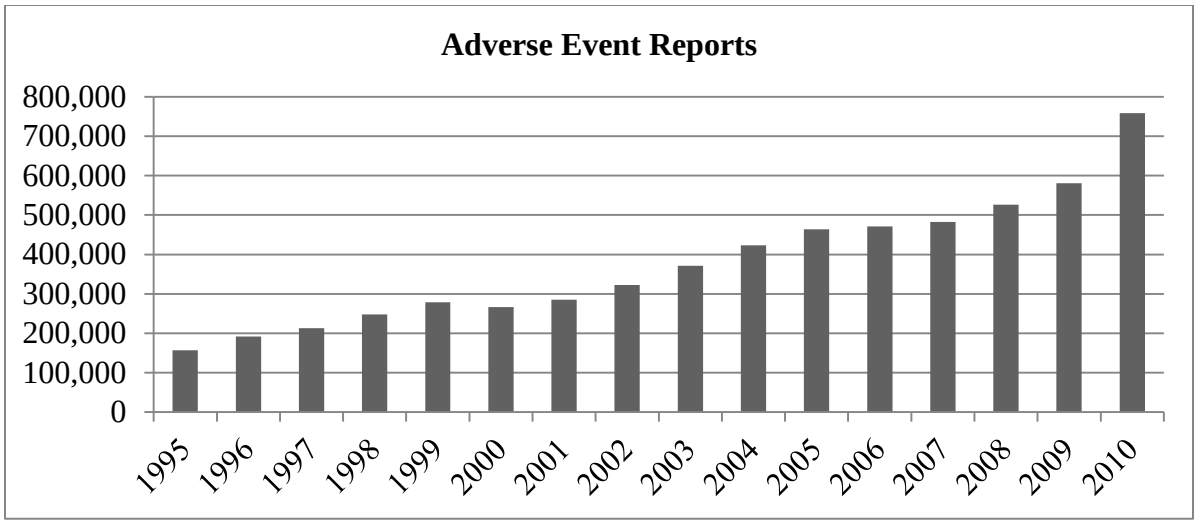

Figure 1: Number of adverse events reported by calendar year (FDA, 2010)

Among many of the adverse events, supply chain-related issues are one of the major reasons for adverse events in healthcare settings. The majority of the supply chain-related issues are caused by inventory discrepancy and performance deficiencies in recall, return, and outdate management at the provider's level. A Harvard study shows that 19.4% of adverse events are caused by medication errors and over 60% of these medication errors are because of using the wrong drug or wrong dosage (Jenkins et al., 2007). Implementing standard product and partner/location identification enables suppliers and buyers to identify and navigate the product along the chain. Therefore, implementing these standards ensures correct products are delivered to correct locations, correct patient, avoiding the adverse events and leading to an increase in patient safety (Kritchanchai, 2012). In addition to misidentification errors that occur during the supply chain operations, there are other issues that can impact patient safety. Inventory accuracy is observed when the recorded perpetual balance of a product varies from the actual on-hand quantity. Product misplacement and mispicking during replenishment operations as well as shrinkage (theft), and transaction errors are major sources of inventory discrepancy. These errors lead to stock outs and as a result delay in providing care (Opolon, 2010). Global data standards

reduce these inventory errors, improve record keeping, improve stock rotation for products, improve efficiency, and reduce stock outs (Bix et al., 2007). Standardized product and partner/location data improves product traceability and reduce the lack of supply visibility (thus shortage of physical inventory). Tracking products helps to improve the performance deficiencies and problems in recall and outdate managements. Faster to find and remove recalled products, more efficient to close recall cases, less time for unsafe products to be available, so less time for harming patients (Jenkins et al., 2007). A study by Tucker (2004), shows that 9% of total nursing time spent on resolving operational failures and 55% of these failures originate outside the nursing units and many of them are linked to supply items. Therefore, insufficient product availability is a frequent problem in hospitals and leads to additional nursing, delayed procedures, and workflow interruptions that put patients at risk (Tucker and Spear, 2006).

In addition to inventory accuracy, performance deficiencies and problems in recall, return, and outdate management are important causes of supply chain related issues that affect patient safety in healthcare settings. Food and Drug Administration (FDA) states that any action taken to address a problem with a product that violates FDA laws is defined recall (FDA, 2011a). Recalls occur when a product is defective, or it is unsafe to use and harmful for health, or both. There are well defined and detailed identification, removal, and return procedures and processes during a recall at the hospitals, which will be discussed in the next sections. In case of outdate, the product is no longer valid or safe to use. Unlike recalls, not every hospital has well defined and detailed procedures for outdated products. Furthermore, monitoring the inventory at different stages and checking for outdated products is a continuous process in the supply chain. Once an outdated product is caught during continuous monitoring, it is removed from the system as soon as possible to avoid any adverse events. Standardized product and partner/location identifier

technologies are emerging, as the long needed approach, to reduce error rates in product identification and expired/recalled product location while moving the products in the supply chain and administering them to the patients. These improvements lead to better inventory visibility in the supply chain as well as efficient product identification and removal; thus, decreased patient risk and increased patient safety. (Jayaraman et al., 2011). As Mr. Kenshi Kinoshita (Director of the Ministry of health, labor and welfare's Economic Affairs Division in Japan) points out, the use of standardized data not only ensures patient safety as it prevents medical errors, but also offers advantages in terms of efficiencies and the overall management of medical organizations (Kreysa, 2008).

Globally accepted Global Standards 1 (GS1) Data Standards provide unique, unambiguous identifiers for product and partner/location identification as an answer to that need. GS1 Data Standards are the essential building blocks for efficient information, product and cash flow (Hubner and Elmhorst, 2008). They also provide a critical foundation for increased quality of care as well as reduced cost and patient risk. The basic set of GS1 identification standards include Global Trade Item Number (GTIN) for product identification, the Global Location Number (GLN) for trading partner identification and the Global Data Synchronization Network (GDSN) provides a synchronization mechanism for sharing accurate product information between manufacturers, distributors, group purchasing organizations (GPOs) and healthcare providers (Jayaraman et al., 2011).

This study investigates the impact of using standard product and partner/location identifying data on inventory accuracy as well as recall, return, and outdates management policies in healthcare supply chain. Standard product identification information also includes *production data* such as expiration dates and lot/serial numbers on products to facilitate efficient

management policies while reducing patient risk and increasing safety by eliminating the opportunities of adverse events. The focus in this study is given to the provider hospital supply chain operations where inventory discrepancy and performance deficiencies in recall, return, and outdate management can directly affect patient safety. Simulation models are developed for various scenarios to compare the performance of different recall, return, and outdate management policies and procedures, and to suggest the best practices. Tested policies and procedures are confirmed and validated by a number of healthcare provider hospitals. The details of the preliminary studies are discussed in the next section. Inventory accuracy, supply chain process error rates, product identification and removal efficiency in recall and outdate management processes, and patient risk are considered as the basis of comparison.

CHAPTER 2

BACKGROUND

Many of the supply chain related issues that cause adverse events occur at the point of care (POC), typically during the product administration, where is it easier to catch and/or prevent because they are typically limited in time and space. Thirty four percent of all medication errors that cause problems for patients are associated with drug administration (Jenkins et al., 2007). The majority of these issues are active errors or near misses and can be caught by error reporting systems, administrative data analysis, chart reviews, electronic medical record reviews, observation of patient care, or clinical surveillance (Thomas et al., 2003). Some of these methods require continuous monitoring of products while some may be triggered after an incident.

Recalls are one of most serious problems in patient safety. Recall management is costly for the manufacturer as well as the healthcare provider because all the recalled products have to be located in the system, returned, and replenished. According to Product Recall Research Group at the University of New Mexico, the danger of unsafe products always exists in healthcare; however, recalls can be managed well by taking proper actions and lives can be saved (CPSC Works..., 1997, 1). FDA classifies product recalls based on the risk it can cause to public health as follows: Class I (High risk), Class II (less-serious risk), and Class III (low risk). In a Class I recall, there is a chance of serious health problems or death due to the effect of recalled product. A Class II recall is not as serious as Class I recall, but still there is a possibility of health issues. A Class III recall represents a less-serious risk. In a Class III recall, the chance of health problems by using the product is low (FDA, 2011a). The number of medical and radiation emitting device recalls by their type is given in Table 1.

Table 1: Recall type statistics per year, (FDA, 2011b)

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012*
Class I	30	61	65	65	44	140	160	426	301	126
Class II	848	1315	1295	1282	1183	2184	2076	2288	2385	2040
Class III	183	205	192	202	113	166	172	106	120	113

Until November 2012

The recall process typically starts with the issue for recall by a manufacturer. Then providers receive alerts through FDA's website or by the manufacturer, and start handling the recall. There are also some notification management services, such as RASMAS and ECRI that notify providers for recalls (Runy, 2007). Manufacturers take actions based on the above-mentioned recall classification; in a Class I recall, the manufacturer notifies its customers (e.g. distributors or vendors) and directs them to notify the intended recipients of the recalled product (e.g. other vendors, hospitals, nursing homes, outpatient treatment facilities, doctors, or individual patients). The manufacturer also issues a press release to notify the public, if appropriate, to minimize health consequences. In a Class II recall, the manufacturer informs its clients and sometimes asks them to notify the intended recipients (FDA, 2009; FDA, 2011a). Since Class I cases are serious threats for health, there are regulations related for alerting the consumers. For the other Classes (II and III) there are no regulations for how consumers have to be alerted. FDA requires only drug companies to have a plan for each type of recall.

Most of the patient safety issues regarding the outdate management process are within the scope of inventory management practices including periodic search in inventory locations and outdated product identification. Disposal is also an important issue because of the impact of toxic materials to the environment as well as the disposed amount. It is estimated that healthcare facilities waste 250 million lbs. of drugs a year (Donn et al., 2008). Outdate management

processes are typically continuous processes that are embedded into the general supply chain operations. Some of the best practices for better outdate management include:

- New products (stock) should be placed in back of the older ones
- All products that have an expiration date should have a clear label
- Every three months, there should be an expiration date check and based on the findings label the products close to expiration date with color codes.
- Check for the products that are not being used frequently and relocate them to other units if it is possible.

According to the U.S. Environmental Protection Agency (EPA, 2008), waste minimization and reverse distribution systems, used in California, Minnesota, and Washington, are some of the good practices identified to date. Waste minimization techniques include identifying the products that are close to expiration and maintaining inventories of highly used products, redistributing and sending them to other places where they are needed and can be used. Focusing on pharmacy products, Joint Commission Resources Inc. suggests each pharmacy to have and apply a system in order to avoid expired products from remaining in stock. Such a system should contain effective methods to find and dispose outdated, deteriorated, recalled or obsolete drugs and supplies. Products that are going to expire in the next 60 to 90 days should have tags to alert staff to select these products first and use them only if administration will be completed before the expiration date (Joint Commission Resources Inc., 2001).

Inventory accuracy is one of the key performance measures that monitor inventory transactions on a continuous basis. It is also an adding factor to patient safety in healthcare. The errors in the inventory records can lead to problems such as insufficient replenishment decisions and high operational costs. The greatest concern in managing inventory is ensuring the right

product is available at the right time. In other words maximizing product availability at the POC (never run out of product) and minimize adverse medical consequences in the event that product is not available (Opolon, 2010).

The complex nature of healthcare supply chains has increased the need of sharing accurate and timely information of products and partners. Increasing costs and disjointed product and partner/location information in the healthcare supply chains strengthen the need for having effective and operative supply chain management practices. The cost of supplies constitutes the second largest expense for healthcare providers (ASU, 2010). Several decades ago, other industries, including retail, grocery, and automotive, employed advanced standardized product and partner identifier technologies and started taking advantage of them. A study estimated that the adoption of Universal Product Code (UPC) helped retail industry save $17 Billion in 1999 (Jayaraman et al., 2011). However, healthcare industry is moving at a slow pace. As reported by Simpson and Kleinberg (2009) the main contributors for the slow adoption include market drivers and technology issues.

Standardized product and partner identifier technologies in the healthcare supply chain are essential for effective information exchange through the supply chain. Existence of global standards for identification, especially when coupled with automatic identification technologies, help to track individual healthcare product (drugs, devices, biologics and blood products) to ensure safety and efficiency. Reduced human errors by enabling automatic data capture reduce ambiguity when identifying products (Zirkle et al., 2012). For drugs, correct identification assures the right product in the right dose reaches the right patient at the right time through the right route (the “five patient rights”). For devices, the five patient rights become eight patient rights: the right patient, the right device, the right location, the right time, the right condition, the

right procedure, the right anatomic site, and the right user (healthcare professional). Standard product identifiers also assist to track back the history of products as they move through the healthcare supply chain (Bix et al., 2007) and provide increased recalled product management and improved service quality. As a result, data standards contribute to increase patient safety.

Currently the adoption of data standards is not prevalent and there is no agreement among the stakeholders in the healthcare supply chain on the identification standards (product and location) that can be used by all of them. The use of stakeholder specific identification numbers is more common and cause to confusion, supply chain process inefficiency, and lack of visibility to track the product flow (Jayaraman et al., 2011). In addition to the patient safety, the benefits of standardized product and partner/location identifier technologies in the healthcare supply chain can be summarized as follows:

- Streamlined inventory management by reducing process errors and redundancies
- Increased visibility into the supply chain and improved decision support with consistent and accurate data (Zirkle et al., 2012)
- Enabled automatic data recording and ensured information quality
- Increased inventory accuracy
- Time savings in product preparing, shipping and receiving
- Efficient order replenishment
- Better and faster inventory management and better monitoring products on the shelves
- Proactive staffs who spend less time trying to obtain data and more time analyzing information to make decisions

Recall and Outdate Management at Providers

In order to investigate the impacts of standard product and partner/location identifying data on inventory accuracy, and recall and outdate management policies, a set of processes was identified. The process flow was developed and validated in collaboration with six different healthcare providers. The flow is illustrated in Figure 2. These processes are the conceptualization of the product and information flow for the recall and outdate management policies from the healthcare provider perspective. The figure contains 3 main parts. As illustrated, the first set of processes, referred as Part 1, is related to outdate management and includes the continuous monitoring of outdated products during standard supply chain operations and internal replenishment processes (box 1) as well as the capturing, storing and retrieving expiration date data for products (box 3). For example, the expiration dates of products can be validated at receiving or while replenishing nursing units. Also, expiration dates of products can be stored in the Materials Management Information Systems (MMIS) in order to trigger alerts when product is close to expiration date.

The second set of processes, referred as Part 2, is related to the recall management and includes the processes triggered by the recall notification until the case is considered closed (box 4). These processes include identifying and notifying provider units that potentially receive the recalled products as well as retrieving, disposing and/or returning. After receiving the notification or alert, materials management at a provider start checking the purchasing history to see whether the recalled product has been purchased or not. If the product was purchased the implicated areas are notified; otherwise the recall case is closed. For the implicated units, the recalled products are identified and retrieved from the storage locations by the materials management and nursing staff to be disposed. In addition, if a recalled product was administered

to a patient, another set of process including patient identification and notification takes place. Capturing, storing, and tracking the recalled product lot number and other related information for recalled products are also required in this set of processes (box 3).

The third set of processes, referred as Part 3 in the figure, is related to the product administration at POC; this is the last point to validate correct product (e.g. correct size, correct dose), correct patient, correct time as well as to identify expired or recalled products before administration. Clinical personnel perform product and patient validation activities in order to maximize patient safety.

