Evaluating the Implementation of a Workflow Management System in a Pharmaceutical Setting through the Examination of Workarounds and System Vulnerabilities

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EVALUATING THE IMPLEMENTATION OF A WORKFLOW MANAGEMENT SYSTEM IN A PHARMACEUTICAL SETTING THROUGH THE EXAMINATION OF WORKAROUNDS AND SYSTEM VULNERABILITIES

A Thesis
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
Industrial Engineering

by
Elizabeth Mansari Jamison
August 2016

Accepted by:
David Neyens, PhD, MPH, Committee Chair
Scott Mason, PhD
Sara Riggs, PhD
ABSTRACT

Technology has increasingly been implemented in healthcare with the intention of reducing errors. One area where errors could be reduced is in the pharmaceutical environment, specifically dispensing errors. A qualitative observational study was conducted in a pharmaceutical environment to identify system vulnerabilities (SVs) and workarounds in the work system. This was done to assess how the implementation of a workflow management system (WFMS) impacts the work system and work practices and to identify opportunities for error reduction. The work system experienced changes in work practices and in the SVs following the implementation of the WFMS. Additionally, the WFMS prompted additional workarounds to occur following implementation. Certain risks were reduced by the WFMS, as shown by the elimination of certain SVs or reduction in the risk rating of other SVs. However, certain risks continued to exist and new risks were introduced as shown by the kinds of workarounds existing after implementation and the creation of new SVs.
DEDICATION

This thesis is dedicated to my father.
ACKNOWLEDGEMENTS

There are so many people who have helped me and supported me in this endeavor and I am incredibly grateful and appreciative for having them in my life. First and foremost I would like to thank my advisor, Dr. David Neyens, for pushing me academically and for his support, patience, insight and guidance. I could not have asked for a better advisor. I would also like to thank Dr. Scott Mason for encouraging me to pursue a graduate degree and for his insightful comments while serving on my committee. Finally, I would like to thank Dr. Sara Riggs for her insightful comments while serving on my committee. Thank you Dr. Neyens, Dr. Mason, and Dr. Riggs for all of your time and assistance – you have truly had a positive impact on my life.

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And most of all thank you to my family and my friends who are like family. Thank you to my family, especially my silly sister Margaret and my father, for always supporting me and believing in me. I am incredibly blessed to be friends with the best people in the world. Marek, Leah, Chelsea, and Spencer, I am so incredibly grateful to have you in my life and for all of your support.
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CHAPTER 1: INTRODUCTION

Healthcare errors are costly both in terms of lives lost and monetary cost. The landmark 2000 report *To Err is Human*, is often cited to illustrate the high cost of medical errors. More recently, a study utilizing claims data estimated the annual cost of medical errors to be $19.5 billion in 2008 dollars (Shreve et al., 2010). Utilizing Medicare data from 2008, another study estimated that 180,000 Medicare beneficiaries alone experienced a medical error which contributed in some way to their death (Levinson & General, 2010). Medical errors often result in a patient experiencing an adverse outcome, often manifested as prolonged hospitalization, disability at the time of discharge, or death as a result of improper medical care as opposed to the natural progression of disease (Andel, Davidow, Hollander, & Moreno, 2012; Kohn, Corrigan, & Donaldson, 2000; Levinson & General, 2010).

Medication errors represent the largest subset of medical errors (accounting for about 19% of medical errors) (Leape et al., 1991). A medication error is an error that occurs anywhere along the medication process from the nurse or doctor ordering the medication to dispensing the medication to administering and monitoring the medication (Gandhi et al., 2005). One study found that 28% of medication errors were preventable. Of the preventable medication errors, 42% were life-threatening or serious medication errors (Bates et al., 1995). Another study found that the majority of medication errors involved medications that were administered via intravenous routes (Ross, Wallace, & Paton, 2000). These types of errors are most often either severe or moderate errors (Taxis & Barber, 2003).
Dispensing errors are a subset of medication errors that occur during the preparation of the dose order. The literature has defined dispensing errors to include medications that are different from the medication ordered such as the wrong drug or wrong strength (Guernsey et al., 1983; Rolland, 2004) as well as deviations from standard pharmacy policy (Cina et al., 2006), mislabeling, missed doses, and doses filled at incorrect times (Rolland, 2004). One study examining errors in concentration of intravenous drugs found that a third of doses contained incorrect concentrations of the medication (Parshuram et al., 2008). Concentration errors are prone to occur for pediatric patients as their dose preparation typically involves more calculations and dilution of stocks than for adult patients (Kaushal et al., 2001). Dose errors in pediatric medications are especially problematic as pediatric patients are more vulnerable and have the potential for higher harm should there be a dosing error (Kaushal et al., 2001). Compared with the other stages of the process (e.g., ordering, administering, monitoring) the least number of medication errors occur in the dispensing process (Bates et al., 1995; Nebeker, Hoffman, Weir, Bennett, & Hurdle, 2005). However, studies have found that unprevented dispensing errors occur in between 0.06 to 18% (James et al., 2009) of doses which indicates that there is an opportunity to reduce errors within the dispensing process.

Implementing technology is one way to address safety and other concerns in a variety of domains including healthcare, manufacturing and transportation. Unfortunately, the implementation of technology can sometimes have unexpected adverse effects which negatively impact safety (Ash, Berg, & Coiera, 2004; Eslami, Abu-Hanna, de Keizer, & de Jonge, 2006; Karsh, Weinger, Abbott, & Wears, 2010; Koppel et
Various technologies, including computer provider order entry (CPOE) systems (Bates et al., 1998; Eslami et al., 2006; Koppel et al., 2005), bar coding medication administration (BCMA) (So, 2012), and electronic health or medical record (EHR or EMR) systems (Nebeker et al., 2005) have been evaluated as ways to reduce medication errors (Ash et al., 2004; Gandhi et al., 2005; Karsh et al., 2010). However, the majority of the research has focused on the prescription process (e.g., orders for medication administration) (Grossman, Cross, Boukus, & Cohen, 2012; Koppel et al., 2005; Magrabi, Li, Day, & Coiera, 2010) or the drug administration process rather than the dispensing process (Rothschild et al., 2005). Consequently, there is the opportunity for more investigation on to improve safety in the dispensing process.

A workflow management system (WFMS) is a type of technology that can be utilized in the dispensing process to potentially reduce errors and improve patient safety. In general, a WFMS should support the work processes performed by an organization. WFMS have been implemented in a variety of domains, including healthcare (Halsted & Froehle, 2008). Because WFMS are designed to interact with the current work system, it is important to understand the actions and activities that comprise the actual work system and processes. There is often a discrepancy between the way actions are intended to be completed and the way actions are actually completed – such that, the intended work system differs slightly from the actual work system. An example of this is a workaround, which occurs when a user executes an action different than the system intended as a
result of something blocking the intended path to execution (Koopman & Hoffman, 2003). The term block will be used in this study to describe the process, event, or system characteristics that blocks the intended path. However, other terminology has been used to describe the same blocking mechanism including gaps (Cook, Render, & Woods, 2000), problems (Holden, Rivera-Rodriguez, Faye, Scanlon, & Karsh, 2013), challenges (McAlearney et al., 2007), operational failures (Tucker & Spear, 2006), and barriers (Holden, 2011). The blocking mechanism can range from a system failure, such as not recognizing a necessary input, to an intentional avoidance of a system due to perceptions that the system is not trustworthy or difficult to use. Another example of a possible block includes situations where the system or technology does not match the work practices in such a way that there is a benefit for the user to interact with the technology or system (Vogelsmeier, Halbesleben, & Scott-Cawiezell, 2008). The workarounds occur in reaction to the blocks. Sometimes the workaround can bridge gaps that exist in the work systems and prevent errors by anticipating and reacting to these gaps (Cook et al., 2000). Other times workarounds can lead to negative consequences including potential errors.