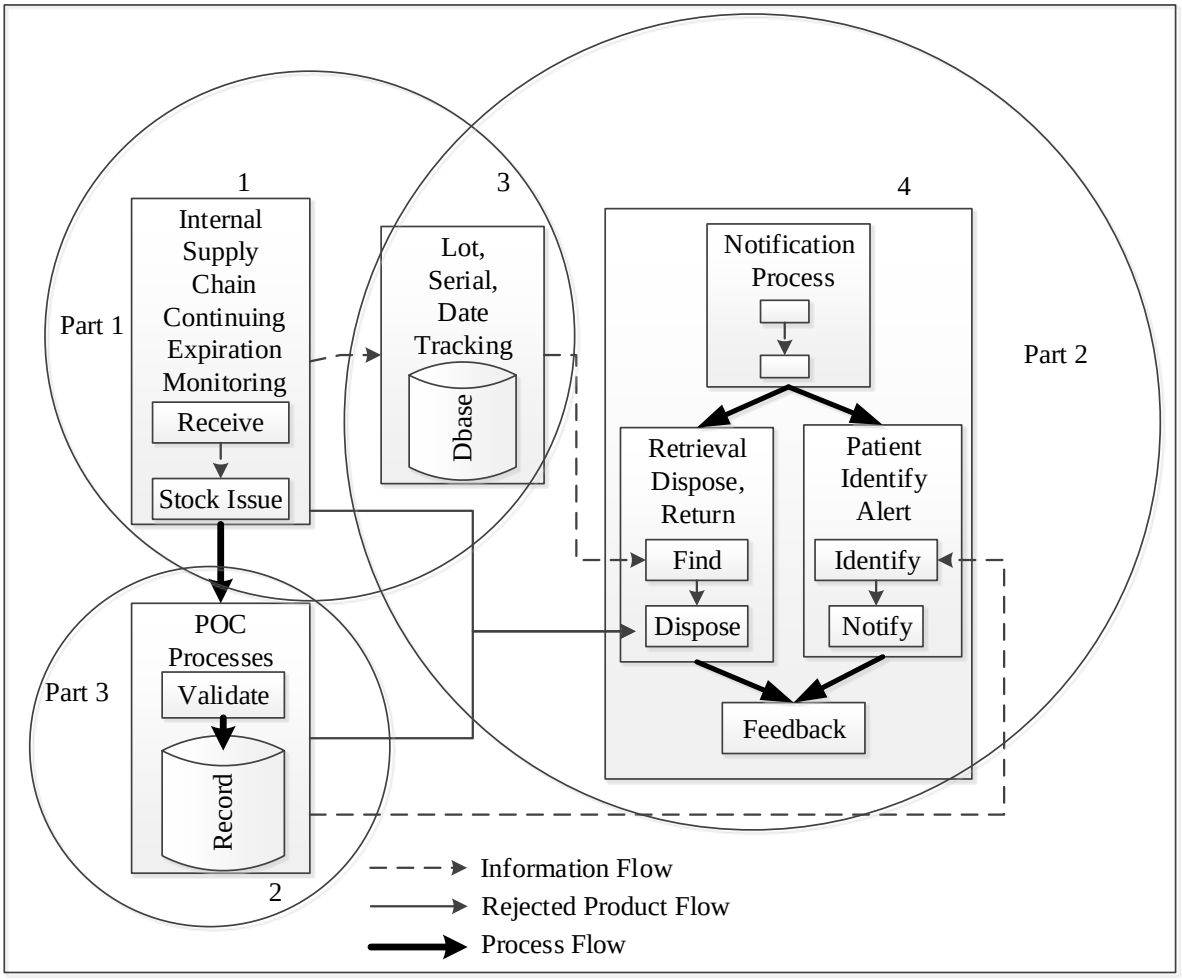

Figure 2: Recall and Outdate management processes

CHAPTER 3

METHODOLOGY

3.1. SYSTEM OVERVIEW

A simulation model is used to model a typical healthcare provider (i.e. hospital) supply chain operations and internal replenishment processes. The system under study covers the supply chain starting from the bedside administration through to the supplier warehouse and manufacturer. The model simulates the product and information flow and considers different location points in the supply chain operations including POC to validate the products for inventory management and accuracy as well as their expiration dates for outdate management, and lot and serial numbers for recall management. In order to measure the impacts of standard product and partner/location identification (GS1 Data Standards), common process errors are added to the system which are used to quantify the probabilities of identifying the products incorrectly, or missing a recalled or outdated product during the validation processes.

The simulation model considers two types of generic medical/surgical (med/surg) products and their PAR locations (i.e. inventory or utility rooms for medical products) as the last inventory holding point at the hospital. In addition, there is one central store (CS) at the hospital where the products are stored in bulk. A warehouse (WH), which supplies products to the hospital, and a manufacturer (MFG), which is the unlimited source of products, are also simulated in the model.

When a demand for either type of products occurs based on patient arrival for treatment, the inventory at the PAR location is checked. In case of enough on-hand product inventory, the demand is fulfilled, on-hand inventory level is reduced by the patient's demand, and the patient leaves. Otherwise, the product is backordered to CS and the patient waits until the demand is

fulfilled. In this case, an emergency order is sent to CS for only the demanded amount of products. In addition to these emergency orders, PAR locations are replenished daily. They operate under an "order-up-to" inventory management policy, where PAR location shelf capacity minus on-hand inventory is ordered every day for each product type. During the daily replenishment process, inventory positions (i.e. on-hand inventory + on-order inventory) are checked. If the inventory positions for products fall below the shelf capacity, the system orders enough amounts of individual products to reach the capacity.

CS operates under a continuous review inventory policy, where inventory position is monitored continuously after every time an order is sent. Products are received in boxes at CS and each product is separated before PAR replenishment. On-order inventory (and inventory position) is updated when receiving an order from WH and on-hand inventory (and inventory position) is updated when sending an order to PAR. When the inventory position of a product goes below its reorder point at CS, a box full of products are reordered and on-order inventory is updated. If on-hand inventory at CS is insufficient to fulfill a daily PAR order, then all on-hand inventory is sent to the PAR, the inventory levels are updated, and one box of products are backordered to WH. Since inventory position is monitored continuously after every time an order is sent, a CS replenishment order may be generated based on the inventory position. If on-hand inventory at CS is insufficient to fulfill an emergency PAR order, then all on-hand inventory is sent to the PAR and same as the case with insufficient inventory to fulfill a daily PAR order, one box of products are backordered to WH, and the inventory levels are updated.

WH operates under a similar inventory policy. Products are received on pallets at WH and each box is separated before CS replenishment. On-order inventory is updated when receiving an order from MFG and on-hand inventory is updated when sending an order to CS.

When the inventory position of a product goes below its reorder point at WH, a pallet full of products are reordered and the inventory position is updated. If on-hand inventory at WH is insufficient to fulfill a regular CS order, then all on-hand inventory is sent and the inventory position is updated. Inventory flow of the model is depicted in Figure 3.

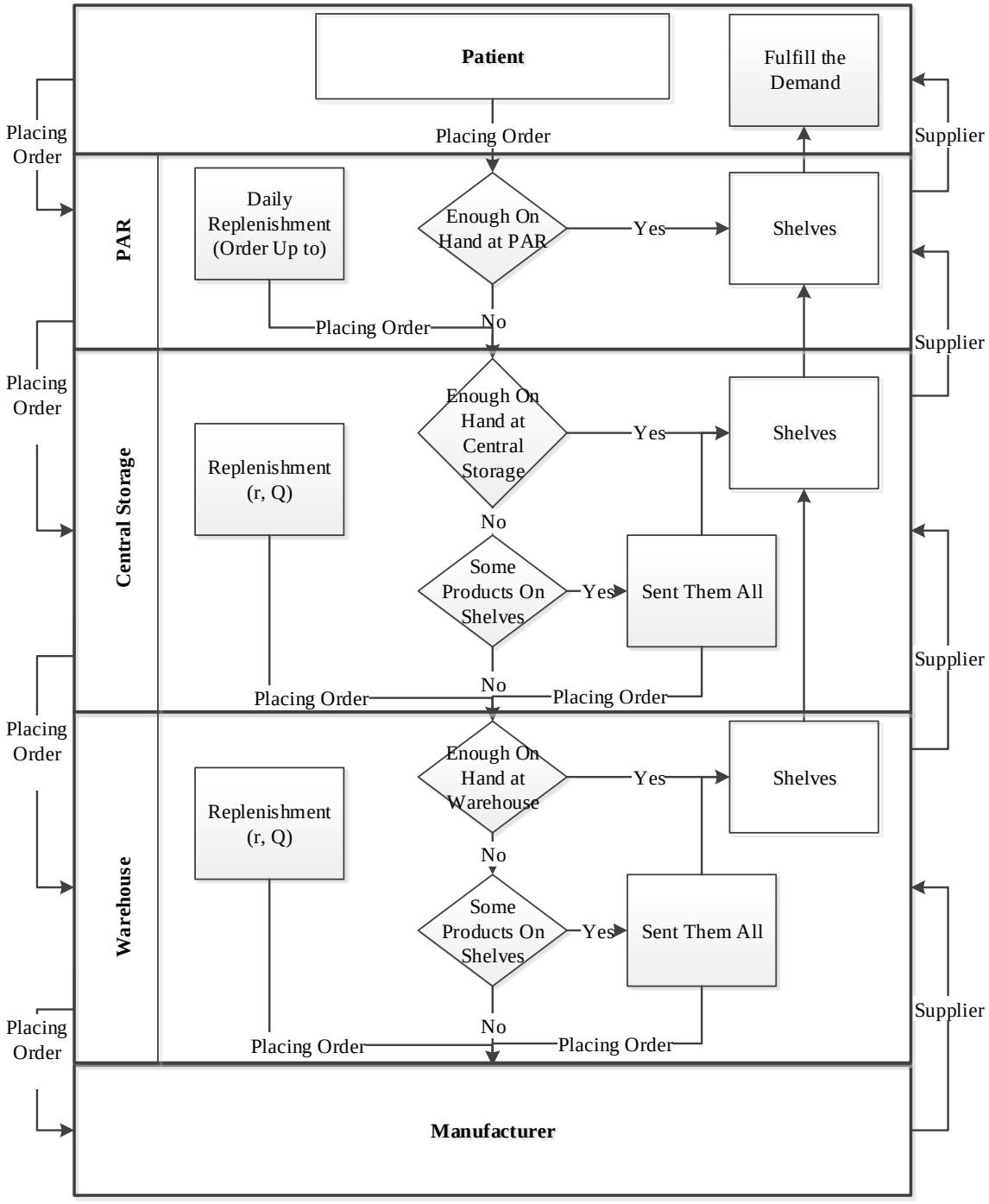

Figure 3: Inventory Flow of the Model

A number of potential validation points are identified in a provider supply chain system where the continuous product monitoring occurs before or after product transactions. Products and/or patients are identified and validated at these points to make sure that right (correct type) and safe (not recalled and not outdated) products are used for right patients. These validation points include:

1. Bedside: A validation process before administering products to patients.
2. PAR Picking: A validation process while picking the products from the PAR locations before using them.
3. PAR Receiving: A validation process while receiving products from central storage.
4. Central Storage Picking: A validation process while picking the products at the central storage to replenish PAR locations.
5. Central Storage Receiving: A checking process while receiving products from the warehouse.
6. Warehouse Picking: A checking process while picking the products to replenish central storage.
7. Warehouse Receiving: A checking process while receiving products from the manufacturer.

Product types, expiration of them, and lot number (for recall purposes) may be checked at these potential validation points. Note that the number of products to be validated, the amount of validation time as well as validation procedure may change at each point. It may not be feasible or practical to utilize validation process at every point in the supply chain; thus, validation process may take place at only a few of these potential points in the hospital.

In addition to the validation points in the supply chain, possible errors that may occur during these processes, are simulated in the model such as misidentifying products, missing expired, or recalled products. Using data standards help improve the validation processes and reduce these errors. Furthermore a number of inventory management related errors are simulated in the model including stock-loss (shrinkage) errors, transaction errors, ordering errors (misordering), and errors during replenishment (misplacement and mispicking).

Stock-loss errors occur when on hand inventory decreases due to some unpredicted events such as theft or personnel mistakes. Stock-loss errors occur at warehouse, central storage, and PAR levels. Transaction errors happen when products are transported from the supplier to the warehouse, from warehouse to central storage, and also from central storage to PAR. These errors can affect replenishment decisions, like reorder point and reorder quantity. Ordering errors happen when replenishment demand is generated and it is either wrong amount ordered or wrong product ordered. Misordering happens while demand is generated for PAR, central storage, and warehouse. Misplacements and mispickings also happen while putting products in wrong shelves or taking them from wrong shelves. Validation related and inventory management related errors and their modeling details will be explained in the next section.

3.2. SYSTEM MODEL

Assumptions

Following assumptions are used in the model:

1. The time between arrivals of patient follows an exponential distribution.
2. System includes two types of products.

3. Since there are two types of product in the system, the entire inventory holding areas contains two shelves for each type.
4. Each patient requires only one type of products, either type one or type two.
5. Each patient requires 1, 2, 3, 4, or 5 products of a same type. The probability of amount demanded is equal and follows a discrete distribution.
6. Manufacturer is assumed as an infinite source of product, so it can fulfill the demand whenever it is required.
7. The reorder point and the reorder quantity for warehouse shelves are 10 boxes and 1 pallet (including 10 boxes respectively).
8. The reorder point and the reorder quantity for central storage shelves are 100 and 100 products respectively.
9. PAR bins capacities are 50 products.
10. Areas for validation are: warehouse receiving, warehouse picking, central storage receiving, central storage picking, PAR receiving, Par picking, and bedside administration.
11. Expiration date for products follow a normal distribution and the manufacturer do not send expired products to the hospital.
12. Recall notification arrivals follow an exponential distribution.
13. Stock-loss error occurs based on exponential distribution.
14. Cart count at PAR location occurs every day and corrects the recorded inventory and misplacements only if the actual on hand inventory is more than twice of recorded inventory or the actual on hand inventory is less than half of recorded inventory.
15. Cycle count in central storage happens every year to correct the recorded inventory and misplacements. It is an immediate action.

16. Cycle count in warehouse happens every year to correct the recorded inventory and misplacements. It is an immediate action.

The time between patient arrivals is assumed to follow an exponential distribution, so the demand process is a Poisson distribution. Two types of products are simulated in the model with the same demand probability. The probability of demand associated with each type has discrete distribution. Upon the customer arrival, product demand type and amount are determined in the model. A discrete distribution is used for the amount of demand and with equal probability the patient demand amount can be 1, 2, 3, 4, or 5.

In addition to patient demand, there is also another demand for replenishment. Replenishment demand for PARs is generated after every cart count (occurs every day) and is sent to the central storage. Replenishment demand amount is the difference between the maximum capacity of PAR bins and numbers of products in the bins.

Replenishment demand for central storage and warehouse also can be generated after each replenishing process when the system checks the inventory position of CS and WH. If inventory position of CS or WH is less than reorder point, replenishment demand is generated and asks for certain amount of products.

Transportation

The system under study has different locations that hold products. Manufacturer where products are created and warehouse are out site locations, central storage and PAR levels are within the hospital locations. So, transportation activities take place between these areas and they are modeled as determined delays. There are costs associated with transportation between manufacturer and WH and transportation between WH and CS since they are out site hospital locations.

Once the order sends to the WH or CS, WH or CS checks the on hand inventory in order to satisfy the demand. When the order is ready and sent, it takes a certain amount of time to reach to the next location. When the next location receives the order, the inventory records are updated.

Stock-loss error

As it mentioned before, stock-loss is the unrecorded loss of inventory because of unexpected events. When the stock-loss error occurs, one unit of products will be deleted from the system without the inventory records are updated (unit of products at WH is boxes that contains 100 products, so as the stock-loss error happens 100 products are deleted at once at WH, unit of products at CS and PAR is individual products so as the stock-loss error happens one product is deleted).

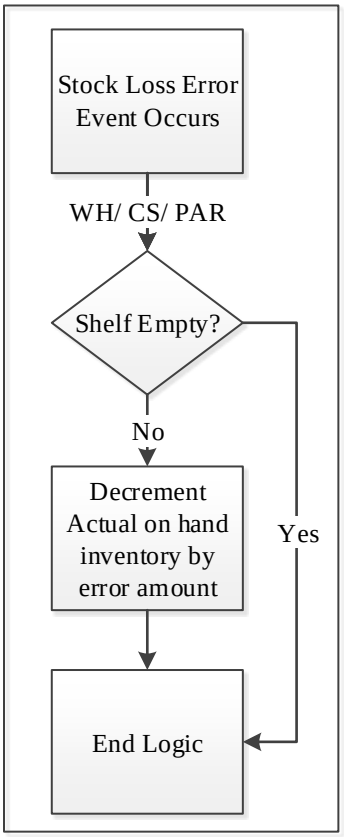

Figure 4: Stock-Loss Error

The implementation of stock-loss error into the model is demonstrated in Figure 4. The time intervals between the stock-loss errors are based on exponential distribution, but the frequency of occurrence is different in different locations (WH, CS, and PAR). Since there are two types of products in the systems, stock-loss error affects the shelf related to only one of the product's type each time it occurs. When stock-loss error occurs the actual inventory on hand inventory is checked and if the value is not zero, then the actual on hand inventory decreased by one.

Transaction error

When the replenishment order is received, there is a probability of making transaction error which is defined by a variable and we can set it to a certain value. Same thing can happen while picking products from shelves. Since two types of product are in the system, we have two types of transaction errors. First, is receiving or picking either one of the products while updating the records for the other product. Second, is updating the wrong amount in the record and the wrong amount can be positive for receiving and negative for picking process. Therefore, when either of these errors happens system updated the recorded inventory and inventory position incorrectly. The wrong amount can be plus or minus 1, 2, or 3 which is followed a discrete distribution. The implementation of transaction error into the model is illustrated in Figure 5.

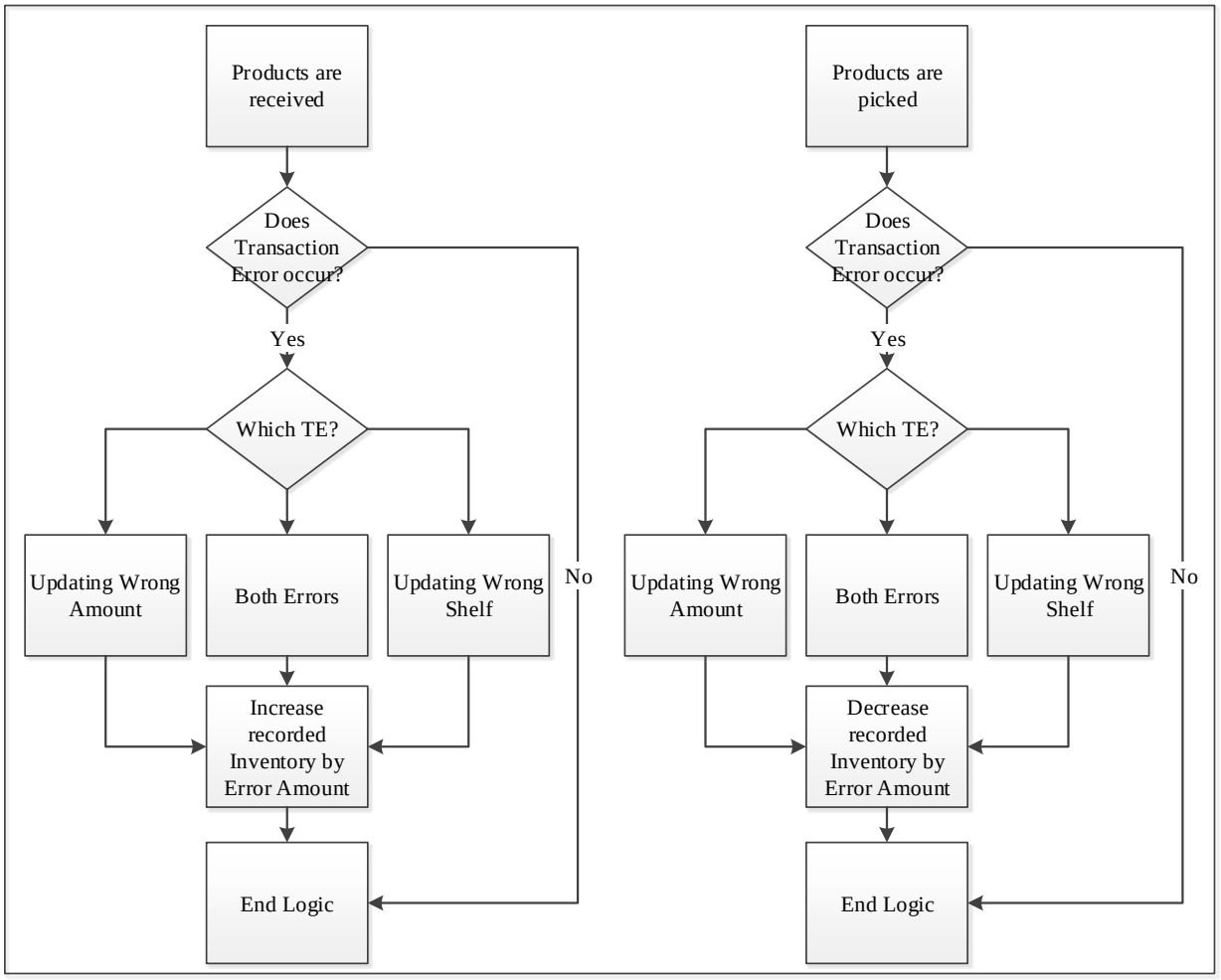

Figure 5: Transaction Error

Misordering

In order to replenish the inventory in different locations (Warehouse, Central storage, and PARs), inventories are checked based on the policy of the location (WH and CS perform under (s, S) policy and PARs follow order up to policy). When the replenishment is required, demand is generated and system places an order. There is a possibility of error while ordering. Two types of errors can occur. Ordering wrong amount which can be positive or negative (in negative case if the demand value becomes zero or less, no order is placed). As an example, when 40 products are needed to replenish PAR, system orders 43 or 38. Ordering wrong product which is ordering

product type two instead of type one and vice versa. In addition to that there is a possibility that the errors happen at the same time since they are independent.

Misplacing and mispicking

In addition to the errors mentioned is previous sections, there is also misplacing and miss-picking errors that can occur during the inventory management processes. Since the model includes two types of products and shelves for stocking them, misplacement can happen by putting product type one into the shelves related to product type two and vice versa, while miss-picking can happen by picking from a wrong shelf. So, when these errors occur, they messes up the whole inventory records. For example, when type one products are put in shelves for type two products, or when type one products should be picked and type two products are picked, the inventory information of the products changes incorrectly. Misplacement is embedded to the system while sending the products. Probability of having misplacement errors is defined by variables that can be set before running the model and with that probability, products are sent to wrong shelves. Probability of having miss-picking errors is also defined by variables that can be set before running the model and with that probability products are picked from wrong shelves.

Cycle counting

Cycle counting is usually used to improve the inventory accuracy. It is common that during the cycle counting the system is shut down to make sure the items are not moving and every one of them is counted. Because of the complexity of the system, it is assumed that cycle counting happens immediately in the model. Cycle count events happen in CS and WH and correct the misplacement errors as well as records. During each cycle count, "product type" of all products is checked to ensure they are in right place and if not, they will be moved to the correct

location. After correcting the misplacement errors, the recorded inventory is reset to the actual on hand inventory value. The logic of cycle count is shown in Figure 6.

Cycle counting is done to reduce the number of stock-loss that might happen in the system. After correcting the records, the inventory position is also checked to determine if the replenishment order needs to be sent or not.

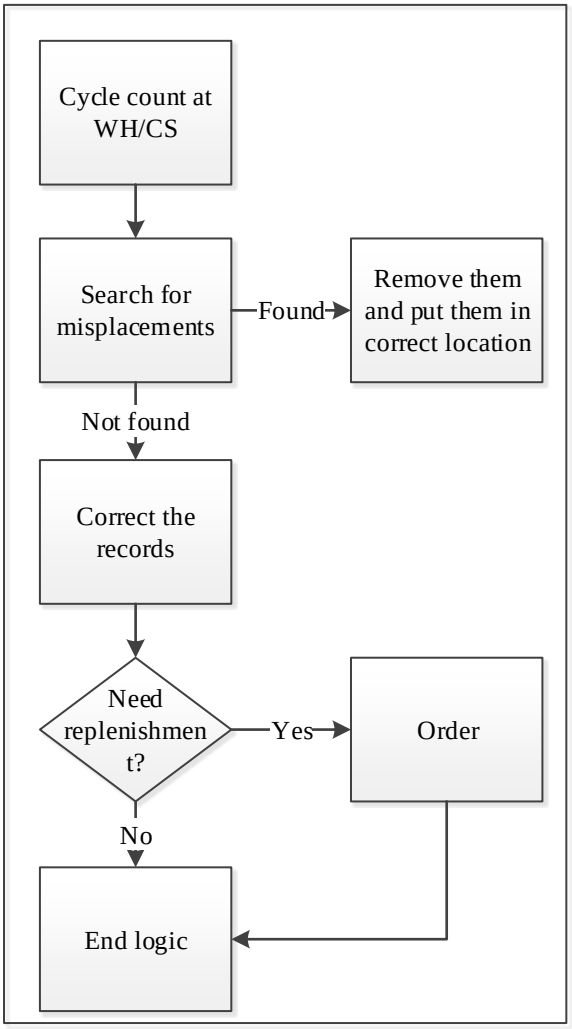

Figure 6: Cycle Counting

Cart counting

Other than cycle counting, which is used in warehouse and central storage to correct misplacements and records, there is a cart counting event in PARs. Since PAR locations are not

big like WH and CS, and also it is closest inventory place to the patients, cart counting occurs on daily bases to correct misplacements, correct records, avoid stock-losses, and ensure enough products are available for patients.

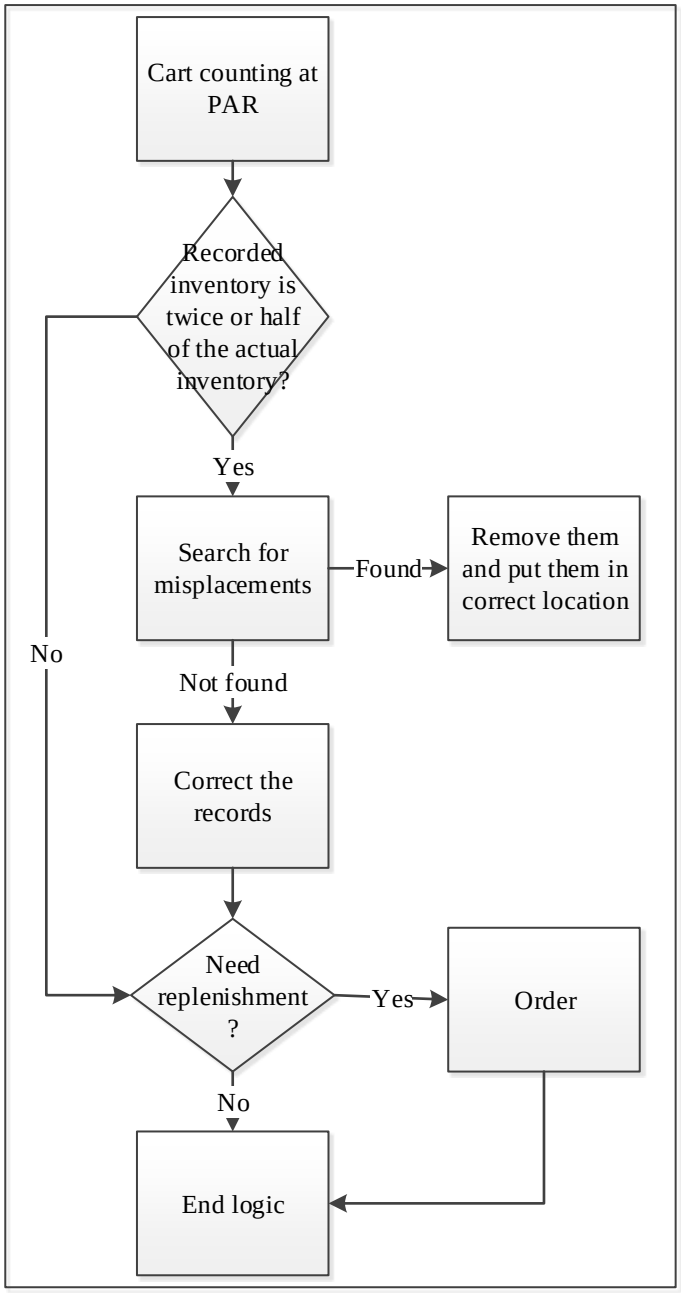

Figure 7: Cart Counting

As mentioned before, PARs are following an “order up to” policy. So, whenever cart counting occurs, the difference between the PAR capacity and PAR inventory position is ordered. But the purpose of cart counting is not only ordering, therefore misplacement and record corrections are also embedded in the system and triggered when the difference between actual on hand inventory and recorded inventory at PARs reaches a certain amount. The idea of cart counting can be seen in Figure 7.

Recall process

The Model generates recall notifications based on exponential distribution. Whenever there is a recall, the recall lot (which is randomly chosen from zero and maximum value of products lot number) and recall type (which is either one or two) added to a list (list of recalls). List of recalls are considered so there is a chance to catch recalled products which are missed in previous recall validations due to the errors.

When recall is notification received, the system searches all the inventory locations. System checks recall lot and recall type value against lot number and type of the products and when it matches, the products will be removed from the shelves. This process continues untill all the products are checked against all the recall notifications in the list.

Validation

Other than the inventory related errors discussed before, there are errors related to validation. Seven locations can be used to validate three issues. The locations are: warehouse while receiving products from the manufacturer, at warehouse while picking the products to replenish central storage, central storage while receiving products from the warehouse, at central storage while picking the products to replenish PAR locations, while picking from the PAR locations to be used, and the last validation point is before administering it to a patient (bedside).

The issues to be checked are: Expiration date, recall check, and identification (if the product is right). It is done to prevent inappropriate products from being used for patients.