Workarounds may themselves foster system vulnerabilities. Likewise, system vulnerabilities, such as those resulting from a poorly designed system, may encourage workarounds. For this study, a system vulnerability (SV) is defined as an undesirable situation or outcome that is created by the interaction of a user, technology, system, or process factor, that can lead to a patient safety event or the potential for a patient safety event (e.g., a precursor). This definition draws on the SV definition used by Yang et al. (2014) of “activities or events that have the potential to risk a patient’s safety, increase
cost and waste, or reduce efficiency of the workflow.” SVs and workarounds can be precursors or manifestations of unintended negative consequences such as decrements in patient safety. Identifying SVs in a work system pre- and post- technology implementation can be a powerful way to examine the success of a system in terms of the incorporation of the technology into the work system or the adaptation of the work system to the technology. Evaluating SVs can function as a robust tool to investigate workarounds and other aspects which impact how a technology is best implemented in a system.

A user’s trust in the technology can play an important role in how a user interacts with a technology or system (Lee & See, 2004) and consequently influences the existence of both SVs and workarounds. When a user’s trust in a technology and its capabilities are mismatched with the technology’s actual capabilities, misuse or disuse occurs (Lee & See, 2004). Misuse occurs when a user’s expectations of the technology’s capabilities are higher than reality and the user over relies on the technology. A consequence of technology misuse includes complacency. For example, users may rely on the technology to notify them of any issue rather than simultaneously monitoring other sources of information (Parasuraman & Wickens, 2008). Disuse is the opposite of misuse, and results when a user underutilizes the technology as a result of underestimating the technology’s capabilities (Lee & See, 2004). When a user disuses a technology, a workaround may result in which the user bypasses the technology in favor of performing an action without the assistance of the technology. When this occurs some of the positive benefits of the system, such as error catching, may be eradicated. SVs may impact the
level of trust a user has in a technology. For example, if a technology is producing excessive and incorrect alerts or alarms the user may disuse the technology and ignore an alert (Parasuraman & Wickens, 2008).

When looking at a work system, artifacts may be examined to learn more about the work practices and how the work system is designed and implemented. An artifact is something that is used or created “in the course of doing work” (Beyer & Holtzblatt, 1998). If a waiter writes down the customer’s order on a notepad and then enters the order into a computer that relays the order to the kitchen, he creates the physical artifact: the piece of paper with the order. This is then transformed into a digital artifact: the electronic computer order. Artifacts contain information (Beyer & Holtzblatt, 1998). Through the user’s interaction with the artifact, the artifact gains information about the user and how the user works. For example, how the order is written on the notepad can give insight into the waiter and his or her work practices. The artifact also may contain information that the user may utilize. For example, a computer may prompt the waiter to select a cook temperature for steak which transfers the information that steaks can be cooked at different temperatures.

In order to properly and successfully implement a technology into a work system it is important to have a comprehensive understanding of the work practices and how the users actually operate within the work system. A system can be qualitatively investigated by examining the workarounds and SVs in order to develop a more robust understanding of the system. Therefore, the goal of this research is to determine the impact of the implementation of a WFMS had on work practices and a work system. This will be done
by identifying SVs in both the pre- and post-implementation work systems and identifying workarounds that users have done as a result of the implementation of the work system.

This section presented the foundation and literature related to the research conducted in this thesis. This review sets the stage for understanding how the complexity in work domains impacts the technology design and implementation. In the following chapter, the methodology used to conduct an observational study examining the impact of a WFMS on a pharmaceutical work system will be detailed.

**Research Objective**

The objective of this study is to evaluate the impact of a WFMS on work practices and a work system by identifying and rating pre- and post-implementation SVs, identifying workarounds that users engage in as a result of the implementation of the work system, and qualitatively examining how these SVs and workarounds could impact patient safety.
CHAPTER 2. METHODOLOGY

The previous chapter provided the background necessary for understanding this research by discussing the importance of improving safety through reducing errors in healthcare settings and the role technology plays. This chapter will outline the methodology used to evaluate the technology’s impact on a pharmaceutical work system through the identification and examinations of SVs and workarounds. First an overview of the work system and environment will be given followed by a description of the methodology used to complete an analysis – work model creation, system vulnerability identification and analysis, and block/workaround identification and analysis.

Observations

In total, 50 hours of observations were completed at several inpatient pharmacies associated with hospitals within a 700 bed academic medical center in the Southeastern United States. The study was approved by both the Institutional Review Boards at the Medical University of South Carolina and Clemson University (IRB# Pro00039896). Observations were conducted post-WFMS implementation during both day and night shifts. Observations involved shadowing pharmacy employees including pharmacists, pharmacy technicians, and students/trainees as they completed tasks associated with IV medication preparation. This included compounding the IV medication doses in the clean room, preparing the IV medication doses that could be filled with pre-made IV bags (and consequently completed outside the clean room), verifying that these doses were prepared correctly, and sorting the doses to be delivered to the specific unit or floor for administration to the patients. Compounding was primarily performed by the pharmacy
technicians, whereas dose verification was exclusively performed by pharmacists. Both pharmacy technicians and pharmacists completed the sorting process.

In addition to shadowing the employees, employees were also asked clarifying and probing questions through informal conversation between tasks. Probing questions were used to determine the work practices pre-WFMS implementation, to determine the intended pre- and post-WFMS implementation work practices and for clarification related to any non-standard work process observed. This was done informally to ensure that the participants feel at ease and comfortable discussing their true work practices. (Barriball & While, 1994)

Observations and conversation were noted on paper and the notes were transcribed immediately following each observation session. Each observation session was limited to two-hour periods to minimize the impact on work productivity, to ensure the observer notes were complete, and to facilitate clarifications with the staff if needed. During the transcriptions, additional clarifying and explanatory notes were added. These were clearly marked as post-observation notes. Once the intended work process (as intended by the technology, policies and procedures in use) was determined, observed system vulnerabilities and workarounds were noted. Actions and situations that constituted a workaround or system vulnerability were determined based on knowledge of the intended process, comments by workers and, when applicable, discussions with domain experts.
**Pharmacies**

Three 24 hour inpatient pharmacies were observed. Each pharmacy serviced a separate hospital: a children’s hospital, a general hospital that handles a variety of patients and a hospital that specializes in digestive health and heart and vascular care. The pharmacies were similar in the number of IV prescriptions prepared daily but were different in terms of the workplace culture, layout, work policies and practices, and employee experience with both job tasks and with the pharmacy technology. Additionally, there were some differences observed between the pharmacies in terms of the specific doses and concentrations created due to the differences in the patient population (especially comparing the children’s hospital with the adult hospitals). Observing multiple pharmacies was crucial to developing a holistic understanding of the dose preparation process both with and without the assistance of the specific pharmacy technology. This assisted in developing a comprehensive understanding of the work system changes in the context of system vulnerabilities and workarounds present in the dose preparation process both with and without the existence of the WFMS.