In the simulated system, every product has an expiration date, lot number, and type number (either 1 or 2). These are assigned as soon as they are produced at the manufacturer. Expiration date, lot number validations, and product identification can be done at different points of the supply chain and there are errors associated with these validation processes. Therefore, different scenarios are created based on validation points to see which ones produce better results based on the number of recalled, outdated, or misidentified products given to a patient. Binary variables are used associated to each validation point in the model so when they are set as one it means that product will be checked there otherwise there is no check at that location. The validation process is depicted in Figure 8.

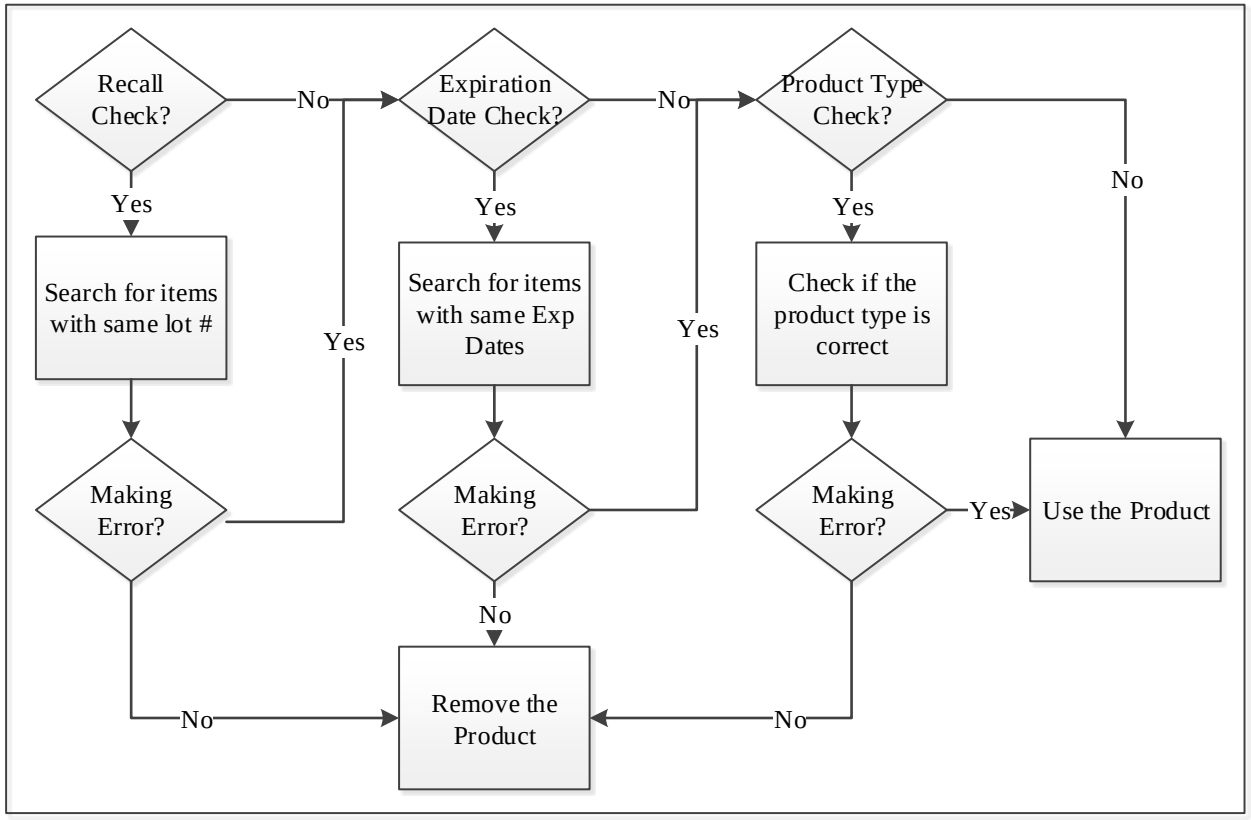

Figure 8: Validation Process

3.3. MODEL INPUT

Table 2 summarizes all the input in the model. Some of the inputs given below are based on the location and might vary in different locations (it is demonstrated in the table). Different locations are warehouse receiving, warehouse picking, central storage receiving, central storage picking, PAR receiving, PAR picking and bedside.

Table 2: Model inputs

Outdate check	WH, CS, PAR, BS	Binary
Recall check	WH, CS, PAR, BS	Binary
Identification check	WH, CS, PAR, BS	Binary
Outdate mgmt. error rate	WH, CS, PAR, BS	%
Recall mgmt. error rate	WH, CS, PAR, BS	%
Misplacement error rate	WH, CS, PAR, BS	%
Mispicking error rate	WH, CS, PAR, BS	%
Reorder quantity	WH	Boxes
Reorder point	WH	Boxes
Reorder quantity	CS	Units
Reorder point	CS	Units
Reorder point	PAR	Units
Capacity	PAR	Units
Time between patient arrival		Hours
Time between stockloss		Days
Stockloss amount		Units
Product expiration time		Minutes

Some of the inputs varied within the experimental design while others are kept the same in order to find the effect of the factors of interest. A detailed explanation of which inputs are changed and why they are changed is given in the result section.

3.4. PERFORMANCE MEASURES

Recall that the system under study tries to find the impact of GS1 standards on patient risk and supply chain. Therefore, the system performance measures are grouped in two categories:

1) **Risk analysis:** In order to investigate the impact of GS1 on risk four different settings are studied. First, the system includes errors in supply chain processes such as ordering receiving, putting away or replenishing and also errors in checking processes such as check for outdates, recalls, and misidentified products. Second, the system that has errors in supply chain processes but no checking errors. This means that checking processes are automated and are using GS1 but there are errors in supply chain processes. Third, system with only errors in checking processes. This means that GS1 has been implemented and used in supply chain processes (processes has been doing automatically) that there is no error in them. Last one is the system with no error in either of the supply chain and checking processes. In all these four settings the performance measures are as follow:
    a. Number of unsafe products (misidentified-incorrect, outdated or recalled products) that are registered to patients.
    b. Patient's demand waiting time which is the delay of providing care
2) **System performance analysis:** Following performance measures are used to explore if the system can be more efficient by reducing the cost of holding inventory and number of transportation as well as more precise records.
    a. Inventory descrepency which is the difference between actual and recorded inventory
    b. Average inventory that shows the mean level of inventory in different locations

c. Number of transportation that occurs between different locations for replenishing

CHAPTER 4

RESULTS AND CONCLUSION

The simulation experimentation was performed for different scenarios and the performance measures introduced in previous section were explored. In addition, cost effectiveness analysis has been done to find the best scenarios based on different cost and risk factors.

4.1. RESULT SUMMARY

The developed model is run for 10 replications for each scenario. Each replication length is 1000 days and the warm up period is 90 days before the system results are collected. Two types of products are considered in the model to have the ability of simulating the misidentification. These products have the expiration date of 180 days. Patients' arrival time in the model is based on a Poisson process with a rate of one every 3 hours and recall notifications are received every 7 days.

Twenty two scenarios were performed based on the 7 different locations to validate products and performance measures were observed. However, there were 128 possible scenarios (2^7, since in each location there is an option to validate products or not), 22 of those were considered due to the high possibility of getting similar results for validating at locations where products' flow happen in short period of time. Therefore, locations warehouse picking and central storage receiving, central storage picking and PAR receiving, PAR picking and bedside

were both either considered as validation point or not at the same time. Table 3 demonstrates the scenarios.

Table 3: Model scenarios

1	No check	wh = warehouse cs= central storage bs = bedside r = receiving p = picking
2	wh r	
3	wh p	
4	cs r	
5	cs p	
6	par r	
7	par p	
8	bs	
9	wh p, cs r	
10	cs p, par r	
11	par p, bs	
12	wh r, wh p, cs r	
13	wh r, cs p, par r	
14	wh r, par p, bs	
15	wh p, cs r, cs p, par r	
16	wh p, cs r, par p, bs	
17	cs p, par r, par p, bs	
18	wh r, wh p, cs r, cs p, par r	
19	wh r, wh p, cs r, par p, bs	
20	wh r, cs p, par r, par p, bs	
21	wh p, cs r, cs p, par r, par p, bs	
22	all checks	

Recall that, in order to do risk analysis and find out the impact of GS1, four systems were examined. The systems with:

1. Supply chain processes error and checking processes error
2. Supply chain processes error but no checking processes error
3. No supply chain processes error but checking processes error

4. No supply chain processes error and no checking processes error

Tables 4, 5, 6, and 7 include 22 scenarios with three performance measures related to unsafe products that are administered to the patients for each one of the systems.

The system which has supply chain process error and checking process error, is more like what exists in reality. In this case, as it is expected, the model shows that when the validation process is closer to the point of care/bedside (where the products are administered to the patients) the number of unsafe products used for a patient is smaller. However, when the number of validation points increases, it does not necessarily mean that the number of unsafe products administered to the patients will be reduced. Considering these three performance measures indicate that scenario with only checking at bedside is good enough to avoid using unsafe product for patients but considering other performance measures might impact it.

Table 4: Supply chain error - Check error

Supply chain error - Check error			
Scenario	Misidentified	Outdated	Recalled
1	2070.3	2642.6	760.8
2	1663.3	1856.9	434.5
3	1567.7	831.6	365.8
4	489.9	516.4	191.3
5	201.7	250.3	86.6
6	35.8	81.2	9.8
7	32.4	52.6	5.9
8	5.2	8.3	1
9	481.9	519.1	177.7
10	30.8	55.6	7.3
11	7.2	7	1.4
12	453.7	491.2	165
13	28.9	49.6	2.6
14	3.2	4.5	0.5
15	17.3	14.5	5.8
16	2.3	1.4	0.8
17	1.7	1.7	0.9
18	9.9	9.9	4.3
19	1.4	1.6	0.4

20	0.6	0.3	0.1
21	0.3	0.2	0.4
22	0.1	0.2	0

The graphic view of the output is also illustrated in the following figure.

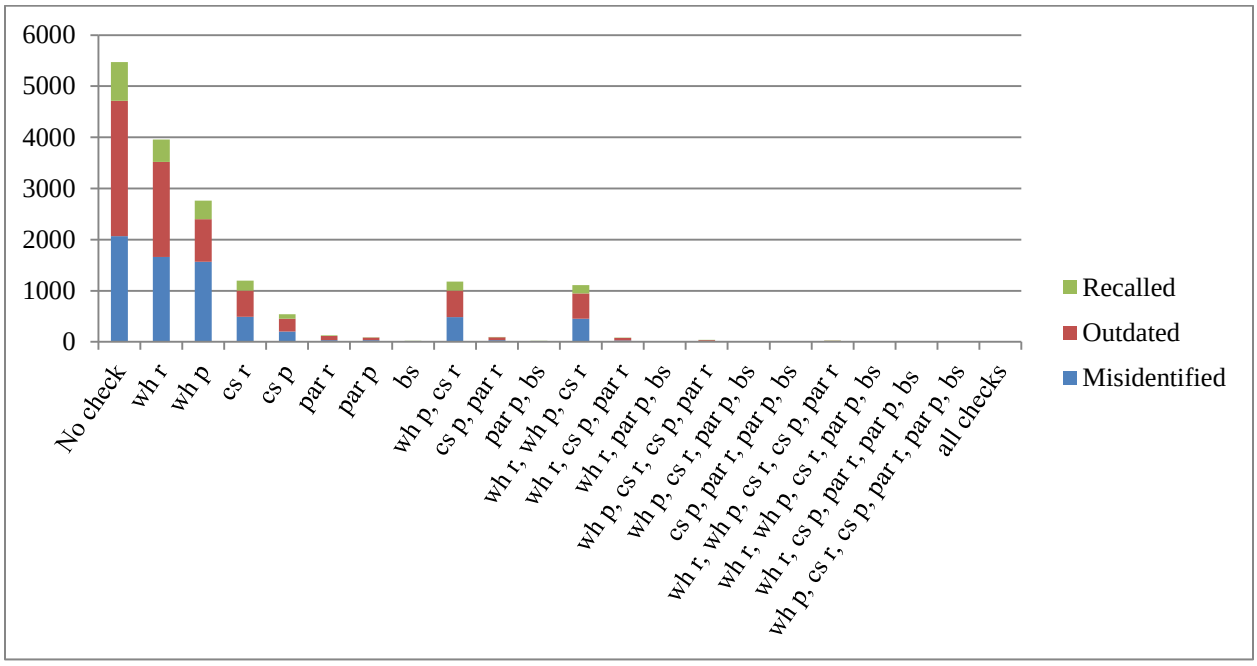

Figure 9: Number of recalled, outdated, and misidentified products for Supply chain error - Check error system

The system with supply chain processes error but no checking processes error is when GS1 implementation is used for checking processes. It is assumed that the checking processes are done automatically using GS1 (e.g. if a product is recalled, by scanning the barcode some warning will appear on the screen). The results for this system also follow the same pattern as the previous system but overall the output values for that are smaller due to the implementation of the GS1.

Table 5: Supply chain error - No check error

Supply chain error - No check error			
Scenario	Misidentified	Outdated	Recalled
1	2024.2	2439.6	715.6
2	1847.4	1925.4	514.9
3	1297.5	801.7	186.6
4	329.1	407.6	55.1
5	96.5	118.3	37.3
6	20.9	23.2	1.6
7	0	0	0
8	0	0	0
9	284.1	407.9	37.2
10	18.6	20.7	1.2
11	0	0	0
12	256.4	351.8	19.4
13	18.8	20.9	1.3
14	0	0	0
15	11.6	17.1	0.8
16	0	0	0
17	0	0	0
18	9.3	15.4	0.8
19	0	0	0
20	0	0	0

21	0	0	0
22	0	0	0

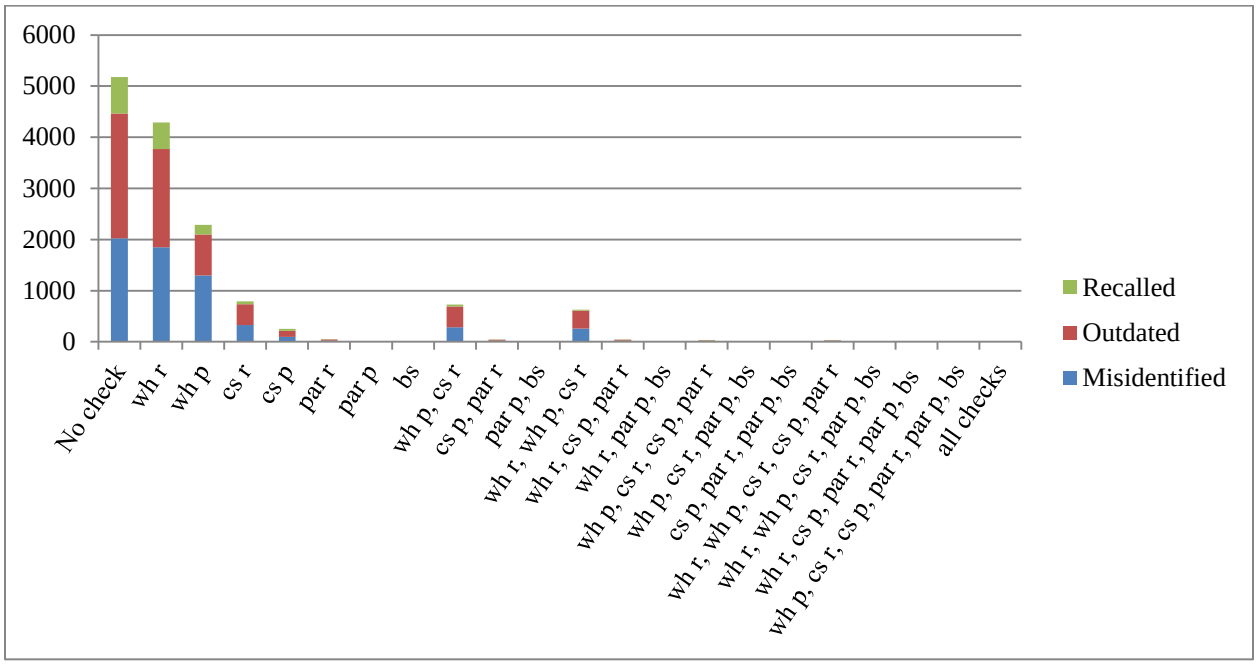

Figure 10: Number of recalled, outdated, and misidentified products for Supply chain error - No check error system

The system with no supply chain error but check error is when supply chain processes are free of errors. This is because of the perfect supply chain processes due to implementing of GS1 and automation. Therefore, there is no misplacement and mispicking in replenishing, no errors in ordering, and no misses in recall management. As a result, there is no misidentified and recalled product administered to the patients. There is still a chance of using outdated products for patients based on the location of the validation point.

Table 6: No supply chain error - check error

No supply chain error - check error			
Scenario	Misidentified	Outdated	Recalled
1	0	2382.2	0
2	0	1922	0
3	0	800.9	0
4	0	501.6	0
5	0	234.9	0
6	0	73.8	0
7	0	52.4	0
8	0	9.4	0
9	0	565.2	0
10	0	48.1	0
11	0	8.1	0
12	0	506.5	0
13	0	49	0
14	0	4.2	0
15	0	15.4	0
16	0	1.9	0
17	0	2	0
18	0	8.8	0
19	0	2.1	0
20	0	0.4	0
21	0	0	0
22	0	0	0

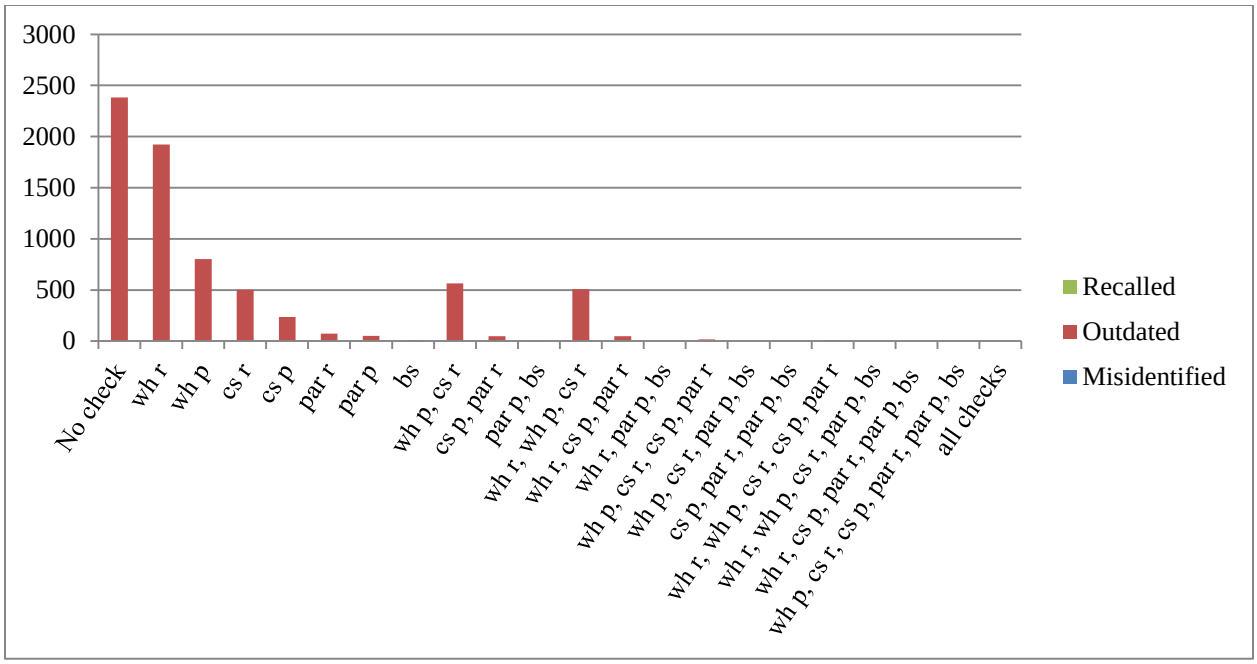

Figure 11: Number of recalled, outdated, and misidentified products for No supply chain error - check error system

This system is the ideal case where there is no error in supply chain and checking processes. So it has the advantages of the two previous cases (no misidentified and recalled products are used for patients as well as mostly smaller values for outdates).

Table 7: No supply chain error - No check error

No supply chain error - No check error			
Scenario	Misidentified	Outdated	Recalled
1	0	2137.2	0
2	0	1953.6	0
3	0	948.2	0
4	0	418.7	0
5	0	90.1	0
6	0	18.4	0
7	0	0	0
8	0	0	0
9	0	372	0
10	0	15.6	0
11	0	0	0
12	0	343.9	0
13	0	21.8	0
14	0	0	0
15	0	18.6	0
16	0	0	0
17	0	0	0
18	0	15	0
19	0	0	0
20	0	0	0
21	0	0	0
22	0	0	0

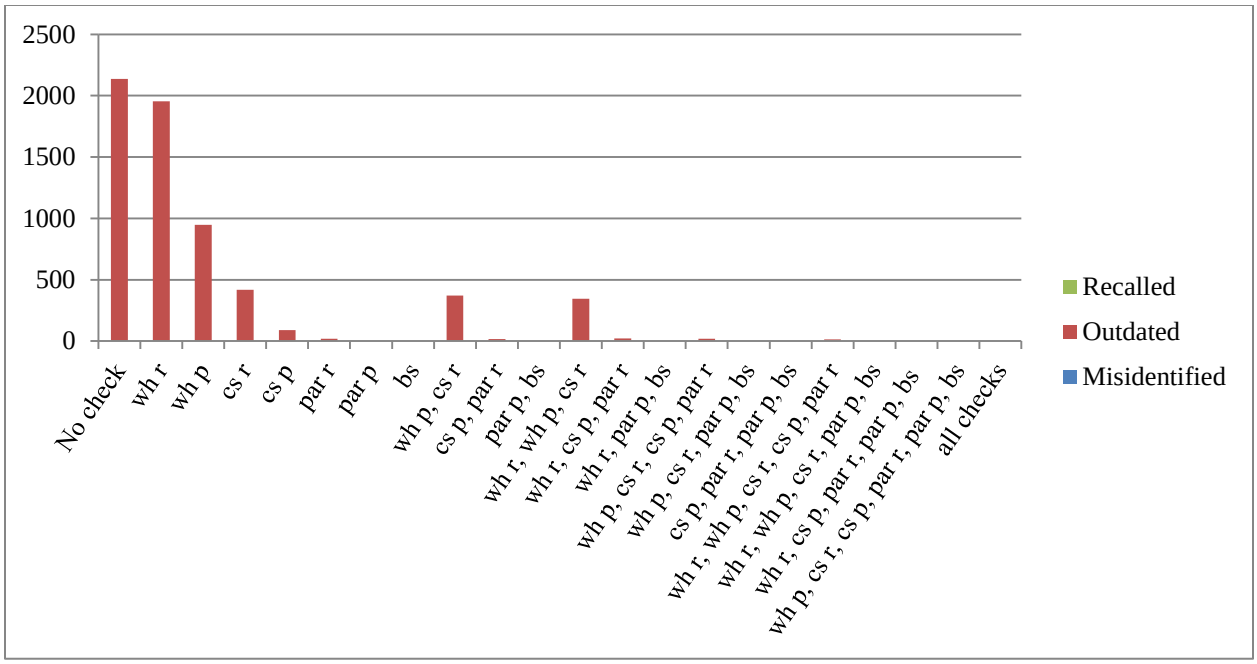

Figure 12: Number of recalled, outdated, and misidentified products for No supply chain error - No check error system

In order to evaluate how to enable the validation points effectively and efficiently, the most realistic system (system with supply chain and checking processes error) was examined. Performance measures that were investigated are average waiting time of a patient's demand to receive products, total time of checking processes per receiving/replenishing, total average inventory in all inventory locations, total inventory discrepancy in all locations, and total number of shipments in 1000 days. The detailed table of each performance measure and graphic view of them are provided.

Table 8 and 9 shows the average waiting time of a patient's demand and time spent on checking in each scenario. Checking the Figure 13 indicates that central storage picking and PAR receiving checking processes have the most impact on the patient waiting time. It is probably because the amount of products that must be validated in these processes, therefore, it might delay the service. Bars associated with time of checking in scenarios including central storage picking and PAR receiving checks also admits that.

Table 8: Average waiting time of a patient's demand

supply chain error & check error		waiting time (min)
1	No check	0.32
2	wh r	1.23
3	wh p	1.18
4	cs r	1.42
5	cs p	4.01
6	par r	3.19
7	par p	2.09
8	bs	1.1
9	wh p, cs r	2.2
10	cs p, par r	5.54
11	par p, bs	2.18
12	wh r, wh p, cs r	1.51
13	wh r, cs p, par r	3.02
14	wh r, par p, bs	1.93
15	wh p, cs r, cs p, par r	4.81
16	wh p, cs r, par p, bs	2.33
17	cs p, par r, par p, bs	5.72
18	wh r, wh p, cs r, cs p, par r	5.18
19	wh r, wh p, cs r, par p, bs	2.6
20	wh r, cs p, par r, par p, bs	4.4
21	wh p, cs r, cs p, par r, par p, bs	4.91
22	all checks	5.37

Table 9: Time spent on checking

time to check (min)					
Scenarios	wh	cs	par	bs	total
1	0	0	0	0	0
2	2.4	0	0	0	2.4
3	0.17	0	0	0	0.17
4	0	13.3	0	0	13.3
5	0	8.24	0	0	8.24
6	0	0	4.19	0	4.19
7	0	0	0.27	0	0.27
8	0	0	0	0.26	0.26
9	0.2	9.25	0	0	9.45
10	0	9.1	4.88	0	13.98
11	0	0	0.33	0.22	0.55
12	2.7	12.4	0	0	15.1
13	2.42	7.8	4.3	0	14.52
14	2.55	0	0.24	0.17	2.96
15	0.18	23.12	4.7	0	28
16	0.16	13.81	0.22	0.2	14.39
17	0	7.9	4.4	0.3	12.6
18	2.63	21.11	4.34	0	28.08
19	2.14	12.57	0.3	0.21	15.22
20	2	8.66	4.5	0.22	15.38
21	0.28	23.77	4.22	0.19	28.46
22	2.5	24.04	4.29	0.26	31.09

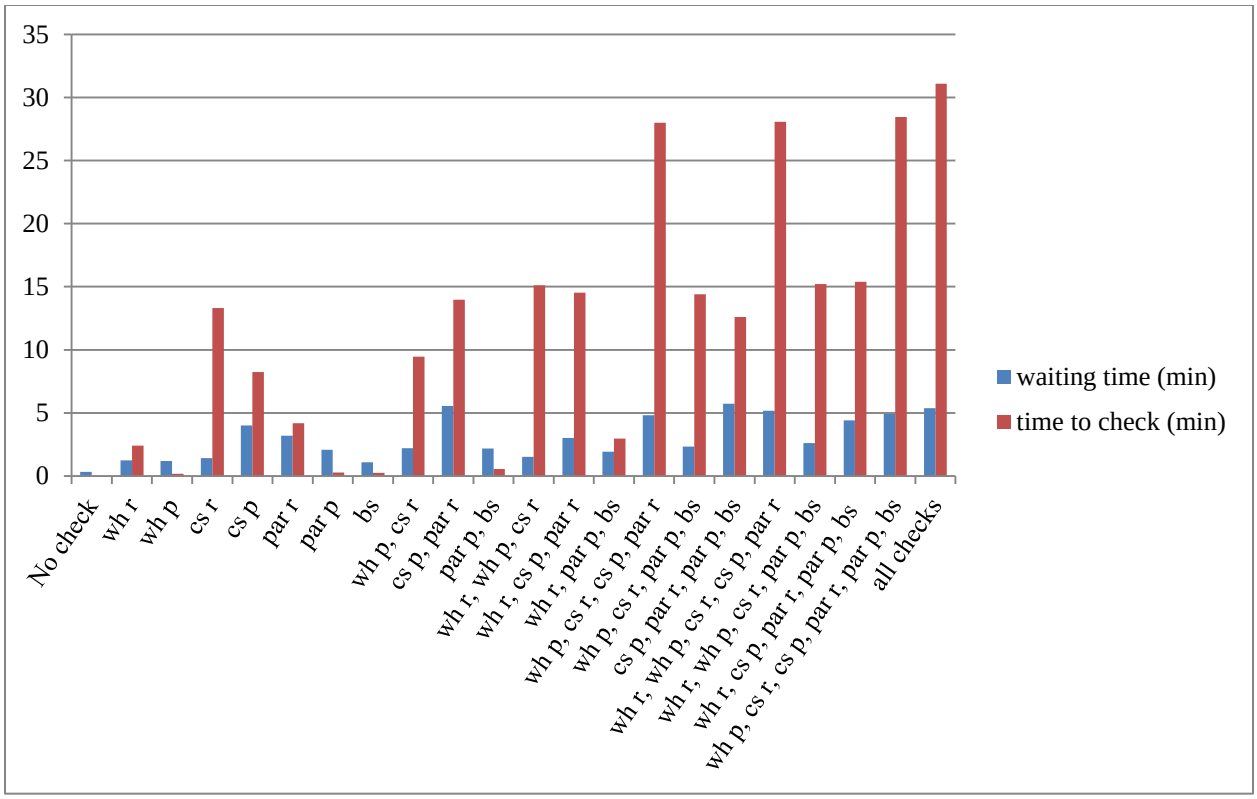

Figure 13: Waiting time and time spent on checking

So far, considering the previous performance measures indicates that validating the products closer to the point of care is the best. It is true that checking at very last validation locations leads to have small values for number of unsafe products administered to the patients, shorter amount of time spent on checking, and shorter waiting time for patients' demand. But it can lead to keep the undesired products (outdated/recalled) on the shelves longer, therefore, increase the inventory holding cost and can increase the risk of running out of products when there is a higher demand in the system.

Table 10 and figure 14 indicate that validating at warehouse can help to reduce overall inventory level. Since warehouse deals with boxes of products (100 products in each box) eliminating the undesired products from staying on the shelves early in the system might be the reason to lower the inventory level.