**Workflow Management System**

The technology that was implemented in the pharmacies is a WFMS with built in safety features to prevent potential medication preparation errors. Orders for the doses are received and assigned to the appropriate workstation (e.g., clean room, pre-made dose station, verification station, sorting station) as they move through the preparation process. Users at each workstation were able to digitally organize the doses and easily monitor their workload. The technology featured a graphical user interface (GUI) which walked
pharmacy technicians through the steps for preparing each dose. As the pharmacy technician was preparing the dose, the technology required them to take pictures of their preparation process at each step. These images were then used by the pharmacist to verify that the dose had been properly prepared. Prior to the technology’s implementation, all items used to complete the dose (e.g., syringes, medication vials) were placed in a basket and the pharmacist used these physical artifacts to verify that the dose had been properly prepared. The technology relied heavily on barcode scanning for tracking and error prevention. Patient-dose barcode-based labels were printed when a dose preparation process was initiated and were scanned in conjunction with the manufacturers’ barcodes on the dose ingredients. When the preparation process was completed the same patient-dose barcode was scanned to move the dose to the queue for verification. To verify that the dose had been properly prepared, the pharmacist viewed the digital images that had been taken during the dose preparation process. Once the dose was digitally verified by the pharmacist, the sorting process could begin. The sorting process involved scanning the patient-dose barcode which triggered the system to automatically print a new label with two barcodes. One barcode facilitated tracking the dose’s location from within the WFMS. The other barcode was for documenting medication administration in a different software that was used throughout the entire hospitals by nurses, doctors and other medical staff.
Work System Analysis

The work system was analyzed through the creation of work models, the coding of the observation transcriptions, and user ratings. Work models, such as information flow diagrams, were created to visualize and more fully comprehend the work system. To better understand the work system and dissect the work system into meaningful parts, the observation transcriptions were coded separately for system vulnerabilities (SVs) and workarounds. The Coding Analysis Toolkit (CAT), a web-based, open source coding software, was used for coding both the system vulnerabilities (SVs) and the workarounds. Finally, users of the system participated in a Failure Mode and Effects Analysis (FMEA), a method commonly used in a variety of fields to quantitatively analyze failure within a system, to rate the identified SVs.

Work Model Creation

Work models were created to illustrate the information flow and the step by step work process for both the pre- and post-WFMS implementation work systems. The information flow work models provided a visualization of how the information moves between entities in the work system and how this movement changed following the implementation of the WFMS. Work process model gave the step by step process for both the dose preparation and dose verification process. How each step was completed in the pre- and post-WFMS implementation work system was laid out side by side for an easy comparison. Additionally, having this side by side comparison allowed for an easy visualization of how certain steps were added or changed following the implementation
of the WFMS. Following the identification of the SVs, stars representing SVs were laid on the work process model to illustrate where each SV could occur in the process. The completed work process model was confirmed to accurately represent the dose preparation process by a subject matter expert familiar with working in the process.

System Vulnerability (SV) Coding

The Coding Analysis Toolkit (CAT) software was utilized to code specific text snippets from the observations transcripts that pertained to SVs observed or described in the conversations, as well as precursors to SVs identified during observation. The 300 identified text snippets were then condensed using common characteristics. This was done by assigning each text snipped one or more common characteristic, such as “interruptions” or “quantity mismatch.” The text snippets were then examined in groups determined by their assigned common characteristics. Text snippets discussing the same SV were reduced and a meaningful list of 21 SVs was created. It was determined whether the SV could occur in the pre-WFMS implementation work system, the post-WFMS implementation work system, or both. A brief description of how each SV manifests itself in the work system was created. The step(s) of the process during which the SV could occur was determined. Stars representing each SV were placed in the appropriate locations of the work process model which had been previously created.
A failure modes and effects analysis (FMEA) was done to assess the risks presented by each SV and determine what effect the implementation of the WFMS had on the risk. A FMEA is a tool for preemptively assessing the risk that exists in a system (Childers & Neyens, 2014). A typical FMEA involves stakeholders rating potential failure modes in three standard areas – probability of occurrence (i.e., likelihood), severity of effect (i.e., impact on safety), and ease of detection (Childers & Neyens, 2014). For this FMEA the stakeholders were determined to be the pharmacists and pharmacy technicians who used the WFMS and SVs were used as potential failure modes.

Users across all shifts from all three pharmacies were asked to individually rate each SV both pre- and post-WFMS implementation on a 5 point Likert scale in the three standard areas – likelihood (extremely unlikely (1) – extremely likely (5)), impact on safety (not at all (1) to always (5)), and ease of detection (very difficult (1) to very easy (5)). A 5 point Likert scale was used as it is commonly used in health care settings (Childers & Neyens, 2014). SVs that were determined to only exist in the pre- or post-WFMS implementation work system were only rated in the work system in which they existed. Participants only rated SVs pre-WFMS implementation if they had experience working in that work system. Ratings were collected from a total of 33 participants over the course of one day. The ease of detection ratings were reversed so that a lower rating indicated less of a risk (i.e., very easy (1) to very difficult (5)). Following the reversal of the ease of detection ratings, mean ratings were determined for each category for each
pre- and post-WFMS implementation SV. For each SV in each work system, the mean ratings were then multiplied to determine a risk priority number (RPN) which represents the overall perceived risk the SV poses to the system. Because a 5 point Likert scale was used the RPN had the potential of ranging from 1 (minimum risk) to 125 (maximum risk). The higher the RPN was the more risk that SV presented to the system. Likewise, a lower RPN represents less risk to a system.

**Workaround Coding**

The observation transcript coding for workarounds was done by utilizing CAT to code text snippets from the observation transcripts and then condensing these text snippets utilizing common characteristics. These text snippets included those that discussed both workarounds and the blocks that created or encouraged workarounds. The categorization of the condensed list of workarounds and blocks was different from the categorization of the SVs. However, it is important to note that some SVs functioned as blocks. In order to properly categorizing workarounds and blocks, a model was developed (see Figure 1). This model provided a visualization of the interaction of three aspects – policy and procedure, technology, and work practices – that could motivate the existence of a block and be involved in the resulting workaround. Workarounds and blocks were to one of the 7 sections of Figure 1 depending on what combination of the three aspects played into the block’s existence or were incorporated in the resultant workaround.
The three circles within the Venn diagram represented the three aspects that could motivate the existence of a block and be involved in the resulting workaround - policies and procedures, technology, and work practices. Policy and procedures represented the rules and how the work was intended to be done – the intended work practice or the standard work practices. Technology was primarily the WFMS although it could also include the label printer in the pre-WFMS implementation work system and any other technology encountered. Work practices were how the tasks were actually completed which may differ by user and may not match the intended work process. Each block or workaround was assigned to one of the seven sections contained in the three overlapping circles. For blocks, the assignment was based on which aspect(s) (i.e., policy and procedure, technology, and/or work practices) the caused the block to exist. For example, if the limitations of technology forced the user to go outside the standard work practice but policy and procedure and actual work practices did not interfere with the path to completing the action then that block was assigned to section 7. For workarounds, the

Figure 1. Block and workaround categorization with sections identified numerically
assignment was based on which aspect(s) were included in the workaround. For example, if the workaround incorporated technology and actual work practices but did not follow the policy and procedures then it would be assigned to the section 4.

In this chapter the methodology developed and used in this research was discussed. The following chapter will give the results found utilizing this methodology to evaluate the impact the implementation of a WFMS had on a pharmaceutical work system.
CHAPTER 3. RESULTS

The previous chapter discussed the methodology developed and used to find the results that will be discussed in this chapter. In this chapter the results will be broken down into three sections – general findings, results relating to SVs, and results relating to workarounds.

Overview

The implementation of the WFMS fundamentally changed aspects of the work system. While the fundamental goal of creating i.v. compounding medications safely and efficiently remained the same, both the intended work process for achieving this goal and the actual work process different users took changed. As can be seen in Figure 2, more steps are required to prepare a dose in the post-WFMS implementation work system. However, verification can begin earlier in the post-WFMS implementation work system. Also, the way each step is completed for the preparation and verification process varies between the pre- and post-WFMS implementation work systems, as seen in Figures 2 and 3. A list of the SVs noted in Figures 2 and 3 can be found in Tables 1 and 2, respectively.

With the implementation of the WFMS several artifacts that were previously physical became electronic. For example, pre-implementation the dose order was represented and signaled by the physical artifact of a label. Post-implementation the dose order was represented and signaled electronically in the WFMS. Another example is the artifacts used to verify that the dose has been properly prepared. Pre-implementation the physical artifacts used to create the dose are used by the pharmacist. However, post-
implementation it is not the physical artifacts that the pharmacist uses but rather pictures of the tools used to create the dose order – the electronic representations of these artifacts.
Table 1. System vulnerability descriptions and manifestations in pre-implementation work system

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<th>Timing of Preparation</th>
<th>Key</th>
<th>Pre-Dose Edge</th>
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<td>Have to wait on reconstitution to dissolve to prepare other dose</td>
<td>1</td>
<td>Delay in dose preparation possible if reconstitution not prepared in advance due to it being unclear which ones are needed.</td>
</tr>
<tr>
<td>Dose prepared early</td>
<td>2</td>
<td>Dose expires before administered or order is cancelled after dose is prepared</td>
</tr>
<tr>
<td>Dose prepared late</td>
<td>3</td>
<td>Dose label could be stored improperly/misplaced and prepared later than intended</td>
</tr>
<tr>
<td>Previously verified reconstitution actually has error in preparation process</td>
<td>4</td>
<td>If already verified there is no way to re-examine preparation process</td>
</tr>
<tr>
<td>Ingredient used but not documented as used (for verification)</td>
<td>5</td>
<td>Pharmacy technician forgets to put vial in basket after using ingredient</td>
</tr>
<tr>
<td>Dose is prepared differently than is conveyed to the pharmacist</td>
<td>6</td>
<td>Syringe pulled back to incorrect location, ingredient not put in basket and used (or vice-versa)</td>
</tr>
<tr>
<td>Different quantity of drug is used than is documented (for verification)</td>
<td>7</td>
<td>Pharmacy technician could pull syringe back to different quantity than used, or if two or more ingredients were used it could be unclear which syringe corresponds with which ingredient</td>
</tr>
<tr>
<td>Delay in when pharmacist can begin verification</td>
<td>8</td>
<td>Verification requires physical dose so pharmacist must wait until pharmacy technician places basket in pass through window</td>
</tr>
<tr>
<td>Crowd pass through window</td>
<td>9</td>
<td>If multiple dose baskets and small pass-through window could run out of space or cause baskets to be misplaced</td>
</tr>
<tr>
<td>Verification is a bottleneck</td>
<td>10</td>
<td>Doses pile up waiting to be verified during busy times</td>
</tr>
<tr>
<td>Pharmacy technician does not know how to properly complete preparation process</td>
<td>11</td>
<td>Pharmacy Technician relies primarily on knowledge in the head to prepare dose</td>
</tr>
<tr>
<td>Incorrect ingredient used</td>
<td>12</td>
<td>Ingredients are verified as correct by pharmacist during verification. If incorrect ingredient used, it results in waste.</td>
</tr>
<tr>
<td>Label is not used or is filled out with incorrect or missing information</td>
<td>13</td>
<td>Pharmacy Technician could forget to or intentionally not update label</td>
</tr>
<tr>
<td>Dose order lost</td>
<td>14</td>
<td>Label could be lost or misplaced and pharmacy would only be notified after dose is not on the floor when needed</td>
</tr>
<tr>
<td>Calculation error in amount of ingredient to use</td>
<td>15</td>
<td>Calculations are done by pharmacy technicians but verified by pharmacist after the preparation of dose is complete</td>
</tr>
<tr>
<td>Ingredient used expires before dose is to be administered</td>
<td>16</td>
<td>Pharmacist visually verifies expiration date but it may not be salient if expiration date is before dose due date</td>
</tr>
<tr>
<td>Pharmacy Technician or Pharmacist may be interrupted</td>
<td>17</td>
<td>Worker may duplicate action or forget where in the process they are when interrupted</td>
</tr>
<tr>
<td>Pharmacy Technician must wait for necessary ingredient to be returned by verifying pharmacist</td>
<td>18</td>
<td>If ingredient is in a multi-use vial, then pharmacy technician must either wait for verification to be complete or open a new vial</td>
</tr>
<tr>
<td>How much ingredient is left in vial is unknown</td>
<td>19</td>
<td>Pharmacy technician who previously used multi-use vial may not record or incorrectly record quantity remaining in vial</td>
</tr>
<tr>
<td>Unable to locate dose once delivered to floor</td>
<td>20</td>
<td>No proof that dose had been delivered or record of where dose is in system</td>
</tr>
<tr>
<td>Excessive and inconsistent warning</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>
Table 2. System vulnerability descriptions and manifestations in post-implement work system

<table>
<thead>
<tr>
<th>Key</th>
<th>Post-WFMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Organization of the WFMS queue increases salience of upcoming dose orders but pharmacy technician must still be aware of which dose orders require slow dissolving reconstitutions.</td>
</tr>
<tr>
<td>2</td>
<td>The WFMS waits until close to due date to put dose orders with short expiration periods in the queue. However, some doses still could be cancelled after preparation if prepared too early.</td>
</tr>
<tr>
<td>3</td>
<td>Organization of the WFMS queue minimizes late preparation of dose but excessive orders in queue could obscure dose order.</td>
</tr>
<tr>
<td>4</td>
<td>Pharmacist can examine images that were used to initially verify but images may be not represent all aspects of the preparation process.</td>
</tr>
<tr>
<td>5</td>
<td>The WFMS requires ingredient to be scanned but pharmacy technician could forget to capture image of all ingredients used.</td>
</tr>
<tr>
<td>6</td>
<td>Photograph misrepresents dose preparation (e.g., not all syringes/vials included in picture). Ingredients not all scanned.</td>
</tr>
<tr>
<td>7</td>
<td>The WFMS requires picture of syringe with ingredient in it. However, the WFMS could be used differently than intended (e.g., take picture of empty, pulled back syringe).</td>
</tr>
<tr>
<td>8</td>
<td>Delay in when pharmacist can begin verification.</td>
</tr>
<tr>
<td>9</td>
<td>Pass-through window could still be crowded with doses but not needing to pass artifacts means there is more space.</td>
</tr>
<tr>
<td>10</td>
<td>Pharmacy technician does not know how to properly complete preparation process.</td>
</tr>
<tr>
<td>11</td>
<td>Low level of detail of instruction or instructions in different order than how completed in real world could cause confusion to novice users.</td>
</tr>
<tr>
<td>12</td>
<td>Incorrect ingredient used.</td>
</tr>
<tr>
<td>13</td>
<td>Label is not used or is filled out with incorrect or missing information.</td>
</tr>
<tr>
<td>14</td>
<td>Dose order lost.</td>
</tr>
<tr>
<td>15</td>
<td>Calculation error in amount of ingredient to use.</td>
</tr>
<tr>
<td>16</td>
<td>Pharmacist visually verifies expiration date and the WFMS does not allow ingredient made in house to be used if it expires soon.</td>
</tr>
<tr>
<td>17</td>
<td>The WFMS reminds worker what has been completed but some information may need to be recalled. Process is still vulnerable to interruptions.</td>
</tr>
<tr>
<td>18</td>
<td>Pharmacy Technician must wait for necessary ingredient to be returned by verifying pharmacist.</td>
</tr>
<tr>
<td>19</td>
<td>When more than one multi-use vial used in preparing a dose then which vial is considered only partially used by the system is unclear.</td>
</tr>
<tr>
<td>20</td>
<td>Predictable warnings (i.e., asking to reprint time med labels) mean that other important warnings could be ignored. Inconsistent warnings (i.e., do not shake not always on unshakeable labels) make warnings lose reliability.</td>
</tr>
<tr>
<td>21</td>
<td>Excessive and inconsistent warning.</td>
</tr>
</tbody>
</table>
### IV Dose Preparation

**Pre-WFMS**

1. **Initial verification**
   - Order verified by the pharmacist

2. **Dose orders received**
   - Batch of labels print on regular interval
   - Urgent labels print immediately

3. **Dose orders organized**
   - Labels organized by pharmacy technician

4. **Preparation process initiated in WFMS**
   - Pharmacy technician retrieves necessary ingredients and supplies
   - Pharmacy technician prepares ingredients that require additional preparation

5. **Ingredients collected**
   - Pharmacy technician scans ingredients into WFMS via ingredient barcode
   - Once all correct ingredients are scanned, WFMS displays instructions on dose preparation.