Table 10: Average inventory

average inventory				
Scenarios	wh (box of 100 products)	cs (units)	par (units)	total (units)
1	12	154	35	1389
2	11	144	39	1283
3	11	141	33	1274
4	12	123	33	1356
5	12	129	30	1359
6	12	137	24	1361
7	12	133	28	1361
8	12	132	29	1361
9	11	117	36	1253
10	12	126	23	1349
11	12	136	22	1358
12	11	119	36	1255
13	11	124	27	1251
14	11	130	28	1258
15	12	116	26	1342
16	11	125	28	1253
17	12	124	21	1345
18	11	116	25	1241
19	11	121	20	1241
20	11	124	20	1244
21	11	116	19	1235
22	11	116	20	1236

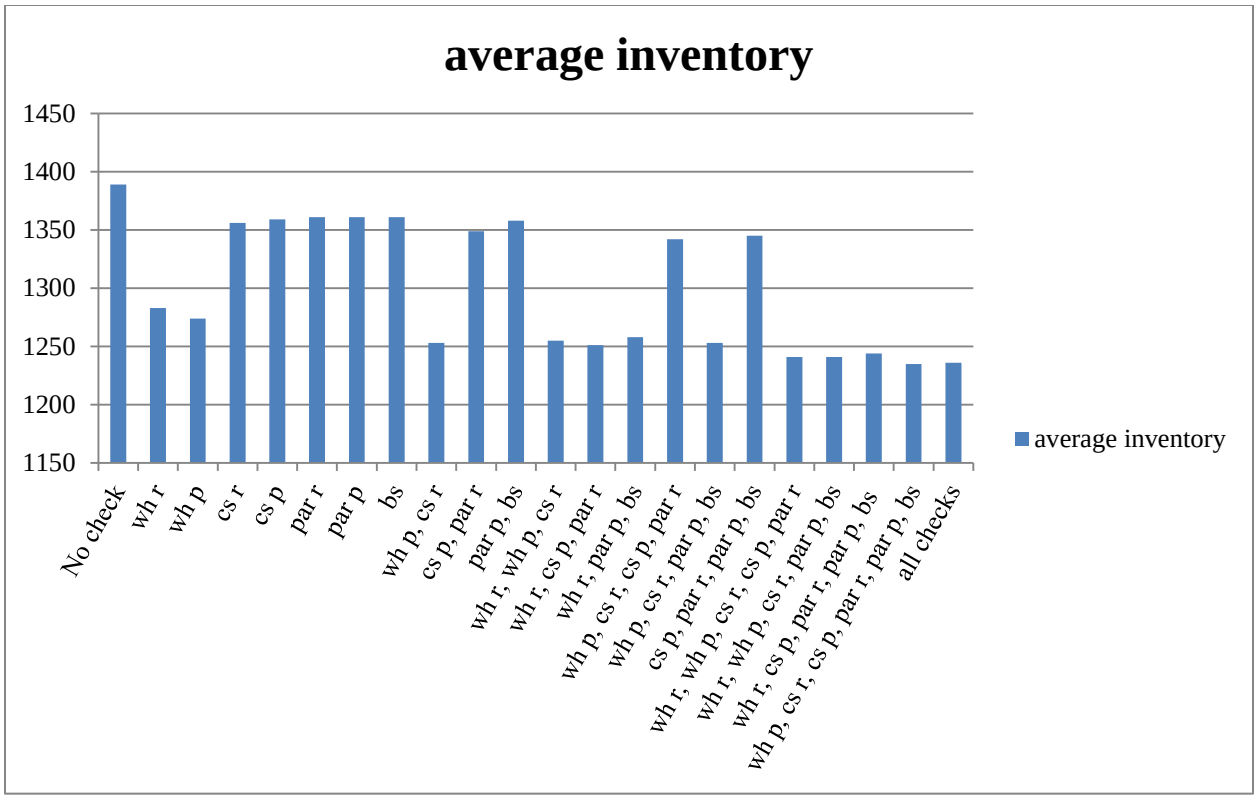

Figure 14: Average inventory

Inventory discrepancy is defined as the difference between the actual on hand inventory and the recorded inventory. During supply chain processes such as receiving and replenishing, there is a possibility of putting products in wrong shelves, picking from wrong shelves, or losing products, therefore, the inventory records will become inaccurate. Results from the scenarios indicate that when validation at warehouse picking occurs the overall inventory discrepancy is smaller than other cases. During the validation, misidentified products will be found and put back to their correct place and records will be updated, so warehouse picking that deals with large amount of products would be an important place for validation to have better and more accurate inventory.

Table 11: Inventory discrepancy

inventory discrepancy				
Scenarios	wh (boxes)	cs (units)	par (units)	total (units)
1	1.2	17	4	141
2	1	18	4	122
3	0.4	15	5	60
4	1	9	4	113
5	1.1	11	4	125
6	1	15	2	117
7	1	16	0	116
8	1.1	16	0	126
9	0.4	9	4	53
10	1	8	2	110
11	1.1	17	0	127
12	0.9	10	4	104
13	0.9	10	3	103
14	1	20	0	120
15	0.4	7	2	49
16	0.5	9	0	59
17	1	10	0	110
18	0.9	7	2	99
19	0.8	11	0	91
20	1	10	0	110
21	0.5	7	0	57
22	0.3	8	0	38

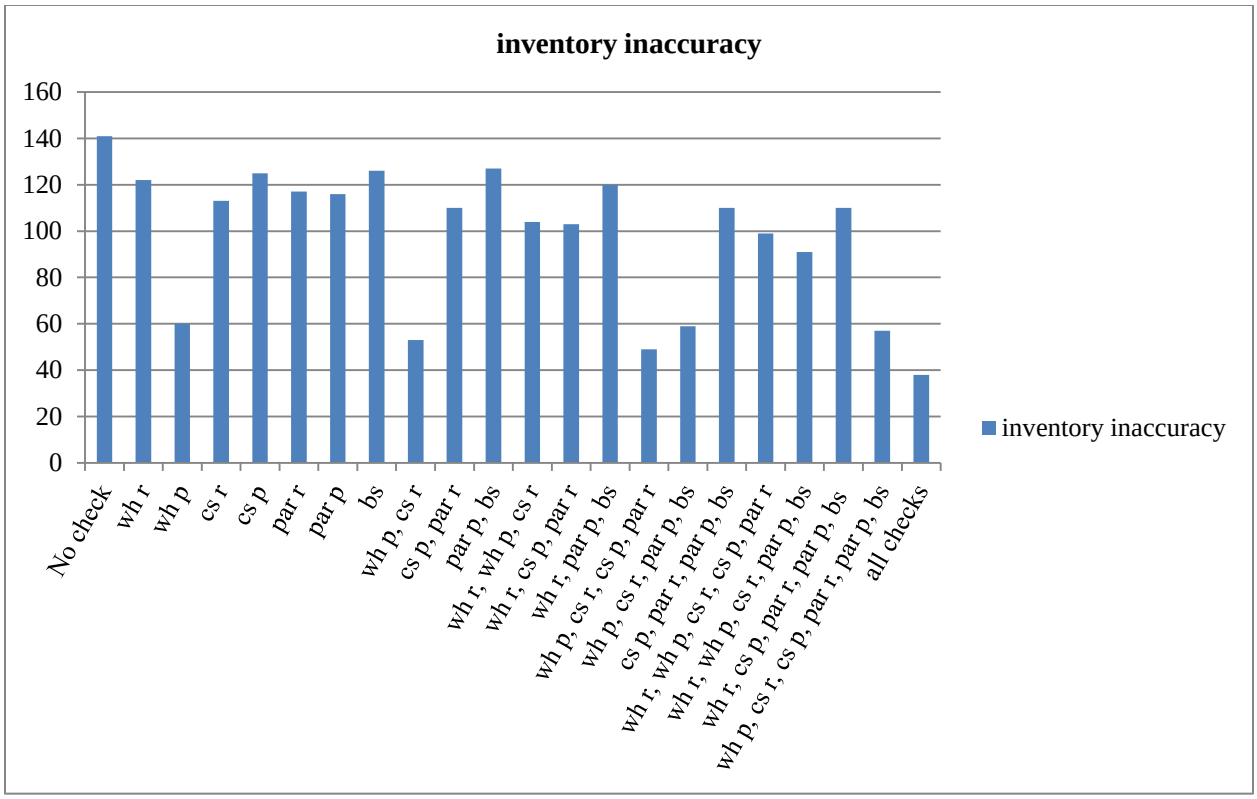

Figure 15: Inventory discrepancy

The number of replenishment is the performance measure to measure the cost of transportation from manufacturer to the warehouse and from warehouse to the central storage. In addition it is used for the cost of FTE (full time employee) to transport (replenish) the PARs from central storage. Figure 16 demonstrates the total number of transportation between the locations through 1000 days and actually there is no obvious trend.

Table 12: Number of replenishment

# of replenishment				
Scenarios	mfg to wh	wh to cs	cs to par	total
1	17	134	943	1094
2	19	145	953	1117
3	17	147	958	1122
4	16	159	949	1124
5	16	151	950	1117
6	17	140	971	1128
7	16	138	964	1118
8	16	136	962	1114
9	17	150	944	1111
10	17	156	967	1140
11	18	141	939	1098
12	16	148	946	1110
13	16	152	951	1119
14	17	150	955	1122
15	17	158	949	1124
16	15	157	950	1122
17	16	161	939	1116
18	16	164	960	1140
19	17	158	948	1123
20	17	161	947	1125
21	17	169	957	1143
22	18	173	941	1132

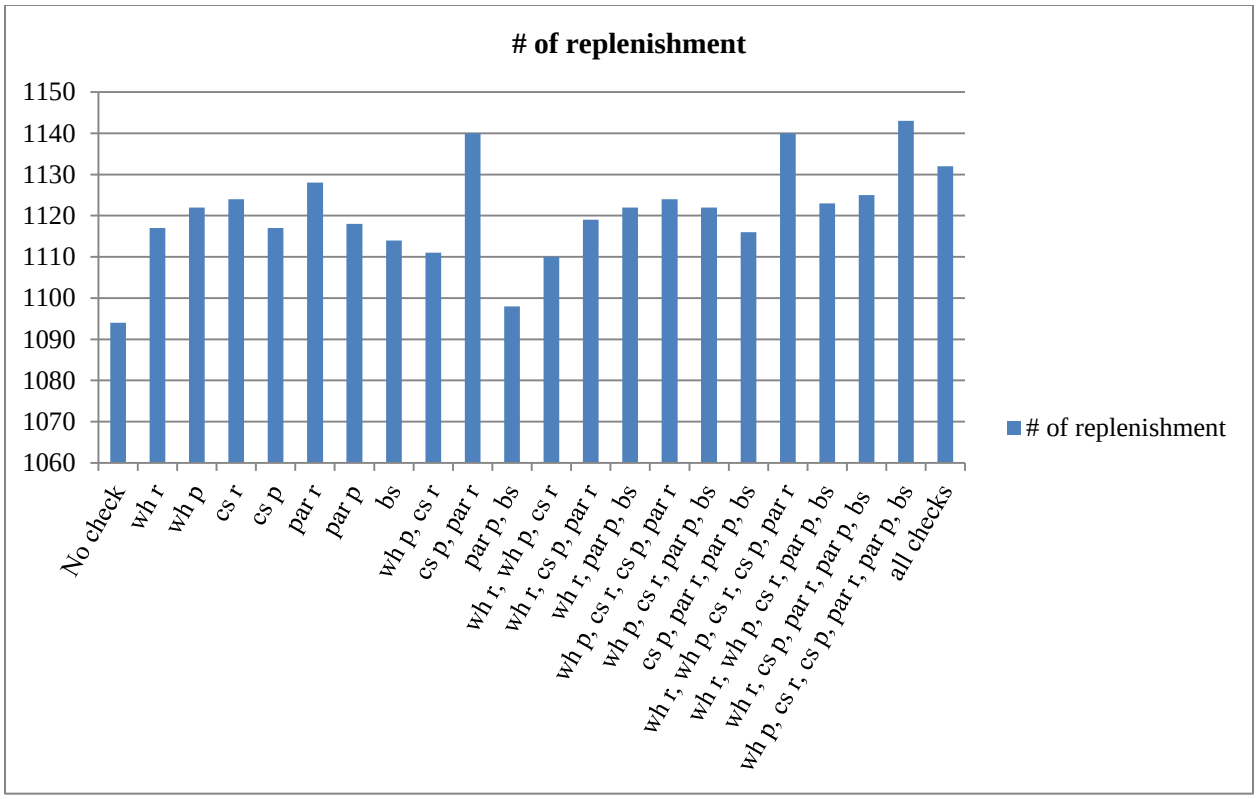

Figure 16: Number of replenishment

4.2. COST-EFFECTIVENESS ANALYSIS

In this section cost-effectiveness analysis of performance measure will be discussed. In order to do cost-effectiveness analysis, "precision tree" tool (one of the Add-Ins in Excel) has been used. Performance measures set to a default value as an indicator of cost or risk (like $5 cost for every minute of validation or $5 for correction of the inventory record, 5% risk to the patient's health due to administration of unsafe product or 5% risk to health of a patient for every minute delay of service). Risk related performance measures (number of unsafe products administered to patients and waiting time of the patients' demand) and supply chain related performance measures (time to check, average inventory, inventory discrepancy, and number of replenishment) considered separately. Total expected value of risk related performance measures and supply chain related performance measures are used to analyze each performance measure (sum of performance measures multiply by cost or risk factor). Therefore, the default value of each performance measure has been changed in the range of (0, 30) and multiplied by the values of the performance measure in each scenario. The results are shown in following figures and discussed.

Figure 17 represents different scenarios and how the expected value of performance measure "time of checking" varies with the cost. As the cost of checking decreases, scenario 22 which is doing the validation in all locations becomes the best scenario and when the cost increases to higher values scenario 9 which is validation at warehouse picking and central storage receiving and scenario 3 which is validating only at warehouse picking become the best cases (the line above the other lines in the graph since it has lower negative expected value of cost).