6. **Ingredients entered**
   - Ingredients and supplies placed in basket
   - Pharmacy technician prepares ingredients that require additional preparation

7. **Instructions Displayed**
   - Ingredients NOT in final state
   - Ingredients in final state
   - WFMS provides preparation instructions for any ingredients requiring additional preparation

8. **Ingredients prepared**
   - Ingredients NOT in final state
   - Ingredients in final state
   - Image(s) are captured of ingredient label showing expiration date and lot number

9. **Ingredients recorded**
   - Drug and diluent placed in basket for preparation with label
   - Tech removes drug from vial with syringe

10. **Ingredients measured**
    - Empty syringe is pulled back to quantity which full syringe contained
    - Empty and pulled back syringe, and drug vial are placed in basket

11. **Quantity of ingredients recorded**
    - Following WFMS instructions pharmacy technician removes drug from vial with syringe

12. **Ingredients added to diluent**
    - Pharmacy technician injects drug into diluent bag

13. **Dose labelled**
    - Label is placed on completed dose

14. **Completed dose recorded**
    - Completed and labelled dose is placed in basket with empty syringes and used vials

15. **Dose signaled as complete**
    - Image captured of complete labelled dose, all ingredients and tools used to create the dose

16. **Dose prepared to leave clean room**
    - Dose label scanned to signify preparation is complete and ready for verification

17. **Dose leaves clean room**
    - Basket placed in pass through window

**Post-WFMS**

1. **Order verified by the pharmacist**

2. **Dose orders received**
   - Batch of dose orders received on regular interval
   - Urgent dose orders received immediately

3. **Dose orders organized**
   - Order routed to destination pharmacy workstation

4. **Preparation process initiated in WFMS**
   - Pharmacy technician retrieves necessary ingredients and supplies
   - Pharmacy technician prepares ingredients that require additional preparation

5. **Ingredients collected**
   - Pharmacy technician scans ingredients into WFMS via ingredient barcode
   - Once all correct ingredients are scanned, WFMS displays instructions on dose preparation.

6. **Ingredients entered**
   - Ingredients and supplies placed in basket
   - Pharmacy technician prepares ingredients that require additional preparation

7. **Instructions Displayed**
   - Ingredients NOT in final state
   - Ingredients in final state
   - WFMS provides preparation instructions for any ingredients requiring additional preparation

8. **Ingredients prepared**
   - Ingredients NOT in final state
   - Ingredients in final state
   - Image(s) are captured of ingredient label showing expiration date and lot number

9. **Ingredients recorded**
   - Drug and diluent placed in basket for preparation with label
   - Tech removes drug from vial with syringe

10. **Ingredients measured**
    - Empty syringe is pulled back to quantity which full syringe contained
    - Empty and pulled back syringe, and drug vial are placed in basket

11. **Quantity of ingredients recorded**
    - Following WFMS instructions pharmacy technician removes drug from vial with syringe

12. **Ingredients added to diluent**
    - Pharmacy technician injects drug into diluent bag

13. **Dose labelled**
    - Label is placed on completed dose

14. **Completed dose recorded**
    - Completed and labelled dose is placed in basket with empty syringes and used vials

15. **Dose signaled as complete**
    - Image captured of complete labelled dose, all ingredients and tools used to create the dose

16. **Dose prepared to leave clean room**
    - Dose label scanned to signify preparation is complete and ready for verification

17. **Dose leaves clean room**
    - Basket placed in pass through window

**Legend**

- Task
  - Action completed for all dose orders
  - Action completed for only certain dose orders
- Task only existing post-WFMS
  - Action completed for only certain dose orders
- System Vulnerability
  - Leads to possible next action

---

**Figure 2. Dose Preparation pre- and post-implementation**
Figure 3. Verification process pre- and post-implementation

Another key difference between the pre- and post-WFMS implementation work system is the manner in which information is transmitted through the work system. As seen in Figure 4, much of the information pre-WFMS implementation was transmitted from and through the dose order label and the information flow through other entities in the process followed a generally linear pattern. In the post-WFMS implementation work system the information flow centers around the WFMS which is represented by the
dotted box on Figure 5 and contains the entities of the dose order information and drug information. Unlike the pre-WFMS implementation work system, information tends to follow a loop formation here and flow in both directions between the WFMS and other entities in the information flow diagram. Part of this transition involved the movement of artifacts from the physical to the electronic.

With these changes in the work process, artifacts, and information flow, the SVs in the work system changed as well as the blocks and workarounds following the implementation of the WFMS.

Figure 4. Pre-implementation information flow
System Vulnerabilities

A number of pre- and post-implementation system vulnerabilities (SVs) were identified. Certain SVs were eliminated with the implementation of the WFMS and exist only in the pre-implementation work system. Certain SVs were created by the implementation of the WFMS and exist only in the post-implementation work system. Most SVs identified exist in both pre- and post-implementation work systems but were affected by the implementation of the WFMS. The list of SVs, and how they manifest...
themselves in both the pre- and post-implementation work system, can be found in Table 1.

Some SVs, such as the pharmacy technician or pharmacist being interrupted, can occur anywhere in the dose preparation process. Other SVs, such as the pharmacy technician not knowing how to properly complete the dose preparation process, only impact certain steps of the dose preparation process. Different SVs can only occur during one particular step in the dose preparation process, such as an ingredient that expires prior to dose administration being used. The pre- and post-implementation dose preparation process, along with visualizations of where in the process the SVs can occur, can be found in Figure 1. Similarly, the dose verification process – where the pharmacist verifies that the dose has been properly prepared based on the artifacts provided by the pharmacy technicians – along with representations of applicable SVs can be found in Figure 2. Again certain SVs, such as the verification process being a bottleneck, apply to the entire verification process. Other SVs, such as the dose being prepared differently than is conveyed to the pharmacist by the artifacts, only apply to a single step of the verification process. One SV, that the dose cannot be located once delivered to the floor, is only applicable following the dose verification process. In both Figures 2 and 3, SVs that can occur in both the pre- and post-implementation work system are indicated by stars spanning both columns. SVs that can occur in only the pre-implementation or post-implementation work systems are indicated by a star in only one column.