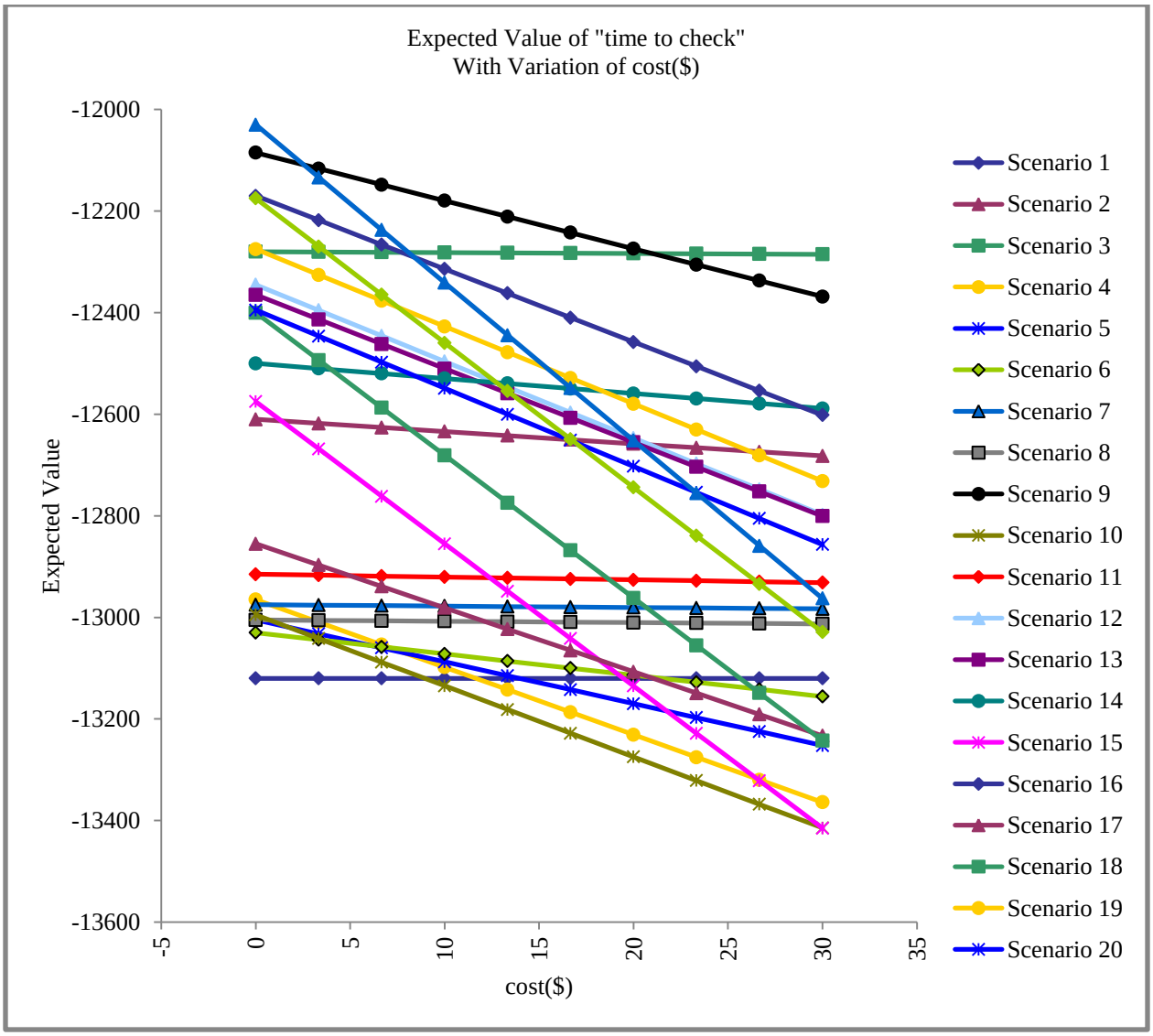

Figure 17: Expected value of "time to check" with variation of cost. Branch number is the same as scenario number

Figure 18 illustrates that there is not much difference between the scenarios in terms of holding cost of the inventory; although, scenario 22 which is validation in every location seems better.

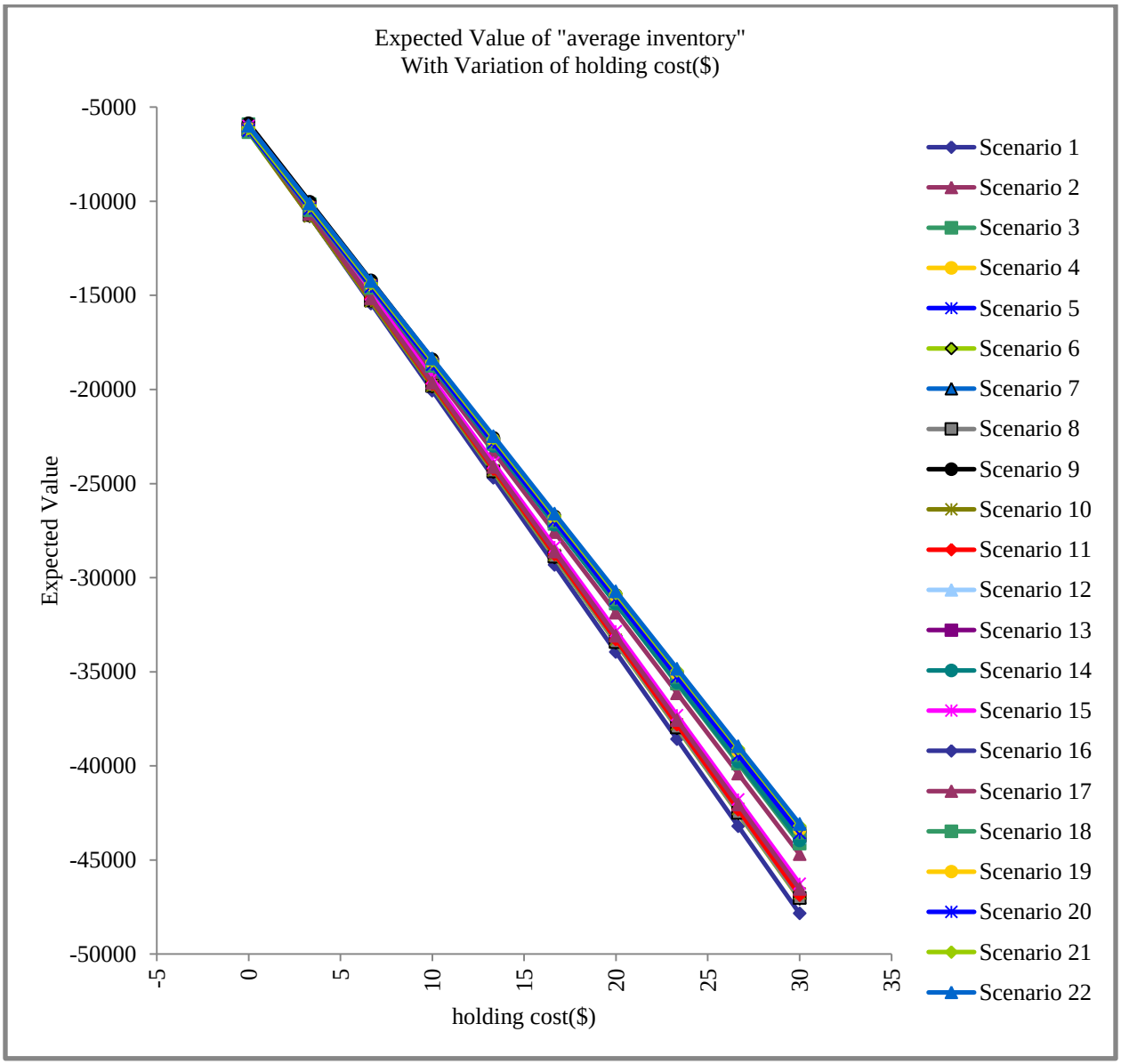

Figure 18: Expected value of "average inventory" with variation of holding cost

Figure 19 indicates that in low costs for managing the inventory discrepancy scenario 9 (validating only at bedside) is minimal and as the cost for that increases scenario 22 (validating everywhere) becomes the best case.

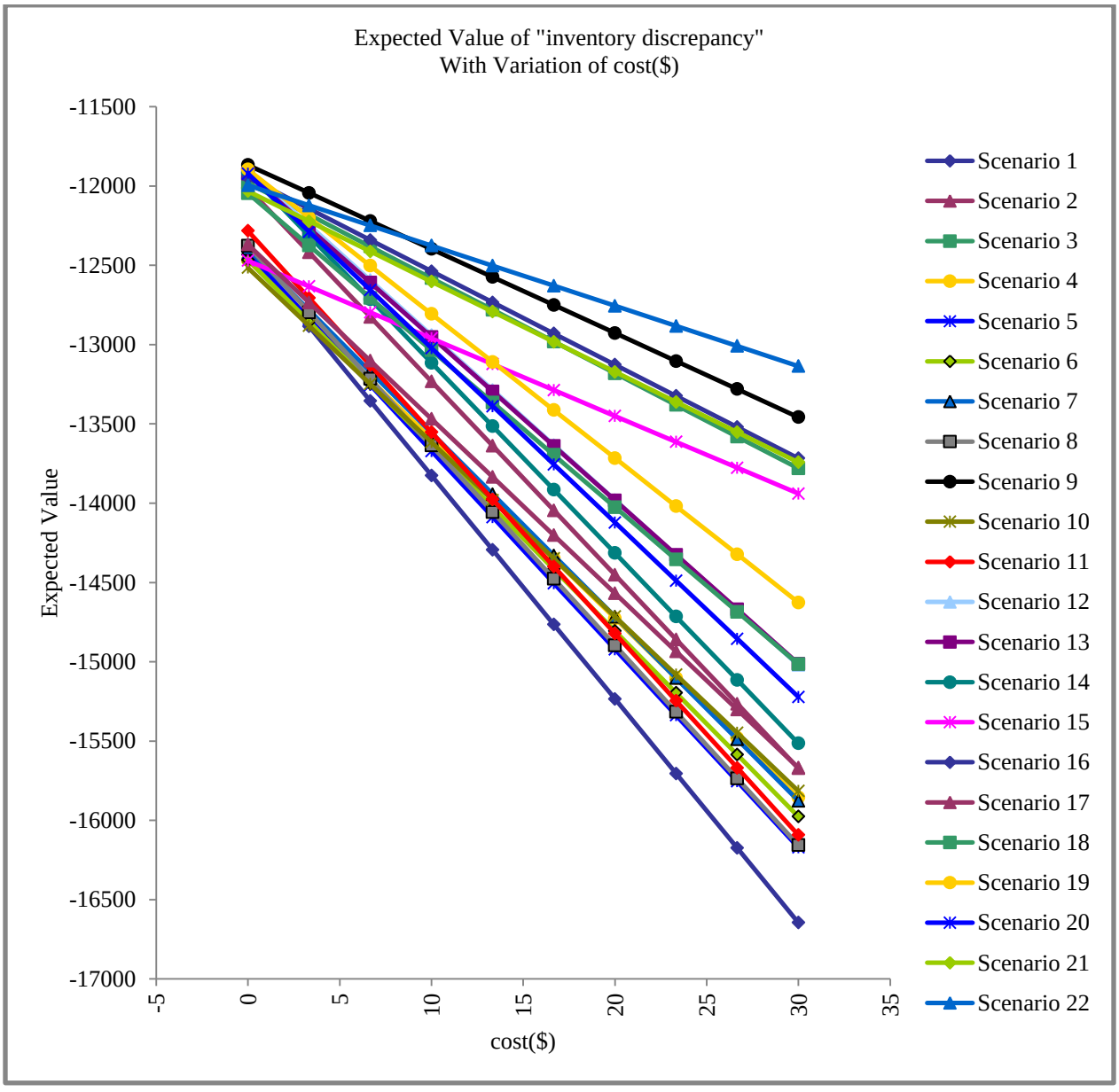

Figure 19: Expected value of "inventory discrepancy" with variation of cost

Figure 20 illustrates almost the same result as figure for average inventory and there is no difference between the scenarios in terms cost of transportation.

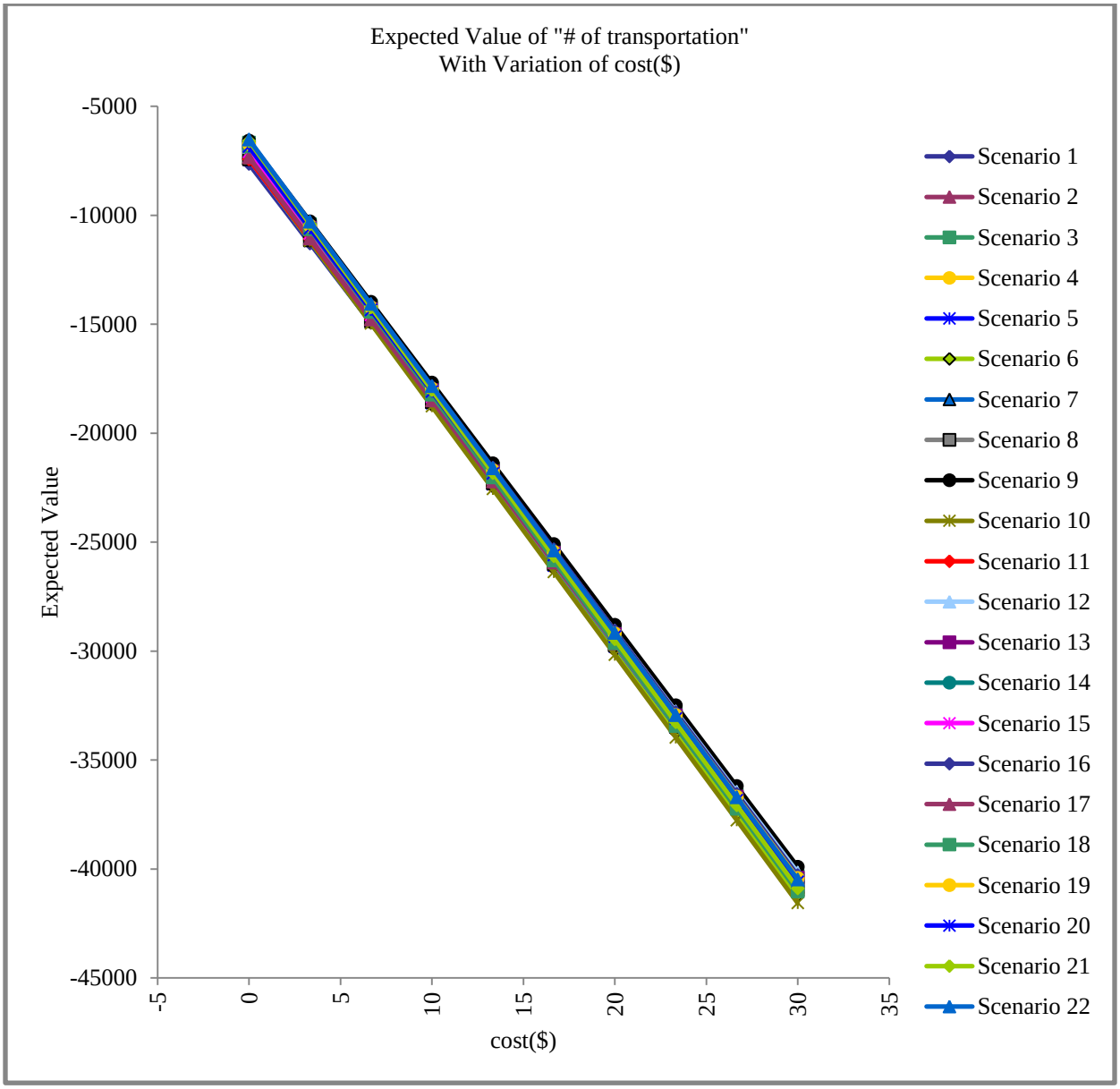

Figure 20: Expected value of "number of transportation" with variation of cost

Figure 21 demontrates that scenario 22 has the lowest risk for patients considering all the risk values.