As shown in Table 2, all SVs that continued to exist following the implementation of the WFMS were found to have a lower risk priority number following the
implementation of the WFMS. In other words, the risk the SV posed to the work system, either through the likelihood of occurrence, impact on safety, ease of detection or some combination of these, was lessened. Once the SVs had been identified, users ranked each of them in three categories used in an FMEA – likelihood of occurrence, impact of safety and ease of detection. The ratings in each of these categories were multiplied to determine a risk priority number (RPN) for each pre- and post- implementation SV. Based on the rating scale, RPNs could potentially range between 1 and 125 with the higher the RPN the greater risk the SV poses to the system. The highest rated SV, with an RPN of 43.51, was doses being unable to be located once delivered to the floor. This SV was eliminated with the implementation of the WFMS and consequently does not have a post-implementation RPN. The amount the RPN was reduced with the implementation of the WFMS varied. The percent change, shown in the right most column of Table 3, shows how the RPN reduction varied between SVs. The SV with the greatest reduction in RPN (27.8 points) was the dose being prepared differently than conveyed to the pharmacist. This SV had a percent change of -68.47%. The SV of the pass through window being crowded experienced the smallest drop in RPN (2.52 points) which was also illustrated in its lower percent change of 14.47%. All SVs that existed pre- and post-implementation experienced a drop in the PRN (and across all three categories that make up the RPN) following the implementation of the WFMS and consequently all percent changes were negative.
### Table 3. FMEA results (higher values indicate higher risk)

<table>
<thead>
<tr>
<th>Timing of Preparation</th>
<th>Key</th>
<th>Likelihood (L)</th>
<th>Safety Impact (S)</th>
<th>Ease of Detection (D)</th>
<th>Risk Priority Number (L<em>S</em>D)</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pre-</td>
<td>Post-</td>
<td>Pre-</td>
<td>Post-</td>
<td>Pre-</td>
</tr>
<tr>
<td>Have to wait on reconstitution to dissolve to prepare other dose</td>
<td>1</td>
<td>3.75</td>
<td>3.50</td>
<td>3.17</td>
<td>2.5</td>
<td>1.91</td>
</tr>
<tr>
<td>Dose prepared early</td>
<td>2</td>
<td>3.63</td>
<td>3.27</td>
<td>2.54</td>
<td>2.24</td>
<td>2.33</td>
</tr>
<tr>
<td>Dose prepared late</td>
<td>3</td>
<td>3.04</td>
<td>2.72</td>
<td>3.88</td>
<td>3.24</td>
<td>2.25</td>
</tr>
<tr>
<td>Previously verified reconstitution actually has error in preparation process</td>
<td>4</td>
<td>2.83</td>
<td>2.06</td>
<td>4.38</td>
<td>4.09</td>
<td>3.30</td>
</tr>
<tr>
<td>Ingredient used but not documented as used (for verification)</td>
<td>5</td>
<td>2.54</td>
<td>1.85</td>
<td>4.21</td>
<td>3.70</td>
<td>3.33</td>
</tr>
<tr>
<td>Dose is prepared differently than is conveyed to the pharmacist</td>
<td>6</td>
<td>2.74</td>
<td>1.88</td>
<td>4.26</td>
<td>3.56</td>
<td>3.48</td>
</tr>
<tr>
<td>Different quantity of drug is used than is documented (for verification)</td>
<td>7</td>
<td>2.74</td>
<td>1.88</td>
<td>4.30</td>
<td>3.94</td>
<td>3.22</td>
</tr>
<tr>
<td>Delay in when pharmacist can begin verification</td>
<td>8</td>
<td>3.50</td>
<td>-</td>
<td>3.79</td>
<td>-</td>
<td>1.96</td>
</tr>
<tr>
<td>Crowded pass through window</td>
<td>9</td>
<td>3.63</td>
<td>3.53</td>
<td>3.29</td>
<td>3.12</td>
<td>1.46</td>
</tr>
<tr>
<td>Verification is a bottleneck</td>
<td>10</td>
<td>3.63</td>
<td>-</td>
<td>3.57</td>
<td>-</td>
<td>1.83</td>
</tr>
<tr>
<td>Pharmacy technician does not know how to properly complete preparation process</td>
<td>11</td>
<td>2.58</td>
<td>2.09</td>
<td>4.04</td>
<td>3.88</td>
<td>1.96</td>
</tr>
<tr>
<td>Incorrect ingredient used</td>
<td>12</td>
<td>2.88</td>
<td>-</td>
<td>4.33</td>
<td>-</td>
<td>2.25</td>
</tr>
<tr>
<td>Label is not used or is filled out with incorrect or missing information</td>
<td>13</td>
<td>2.46</td>
<td>-</td>
<td>4.25</td>
<td>-</td>
<td>1.96</td>
</tr>
<tr>
<td>Dose order lost</td>
<td>14</td>
<td>3.13</td>
<td>-</td>
<td>4.38</td>
<td>-</td>
<td>2.67</td>
</tr>
<tr>
<td>Calculation error in amount of ingredient to use</td>
<td>15</td>
<td>2.91</td>
<td>-</td>
<td>4.38</td>
<td>-</td>
<td>2.46</td>
</tr>
<tr>
<td>Ingredient used expires before dose is to be administered</td>
<td>16</td>
<td>3.00</td>
<td>2.24</td>
<td>4.29</td>
<td>3.79</td>
<td>2.79</td>
</tr>
<tr>
<td>Pharmacy Technician does not know how to properly complete preparation process</td>
<td>17</td>
<td>4.04</td>
<td>3.62</td>
<td>4.08</td>
<td>3.97</td>
<td>1.96</td>
</tr>
<tr>
<td>Pharmacy Technician may be interrupted</td>
<td>18</td>
<td>3.25</td>
<td>-</td>
<td>3.58</td>
<td>-</td>
<td>1.92</td>
</tr>
<tr>
<td>Pharmacy Technician must wait for necessary ingredient to be returned by verifying pharmacist</td>
<td>19</td>
<td>3.42</td>
<td>2.59</td>
<td>2.75</td>
<td>2.27</td>
<td>2.29</td>
</tr>
<tr>
<td>How much ingredient is left in vial is unknown</td>
<td>20</td>
<td>4.00</td>
<td>-</td>
<td>4.17</td>
<td>-</td>
<td>2.61</td>
</tr>
<tr>
<td>Unable to locate dose once delivered to floor</td>
<td>21</td>
<td>-</td>
<td>2.53</td>
<td>-</td>
<td>2.82</td>
<td>-</td>
</tr>
<tr>
<td>Excessive and inconsistent warning</td>
<td>22</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Workarounds

A number of pre- and post-implementation blocks and workarounds were identified through observation and confirmed with a subject matter expert. An illustration of how a block and its subsequent workaround works can be found in Figure 6. The workaround is illustrated by the dashed arrow and the solid arrow that go around the block. The dashed arrow illustrates a workaround that is outside the norm but still considered an acceptable work process. This usually occurs when a work system has been set up to anticipate certain blocks and has a standard procedure for working around them. The solid arrow is a larger deviation from the standard procedure and may move outside of what is an acceptable or anticipated work process. The aspects which impacted the existence of the blocks – policy and procedures, technology and/or work practices – were identified and blocks were assigned as belonging to a region of Figure 1 which can be found in the methodology section. Similarly, the aspects that each workaround incorporated – policy and procedures, technology and/or work practices – were also identified and workarounds were classified into one of the regions shown in Figure 1. Most blocks were identified as motivating one or more workarounds.
The majority of blocks were determined to be a category 7 block meaning they fall into section 7, technology, of the diagram. This indicates that most blocks standing in the way of carrying out the work practices as intended were the result of technology. Several blocks motivated by the existence of technology include issues with scanning. A couple examples of these sorts of blocks include the barcode on a diluent bag being scratched and therefore not scanning or the WFMS not recognizing a scanned ingredient. Another block motivated by technology is the WFMS recording a different quantity of ingredient remaining in a vial than is actually remaining, which is also a SV.