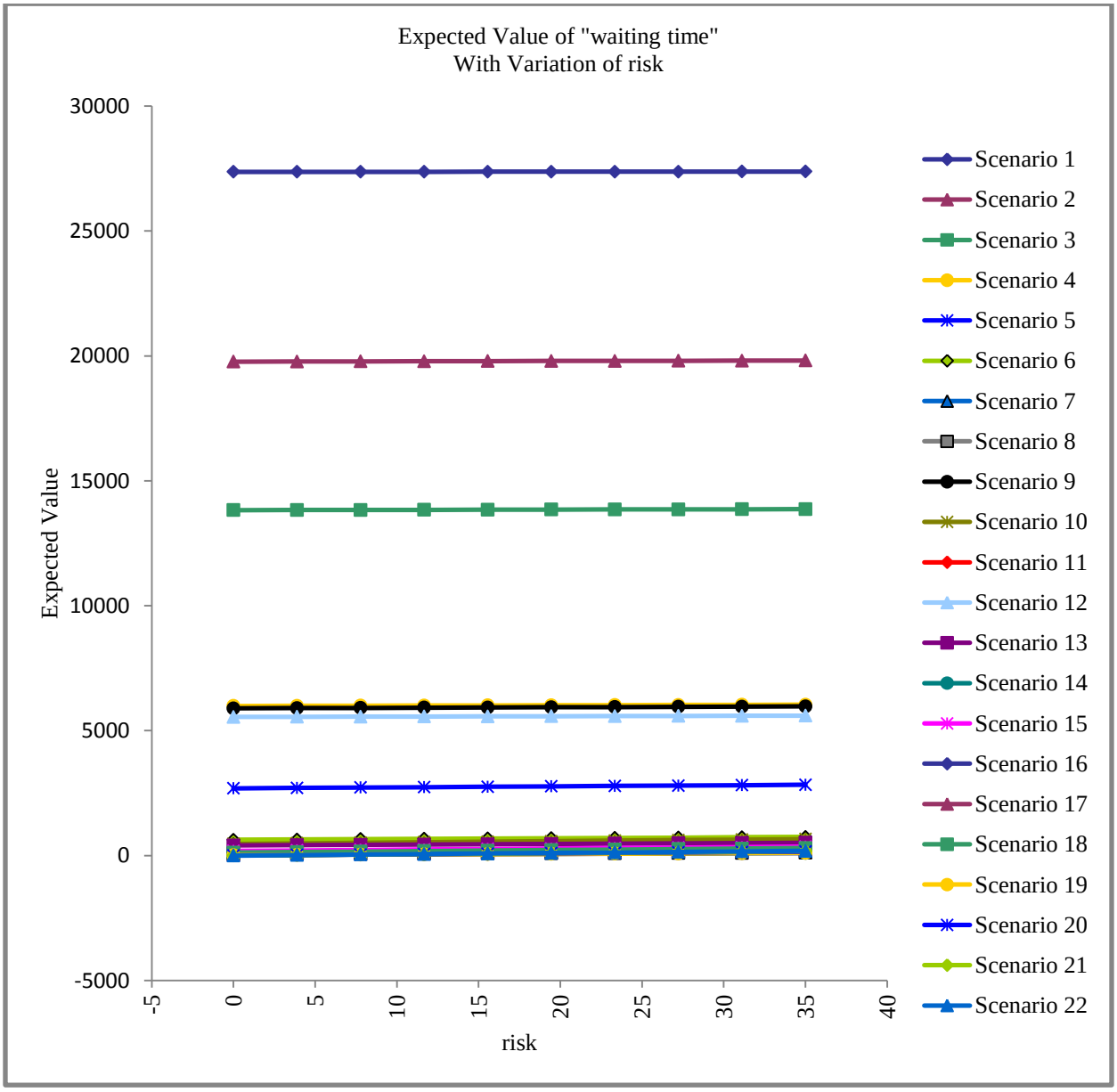

Figure 21: Expected value of "waiting time" with variation of risk

Since the difference in waiting time of the patients' demand are small, in lower risk rates there is not much difference between the scenarios in terms of waiting time but as the risk factor gets bigger the importance of having more validation points appears (Figure 21).

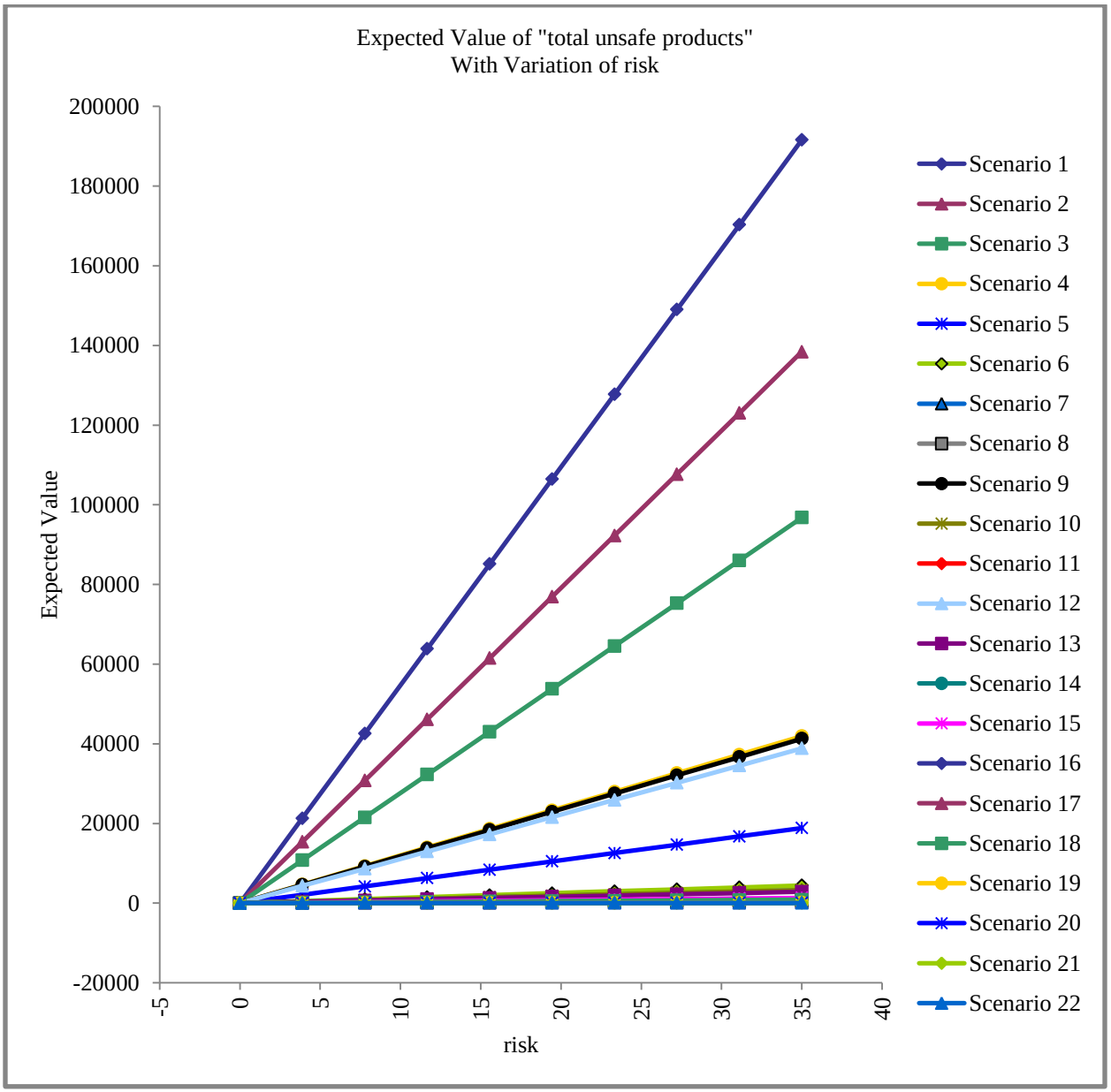

Figure 22: Expected value of "total unsafe products" with variation of risk

4.3. CONCLUSION

All four different systems that have been studied demonstrated that as the number of validation points increases the number of recalled, outdated, and misidentified products administered to a patient reduces (as we expect), but systems that use GS1, in most scenarios, have really smaller values for the total number of unsafe products that are used for patients due to the more accurate validation. Another thing that we can conclude is that as the validation points are closer to the point of use (at PAR or bedside), without using other validation points, the number of recalled or outdated products administered to a patient are still reduced significantly so checking at the bedside or PAR is critical.

Waiting time of the patients' demand that is another performance measure of risk is not affected based on the number and location of the validation points but scenarios including central storage picking and PAR receiving checking processes have a little bit longer average patient's demand waiting time. It can be caused by amount of products that are validated in these locations.

Validation at warehouse picking would help to have more accurate inventory records. Since doing validation at that point helps to find the misidentified products and put them at their correct location and correct the records, therefore, inventory records would be more accurate.

Cost-effectiveness analysis results for average inventory (holding cost) and cost of transportation as variants performance measures while the other performance measures are constant shows that these two factors are not impacted by the location of the validation because the values for these two factors are really bigger than the others. For "time of checking" as the cost increase while the other factors have constant cost, validation everywhere, validation at only bedside, and validation at only warehouse picking are the best cases consecutively. For the

inventory discrepancy also when the cost increases validating only at bedside and validating everywhere are minimal consecutively.

4.4. SUMMARY

Patient safety is one of the most important health care challenges. It is a big concern since 1 in every 10 patients around the world is affected by healthcare errors. The focus of this study is given to preventable adverse events that caused by the errors or system flaw that could have been avoided. The preventable adverse event statistics over the years reveal enormous and astonishing number of errors and among them supply chain-related issues are one of the major reasons in healthcare settings. The majority of the supply chain-related issues are caused by inventory discrepancy and performance deficiencies in recall, return, and outdate management at the provider's level. Global Standards 1 (GS1) provides unique, unambiguous identifiers for product and partner/location identification is a good answer to eliminate these errors.

In this study, simulation models are developed using Arena to evaluate the impact of GS1 data standards on patient risk in healthcare supply chain. The focus was given to the provider hospital supply chain operations where inventory discrepancy and performance deficiencies in recall, return, and outdate management can directly affect patient safety. Simulation models are developed for various systems and scenarios to compare different performance measures and analyze the impact of GS1. The systems under the study were system includes errors in supply chain processes and errors in checking processes, system with errors in supply chain processes but no checking errors, system with only errors in checking processes, and system with no error in either of the supply chain and checking processes. In these systems the performance measures were categorized in two groups of risk related such as number of unsafe products administered to

a patient and patient's demand waiting time, and system performance related such as inventory discrepancy, average inventory level, and number of transportation.

The results indicates that as the validation points are closer to the point of use (at PAR or bedside), the number of recalled or outdated products administered to a patient are reduced significantly so checking at the bedside or PAR is critical. But validating products only at these points can cause to have a lot of unwanted outdated or recalled products remained on the shelves and increase the holding cost. It may also cause future problems such as running out products (stock outs) in emergency cases; therefore, validating in other locations is needed. The best place to do that based on the results is warehouse picking. It helps to have a better inventory records. Waiting time of the patient's demand which is another factor of risk in our study is not affected by the location of the validation so overall we can say that validation at PAR or bedside and at warehouse picking can be the optimal case in terms of the performance measures discussed.

.

REFERENCES

1. Attarian, D. E. (2008). What is a preventable adverse event? Retrieve from: http://www.aaos.org/news/aaosnow/may08/managing6.asp

2. Brennan, T.A., Leape, L.L., Laird, N.M., Hebert, L., Localio, A. R., Lawthers, A. G., . . . Hiatt, H.H. (2009). "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study 1," New England Journal of Medicine, 324(6), pp. 370–376.

3. Donn, J. Mendoza, M. & Pritchard, J. (September, 2008). Retrieved from: http://www.usatoday.com/news/health/2008-09-14-drugs-flush-water_N.htm

4. Elder, N.C., Dovey, S.M. (2002). Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. J Fam Pract.51:927-32.

5. Emanuel, L., Berwick, D., Conway, J., Combes, J., Hatlie, M., Leape, L., . . . Walton, M. (2008). What exactly is patient safety? En: Henriksen K, Battles JB, Keyes MA, Grady ML, editores. Advances in patient safety: New directions and alternative approaches. Vol 1. Assessment. AHRQ Publication No. 08-0034-1. Rockville, MD: Agency for Healthcare Research and Quality.

6. EPA, United States Environmental Protection Agency. (2008). *Unused Pharmaceuticals in the Health Care Industry*: Interim Report. Retrieved from: http://water.epa.gov/scitech/swguidance/ppcp/upload/2010_1_11_ppcp_hcioutreach.pdf

7. FDA. Food and Drug Administration. (2009). Citing websites. *Recalls, background and definitions*. Accessed, August 16th 2011 from: http://www.fda.gov/Safety/Recalls/ucm165546.htm

8. FDA. Food and Drug Administration. (2010). Citing website. *Reports Received and Reports Entered to AERS by Year.* Accessed May 12th 2012 from: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm

9. FDA. Food and Drug Administration. (2011a). Citing websites. *Medical devices Recalls*. Accessed, August 16th 2011 from: http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm

10. FDA. Food and Drug Administration. (2011b). Citing websites. *Medical & Radiation Emitting Device Recalls.* Accessed, May 12th 2012 from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm

11. Ginsburg, L., Chuang, Y., Richardson, J., Norton, P.G., Berta, W., Tregunno, D, Ng, P. (2009). Categorizing Errors and Adverse Events for Learning: The Provider Perspective. Healthcare Quarterly. Vol 12:154–60.

12. Hubner, U. and Elmhorst, M. (2008). eBusiness in Healthcare. From eProcurement to Supply Chain Management. *Health Informatics Series.* ed. London: Springer Verlag.

13. Joint Commission Resources, Inc. (2001). Preventing medication errors: Strategies for pharmacists. Oakbrook Terrace, IL: Joint Commission Resources.

14. Jayaraman, R., Rardin, R., Buyurgan, N., Varghese, V., Burbano, A., Pazour, J., . . . Dixon, D. (2011). Data Standards in Healthcare Supply Chain Operations. *Proceedings of the 2011 Industrial Engineering Research Conference.*

15. Opolon, D.C. (2010) 'Improving Product Availability in Hospitals: the Role of Inventory Inaccuracies', Massachusetts institutes of technology.

16. Reducing healthcare costs with supply chain best practices. Retrieve from: http://www.motorola.com/web/Business/Products/_ChannelDetails/_Documents/_StaticFiles/Healthcare-Industry-Brief-0610.pdf?localeId=33

17. Runy, L. A. (2007). Is that product safe? Hospitals & Health Networks. 81(8), 47-49, 52-53.

18. Sasou, K. and Reason, J. (1999) Team errors: Definition and taxomony. *Reliability engineering and system safety 65* (1):1-9.

19. Simpson, N. and Kleinberg, K. (2009). Implementation Guide to Bar Coding and Auto-ID in Healthcare: Improving Quality and Patient Safety. *Healthcare Information and Management Systems Society*, Industry Report.

20. Thomas, E.J., Petersen, L.A. (2003). Measuring errors and adverse events in health care. *J Gen Intern Med*;18:61-67.

21. Thomas, E.J., Studdert, D.M., Burstin, H.R., Orav, E. J., Zeena, T., Williams, E. J., . . . Brennan, T. A. (2000). Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. *Medical Care*, 38(3), pp. 261–271.

22. Tucker, A. (2004). The impact of operational failures on hospital nurses and their patients. *Journal of Operation Management, 22*(2),151-169.

23. Tucker, A., & Spear, S. (2006). Operational failures and interruptions in hospital nursing. *Health Services Research, 41*(3 pt 1), 643

24. U.S. Food and Drug Administration. CDER 2005. Report to the Nation: Improving Public Health Through Human Drugs. Rockville, Maryland. 2005.

25. Wen, P. (2008). 1 in 10 patients gets drug error. Retrieve from: http://www.parchealth.com/1%20in%2010%20patients%20gets%20drug%20error.pdf

26. *PRRG: Product Recall Research Group. University of New Mexico. News Releases In Product Recall Public Relations. Retrieved from www.unm.edu/~dirkcgib/newsrelease.pdf.

27. *Reducing Healthcare Costs through Supply Chain Management, Knowledge@W.P. Carey-Health Management and Policy, (2010), Retrieved online: http://knowledge.wpcarey.asu.edu/article.cfm?articleid=1871.

28. *Zirkle, M., Gallagher, R., Rogler, S. (2012). Supply Chain Data Standards in Healthcare.