The majority of workarounds were categorized as belonging to category 4 of the diagram meaning that they incorporated technology and work practices. Most category 4 workarounds were prompted by blocks categorized as category 7. In fact, the category 7 block and category 4 workaround was the most common block/workaround pair. For example, when the product bag does not scan due to the barcode being scratched two
category 4 workarounds were determined. The first is scanning another product bag and then using either the scanned bag or the bag that did not scan. Alternatively, it was observed that certain product bags failed to scan on such a consistent basis that a “scanning bag” had been established – that is a bag of product was marked “for scanning only” and was used to scan whenever that product was needed. In addition to the previously mentioned category 7 block of a WFMS recording a different quantity of ingredient remaining in a vial than is actually remaining, two category 4 workarounds were determined. One, used when the WFMS thinks there is less ingredient remaining than is actually there, is to scan an additional vial but only use the initial vial. When dealing with a reconstituted dose, the pharmacy technician could reconstitute more of that ingredient and do the same thing (i.e., scan the additional reconstituted vial but not use it).

When the WFMS thinks there is more ingredient remaining than is actually there, also a category 7 block, there are two response workarounds, both categorized as a category 5 workaround. Category 5, which incorporates actual work practices but not the technology or policy and procedures, is a common categorization for workarounds. Workarounds classified as category 5 form the second largest group.. This makes sense since workarounds reflect actual work practices that fall outside of standard work practices. Several category 5 workarounds involve the user working outside of the technology rather than incorporating the technology into the task. For example, bag and vial system doses (e.g., diluent bags that connect to a powdered ingredient vial) being made prior to receiving orders for these doses and other doses (primarily insulin) being
made prior to interacting with the WFMS. Other related examples of category 5 workarounds include drawing the ingredient into the syringe prior to scanning the ingredient vial and taking pictures of pulled back syringes (rather than syringes full of the ingredient to be injected into the diluent bag).

Category 2 is another common category for workarounds. Category 2 involves workarounds that incorporate both actual work practices as policy and procedure but do not incorporate technology. As such, category 2 often involves bypassing the WFMS. Bypassing the WFMS is a built in workaround for users to utilize when it is not possible to incorporate the WFMS. Blocks that may motivate a user to formally bypass the WFMS include a correct ingredient not scanning due to a new manufacturer’s barcode or the ingredient not having been added to the WFMS yet. Unlike when users do not use the WFMS as intended by creating the dose prior to interacting with the system, there is a formal bypass procedure that follows policy and procedures. In situations where it is not possible to scan an ingredient, the user may, within the WFMS, select an option to bypass. This prompts the system to print labels for the dose and allow the user to create the dose without interacting with the system (e.g., pictures of the dose preparation process are not made). As such, the built-in workaround of bypassing incorporates both the work practices and policy and procedures.

While it may initially appear that category 1 would not encompass any workarounds since it incorporates the three things – technology, work practices, and policy and procedures – there are a few workarounds that fall in this category. No workarounds were classified as category 3, 6 or 7. One example of a category 1
workaround is again in response to the WFMS not recognizing a scanned ingredient. If the dose is not urgent, the user can submit the unrecognized ingredient to a list of ingredients to be added and wait for the ingredient to be added which usually takes no more than a couple hours. Once the ingredient is added, the dose can be prepared as usual. Because this follows an established protocol it incorporates the policy and procedures. It is a process that users actually complete and therefore incorporates work practices. And finally, because it allows technology to be involved as intended, it incorporates technology. However, because it is a deviation from a standard work practice (e.g., the system works as intended and accepts the correct ingredient when scanned), it is a workaround. Similarly, if the scanner used to scan doses into their location on the floor loses connectivity and fails (a category 7 block), a user may neglect to use the scanner entirely (a category 5 workaround) or may restart the scanner in order to allow connectivity to be re-established. The latter is again a category 1 workaround because it incorporates policy and procedure (this is the established protocol for users to follow in situations when the scanner fails), incorporates actual work practices and leads to the technology being used as intended.

Blocks, unlike the workarounds they motivate, fall into all 7 categories. Category 7 blocks, which we have already discussed, are by far the most common category. Category 2 blocks, which include things such as an urgent dose being needed while in the middle of working on another dose and a pharmacist being unsure from the artifacts (physical or digital) given whether the dose was properly prepared, is the second most common block category. Fewer blocks were categorized into category 1, 3, 4, 5, and 6.
An example of a category 1 block is the perception that incorporating the WFMS into the insulin preparation process increases the preparation time. One category 3 block is a block intentionally built into the system – the WFMS does not allow two people to be in (e.g., working on) the same dose at the same time. This, when the system is used as intended, prevents duplicate doses from being created. Category 4 blocks, which are motivated by both technology and actual work practices but not policy and procedures, include not knowing which doses at the sorting station have been verified and not being able to see the quantity of insulin in the syringe with the cap on. A category 5 block, which is motivated solely by technology, is a picture missing from the digital dose artifacts sent to the verifying pharmacist. Blocks motivated solely by policy and procedures, which are category 6 blocks, include pharmacy technicians needing a label to order a controlled substance ingredient from the pharmacist and it being unclear what needs to be in each picture.

This concludes the description of the results found in three main areas – general results, results specific to SVs and results specific to workarounds. The following chapter will discuss these results, what they mean, and how they fit into the research of others.
CHAPTER 4. DISCUSSION

The objective of this study is to investigate the impact that implementing a WFMS has on a work system, work practices, and subsequent patient safety. This was done by identifying SVs pre- and post-WFMS implementation and workarounds that users engage in as a result of the implementation of the WFMS and the blocks that create these workarounds. A key finding was that the risk, as indicated by the RPN, associated with SVs existing in both the pre- and post-implementation work system, decreased with the implementation of the WFMS. However, certain SVs were introduced as a result of the WFMS, indicating that a technology may simultaneously reduce risk in one area but introduce it in another area. This finding is supported by previous studies examining the impact of technology in healthcare which have found that the technology eliminates certain safety concerns while introducing unexpected new safety concerns (Ash et al., 2004; Grossman et al., 2012; Karsh et al., 2010).

In regards to blocks and workarounds, it was found that the majority of blocks were identified as category 7 blocks, meaning that they were the result of technology. These blocks often resulted in workarounds which were identified as category 4 workarounds meaning that they incorporated work practices and technology. Category 4 was the most common category identified for workarounds. Following the implementation of a technology, in this case a WFMS, it follows that the new technology creates blocks for the users who are adapting to the new work system and new work practices. A study examining nurse’s work practices and workarounds following the implementation of a Bar Code Medication Administration (BCMA) Holden et al. (2013)
found that in some cases the technology blocked previous preferential problem-solving behaviors, resulting in the nurses needing to develop new work practices. Technology could motivate a block for a variety of reasons including the technology not accommodating actual work practices, the user having an inappropriate level of trust in the technology, and the technology requiring a change in work practices from the pre-technology implementation work system. In the post-implementation work system, the use of technology is necessary to complete the dose preparation process, so it makes sense that most of the workarounds resulting from the technology blocks incorporate both work practices (i.e., how the work is actually done) and technology, albeit perhaps differently than intended.

Often actual work practices differ from the intended work practices. When changing a work system, such as by implementing a new technology, it is important to consider what actual work practices are and design the new work system to accommodate these actual work practices (as opposed to intended work practices). If a new work system is designed based on the intended work practices without consideration for the actual work practices (and why these differ), then it is possible that it may invite SVs and encourage workarounds since the system does not support the actual work practices.

Relatedly, in the post-implementation work system, workarounds may result in actual work practices being different from intended work practices. This may happen if the technology does not support the way users have grown accustomed to doing work. For example, in the pre-implementation work system creating multiple doses of the same medication at a time, particularly doses such as insulin that only require drawing one
medication into a syringe, was common. However, if the WFMS has been set up to only create one dose at a time, this results in a workaround when pharmacy technicians are creating multiple insulin doses at a time and then interacting with the WFMS. The perception is that interacting with the WFMS while creating doses such as insulin slows down the dose preparation process. While almost all pharmacy technicians created insulin doses in this way, very few pharmacy technicians were observed preparing other types of doses prior to interacting with the system. The pharmacy technicians who did prepare doses independently of the WFMS may have done so as a result of their level of trust in the system.

The user’s perception of the technology with which they interact impacts how they interact with the technology. One aspect of the user’s perception is their trust in the system. A user who thinks the WFMS is capable of less than it actually is may disuse the technology – that is, reject the technology and only rely and use it as little as possible. We see the results of users disusing technology in the workarounds involving pharmacy technicians creating doses prior to interacting with the WFMS. These workarounds ranged from drawing the ingredients into the syringe prior to scanning the ingredients to creating the entire dose prior (i.e., drawing the ingredients and injecting them into the diluent) to interacting (e.g., scanning, taking pictures) with the WFMS. In these cases disusing the technology is harmful as it eliminates some of the safety aspects of the WFMS – ensuring the correct ingredients are used and a closer representation of the work process is relayed to the pharmacist for verification than in the pre-implementation work system when the pharmacist had to determine if a dose was properly prepared based
solely on the physical artifacts utilized in the dose preparation process. Conversely, misuse is trusting a technology beyond its capabilities. Misuse, like disuse, can have a negative impact on how the user interacts with the system.

With the implementation of the WFMS several artifacts moved from physical to digital, changing the way in which external knowledge, or knowledge in the world, is presented. This made it more accessible for the user. It also moved certain knowledge, such as the actual quantities of the ingredient to use, from being in the head to being in the world. Pre-implementation the knowledge required to create the dose could primarily be found in the world and combined with the user’s internal knowledge (i.e., knowledge in the head). However, the knowledge in the world was not easily accessible – it was on drug inserts (paper inserts from the manufacturer with details on how to properly prepare a dose using that particular ingredient), labels and reference sheets created by the pharmacist and pharmacy technicians. It was not centrally located and often the information found required additional calculations or manipulations before it could be used. The inconvenience of locating all of this information incentivized the user to internalize some of the external knowledge. For example, a pharmacy technician may be more acutely aware of which doses expired quickly or any particularity of using a certain ingredient (e.g., requires a filter needle, can only be used with saline, etc.). This is because reading the entire ingredient insert or looking at all supplementary guides for each dose order is impractical and a nuisance. Once that information was presented through electronic artifacts – the WFMS – it was much more easily accessible for the user since it was all in one location. The WFMS told the pharmacy technician how to
prepare the dose including any special preparations that were needed such as using a filter needle. As a result of the ease of accessing this knowledge in the world, the user may no longer feel the need to retain the same knowledge in their head (Norman, 2013). This means that when the WFMS is bypassed there is an increased risk not only because the safety features, such as scanning, are not used but also because the user may not have all requisite knowledge in the head.

In conclusion, introducing a new technology into a work system can reduce certain risks, as shown by the elimination of SVs and reduction of RPN for SVs that continued to exist. However, the new technology also opens the work system up to new risk, as shown by the introduction of new blocks and there subsequent workarounds and a new SV. Nevertheless, in this case the positive impact the WFMS has on safety are greater than the potential negative impact and the WFMS implementation is concluded to have an overall positive impact. The positive impact of technology, such as the WFMS, implementation can be increased by being mindful of the potential risks introduced by the implementation of the technology.

Limitations

As an observational study there was the risk that the Hawthorne Effect impacted subject’s behavior during observation. Efforts were made to minimize this (e.g., multiple observations, being an impartial observer).

All observations were done after the WFMS had already been implemented and therefore an understanding of the pre-implementation work system was developed
through conversations with those who had worked in the pre-implementation work system. Observing the pre-implementation work system may have allowed for a deeper understanding of certain aspects and may have led to observing aspects that the users did not mention in our discussions. Therefore, future research should consider observing the pre-implementation work system.

All observations and coding were done by one person. Consequently there is the risk of bias. Efforts were made to minimize any user bias by consulting with others on the list of system vulnerabilities, workarounds and observations.

**Impacts and Implications**

The categorization structures used in this research can be utilized in future engineering needs assessments which analyze potential technology’s integration into work systems. Both the identification of SVs and workarounds and the manner in which the SVs and workarounds were examined is unique.

While this research examined the implementation of a WFMS in a pharmaceutical environment, the outcomes can be generalized to the implementation of other types of technologies in other areas. Technology, already prevalent in several aspects of our lives, is becoming more and more prevalent in new ways and in new areas. A few examples include small business owners transforming phones and tablets into cash registers, automobiles offering increased automation for driving tasks that were once manual or only partially automated, or the incorporation of web-based learning into our educational experience. All of these technologies offer benefits – the convenience of having point of
service software without having to make the expensive upfront investment, making the driving experience more comfortable, efficient, and safe for drivers, and increased learning time without increasing the work load on instructors. However, there may be unintended consequences or inconveniences to implementing these technologies – having to sign a screen instead of a paper receipt may alienate some customers, the loss of the ability to do the driving tasks manually, or connectivity issues causing students to miss out on assignments and causing additional hassle for instructors. Consequently, it is important that technology and its impact on the work system is understood. The methodology used in this study can be applied to areas such as those previously given and help develop the necessary understanding. The analysis methodology and framework of this analysis can be applied to areas where technology continues to play an increasingly important role.

As a qualitative study, this research also fills a gap in the medication error research which has primarily focused on a quantitative analysis of specific outcomes (e.g., error reduction) following the implementation of a specific technology (Bates et al., 1998; Eslami et al., 2006; Moniz et al., 2014; Nebeker et al., 2005). Also, unlike previous research, this research focuses on potential errors or situations which may give rise to errors. The framework of this study allows the examination of a work system prior to an error which can help prevent the error from occurring rather than relying on the occurrence and detection of an error to assess the system.
**Future Research**

This research developed a new methodology of categorizing SVs and workarounds which provides a new way in which to analyze a work system. This research applied this methodology to a pharmaceutical environment where a WFMS was recently implemented. The methodology allows for a proactive identification of problem areas which allows for analysis prior to a safety event occurring.

This methodology is applicable to other areas of healthcare, such as electronic health records (EHR), as well as in other domains such as manufacturing. Further research will utilize this methodology in other domains as well as with different technologies in order to evaluate how it works in other domains. Additionally, future research will, if possible, observe the work system prior to the implementation of the technology as well as following implementation.

Through further research it will be possible to evaluate how SVs and workarounds translate into engineering user needs assessments for iterative design cycles. By utilizing the methodology used in this research in other domains, the role of SVs and workarounds in a variety of domains will be better understood. This will allow for the SVs and workarounds, and the benefits from identifying them prior to implementation, to be utilized to better identify the needs of the user. This can result in a better implementation process.

Further research should also evaluate how this methodology of identifying SVs and workarounds can fit into the design cycle for future technologies. Similar to utilizing SV and workaround identification to better understand the user needs, identifying how
this methodology can be utilized in the design of future technologies is necessary. It should be evaluated, in a variety of domains, how this methodology can assist with developing a better design of technology.

Additionally, there is room for future research in how users adapt to technology. Identifying workarounds is the beginning of identifying how users adapt to technology, and there is the opportunity for additional research in this field such as identifying the role complacency plays in the user-technology interaction.
REFERENCES


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